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COMMISSION STAFF WORKING DOCUMENT

Union overview 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 in 2018 - 2022

CONTENTS

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EXECUTIVE SUMMARY 2024

1. Introduction

This report presents information on the implementation of Directive 2010/63/EU on the protection of animals used for scientific purposes[1] ("the Directive") in the Member States of the European Union (EU) and Norway between 2018-2022.

Under the European Economic Area agreement, Norway has transposed the Directive in the national legislation and was therefore invited, for the first time, to submit the implementation report to the European Commission together with Member States. References to "EU", "Union" and "Member State" data from here on in this report, are to be understood to cover 27 EU Member States and Norway, unless specified otherwise. This is the second EU implementation report. The first EU report on the implementation of the Directive was published in 2019 covering years 2013-2017[2]. The first report included data from the United Kingdom which is no longer covered by this second implementation report.

The Member State reports' timeliness, quality and consistency of the information provided showed significant improvements from the first reporting period, partly thanks to the establishment of a standardised online reporting submission portal allowing the gathering of harmonised and comparable data. Most Member States submitted their report by the deadline of 10 November 2023, with the last report submitted on 24 January 2024.

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

The executive summary covers the highlights of various elements of the Directive's implementation including comparisons to the first five-year period, where relevant. Detailed information on the second reporting period are contained in Part G of this report.

2. Changes to national legislation

Changes to national legislation in the period 2018-2022 were almost exclusively related to issues on correct and complete transposition, as initially identified by the European Commission.

3. Structures and framework of competent authorities

22 Member States indicated that they coordinate the implementation of the Directive in a single ministry. In other Member States, several ministries are responsible for different functions. In some cases where more than one ministry is involved, each ministry co-ordinates only a single

[1] OJ L 276, 20.10.2010, p. 33–79
[2] https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1581689520921&uri=CELEX:52020DC0015

responsibility/function. In others, there are multiple ministries co-ordinating single responsibilities/functions. Some Member States have structures for co-ordination at a national level, but also have regional bodies responsible for implementation.

One of the main goals of the Directive is to provide a level playing field for user, breeders and suppliers of animals for scientific purposes. The table below presents the numbers of competent authorities (CA), the level at which they operate, the type of authority (public or non-public) and the distribution of the five tasks assigned by the Directive for competent authorities.

Number of CAs																												
Type of authority	AT	BE	BG	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HR	HU	IE	IT	LT	LU	LV	MT	NL	NO	PL	PT	RO	SE	SI	SK	**Total**
National	1		1	1	8		1	2	1	93	2	4	2	1	1	1	1	2	3	1	2	1	3	1		2	1	1	**137**
Regional	9	3	28		14	23			87	19	2	89		19		20	2						314			27			**656**
Local - shared by more than one establishment		20				550										224					15		11		42			40	**902**
Local - within establishment		11																											**11**
Total	**10**	**34**	**29**	**1**	**22**	**573**	**1**	**2**	**88**	**112**	**4**	**93**	**2**	**20**	**1**	**245**	**3**	**2**	**3**	**1**	**17**	**1**	**328**	**1**	**42**	**29**	**1**	**41**	**1 706**

Number of CAs																												
Public or non-public	AT	BE	BG	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HR	HU	IE	IT	LT	LU	LV	MT	NL	NO	PL	PT	RO	SE	SI	SK	**Total**
Public	10	3	29	1	22	573	1	2	88	89	4	4	2	20	1	245	3	2	2	1	2	1	316	1	42	29	1	41	**1 535**
Non-public		31								23		89							1		15		12						**171**
Total	**10**	**34**	**29**	**1**	**22**	**573**	**1**	**2**	**88**	**112**	**4**	**93**	**2**	**20**	**1**	**245**	**3**	**2**	**3**	**1**	**17**	**1**	**328**	**1**	**42**	**29**	**1**	**41**	**1 706**

Number of CAs																												
Responsibility	AT	BE	BG	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HR	HU	IE	IT	LT	LU	LV	MT	NL	NO	PL	PT	RO	SE	SI	SK	**Total**
Authorisation of establishments	10	3	28	1	1	305	1	1	14	19	2	2	1	19	1	245	2	1	1	1	1	1	1	1	42	1	1	1	**707**
Inspections	10	3	28	1	14	245	1	1	88	19	2	2	1	19	1	225	2	1	1	1	1	1	315	1	42	21	1	41	**1 088**
Project authorisation	10	31	1	1	7	23	1	1	14	19	1	2	1	19	1	1	1	1	1	1	1	1	12	1	42	6	1	1	**202**
Project evaluation	10	31	1	1	7	23	1	1	14	93	1	89	1	1	1	1	1	2	3	1	16	1	12	1	42	6	1	1	**363**
Retrospective assessment	10	31	1	1	7	23	1	1	14	93	1	89	1	1	1	1	1	1	1	1	1	1	11	1	42	1	1	1	**339**

It may be challenging to provide a consistent approach where there are multiple competent authorities responsible for the same individual tasks/function. Large numbers of competent authorities for any or all tasks increase the risk of inconsistencies, especially where throughput is low. Moreover, low throughput provides limited opportunities for competent authorities to gain sufficient expertise and experience. Where multiple bodies are involved, excellent cross ministry/region communication will be required for effective and consistent implementation and outcome.

4. National Committees

During the first implementation reporting period, it took many Member States a few years to get the National Committee fully functional, especially those who did not previously have such a committee. In contrast, in this reporting period, a vast majority of Member States have effective National Committees in place, evidenced by the advice and guidance provided to competent authorities and Animal Welfare Bodies.

In line with the Directive, National Committees developed information for competent authorities and Animal Welfare Bodies on best practices with regard to breeding, acquisition, accommodation and care and use. Most have also shared information on the operation of Animal Welfare Bodies and project evaluation. Some National Committees seem to be well supported and resourced and disseminate information effectively, while others could benefit from improved resources.

5. Education and Training

The competence for matters on education and training rests largely with Member States. The Directive requires appropriate education and training for staff carrying out procedures, caring for animals, killing animals and designing procedures and projects. The Commission published an Education and Training Framework document[3] which is used extensively by Member States to define the required training for these four functions. Most Member States have published a link to their education and training requirements, as required by the Directive.

Mutual acceptance of training in another Member State is reported to reduce duplication of training significantly. However, differences in national legislation and processes still require some specific in-Member-State training.

Training for persons responsible for care and welfare of animals, for information, and training and competence of staff (Article 24), for designated veterinarians (Article 25) and for project evaluators (Article 38) either follows the Education and Training Framework document or the recommendations are taken into account otherwise in most Member States.

Staff must be supervised until their competence is assessed, however, not all Member States have formal systems in place for supervision and competence assessment. An open access e-learning module on competence assessment is under development by the Commission.

6. Project evaluation and authorisation, and retrospective assessment of projects

[3] https://data.europa.eu/doi/10.2779/311480

During project evaluation, applications must be carefully considered to ensure that animal use is justified, the Three Rs are applied, and that the benefits are expected to outweigh the anticipated harms. Projects may only be authorised if there is a favourable project evaluation.

Most Member States publish the process of project evaluation and/or authorisation, ensuring transparency. Many Member States provide tools to promote the consistency of collecting the correct information and for evaluating it, but this is not always the case. In most cases, all the legal criteria are evaluated. Relevant legally required expertise is available for project evaluation in most Member States. These may be carried out at local, regional or national level. Impartiality is assured in different ways.

Training of project evaluators is provided in many Member States to provide sufficient knowledge and experience to perform the role as required, legally and consistently. The open-access project evaluator e-learning module[4] is used by some.

The Directive requires authorisation decisions to be made within 40 working days unless extension is justified by the complexity or the multidisciplinary nature of the project. In that case, the period can be extended by maximum 15 days.

Whilst the number of projects evaluated and authorised has remained constant over this reporting period, the overall percentage of projects for which the authorisation decision exceeds 40 days was reduced across the Union for this reporting period from 33% in 2018 to 25% in 2022, which reflects significant progress from the previous report, 40% in 2017. In 2022, four Member States reported that more than 50% of project authorisation decisions exceeded 40 days, whereas five Member States recorded that a decision was made on all projects in less than 40 days.

The table below compares the number of decisions taking longer than 40 days in Member States where this was an issue in 2022 or was an issue in 2017 report.

Year		
Member State	2017	2022
SI	43%	92%
PT	61%	66%
HR	18%	65%
FR	66%	58%
IT	73%	49%
DE	79%	21%
LT	100%	10%
LU	100%	25%

Inconsistencies in operation and reporting of timing of the decision regarding authorisation were detected. Compliance with the Directive's obligations and reporting should be calculated in working days from the receipt of the complete and correct application.

Whilst Union-wide improvements have been identified, the results suggest that decision making time differs considerably between Member States. Prolonged delays in project authorisation can

[4] https://learn.etplas.eu/all-courses/

impact negatively on competitiveness and on the desired level playing field for the scientific community within the Union.

Around 30% of all authorised projects were submitted for retrospective assessment. Of these, two-thirds were required for retrospective assessment by the Directive and the remaining third was selected during the project evaluation.

Throughout the five-year reporting period, of those projects requiring a retrospective assessment, the majority (61%) were submitted as containing severe procedures, with 5% as authorised the use of non-human primates (without any severe procedures) and 0.8% as authorised the use of non-human primates and severe procedures.

7. Non-technical project summaries

The previously identified issues on the quality of content, the timeliness of publication and accessibility of non-technical project summaries (NTS) have been largely addressed by the Commission through legislative changes, harmonising the content and introducing a six-month deadline for publication, and through the introduction of an open-access searchable central database (EU ALURES NTS database[5]). EU guidance on non-technical project summaries[6] has been made available but there are indications that it is not used extensively.

The Directive allows the possibility for Member States to update non-technical project summaries with the results of retrospective assessment. 16 Member States have transposed this requirement in their national legislation. The update must be published within six months from the completion of the retrospective assessment.

8. Animals bred for use in procedures

Under the Directive, Member States must provide data once every five years on all animals bred for scientific use, killed and not used in procedures. These animals are not reported in the annual statistics.

Animals bred, killed and not used in procedures include those killed for their organs and/or tissues, for example to use animal-based *ex-vivo* methods, animals used for breeding when they reach the end of their breeding life, animals which were ill and humanely killed before being used, and animals killed in order to protect the health and scientific integrity of the colony.

Of the conventional (not genetically altered) animals bred and killed, 37% were used for collection of organs and tissues. This percentage increased for the higher species such as marmosets (88%), baboons (68%) anddogs (52%). However surprisingly, only few (7%) Cynomolgus macaques had tissues harvested for scientific purposes. It is important that tissues and organs are utilised wherever possible.

Whilst the reported numbers of animals bred, killed and not used have reduced from 12.5 million in 2017 to 9.5 million in 2022, when account is taken of the withdrawal of the UK data in 2017 (3 053 598) and the addition of the Norwegian figures in 2022 (16 059) the total number has not changed.

[5] https://webgate.ec.europa.eu/envdataportal/web/resources/alures/submission/nts/list
[6] https://data.europa.eu/doi/10.2779/778680

Table comparing number of animals bred, killed and not used in different categories in 2017 and 2022, accounting for the changes in Member States between those years:

Types of animals	2017 excluding data of UK	2022 excluding data of Norway	Change
Number of conventional animals bred, killed and not used in procedures	4 939 269	3 491 678	-29%
Number of genetically normal animals (wild type offspring) produced, bred and killed as a result of creation of a new genetically altered line	470 653	185 515	-60%
Number of animals bred and killed for the maintenance of an established genetically altered line (those not covered by project authorisation and excluded from annual statistical reporting)	4 134 305	5 879 507	42%
Total	**9 544 227**	**9 556 700**	
Of the total bred, killed and not used: collection of organs and/or tissues		1 617 213	

When the different sub-groups of these animals are looked at, it appears that there has been a significant reduction (29%) in the number of conventional animals bred and killed without use. However, in contrast, the number of animals bred and killed for the maintenance of an established genetically altered line increased by 42%. In the case of maintenance of established lines, often the surplus is unavoidable as the number of unsuitable animals (not of the correct genotype) is dependent on the methodologies used and on the complexities of breeding of genetically altered animals with multiple genetic modifications, as well as a desire to reduce harms e.g., by breeding as heterozygotes. Discrepancies in understanding the reporting obligations were noted in the past both for annual statistical reporting and for the purposes of the five-year implementation report. To improve the reporting accuracy, a guidance document Framework for the Genetically Altered Animals[7] was developed.

Many initiatives to manage and reduce a surplus of animals bred for scientific use were identified and reported. Methods to optimise matching of supply and demand are also discussed in the guidance document.

9. Sourcing of non-human primates

Only 12 Member States reported active users, breeders or suppliers of non-human primates. Four Member States that acknowledged the continued use of first-generation (F1) purpose-bred non-human primates between 2018-2022. They provided information on their strategy to move to the use of second or higher generation (F2/F2+) purpose-bred animals. The Directive now requires the use of F2/F2+ or those supplied from self-sustaining colonies. However, this requirement only entered into force in November 2022 whereas this report covers the entire period of 2018-2022.

[7] https://data.europa.eu/doi/10.2779/499108

10. Exemptions from requirements within the Directive

Instead of detailed, numerical data, Member States are required to provide information on the type of circumstances under which exemptions are granted.

During this five-year reporting period, no Member State granted an exemption for the reuse of an animal after a procedure in which the actual suffering was assessed as severe.

Exemptions from work being performed at an establishment were granted for veterinary and/or agricultural research or aquaculture research, research involving wild animals when study of the animals in their home environment is critical to science.

Exemptions from the requirements for accommodation and care were granted. These included scientific requirements on restricting diet; exposure to cold, sound, or altered light regime, which may be harmful, or on single housing conditions.

Purpose-bred animals are not always suitable for the type of study undertaken. Exemptions were granted *inter alia* for research on wild animals, veterinary research and research on specific pet dog breeds. Few species that are not required to be purpose-bred (such as farm animals) were incorrectly reported by some Member States.

No Member State has initiated the use of safeguard clauses, foreseen by the Directive for scientifically justified exceptional cases, during the first ten years of the Directive taking effect.

11. Animal Welfare Bodies

Twelve Member States require additional persons on Animal Welfare Bodies beyond those required in the Directive. Ten of these require the designated veterinarian to be included in the Animal Welfare Body. Other staff required are a layperson and a statistician. Eight Member States have policies requiring training for members of Animal Welfare Bodies. Some members have training as a result of their pre-existing role (functions A-D). The main mechanism used by Member States to ensure compliance with the requirements for Animal Welfare Bodies is through the inspection programme.

Animal Welfare Bodies are recognised as valuable for improving welfare, science and communications between those involved in the breeding and use of animals for scientific purpose.

12. Principles of replacement, reduction and refinement, the Three Rs[8]

The Directive requires systematic application of the Three Rs in all interactions with animals. The Three Rs are addressed during project application, evaluation and authorisation, in advice from the Animal Welfare Bodies, and reviewed during inspection. Many initiatives were identified and introduced to optimise application of the Three Rs. Examples are provided in the main report. Several Member States report improvements in these areas across the Union over the past five years, including by better knowledge-sharing.

13. Tissue sampling of genetically altered animals

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

Member States are required to submit representative data on the methods used for genetic characterisation during creation, maintenance and use of genetically altered animals.

Information on genotyping methods of around 6 million animals was provided. Both the data quality and the level of detail improved significantly compared to the first implementation report, for which only the data from mouse tissue sampling could be analysed.

Around 80% of the animals were genotyped using non-invasive methods. In many Member States, there is an expectation that non-invasive methods will be used, and that invasive methods are only authorised when justified and the use of non-invasive methods is not possible. One Member State indicated that only non-invasive methods were used. There may be opportunities in some Member States to replace currently used genotyping methods with the use of surplus tissue from marking.

For 93% of mice non-invasively genotyped (total 4 367 450), surplus tissue from marking was used, either from ear punch or toe clip (in 2017, just over 50%). Of these 93%, 84% were from ear punch (89% in 2017) and 16% were from toe clipping (11% in 2017).

6% of mice were genotyped using non-invasive methods which included observation under special lighting, post-mortem tissue sampling and apparent from phenotype. This compares to 2% in 2017.

In terms of methods used under project authorisation, mice tail biopsy continued to be the most common method, followed by ear clipping. These were generally reported as of mild severity, although around 17 000 animals were reported as having experienced moderate severity as a consequence of the tissue sampling procedure.

Fin biopsy was the main method of genotyping in zebrafish. Some refined methods included detecting fluorescent markers, skin swabbing and genotyping fish at an early stage. Blood sampling was the commonest method used in other species.

The obligation to refine tissue sampling methods should be systematically addressed. When invasive methods are used for identification, these should provide surplus tissue for genotyping. Tail biopsy is not generally a method which can be used to identify an individual. Given the availability of refinements, it would seem there is no need for more than mild severity of invasive sampling methods . When all known refinements are applied effectively, there should be improved welfare and consistency in severity assignment across the Union in this context.

14. Enforcement

14.1. Authorisation of breeders, suppliers and users

In 2022, there were 667 breeders and suppliers, not using animals,, and 3 487 users which may also breed and supply, making a total of 4 154 establishments (in 2017 just under 3 862).

The number of breeders, suppliers and users have remained reasonably static over the five-year reporting period. However, there is a difference in the numbers reported between 2017 and 2018. For example, the number of users (including those authorised also to breed/supply) compared to those reported in 2017 in the first implementation report have increased by 30% despite the data from the UK no longer included in 2018. It is not clear why there is this difference between the two reporting periods.

Year	Number of active establishments authorised to only use animals	Number of active establishments authorised to use and breed animals	Number of active establishments authorised to use and supply animals	Number of active establishments authorised to use, breed and supply animals	Total number of active users, including those also authorised to breed and/or supply
2017	1 338	1 197	10	216	2 769
2018	2 130	740	239	492	3 601
2019	2 050	738	254	613	3 655
2020	2 043	720	245	559	3 567
2021	2 058	705	263	617	3 643
2022	1 908	707	251	621	3 487

There is some discrepancy concerning the interpretations of "establishment" and "user", "breeder", and/or "supplier". Some Member States may give one establishment multiple authorisations, either for each or a combination of the types listed, or multiple authorisations of the same type may be given within one place/company/educational establishment. The numbers of establishments in the different Member States vary significantly, between 1 and 1 434, which includes just over 100 establishment authorisations for using, breeding and/or supplying non-human primates across all Member States.

14.2. Withdrawals of authorisations of establishments and projects, and penalties

61 establishment authorisations were reported to have been withdrawn or suspended over the five-year period, most of them due to issues or problems identified, but some for other reasons, such as discontinued operation. 57 project authorisations were withdrawn over the five-year period.

There appears to be varied interpretation of what constitutes administrative *versus* legal actions in regard to penalties across the Union. Legal actions included fines, the magnitude of which varies significantly in the different Member States.

14.3. Inspections

Most Member States complied with the requirement to inspect one-third of their user establishments each year. The COVID-19 pandemic provided challenges and some Member States had issues with staffing. However, three Member States appear not to have met this criterion for any of the years reported.

According to the Directive, an appropriate proportion of inspections must be carried out without a prior warning. Across the Union, around one-third of inspections were unannounced. However, the proportion of unannounced inspections varied between Member States from 0-100%. This suggests that different criteria are being applied to determine "an appropriate proportion."

The table below shows the numbers of announced and unannounced inspections performed in 2022 by each Member State. It demonstrates the proportion of unannounced inspections and compares with the performance in 2017. Numbers of inspections are expected to be higher in Member States with more establishments.

Country	Number of announced inspections	Number of un-announced inspections	Total number of inspections	Proportion unannounced	Proportion unannounced in 2017
AT	7	73	80	91%	84%
BE	129	74	203	36%	51%
BG	15	2	17	12%	10%
CY	0	0	0		
CZ	51	10	61	16%	0%
DE	450	284	734	39%	40%
DK	7	6	13	46%	59%
EE	10	0	10	0%	100%
EL	6	0	6	0%	0%
ES	136	13	149	9%	32%
FI	36	13	49	27%	33%
FR	185	92	277	33%	16%
HR	3	0	3	0%	0%
HU	21	1	22	5%	11%
IE	12	11	23	48%	18%
IT	126	74	200	37%	41%
LT	1	16	17	94%	100%
LU	3	3	6	50%	40%
LV	0	0	0		71%
MT	0	0	0		0%
NL	71	11	82	13%	19%
NO	39	0	39	0%	NA
PL	80	38	118	32%	0%
PT	12	0	12	0%	0%
RO	14	19	33	58%	50%
SE	37	32	69	46%	35%
SI	1	4	5	80%	67%
SK	5	2	7	29%	60%

8 Member States performed no unannounced inspections which is the same number as in the 2017 report. 2 Member States performed no unannounced inspections over the ten years covered by the two implementation reports.

Many of the inspection findings confirmed compliance with requirements whilst a minority identify issues, some of which were of low impact, and resolved quickly with administrative actions.

15. Commission activities to facilitate the implementation of the Directive

As guardian of the Treaties, the Commission has assessed the conformity of national legislation transposing the Directive. The first implementation report noted issues of potential incorrect transposition leading to dialogues with all Member States. By 2019, discussions were successfully concluded with eight Member States, while discussions continued and/or formal infringement procedures were opened for others. As a result, most Member States have amended their national legislation transposing the Directive. By April 2024, the cases have been successfully closed for

23 Member States, with the remaining four pending either the assessment of amendments to national legislation or determination of further steps.

The European Commission continued to work closely with experts from Member States and key stakeholders on topics crucial for the correct implementation of the Directive. Three more guidance documents were developed covering genetically altered animals[9], non-technical project summaries[10], and results of retrospective assessment[11]. Especially the guidance on genetically altered animals is expected to improve the understanding and proper implementation of the rules concerning authorisation, genetic characterisation, and reporting of genetically altered animals, which had proven challenging.

Further training tools are being developed thanks to the European Parliament funded Preparatory Action with a focus on education and training, and implementation of the Three Rs. Material has already been made available for educators in secondary schools and universities. Thirteen additional open-access e-learning modules will be delivered in 2025, aimed at ensuring the competence of staff involved in care and use of animals across the Union.

In response to the European Citizens' Initiative "Save Cruelty-Free Cosmetics – Commit to a Europe without Animal Testing", the European Commission committed to developing together with agencies, Member States and stakeholders a roadmap to ultimately phase out animal testing for chemical safety assessments. The roadmap is to be finalised early in the mandate of the new Commission.

Finally, in 2021, the Union took the world lead in transparency on the use of animals in science with the launch of two public databases on annual statistics on animal use, and non-technical project summaries ("ALURES[12]"). These open-access databases allow stakeholders and decision makers to determine where alternatives are most urgently needed to progress towards the Directive's ultimate goal of full replacement.

[9] https://data.europa.eu/doi/10.2779/499108

[10] https://data.europa.eu/doi/10.2779/778680

[11] https://data.europa.eu/doi/10.2779/896767

[12] https://environment.ec.europa.eu/topics/chemicals/animals-science/statistics-and-non-technical-project-summaries_en

INTRODUCTION

Under Article 54(1) of Directive 2010/63/EU on the protection of animals used for scientific purposes[13] ("the Directive"), Member States are required to send 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 II of Commission Implementing Decision 2020/569/EU [14] ("the Annex").

Under the European Economic Area agreement, Norway has transposed the Directive in their respective national legislation and was therefore invited to submit the implementation report to the European Commission together with Member States. References to "EU", "Union" and "Member State" data from here on in this report, are to be understood to cover 27 EU Member States and Norway, unless specified otherwise.

The first EU report on the implementation of the Directive was published in 2019 covering years 2013-2017. This second report presents a Union summary for years 2018-2022 on how Member States have implemented the Directive and highlights any identified issues and good practice.

i. Information from the Member States

In 2019, the Directive was amended by Regulation (EU) 2019/1010[15] ("the Regulation"). In particular, Article 54(1) was amended to require the Member State implementation reports to be submitted to the Commission through electronic transfer by 10 November 2023, and every five years thereafter.

Member States were requested to submit their national implementation reports using a tailored questionnaire through an electronic submission platform. The questionnaire covered all the elements described in the Annex. In addition, some non-compulsory questions were included in the questionnaire and Member States could choose whether or not to answer these on a voluntary basis. The purpose of these questions was to provide additional helpful information to better understand the implementation of the Directive. All voluntary questions are identified as such in this report.

The individual Member State submissions are available at the European Commission web-site[16].

ii. Structure of the Report

The structure of the report will follow the order as set out in the Annex. Where available, consolidated Union data is provided for the five-year period, however, when making Member State comparisons, mostly 2022, as the most recent year, is being used as the year of reference.

[13] *OJ L 276, 20.10.2010, p. 33–79*
[14] *OJ L 129, 24.4.2020, p. 16-50*
[15] *OJ L 170, 25.6.2019, p. 115–127*
[16] https://environment.ec.europa.eu/topics/chemicals/animals-science_en#implementation

A. NATIONAL MEASURES ON THE IMPLEMENTATION OF DIRECTIVE 2010/63/EU

Reporting obligation

"Provide information on changes made to national measures regarding the implementation of Directive 2010/63/EU since the previous report."

Questions

A - 1 Is the coordination of the implementation of Directive 2010/63/EU a responsibility of a single ministry?

A - 1.bis Name and responsibilities of the each of the ministries involved.

Answer	Count	%	Member States
Yes	22	79%	AT, BG, CY, CZ, DE, DK, EE, FI, HU, IE, IT, LT, LU, LV, MT, NL, NO, PT, RO, SE, SI, SK
No	6	21%	BE, EL, ES, FR, HR, PL

22 Member States indicated that the coordination of the implementation of Directive 2010/63/EU is the responsibility of a single ministry.

6 Member States indicated that more than one ministry is involved.

Some responses suggest incomplete understanding of the question as they also reported only a single ministry involved but listed two ministries.

Article 59 of the Directive requires Member States to designate one or more competent authorities to be responsible for the implementation of the Directive. Some Member States have decided that different ministries would be responsible for different functions. The table below lists all the ministries and their responsibilities by Member State. Where Member States are coloured green, these have a single ministry for each responsibility.

Responsibility		Authorisation of establishments	Education, training and competence	Inspections	National Committee	Project authorisation	Project evaluation	Retrospective assessment	Statistical reporting
BE	Leefmilieu Brussel. Afdeling Inspectie en verontreinigde bodems, Departement Dierenwelzijn	✓	✓	✓	✓	✓	✓	✓	✓
	Service Public de Wallonie, Département du Développement, de la Ruralité, des Cours d'eau et du Bien-être animal et Département de la Police et des contrôles	✓	✓	✓	✓	✓	✓	✓	✓
	Vlaamse overheid, Departement Omgeving, Afdeling Dierenwelzijn	✓	✓	✓	✓	✓	✓	✓	✓
CZ	Akademie věd České republiky		✓			✓	✓	✓	
	Ministerstvo průmyslu a obchodu; Ministerstvo životního prostředí; Ministerstvo školství, mládeže a tělovýchovy; Ministerstvo zdravotnictví; Ministerstvo obrany					✓	✓	✓	
	Ministerstvo zemědělství	✓	✓	✓	✓	✓	✓	✓	✓
	Státní veterinární správa skládající ze 14 podřízených organizací dle územního členění (kraje).			✓					
EL	Ministry of Interior Affairs, Regional Units of Regions, Departments of Veterinary Services			✓					
	Ministry of Interior Affairs,a) Regions of Greece, Directorates of Veterinary Services	✓				✓	✓	✓	
	Ministry of Rural Development and Food	✓	✓	✓	✓	✓	✓	✓	✓
ES	Ministerio de Agricultura, Pesca y Alimentación	✓		✓	✓	✓	✓	✓	✓
	Ministerio de Ciencia e Innovación		✓						
FR	Ministère de la défense	✓		✓		✓	✓	✓	
	Ministère de l'agriculture et de la souveraineté alimentaire	✓	✓	✓					
	Ministère de l'enseignement supérieur et de la recherche.				✓	✓	✓	✓	✓
HR	Ministry of Agriculture, Veterinary and Food Safety Directorate	✓	✓		✓	✓	✓	✓	✓
	State inspectorate, Veterinary and Food Safety Inspection Sector			✓					
LU	Ministry of Agriculture, Viticulture and Rural Development	✓	✓	✓	✓	✓	✓	✓	✓
	Ministry of Health				✓		✓		
	Ministry of higher education and research				✓				
LV	Food and Veterinary service	✓	✓	✓		✓	✓	✓	✓
	Ministry of Agriculture						✓		
	The National Committee for the protection of animals used for scientific purposes		✓		✓		✓		
NO	Ministry of Agriculture and Food				✓				
	Norwegian Food Safety Authority	✓	✓	✓		✓	✓	✓	✓
PL	Ministerstwo Edukacji i Nauki	✓	✓		✓	✓	✓	✓	✓
	Ministerstwo Rolnictwa i Rozwoju Wsi			✓					
SK	District Veterinary and Food Administrations - Local Level, under the Ministry of Agriculture and Rural Development of the Slovak Republic			✓					
	Ministry of Agriculture and Rural Development of the Slovak Republic		✓		✓				
	State Veterinary and Food Administration of the Slovak Republic - Central level, under the Ministry of Agriculture and Rural Development of the Slovak Republic	✓	✓	✓		✓	✓	✓	✓

Within the Member States responses, there are more than one ministry indicated for the same responsibility in the following Member States.

Responsibility	Authorisation of establishments	Education, training and competence	Inspections	National Committee	Project authorisation	Project evaluation	Retrospective assessment	Statistical reporting
BE	3	3	3	3	3	3	3	3
CZ	1	2	2	1	3	3	3	1
EL	2	1	2	1	2	2	2	1
FR	2	1	2	1	2	2	2	1
LU	1	1	1	3	1	2	1	1
LV	1	2	1	1	1	3	1	1
SK	1	2	2	1	1	1	1	1

Two ministries

Spain has two ministries coordinating responsibilities: one for education and training, the other for all the other functions.

Croatia and Poland indicated that all responsibilities except inspection was coordinated by a single ministry.

Norway indicated that all responsibilities were carried out by one ministry except for the National Committee.

Three ministries

Belgium has three regional authorities who each have all of the separate responsibilities for implementation of the Directive in their region.

Greece has three ministries, one was reported to perform all the responsibilities, and two which cover only some responsibilities.

France has three ministries with split responsibilities for implementation, one performing authorisation of establishments, education and training and inspections, one for project evaluation and authorisation, retrospective assessment and National Committee, but also has a ministry performing all the responsibilities within a specific research area.

In addition, in some other Member States there is more than one ministry involved in the implementation of the Directive, but the overall coordination is through one ministry. For example, in Czechia, although one ministry co-ordinates all functions, a separate ministry has the responsibility for inspection, and another for project evaluation, authorisation and retrospective assessment.

In others, there are more complex structures, where although there is a national co-ordinating ministry, there are regional bodies responsible for implementation within each region, for example in Germany, Spain and Austria.

Questions

A - 2 Have any changes been adopted to the national legislation which implements Directive 2010/63/EU since 2017?

A - 2.bis Please summarise the changes that have been adopted since 2017 to the national legislation transposing Directive?

Answer	Count	%	Member States
Yes	25	89%	AT, BE, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK
No	3	11%	BG, HU, NO

24 Member States provided a summary of changes since 2017 to the national legislation transposing Directive 2010/63.

Most Member States have made changes to the legislation since the initial transposition into national legislation. Most amendments have been the direct result of conformity checks performed by the Commission on the transposition.

Legal

Some examples of legal changes highlighted by Member States include:

- In Belgium, animal welfare has been a regional competence since 2014 and as a consequence the Directive has now been transposed into regional legislation;
- Italy has extended the possibility to use animals for xenotransplantation and substance abuse studies until July 2025;
- Luxembourg adopted a new national animal welfare law in 2018, part of which sets out the Ministries responsible for different aspects of the Directive;
- Austria clarified issues relating to competence of personnel, and rules on project evaluation;
- Finland has extended the scope of its national legislation to include the foetal forms of birds and reptiles during the last third of their normal development.

Optimisation of delivery of requirements

- A few Member States reported that additional guidance has been introduced to assist understanding of the legislative requirements:

  For example, Belgium acknowledged differences in legislation and guidance between the regions. The Brussels Capital Region has provided a wide range of guidance documents such as on animal records, continuing professional development and responsibilities for project evaluators. The Flemish and Walloon regions reported fewer guidance documents for operators;

- Croatia has restructured their inspectorate;
- Netherlands have updated the project application templates;
- Romania has introduced standard assessment sheets for project evaluation.

B. STRUCTURES AND FRAMEWORK

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

Reporting obligation

"*Explain the framework for competent authorities, including the numbers and types of authorities as well as their respective tasks, and explain the measures taken to ensure compliance with the requirements of Article 59(1) of Directive 2010/63/EU.*"

Background

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

1) Authorisation of breeders, suppliers and users (Article 20(1))
2) Inspections (Article 34(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

Question

B - 1.1 Please describe each distinct type of authority and the number of units (CAs) of each type.

Structure of competent authorities for the five key responsibilities (authorisation of establishments, inspections, project authorisation, project evaluation, retrospective assessment).

Number of CAs																												
Type of authority	AT	BE	BG	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HR	HU	IE	IT	LT	LU	LV	MT	NL	NO	PL	PT	RO	SE	SI	SK	**Total**
National	1		1	1	8		1	2	1	93	2	4	2	1	1	1	1	2	3	1	2	1	3	1		2	1	1	**137**
Regional	9	3	28		14	23			87	19	2	89		19		20	2						314			27			**656**
Local - shared by more than one establishment		20				550										224					15		11		42			40	**902**
Local - within establishment		11																											**11**
Total	**10**	**34**	**29**	**1**	**22**	**573**	**1**	**2**	**88**	**112**	**4**	**93**	**2**	**20**	**1**	**245**	**3**	**2**	**3**	**1**	**17**	**1**	**328**	**1**	**42**	**29**	**1**	**41**	**1 706**

Number of CAs																												
Public or non-public	AT	BE	BG	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HR	HU	IE	IT	LT	LU	LV	MT	NL	NO	PL	PT	RO	SE	SI	SK	**Total**
Public	10	3	29	1	22	573	1	2	88	89	4	4	2	20	1	245	3	2	2	1	2	1	316	1	42	29	1	41	**1 535**
Non-public		31								23		89							1		15		12						**171**
Total	**10**	**34**	**29**	**1**	**22**	**573**	**1**	**2**	**88**	**112**	**4**	**93**	**2**	**20**	**1**	**245**	**3**	**2**	**3**	**1**	**17**	**1**	**328**	**1**	**42**	**29**	**1**	**41**	**1 706**

Number of CAs																												
Responsibility	AT	BE	BG	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HR	HU	IE	IT	LT	LU	LV	MT	NL	NO	PL	PT	RO	SE	SI	SK	**Total**
Authorisation of establishments	10	3	28	1	1	305	1	1	14	19	2	2	1	19	1	245	2	1	1	1	1	1	1	1	42	1	1	1	**707**
Inspections	10	3	28	1	14	245	1	1	88	19	2	2	1	19	1	225	2	1	1	1	1	1	315	1	42	21	1	41	**1 088**
Project authorisation	10	31	1	1	7	23	1	1	14	19	1	2	1	19	1	1	1	1	1	1	1	1	12	1	42	6	1	1	**202**
Project evaluation	10	31	1	1	7	23	1	1	14	93	1	89	1	1	1	1	1	2	3	1	16	1	12	1	42	6	1	1	**363**
Retrospective assessment	10	31	1	1	7	23	1	1	14	93	1	89	1	1	1	1	1	1	1	1	1	1	11	1	42	1	1	1	**339**

Type of authority	Count	%	Member States
National	25	89%	AT, BG, CY, CZ, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, NO, PL, PT, SE, SI, SK
Regional	14	50%	AT, BE, BG, CZ, DE, EL, ES, FI, FR, HU, IT, LT, PL, SE
Local - shared by more than one establishment	7	25%	BE, DE, IT, NL, PL, RO, SK
Local - within establishment	1	4%	BE

Public or non-public	Count	%	Member States
Public	28	100%	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, NO, PL, PT, RO, SE, SI, SK
Non-public	6	21%	BE, ES, FR, LV, NL, PL

Although 25 Member States have a competent authority at national level, 14 have competent authorities at a regional level and 7 at a local level (shared by more than one establishment) and 1 Member State has a competent authority within individual establishments. Hence, most Member States have more than one type of competent authorities.

The total number of competent authorities per Member State also varies significantly, from 1 (six Member States) to over 100 (112 in Spain; 245 in Italy, 328 in Poland and 573 in Germany).

The distribution of tasks to competent authorities also varies significantly.

For example, in Germany, where there is one ministry responsible for the coordination of the implementation of the Directive, of the 573 competent authorities, (all of which are public bodies) 305 are responsible for the authorisation of establishments, 245 responsible for inspections, and 23 responsible for project evaluation, authorisation and retrospective assessment.

In contrast, in Italy, where there is also one ministry responsible for the coordination of the implementation of the Directive, of the 245 competent authorities (all of which are public bodies), one competent authority has responsibilities for all 5 functions, 224 local competent authorities are responsible for the authorisation of establishments and inspection, with a further 20 regional competent authorities which are also responsible for authorisation of establishments. Italy reported (not within submission but within correspondence relating to it) that it has separated authorisation of users (national) from that of breeders/suppliers (local) to separate competent authorities.

Greece has three ministries involved in the coordination of the Directive, and a total of 88 competent authorities (all public bodies) responsible for aspects of implementations with 1 national and 13 regional competent authorities responsible for all five functions, and a further 74 competent authorities responsible for inspections at the local level.

Sweden has a single ministry responsible for coordination of implementation, with a total of 29 competent authorities responsible for implementation, one national competent authority responsible for authorisation of establishments, one national competent authority responsible for retrospective assessment, six regional competent authorities for project evaluation and authorisation and competent authorities regional competent authorities for inspections.

Public versus non-public

Under the Directive, a competent authority does not have to be a public body, provided it has the expertise and infrastructure and is free from conflict of interest.

All Member States have public competent authorities, but in additon six Member States have some which are not public. Where there are non-public authorities there would need to be assurances that there is appropriate expertise and infrastructure and there are no conflicts of interest.

Distribution of competent authorities among the five key responsibilities

Some Member States have only one competent authority for each of the five tasks (Denmark, Ireland, Cyprus, Malta, Portugal, Slovenia, Norway).

Others have very large numbers of competent authorities (Germany, Greece, Spain, France, Italy, Poland).

The number of competent authorities per Member State might be expected to relate to a certain extent on the size of the animal research activities as indicated by the number of establishments, number of research projects and numbers of animals used. However, this indication does not always hold.

Authorisation of establishments

Authorisation of establishments may be done by between 1 and 305 competent authorities within a Member State. Two Member States have over 200 competent authorities for this task (Italy: 245, Germany: 305).

In 2022, Italy reported having 36 breeders and suppliers and 227 users (total establishments: 263) while 245 competent authorities were responsible for authorisation of establishments i.e. close to one competent authority for each establishment. In 2022 in Germany, there were 469 breeders and suppliers and 965 users (total establishments: 1 434) and 305 competent authorities responsible for authorisation.

This issue is not just limited to large Member States as Bulgaria has 24 establishments and 28 competent authorities for authorisation of establishments, and Slovakia has 26 establishments and 40 competent authorities for authorisation of them.

Inspections

Inspections may be done by between 1 and 315 competent authorities, with three Member States having more than 200 competent authorities (Germany, Italy, Poland).

Number of inspections per competent authorities, shown in the table below, range from less than 1 to 139. Number of establishments range from 1 to 288.

Member State	CAs for Inspection	Number of Inspections 2022	Inspections per CA	Number of user establishments. Includes users that also breed and/or supply	Establishments per CA
AT	10	80	8	57	5.7
BE	3	203	68	244	81.3
BG	28	17	0.6	24	0.8
CY	1	0	0	8	8
CZ	14	61	4.4	81	5.8
DE	245	734	3	965	3.9
DK	1	13	13	47	47
EE	1	10	10	9	9
EL	88	6	0.07	62	0.7
ES	19	149	7.8	243	12.8
FI	2	49	25	98	49
FR	2	277	139	575	288
HR	1	3	3	67	67
HU	19	22	1.2	24	1.3
IE	1	23	23	23	23

IT	225	200	0.9	227	1
LT	2	17	9	24	12
LU	1	6	6	3	3
LV	1	0	0	9	9
MT	1	0	0	1	1
NL	1	82	82	77	77
NO	1	39	39	83	83
PL	315	118	0.4	142	0.45
PT	1	12	12	50	50
RO	42	33	0.8	46	1.1
SE	21	69	3.3	205	9.8
SK	41	7	0.2	26	0.6
SL	1	5	5	11	11
Total	**1 088**	**2 235**		**3 431**	

Half of the Member States performed less than five inspections per competent authority in 2022. Further, in ten Member States there were five user establishments per competent authority. The small workload makes it challenging to attain and maintain competence in inspection. The table above refers to 2022, but during the five-year reporting period one Member State has completed a total of 23 inspections over the five years, which may mean that in that Member State approximately 25% of the competent authorities may have carried out only one inspection in five years, and 75% may have carried out no inspections. It seems that some competent authorities are unlikely to perform any inspections in a five-year period, given the number of competent authorities and the number of inspections performed.

Project evaluation

Project evaluation may be performed by between 1 and 93 competent authorities. Numbers of project applications in the Members States range between 1 and 2 901 as shown in table below, ordered by number of competent authorities.

Member State	Competent authorities for project evaluation	Number of applications	Project evaluations per competent authority
ES	93	1 668	18
FR	89	2 901	33
RO	42	89	2
BE	31	1 459	47
DE	23	2 538	110
NL	16	256	16
EL	14	187	13
PL	12	880	73
AT	10	601	60
CZ	7	436	62
SE	6	380	63
LV	3	11	4
LU	2	8	4

IT	1	843	843
NO	1	438	438
HU	1	287	287
DK	1	257	257
FI	1	112	112
IE	1	92	92
PT	1	87	87
LT	1	50	50
SK	1	37	37
HR	1	26	26
EE	1	25	25
SL	1	13	13
CY	1	11	11
BG	1	10	10
MT	1	0	0
Total	**363**	**13 702**	

It might be expected where there is a high workload that there might be more competent authorities, but there is no clear correlation. Romania stands out as having a large number of competent authorities for the number of project evaluations to be carried out. Three Member States had fewer than five evaluations per competent authority in 2022. Low workload would make attainment and maintenance of competence as well as coherence between evaluations significantly more difficult.

Project authorisation

Member State	Competent authorities for project evaluation
AT	10
BE	31
BG	1
CY	1
CZ	7
DE	23
DK	1
EE	1
EL	14
ES	19
FI	1
FR	2
HR	1
HU	19
IE	1
IT	1
LT	1
LU	1
LV	1
MT	1

NL	1
NO	1
PL	12
PT	1
RO	42
SE	6
SI	1
SK	1
Total	**202**

Project authorisation may be done by between 1 and 42 competent authorities. Interestingly, the Member State with 42 competent authorities (Romania) reported that they have only 46 establishments and 89 projects. In contrast, Germany has 23 competent authorities for project authorisation with 2 516 projects held within 965 reported user establishments. In France, two competent authorities authorise 2 759 projects in 589 establishments. This indicates a wide variability on the way competent authorities are organised and the throughput of tasks they are required to perform.

One of the main goals of the Directive is to provide a level playing field for the research community. It would seem to be challenging to provide a consistent approach where there are multiple competent authorities responsible for individual tasks. Large numbers of competent authorities for any or all tasks creates a larger problem to deliver consistency, especially where throughput is low (e.g., when the number of competent authorities exceeds the total number of establishments or projects to be authorised). From the figures provided, it would seem challenging for the competent authorities in certain Member States to gain sufficient expertise and experience when some of they have very limited opportunities to do so.

Question

B - 1.2 Explain the measures taken to ensure that it has the expertise and infrastructure required to carry out the tasks (Art 59(1)) MANDATORY QUESTION if non-public authority was selected for any of the above tasks.

All Member States used public bodies. In addition, six Member States indicated that non-public bodies were responsible for at least part of the implementation of the Directive.

In Belgium, only non-public bodies are responsible for project evaluation, authorisation and retrospective assessment. These are either based in individual establishments (11) or local where shared by more than one establishment (20). The benefits stated that there is knowledgeable local expertise to deal with complex research topics, IT and administrative support. Each “ethical commission” has a minimum of seven members, with expertise meeting the requirements set out in Article 38 of the Directive. Members of such bodies need to provide evidence to the regional ministry of their expertise and a signed document regarding conflicts of interest and confidentiality. Confirmation of the necessary expertise is done by the regional ministry.

In Spain, authorisation of establishments and projects and the responsibility for inspection remain with public bodies. Responsibility for project evaluation and retrospective assessment lies with a mix of public (70) and non-public (23) bodies. The non-public organisations can be private or mixed entities. Their suitability to conduct their roles is approved by the autonomous communities

(19). Although the process for approval is not harmonised, it generally requires confirmation of the necessary expertise within the membership.

France has appointed the local animal ethics committees (89) as competent authorities for project evaluation and retrospective assessment. The committees are approved by the ministry and audited annually. The approval takes into account compliance with the National Charter on the Ethics of Animal Testing[17], covering the training of members, competence, independence, impartiality and operation of the committee.

In the Netherlands, a single national public body is the competent authority for project authorisation and evaluation. It recognises and is supported by 15 local animal experiment committees which are competent authorities for the purpose of project evaluation.

In Poland all competent authorities, 12 responsible for project evaluation and authorisation and 11 for retrospective assessment are non-public bodies. The national implementing legislation requires that only persons with the expertise, training and competence can carry out tasks in national and local ethics committees.

Latvia indicated that one of the three competent authorities responsible for project evaluation is not a public body, but no further explanation was provided.

Question

B - 1.3 Explain the measures taken to ensure it is free of any conflict of interests as regards the performance of the tasks (in reference to requirements under Art 59(1))

MANDATORY QUESTION if non-public authority was selected for any of the above tasks.

In Belgium, the non-public ethical commissions ensure that they are free of conflicts of interest and guarantee impartial judgement by taking into account the opinions of parties independent of the user applying for project authorisation. Members must declare their interests through a general declaration of interests. These declarations are submitted to the president of the commission who makes sure they are available for consultation by the regional ministry. The regional ministry monitors the functioning of the ethical commissions. To this end, the regional ministry may participate in the work of the ethical commissions and may inspect all documents related to the work of the ethical commissions.

In Spain, members of the non-public competent authorities submit a signed declaration of confidentiality and impartiality to the regional authority, with a commitment not to participate in the evaluation of projects which could give rise to a conflict of interest. The activities of the non-public competent authorities can be monitored (often by attendance at evaluation by the regional autonomous communities which have authorised them).

In France, it was reported that all non-public competent authorities are independent and impartial and guarantee the confidentiality of the files submitted to them. Persons responsible for an application may not participate in discussions on their project. The National Committee has produced guidance on avoiding conflicts of interest.

[17] https://www.enseignementsup-recherche.gouv.fr/sites/default/files/2023-10/national-charter-on-the-ethics-of-animal-experimentation-29697.pdf

Latvia reported that the meetings are generally held in public.

In the Netherlands, the competent authorities for project evaluation consider potential conflicts of interest with every application, and members are withdrawn from discussions should any arise.

In Poland, as well as the law stating that there shall be no conflict of interest in dealing with projects, the competent authorities also include representatives of animal protection organisations which broadens discussions and gives further independent input.

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

Reporting obligation:

"*Explain the structure and operation of the national committee, and the measures taken to ensure compliance with the requirements of Article 49 of Directive 2010/63/EU.*"

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

Questions

B - 2.1 Provide information on the expertise of your National Committee.

B - 2.1.bis Please explain 'other' expertise.

Answer	Yes		
Expertise	Count	%	Member States
animal welfare and care	28	100%	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, NO, PL, PT, RO, SE, SI, SK
veterinary	28	100%	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, NO, PL, PT, RO, SE, SI, SK
animal behaviour	27	96%	AT, BE, BG, CY, CZ, DE, DK, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, NO, PL, PT, RO, SE, SI, SK
animal protection work	27	96%	AT, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, NO, PL, PT, RO, SE, SI, SK
procedures on animals	27	96%	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, NL, NO, PL, PT, RO, SE, SI, SK
relevant species	27	96%	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, NL, NO, PL, PT, RO, SE, SI, SK

scientific research	27	96%	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, NL, NO, PL, PT, RO, SE, SI, SK
Three Rs	27	96%	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, NL, NO, PL, PT, RO, SE, SI, SK
ethics	26	93%	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LV, MT, NL, NO, PL, PT, RO, SE, SK
legislation	26	93%	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SK
regulatory / safety evaluation	26	93%	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LV, MT, NL, PL, PT, RO, SE, SI, SK
non-animal alternatives	25	89%	AT, BE, BG, CY, CZ, DE, DK, EE, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, NL, NO, PL, PT, RO, SE, SK
other	4	33%	FR, IT, MT, SI

The great majority of Member States have a very wide range of expertise within their National Committees, with over 25/28 encompassing all the areas identified in Question B 2.1.

Eight Member States identified other areas of expertise which they have included within their National Committee, for example animal protection organisations (France, Slovenia) and education and training (Italy).

Questions

B - 2.2 Is the National Committee impartial and independent from the Competent Authority/ies responsible for the implementation of the Directive?

B - 2.2.bis If no, please explain.

Answer	Count	%	Member States
Yes	18	64%	AT, CZ, DE, DK, FI, FR, HR, HU, IE, IT, LT, LV, NL, NO, PL, PT, SE, SK
No	10	36%	BE, BG, CY, EE, EL, ES, LU, MT, RO, SI

18 Member States indicated that the National Committee is impartial and independent from the competent authorities responsible for the implementation of the Directive.

In the remaining 10, competent authority representatives participate in the work of the National Committee. The National Committee also acts as the competent authority for project evaluation in Bulgaria, Croatia, Cyprus, Latvia, Hungary and Slovenia. In Romania, the National Committee advises on the quality of non-technical project summaries.

The competent authority often provides administrative support, for example secretarial support and meeting venue for National Committees.

These 10 indicated a number of strategies to overcome any concerns over impartiality or independence, including obligations on members to avoid such conflicts, appointment of independent members/experts, a transparent constitution acknowledging risks and promoting publication of independent advice.

Question

B - 2.3 Between 2018 and 2022, has your National Committee advised the competent authority on the following?:

Answer	Yes			No		
Question	Count	%	Member States	Count	%	Member States
use of animals in procedures	23	82%	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FR, HR, HU, IE, IT, LT, LV, NL, NO, PL, RO, SI, SK	5	18%	FI, LU, MT, PT, SE
accommodation and care	21	75%	AT, BE, BG, CZ, DE, DK, EE, EL, ES, FR, HR, HU, IE, IT, LT, LV, NL, PL, RO, SE, SK	7	25%	CY, FI, LU, MT, NO, PT, SI
acquisition of animals	12	43%	AT, BG, CY, DE, ES, FR, HR, LT, LV, NL, PL, RO	16	57%	BE, CZ, DK, EE, EL, FI, HU, IE, IT, LU, MT, NO, PT, SE, SI, SK
breeding	11	39%	AT, BE, DE, FR, HR, LT, LV, NL, PL, RO, SK	17	61%	BG, CY, CZ, DK, EE, EL, ES, FI, HU, IE, IT, LU, MT, NO, PT, SE, SI

Article 49 requires that National Committees provide advice to competent authorities and Animal Welfare Bodies on certain prescribed topics. The most common prescribed topic on which advice was offered was on the use of animals in procedures, closely followed by advice on accommodation and care.

9 National Committees have offered advice to the competent authorities on all the topics, whereas 4 (Luxembourg, Malta, Portugal, Finland) appear not to have offered advice to the competent authorities on any of these topics.

Question

B - 2.4 What information has the National Committee shared to inform Competent authority/ies on best practices with regards to project evaluation?

In line with Article 49(2), many National Committees have developed advice and guidance in relation to project evaluation to promote a harmonised approach and consistent outcomes.

For example:

- Belgium has developed a new project application form and an evaluation table including a harm benefit analysis. A good practice guide was also developed for evaluation and authorisation of animal procedures;
- Austria has developed an aid to improve the quality of the harm-benefit analysis.

A range of good practice guidance documents and codes of practice have been developed to assist applicants and evaluators, for example: guidance on rehoming, blood sampling methods and

volumes, methods for identification and genetic characterisation of laboratory animals, housing of male mice, assessing impacts of food and water deprivation, peri-operative care, methods of euthanasia, and monitoring of animal welfare.

Training material has also been developed for project evaluators, including information on experimental design and application of the Three Rs within projects. Training for scientists, project evaluators and Animal Welfare Bodies' members have been held as face-to-face meetings or webinars on aspects of the Three Rs -for example Reduction and good experimental design, Refinement (environmental enrichment, welfare scoring and humane endpoints and adverse event management), Replacement (new methods) and assessment of severity.

Workshops have been held on ethical acceptability of animal use and safety evaluation of new medicines and chemicals. A number of National Committees have given their views on the EURL/ECVAM Recommendations on non-animal derived antibodies.

Question

B - 2.5 Between 2018 and 2022, has your National Committee advised animal welfare bodies on the following?:

Answer	Yes			No		
Question	Count	%	Member States	Count	%	Member States
accommodation and care	19	68%	AT, BG, DE, DK, EL, FI, FR, HR, HU, IE, IT, LT, LV, NL, NO, PL, SE, SI, SK	9	32%	BE, CY, CZ, EE, ES, LU, MT, PT, RO
use of animals in procedures	19	68%	AT, BG, DE, DK, EE, EL, FI, FR, HR, HU, IE, IT, LT, LV, NL, NO, PL, SI, SK	9	32%	BE, CY, CZ, ES, LU, MT, PT, RO, SE
acquisition of animals	10	36%	BG, DE, DK, HR, HU, LT, LV, NL, PL, SI	18	64%	AT, BE, CY, CZ, EE, EL, ES, FI, FR, IE, IT, LU, MT, NO, PT, RO, SE, SK
breeding	10	36%	BG, DE, FR, HR, LT, LV, NL, PL, SI, SK	18	64%	AT, BE, CY, CZ, DK, EE, EL, ES, FI, HU, IE, IT, LU, MT, NO, PT, RO, SE

Just over two-thirds of the National Commitees offered advice to Animal Welfare Bodies on accommodation and care and the use of animals in procedures. One-third provided advice on the acquisition of animals and matters relating to breeding.

9 National Committees offered advice on all the topics, and 8 Member States did not offer advice to Animal Welfare Bodies.

Whilst Romania advised competent authorities on all topics it did not directly provide advice Animal Welfare Bodies. This may be because there are processes within Member States for this to be fed on to Animal Welfare Bodies by competent authority. One Member State (Portugal) reported that it has struggled to meet some of the requirements.

In some Member States, there does not seem to be a direct link between National Committee and Animal Welfare Bodies, although in some cases an indirect link was mentioned (via competent authorities or ethics committees).

Many National Committees have their own web-site, and a few provide regular newsletters to Animal Welfare Bodies. Germany has launched an online dialogue forum for members of Animal Welfare Bodies.

The developed guidance, codes of practice, training material and training mentioned earlier were also addressed to Animal Welfare Bodies improving consistent approach within the Member State.

Voluntary question

B - 2.6 What successes has the National Committee had in sharing best practice within Member State and across EU? What challenges have arisen?

Nine Member States responded to this question of which some examples are presented below:

Successes within Member State

- Regular meetings among competent authorities responsible for project evaluation and authorisation to promote consistency through guidance etc.;
- Workshops on important topics such as regulatory safety testing requirements and the Three R developments;
- National meetings for all Animal Welfare Bodies to update and inform on new developments;
- Co-ordinated training for Animal Welfare Body members;
- Advice to ministry.

Challenges within Member State

- Harmonisation of staff training system to clarify legal framework where regional structures, and ensuring appropriate training for those involved in project evaluation;
- Remaining current with new Three R initiatives.

Successes across the Union

- Meetings hosted by European Commission and National Committees of Member States (voluntary joint meetings);
- Representatives of National Committee being involved in international Three R initiatives;
- Opening national meetings to National Committee representatives from other Member States.

Challenges across the Union

- Mutual recognition of projects across Member States with differing expectations evident. Some further harmonisation is desired. Sharing of applications to assist harmonisation of evaluation was proposed;
- Continuation of voluntary joint meetings would be beneficial;
- Agreement on how to handle applications for continued use of antibody production in animals would be helpful.

Voluntary question

B - 2.7 Has EU guidance on Animal Welfare Bodies and National Committees been made available to the National Committee?

Answer	Count	%	Member States
Yes	27	100%	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LU, LV, MT, NL, NO, PL, PT, RO, SE, SI, SK
Total	**27**	**100%**	

Of the 27 Member States that responded, all have made the guidance on Animal Welfare Bodies and National Committees available.

During the period of the first implementation report, many Member States who had not previously had a "national committee" had taken a few years to get the National Committee fully functional. In contrast, given the advice and guidance provided by National Committees to competent authorities and Animal Welfare Bodies in this second implementation report, in the great majority of Member States, a much more effective National Committee is in place.

However, there appear to be a few Member States still struggling to deliver the required advice.

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

Reporting obligation

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

Background

The 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

Questions

B - 3.1 The minimum requirements for education and training for functions in Article 23(2) are set out the Education and Training Framework document. Does your Member State enforce standards at least equivalent to these for the following functions?

B - 3.1.bis What other provisions are in place to comply with Art 23(2)?

Answer:	Yes			No		
Function	Count	%	Member States	Count	%	Member States
(a) carrying out procedures on animals	27	96%	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, NL, NO, PL, PT, RO, SE, SI, SK	1	4%	MT
(b) designing procedures and projects	27	96%	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, NL, NO, PL, PT, RO, SE, SI, SK	1	4%	MT
(c) taking care of animals	27	96%	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, NL, NO, PL, PT, RO, SE, SI, SK	1	4%	MT
(d) killing animals	27	96%	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, NL, NO, PL, PT, RO, SE, SI, SK	1	4%	MT

27 Member States enforce the minimum standards for the four main functions of staff described in Art 23(2).

The remaining Member State (Malta) reported that their competent authority assesses the suitability of each individual.

Question

B - 3.2 What methods are used to demonstrate competence?

The legislation does not prescribe how competence must be demonstrated, only that a person is named as being responsible for ensuring competence. Member States / establishments can decide independently how such competence should be demonstrated.

A minority of Member States (Germany, Netherlands, Austria, Finland) discriminated between the four functions required to demonstrate competence and different methods used when describing these methods, e.g., apprenticeships for those responsible for the care of animals.

Many Member States answered by providing the legal requirements only, e.g., completion of theoretical and practical training courses (in some cases reporting examinations) although the Directive specifies a requirement to demonstrate competence beyond having obtained the required education.

14 Member States (Belgium, Czechia, Denmark, Estonia, Ireland, Greece, Spain, Italy, Luxembourg, Austria, Portugal, Romania, Slovenia, Sweden) reported using supervision by a person with extensive experience or a designated expert to demonstrate competence. It seems likely that others also use this method, given the legal requirements. Written evidence of competence was reported as sporadic in some Member States: most did not report written evidence. However, a few Member States reported excellent record keeping of individual competences e.g., Sweden.

Some Member States specified checking additional constraints on some roles e.g. persons performing surgical procedures on animals must have completed a university degree, and in some cases specifying a veterinary degree (Netherlands, Austria).

Inspection was reported to be used (Belgium, Denmark, Poland) to determine whether the required legal standards are attained and specifically to observe complex procedures (Denmark).

Good practice includes the use of Directly Observed Procedures (DOPs) (Belgium), “procedural certification for all procedures” (Sweden), assessment of competence by a specialist or veterinarian, however, not by the person who taught the module (Sweden), targeted inspections on training and competence (Denmark), and development of a guidance document to help the establishments by creating a national "Programme to ensure the competence of persons performing certain functions"(Portugal).

Question

B - 3.3 How do you ensure maintenance of competence?

Not all Member States demonstrated clearly that they ensure maintenance of competence, but there was frequent mention of continuous professional development by training courses, e-learning (on subjects including legislation, the Three Rs, anaesthesia, microsurgery, scientific validity), competence of practical skills ensured by observing procedures and the role of the person responsible for training and competence.

Where the competent authorities are regional, good practice in one region is not necessarily shared by all regions (Belgium).

Good practice examples were given by some Member States, e.g., re-training for procedures not performed on a regular basis (Czechia, Estonia, Ireland, Luxembourg, Sweden), reviewing training in cases where problems or difficulties arise (Czechia), approved attendance in other research centres (Spain), competence officer is knowledgeable and disseminates information on training opportunities (Netherlands), a minimum number of hours to be completed annually (Luxembourg, Romania, Slovakia), maintaining competency documented in the individual training and competence record (Belgium, Luxembourg, Romania, Slovenia), inspection of these issues (Belgium, Denmark, Ireland, Greece, Luxembourg, Slovenia, Finland, Norway), and development of regional (Belgium) / national guidance on continued professional development (Netherlands, Portugal) e.g., Lifelong Learning | Brochure | National Committee for the Advice on Animal Testing Policy[18] available in English.

Question

B - 3.4 Art 23(3) requires that you publish minimum requirements for education and training, maintaining and demonstrating requisite competence. Please provide a link to this publication, providing page number / paragraph reference if included within a broader content document.

Member State	Answer
AT	https://www.ris.bka.gv.at/eli/bgbl/I/2012/114 https://www.ris.bka.gv.at/eli/bgbl/II/2012/522/20121228 https://www.ris.bka.gv.at/eli/bgbl/ii/1997/64/P0/NOR11008054
BE	http://www.ejustice.just.fgov.be/eli/arrete/2013/05/29/2013024221/justel Integrated in the Royal Decree of the 29th of May 2013 on the protection of animals used for scientific purposes, at articles 32, 33 and annexes 8 to 11. The annexes can only be found in the original version of the legislation, not in the consolidated version.
BG	https://lex.bg/laws/ldoc/2135820878 ; art. 33
CY	https://www.moa.gov.cy/moa/vs/vs.nsf/All/DE2192F6E679A039C225830F0026534D ; pg14, pr4.1.4.2
DE	https://www.gesetze-im-internet.de/tierschversv/__3.html https://www.gesetze-im-internet.de/tierschversv/anlage_1.html
DK	https://www.retsinformation.dk/eli/lta/2022/1107 Sections 56, 57 and 58 of the Laboratory Animal Act
EE	https://www.riigiteataja.ee/en/eli/512012023005/consolide Animal Protection Act § 41.4 and § 42.1 https://www.riigiteataja.ee/akt/128052019004 Specific requirements regarding the training program and topics covered in the training program for the care and killing of experimental animals, carrying out procedures and designing projects
ES	https://www.boe.es/diario_boe/txt.php?id=BOE-A-2015-3564
FI	https://avi.fi/en/services/individuals/licences-notices-and-applications/animals/laboratory-animals
FR	https://www.legifrance.gouv.fr/loda/id/JORFTEXT000027037960/
HU	https://njt.hu/jogszabaly/2013-40-20-22 ; 35.§

[18]https://www.ncadierproevenbeleid.nl/documenten/publicatie/19/25/leven-lang-leren/lven-lang-leren

IE	https://www.hpra.ie/docs/default-source/publications-forms/guidance-documents/aut-g0118-guide-to-training-education-and-competency-requirements-under-scientific-animal-protection-legislation-v4.pdf?sfvrsn=10.%20
IT	https://www.gazzettaufficiale.it/eli/id/2021/09/23/21A05569/sg https://www.salute.gov.it/portale/temi/p2_5.jsp?lingua=italiano&area=sanitaAnimale&menu=sperimentazione https://www.salute.gov.it/portale/moduliServizi/dettaglioSchedaModuliServizi.jsp?lingua=italiano&menu=ufficio&label=servizionline&ufficio=&idMat=SA&idAmb=PA&idSrv=ACOF&flag=P&parolaUfficio=&gruppoUfficio=ALL&gruppoUfficioDir=DGSAF-UFFXVI
LT	https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/TAIS.437081/asr
LU	https://agriculture.public.lu/de/veroeffentlichungen/tiere/labortiere/formation-personnel-experimentation-animale.html
LV	https://likumi.lv/ta/id/304167-zinatniskiem-merkiem-izmantojamo-dzivnieku-aizsardzibas-noteikumi
NL	https://wetten.overheid.nl/BWBR0035873/2023-01-01
NO	https://www.mattilsynet.no/dyr/forsoksdyr/soke-godkjenning-som-forsoksdyrvirksomhet?kapittel=3-krav-til-kompetanse
PL	https://eli.gov.pl/eli/DU/2022/2576/ogl
PT	https://www.dgav.pt/animais/conteudo/animais-para-fins-cientificos/bem-estar-animal/bem-estar-introducao
RO	https://legislatie.just.ro/Public/DetaliiDocumentAfis/238130
SE	https://jvdoc.sharepoint.com/sites/sjvfs/Shared%20Documents/2019_9/2019-009.pdf?ga=1 The provisions also refer to the EU Guidance on Education and Training Framework.
SI	https://www.gov.si/teme/zascita-zivali-v-postopkih/
SK	https://www.ivvl.sk/resources/attachment/minimalnepoziadavkynavykonpraktickejvyucbyprevykonurcenychfunkcii.pdf https://www.ivvl.sk/ochrana-zvierat-pouzivanych-na-vedecke-ucely

2 Member States (Czechia, Croatia) provided descriptors of requirements of legislation for education and training without publication link. 2 Member States (Greece, Malta) did not provide a link, nor description.

Question

B - 3.5 Apart from requiring training in local legal elements (Module 1), do you accept training if completed in another MS (mutual acceptance)?

Answer	Count	%	Member States
Yes	22	79%	AT, BG, CY, CZ, DK, EE, EL, ES, FI, FR, HR, IT, LT, LU, LV, MT, NO, PT, RO, SE, SI, SK
Not always	6	21%	BE, DE, HU, IE, NL, PL

Approximately 80% Member States accept training performed in other Member States.

Question

B - 3.5.bis Provide information on additional education and training requirements for staff coming from another Member State.

Requirements from other Member States include: determination of equivalence of content to national training (Belgium, Ireland, Hungary, Netherlands, Poland), in some cases referring specifically to the Education and Training Framework document. One Member State (Belgium) reported requiring a specified number of hours to be completed for each function.

Sweden provided a clear explanation of their system of mutual acceptance (in Section F5 of their submission) which might be useful to others:

"*Training completed in another Member State is accepted, however, there is a case-by case check to see that staff has the required competence. ... Researchers trained in another EU Member State must be trained in Swedish legislation. They also need to demonstrate practical skills to a supervisor and in some cases be examined by a veterinarian (the need for examination is assessed on a case-by-case basis). Their certifications are checked to see that their theoretical species-specific training covers everything that the regulations require. If not, they also need to take the species-specific theoretical course.*

All staff undergo an individual assessment and they are offered the practical course before they are accepted into facilities (e.g. see their list of publications if they have practical experience of animal testing). Here, it will be very much up to each individual if they want to take the practical course, but it is not uncommon for them to accept to take that course.

We accept theoretical education from other EU countries with the exception of Swedish legislation and ethics. However, practical skills must be demonstrated and documented on the training card. - Information on competencies for staff wanting to work with animals is collected in a form and reviewed by a group that assesses what needs to be supplemented.

For the Union, UK, Norway, Switzerland: Certificates are checked and if the EU modules corresponding to Function A are met, applicants may attend the Swedish Law/Ethics module and demonstrate practical skills, always species-specific.

For countries outside the Union: Full Function A needs to be taken regardless of certificate.

For researchers who intend to write an ethical application: Same procedure as above but for Function B. However, it is recommended to take the Function B course as there can be differences between the Swedish system and other Member States. People outside the Union must take Function B (everything is species-specific).

If researchers are not to actively work with animals, practical skills do not need to be demonstrated."

Voluntary question

B - 3.6 Does training in your Member State follow the EU Guidance on Education and Training Framework for the following functions?

If you stated "No", then describe briefly (e.g. key elements and whether the requirements must be fulfilled before assuming these roles or are only recommended).

If you stated "Not always", please explain.

Answer:	Yes			Not always			No			**Total**	
Function	Count	%	Countries	Count	%	Countries	Count	%	Countries	**Count**	**%**
Article 24 person responsible for access to information	15	60%	BG, CZ, EL, FI, FR, HR, IE, LT, LU, LV, NL, NO, PL, SI, SK	5	20%	CY, DE, ES, PT, SE	5	20%	BE, DK, HU, IT, MT	**25**	**100%**
Article 24 person responsible for education, competence and CPD	15	60%	BG, CZ, EL, FI, FR, HR, IE, LT, LU, LV, NL, NO, PL, SI, SK	5	20%	CY, DE, ES, PT, SE	5	20%	BE, DK, HU, IT, MT	**25**	**100%**
Article 24 person responsible for the welfare and care of animals	17	68%	BG, CZ, EL, ES, FI, FR, HR, IE, IT, LT, LU, LV, NL, NO, PL, SI, SK	4	16%	CY, DE, PT, SE	4	16%	BE, DK, HU, MT	**25**	**100%**
Article 25 Designated Veterinarian	13	52%	BG, EL, ES, FI, FR, HR, IT, LT, LU, LV, NL, SI, SK	7	28%	CY, CZ, DE, IE, NO, PT, SE	5	20%	BE, DK, HU, MT, PL	**25**	**100%**
Article 38 Project Evaluator	13	52%	BG, DK, FI, FR, HR, IE, IT, LT, LU, LV, NL, NO, SK	7	28%	BE, CY, CZ, DE, ES, PT, SE	5	20%	EL, HU, MT, PL, SI	**25**	**100%**

25 Member States responded to this question. It was stated by some Member States (Spain, Sweden) that there are no legally binding training requirements for these persons imposed by the Directive.

However, most Member States follow the Education and Training Framework document for training of the four statutory named persons. Some others take the recommendations into account. Some Member States (Hungary, Portugal, Slovenia) reported using the core and function specific modules for the purpose of training these named members of staff, which may be partially or entirely compliant with the Education and Training Framework document. Some Member States reported that the decision about whether the staff members are adequately trained is made by the competent authority (Germany) or checked by inspectors (Denmark).

For the designated veterinarian, some Member States reported that the graduate education programme contained required training (Hungary, Poland). Some Member States explicitly stated that any additional training and/or experience required for designated veterinarians would be identified and provided where necessary (Sweden, Norway).

For project evaluation, 1 Member State (Finland) responding "not always", specifically mentioned the use of EU module 25 (project evaluator). 3 Member States referred to nationally organised training for project evaluators (Greece, Poland, Sweden).

One Member State reported that knowledge and/or experience of science and animal welfare is deemed sufficient without specific training in project evaluation (Czechia).

In summary, it seems that the recommendations in the Education and Training Framework document are thought to be suitable by most Member States/regions, but it is likely that there is scope to improve consistency if a more structured application of the recommendations was enforced, either at the level of Member State, region or establishment. In this way, all of the requirements of each of the roles should be fully understood by each of the post holders in every establishment across the Union, and training and competence could be verified by inspectors or others working under the Directive.

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

Reporting obligation:

"*Explain the processes of project evaluation and authorisation, and the measures taken to ensure compliance with the requirements of Articles 38 and 40 of Directive 2010/63/EU.*"

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

Question

B - 4.1 Have the processes of project evaluation and authorisation been published as a means to implement the requirement of Article 38(4) (process shall be transparent)?

Voluntary question

** B - 4.1.bis Please provide the web-address where these processes have been published.*

Question

B - 4.1.tris Please explain by which other means you ensure that evaluation process is transparent.

Answer	Count	%	Member States
Yes	21	75%	AT, BE, BG, CY, CZ, DE, DK, EE, EL, FI, FR, IE, IT, LT, LU, NL, PL, PT, SE, SI, SK
No	7	25%	ES, HR, HU, LV, MT, NO, RO

21 Member States have published their project evaluation processes in line with Article 38(4) and provided links. These have been consolidated and listed below.

Member States	Answer
AT	https://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10005768 https://www.ris.bka.gv.at/eli/bgbl/I/2012/114
BE	https://leefmilieu.brussels/themas/dierenwelzijn/dierproeven-een-strikt-omlijnde-praktijk (Brussels) https://www.vlaanderen.be/natuur-milieu-en-klimaat/dieren-en-dierenwelzijn/proefdieren (Flanders) http://bienetreanimal.wallonie.be/home/animaux/animaux-dexperience.html (Wallonia).
BG	https://bfsa.egov.bg/wps/wcm/connect/bfsa.egov.bg19113/037c9f81-02e4-471e-ab29-406a780f528b/6a.pdf?MOD=AJPERES&CVID=olY.QoU
CY	https://www.moa.gov.cy/moa/vs/vs.nsf/All/DE2192F6E679A039C225830F0026534D/
CZ	https://eagri.cz/public/web/mze/ochrana-zvirat/pokusna-zvirata/ https://eagri.cz/public/portal/mze/ochrana-zvirat/pokusna-zvirata/projekty-pokusu-1 https://eagri.cz/public/portal/mze/ochrana-zvirat/pokusna-zvirata/stranky-ek-o-pz
DE	https://www.gesetze-im-internet.de/tierschversv/BJNR312600013.html#BJNR312600013BJNG000600000
DK	https://dyreforsoegstilsynet.dk/fileadmin/user_upload/dyreforsoegstilsynet.dk/Vejledninger/Introduktion_til_den_opgraderede_version_af_AIRD.pdf https://dyreforsoegstilsynet.dk/fileadmin/user_upload/dyreforsoegstilsynet.dk/Ansoegninger/Vejledninger/19453_Flow_poster_Final__003_.pdf
EL	https://www.minagric.gr/for-citizen-2/zoagiaepistimones https://anilab.decentral.minagric.gr/index.php/el/recommendations-of-the-national-committee-gr/156-national-committee-establishments-gr-6
FI	https://avi.fi/en/services/individuals/licences-notices-and-applications/animals/laboratory-animals
FR	https://www.legifrance.gouv.fr/loda/id/JORFTEXT000027038013/

IE	https://www.hpra.ie/docs/default-source/publications-forms/guidance-documents/aut-g0098-guide-to-project-applications-under-scientific-animal-protection-legislation-v13.pdf?Status=Master&sfvrsn=36
LT	https://vmvt.lt/gyvunu-sveikata-ir-gerove/gyvunu-gerove/gerove-moksliniu-tyrimu-metu
LU	https://agriculture.public.lu/de/tiere/tierschutz-tierwohl/labortiere.html#bloub-3
NL	https://www.centralecommissiedierproeven.nl/onderwerpen/aanvraag-vergunning https://www.centralecommissiedierproeven.nl/onderwerpen/dierexperimentencommissie-dec
PL	https://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20150000266 https://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU19600300168
PT	www.dgav.pt/animais/conteudo/animais-para-fins-cientificos/bem-estar-animal/bem-estar-introducao/autorizacao-de-projetos www.dgav.pt/animais/conteudo/animais-para-fins-cientificos/bem-estar-animal/bem-estar-introducao/autorizacao-de-projetos-que-utilizam-animais/analise-do-dano-beneficio/
SE	https://jvdoc.sharepoint.com/sites/sjvfs/Shared%20Documents/2019_9/2019-009.pdf?ga=1 https://jordbruksverket.se/djur/ovriga-djur/forsoksdjur-och-djurforsok/forsoksdjur#h-Etisktgodkannandeavdjurforsok

Question

B - 4.1.tris Please explain by which other means you ensure that the evaluation process is transparent.

In Spain, some of the competent authorities have published the processes and others have the rules governing the evaluation available to interested parties. In Romania, the processes are available on request. Some Member States reported that transparency is delivered by ensuring the applicant has access to or is given feedback during the process (Hungary, Malta, Norway). This appears to be related to the transparency of (intermediate and final) outcome of the individual project evaluation rather than to the transparency of the process per se.

One Member State (Latvia) described the process but did not comment on its publication.

There is scope for improvement in publication of the process of project evaluation and authorisation in some Member States.

Questions

B - 4.2.1 Do all applicants in the Member State have to provide the same information and with the same level of detail within the project application (e.g., by the use of a standardised form)?

B - 4.2.1.bis If not, or not always, how do you ensure that you get all the correct information?

Answer	Count	%	Member States
Yes	24	86%	AT, BG, CY, CZ, DE, DK, EE, EL, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK
Not always	4	14%	BE, ES, FI, NO

24 Member States stated that applicants have to provide the same information e.g., by the use of a standardised form. 1 additional Member State (Spain) stated that the different forms used in different regions have to be validated by the relevant competent authority to ensure they are requesting the correct and required information.

2 Member States stated that the minimum requirements are laid out in the law (Belgium, Spain). In 2 Member States, the information is different for regulatory use, routine production and diagnostic purposes than for other projects (Belgium, Spain) and level of detail is reported to be different for simple projects in 2 Member States (Finland, Norway).

Questions

B - 4.2.2 Are tools provided for all competent authorities tasked with project evaluation in the MS to facilitate consistent project evaluation (e.g., a project evaluation check list)?

B - 4.2.2.bis Please explain.

Answer	Count	%	Member States
Yes	24	86%	AT, BG, CY, CZ, DK, EE, EL, FI, FR, HR, HU, IE, IT, LT, LU, LV, NL, NO, PL, PT, RO, SE, SI, SK
Not always	2	7%	BE, ES
No	2	7%	DE, MT

24 Member States provide tools e.g., a project evaluation checklist, to promote consistency in project evaluation.

2 Member States stated that they do not provide any tools for consistency in this task (Germany, Malta).

Two of the three regions in one Member State (Belgium) use a form and are provided with training which should improve consistency. In another Member State (Spain), project assessors may sit on more than one body and so there is information sharing, in some cases.

Question

B – 4.2.3 Does project evaluation assess the following:

Answer	Yes			No		
Question	Count	%	Member States	Count	%	Member States
the project is designed to enable procedures to be carried out in the most humane manner?	28	100%	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, NO, PL, PT, RO, SE, SI, SK	0	0%	
the project is justified from a scientific or educational point of view or required by law?	28	100%	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, NO, PL, PT, RO, SE, SI, SK	0	0%	
the purposes of the project justify the use of animals?	28	100%	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, NO, PL, PT, RO, SE, SI, SK	0	0%	
the project is designed to enable procedures to be carried out in the most environmentally sensitive manner?	26	93%	AT, BE, BG, CY, CZ, DE, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK	2	7%	DK, NO

All Member States assess three of the four required elements of the application. Two Member States (Denmark, Norway) do not assess whether the project is designed to be carried out in the most environmentally friendly manner. This may not always be relevant but can be particularly important for wildlife studies.

Question

B - 4.2.4 Do evaluators demonstrate that they assess the following:

Answer	Yes			No		
Question	Count	%	Member States	Count	%	Member States
predicted scientific benefits or educational value?	27	96%	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, NL, NO, PL, PT, RO, SE, SI, SK	1	4%	MT
the objectives of the project?	27	96%	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, NL, NO, PL, PT, RO, SE, SI, SK	1	4%	MT

27 Member States assess the required elements of Art 38(2)(a). 1 Member State (Malta) stated that they do not. This Member State has authorised only two projects within the last five years.

Question

B - 4.2.5 Does the evaluation demonstrate the justification (where appropriate) for:

Answer	Yes			No		
Question	Count	%	Member States	Count	%	Member States
animals taken from the wild	27	96%	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, NL, NO, PL, PT, RO, SE, SI, SK	1	4%	MT
care and accommodation which does not comply with Annex III	27	96%	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, NL, NO, PL, PT, RO, SE, SI, SK	1	4%	MT
methods of killing that are not listed in Annex IV	27	96%	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, NL, NO, PL, PT, RO, SE, SI, SK	1	4%	MT
no anaesthesia / analgesia	27	96%	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT,	1	4%	MT

			LT, LU, LV, NL, NO, PL, PT, RO, SE, SI, SK			
procedures	27	96%	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, NL, NO, PL, PT, RO, SE, SI, SK	1	4%	MT
re-use	27	96%	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, NL, NO, PL, PT, RO, SE, SI, SK	1	4%	MT
use of endangered species	27	96%	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, NL, NO, PL, PT, RO, SE, SI, SK	1	4%	MT
use of NHPs	27	96%	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, NL, NO, PL, PT, RO, SE, SI, SK	1	4%	MT
animals in Annex I not bred for procedures	25	89%	AT, BE, BG, CY, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, LT, LU, LV, NL, NO, PL, PT, RO, SE, SI, SK	3	11%	CZ, IT, MT
use of stray / feral animals	24	86%	BE, BG, CY, CZ, DE, DK, EE, ES, FI, FR, HR, HU, IE, LT, LU, LV, NL, NO, PL, PT, RO, SE, SI, SK	4	14%	AT, EL, IT, MT

27 Member States evaluate 8 of the 10 justifications listed in Article 38(2)(e). 3 Member States (Czechia, Italy, Malta) stated that they do not evaluate the justification for the use of animal species listed in Annex 1 not bred for use in procedures, and 4 Member States (Greece, Italy, Austria, Malta) stated that they do not evaluate the justification of the use of stray or feral animals. It may be that this has been interpreted in this way as this criterion has not been requested in any projects to date, although the question was worded to include "where appropriate" which was intended to exclude this interpretation.

Question

B - 4.2.6 Does the evaluation determine if the project should be assessed retrospectively?

Answer	Count	%	Member States
Yes	27	96%	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, NL, NO, PL, PT, RO, SE, SI, SK
No	1	4%	MT

Only one Member State (Malta) stated that they do not determine whether a project should be assessed retrospectively.

Question

B - 4.2.7 Provide two examples on how project evaluation assesses compliance with replacement.

Examples provided for the assessment of compliance with replacement include:

Training

- Use of dummies for training purposes;
- Use of video for training purposes;
- Evaluation of whether necessity of use of animals in training is demonstrated in application.

Information research

- Performance of literature search for non-animal data and methods;
- Verification of types and number of databases consulted;
- Evaluation of whether systematic reviews have been used;
- Verification of regulatory/marketing authorisation requirements necessitating testing;
- Applicant must produce print screens of search results from at least 3 databases to demonstrate no alternative methods were available.

Applicants' duties on replacement justification

- Assessment of whether necessity of animal use is demonstrated by applicant, and no alternative exists;
- Reporting of non-animal methods used;
- Verification of use of *in vitro* testing and/or 3D tissue cultures, and, if available; whether patient cell organoids were used;
- What alternatives were considered, and why were they rejected;
- Replacement given a specific space on the application form;
- Estimate of reduction of animals needed through implemented non-animal methods.

Evaluators' duties and activities

- Evaluators will question applicant for further justification if there is doubt on the necessity of animal use;
- Evaluators perform literature review and verify applicant's justification;
- National Committee verifies use of alternative methods;
- Evaluator's analysis of existing non-animal models which could be used in the project;
- Evaluator's analysis of whether research is a duplicate.

Miscellaneous

- Declaration must be made that compounds are tested in animals by contract research organisations only after applying the replacement principle;

- Project authorisation on animal use can be removed if a new non-animal alternative is adopted by OECD guidelines[19];
- Encouragement to use *in vitro* tests for molecules/drugs screening;
- Application of EURL ECVAM recommendations for monoclonal antibody production[20].

Question

B – 4.2.8 Provide two examples on how project evaluation assesses compliance with reduction.

Examples provided for the assessment of compliance with reduction include:

Statistics

- Use of statistical methods to minimize number of animals used;
- (External) biostatistician involved to optimise animal numbers;
- Project will not be authorised until the statistical expert of the competent authority is satisfied;
- Reduction of control groups required when possible;
- Evaluators analyse power calculations of the applicant, and can propose further reduction opportunities;
- Minimum power for statistical analysis set at 80%;
- Pilot projects required to have minimum 3-6 animals per group to ensure statistically significant results achieved;
  [NB. Pilot studies are rarely designed to be statistically valid but are valuable to provide insight to adverse effects/technical issues which can better inform design of main study];
- Norway provided a specific example of a successful case of reduction produced by better statistical assessment. In that case, it was known that by the use of male C57Bl/6 mice in a glucose tolerance/T2DM-study, a rapid and consistent development of diet-induced glucose intolerance could be achieved. The applicant assumed a too high margin of error for a specific procedure, which following communication with the project evaluator, reduced the animal numbers in the experimental design.

Applicants

- Applicants required to justify animal numbers;
- Information on the use of both sexes and on numbers likely to be lost during study;
- Applicants required to describe efforts for minimization of animal use;
- Reduction given a specific space on the application form.

Assessment

- Evaluators analyse experimental design;
- Assessment of project design to minimize use of animals in procedures;
- Assessment to ensure project will produce reliable information;
- Assessment of project design to reduce unnecessary repetition of research or duplication;

[19] https://doi.org/10.1787/72d77764-en
[20] https://dx.doi.org/10.2760/80554

- Czechia provided a specific example in which specification of the number of animals (in total and group) was required to assess the necessity of the number of animals proposed and to justify the necessity of experiments as regards the testing of substances already in use.

Tissue and/or animal sharing

- Applicant to explain on whether collaboration with other laboratories is possible or if animals can be shared;
- Assessment of reuse of animals for several procedures;
- Assessment of whether reuse of tissues and previous pilot studies considered.

Miscellaneous

- Execution of preliminary non-animal studies to determine the properties of substances before moving to animal testing;
- Number of animals used is discussed retrospectively. It is presumed that this will inform future experiments.

Question

B - 4.2.9 Provide two examples on how project evaluation assesses compliance with refinement.

Procedures

- For models of neurodegenerative diseases or spinal injuries, feed is required to be placed in a plate on the bottom of the cage and the use of longer nozzles in bottles to encourage water intake;
- For gavage, immerse the gavage needle initially in sugar solution to encourage intake;
- Field study with badgers: maximum response time of 12 hours after capture in box-traps reduced to 6 hours;
- Treats are given to animals as rewards following surgical procedures;
- Use of microdosing pumps rather than repeated manual injections;
- Optimising dosing routes;
- Optimising blood sample volumes and frequencies;
- Ensuring optimised handling.

Evaluators' duties and activities

- Verification of appropriate use of analgesia;
- Ensuring that humane endpoints are maximally refined;
- Assessment of the choice of animals and their suitability for the project;
- Use of key guidelines to ensure most refined model used;
- Review of literature on proposed killing methods and housing;
- Assessment of the feasibility of refinement in individual projects;
- Norway provided a specific example in a behavioural testing of mice in a mood disorder study. The application described applying the tail suspension test for assessing depression-like behaviour. The project evaluator questioned the validity of the test, which must be unequivocal, especially because of its severity. The applicant agreed to replace the test with the splash test, which has a lower severity.

Husbandry, Housing

- Applicants to clarify enrichment and husbandry;
  [NB. Enrichment is required but if they want to have low level of enrichment or none, then this is a welfare cost not a refinement and would need to be justified];
- Evaluators to verify if enrichment materials supplied to animals;
- Evaluators to verify appropriate housing;
- Alternative handling (welfare friendly e.g., cupping) must be carried out unless scientifically justified otherwise;
- Delicacies (treats) as part of praising are given out to animals following surgical procedures;
- Use of specific adaptation protocols to minimise the impact of tests and interaction with the experimenter;
- Encourage foraging by hiding cereal grains in the substrate on the day of the change of cage.

Evaluator-applicant collaboration

- Evaluators scrutinise interventions/techniques and will propose additional refinements;
- Evaluators work with applicants to ensure relevant severity assessment score sheets are fit for purpose;
- Evaluators question applicants and may require modifications if available refinement opportunities not implemented;
- National Committee follows literature with focus on refinement, and if refined methods exist recommendation is sent to project applicants and official veterinarian tasked with approval.

Miscellaneous

- Training of animals to reduce stress;
- Applicants must produce flowchart of experimental protocols so that overall harm inflicted can be evaluated;
- Humane endpoints and monitoring system required for moderate and severe proceduress [NB. Adequate monitoring and reporting should apply to all procedures irrespective of severity];
- Inspection frequencies are increased for particularly high impact models and phenotypes.

Voluntary question

B - 4.2.10 Has the EU guidance on Severity Assessment Framework been made available to competent authorities tasked with project evaluation?

B - 4.2.10.bis If not, provide information on how severities are assigned

B - 4.2.10.tris Please explain 'Not always'

Answer	Count	%	Member States
Yes	28	100	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, NO, PL, PT, RO, SE, SI, SK
No	0	0	
Total	**28**	**100**	

Severity assessment framework has been made available to competent authorities responsible for project evaluation by all Member States.

Voluntary question

B - 4.2.11 If possible, how extensively do you estimate it being used in your MS by those tasked with project evaluation?

Answer	Count	%	Member States
By all	10	42%	DK, EL, FR, IE, IT, LU, MT, NO, PT, SI
By most	8	33%	BG, EE, HR, HU, LV, NL, PL, SK
By some	6	25%	BE, CY, CZ, DE, FI, SE
Total	**24**	**100%**	

Of the 24 Member States that responded to the question on whether it is used, the majority (75%) considered that all or most are using it.

Questions

B - 4.2.12 Are tools provided for all competent authorities tasked with project evaluations to facilitate consistent harm-benefit assessment?

Answer	Count	%	Member States
Yes	21	75%	AT, BG, CY, CZ, DK, EL, FI, FR, HR, HU, IE, IT, LT, LU, NL, NO, PL, PT, RO, SE, SK
Not always	2	7%	BE, ES
No	5	18%	DE, EE, LV, MT, SI

21 Member States provide tools.

Question

B - 4.2.12.bis Please explain 'Not always'

One Member State (Belgium) described the use of some structured tools in one region. Another Member State (Spain) stated that although there appears to be structure in the assessments there is no information available on whether this is provided by competent authorities.

Questions

B - 4.2.13 Do competent authorities (the entities/not each individual) tasked with project evaluation have expertise in the following:

B - 4.2.13.bis Please explain how the expertise that is not available within the competent authority is considered during project evaluation process.

B - 4.2.13.tris Please explain 'Not always'.

Answer	Yes			Not always			No		
Question	Count	%	Member States	Count	%	Member States	Count	%	Member States
Animal husbandry and care	28	100%	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, NO, PL, PT, RO, SE, SI, SK						
Three Rs	28	100%	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, NO, PL, PT, RO, SE, SI, SK						
Areas of scientific use	27	96%	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, IE, IT, LT, LU, LV, MT, NL, NO, PL, PT, RO, SE, SI, SK	1	4%	HU			
Experimental design	26	93%	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, NL, NO, PL, PT, SE, SI, SK	1	4%	MT	1	4%	RO
Veterinary practice in lab animal science	25	89%	AT, BE, BG, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, NL, NO, PL, PT, RO, SI, SK	2	7%	MT, SE	1	4%	CY

Wildlife veterinary practice, where appropriate	20	71%	AT, BE, BG, CZ, DE, DK, ES, FI, FR, HR, IE, IT, LT, LU, NL, NO, PL, PT, SI, SK	5	18%	EE, EL, LV, MT, SE	3	11%	CY, HU, RO

Article 38(3) requires that the competent authority carrying out the project evaluation shall consider expertise in the listed areas.

Most Member States reported that the competent authorities have expertise in each of these areas. It will be difficult where there are large numbers of competent authorities tasked with project evaluation within a Member State to ensure that the level of expertise available in these areas is sufficient.

It is unclear how high-quality project evaluation can be delivered if expertise is not available as reported by some Member States for some of the areas.

Whilst not having indicated all of the expertise categories listed in the table, in the explanation on how exepertise in those cases was obtained, one Member State stated that all necessary expertise was available (Hungary). This may imply that there are no wildlife studies in this Member State. Other Member States specifically stated that they request additional expertise in some cases, including for wildlife studies. It may be that there is scope to improve the expertise of project evaluator panels in some cases.

1 Member State (Sweden) reported that veterinarians have the right to be present and heard at the committees' meetings. This appears to fulfil the requirement for this expertise, even though they may not be a part of the competent authority.

1 Member State (Malta) reported providing basic training in project design and project evaluation.

External experts are recruited if required in 3 Member States (Estonia, Latvia, Sweden).

Questions

B - 4.2.14 Which modules are project evaluators required to complete, if any?:

B - 4.2.14.bis Please explain how the required competence in the areas covered by the above modules is obtained to enable the evaluation of the compliance with the requirements of Article 38.

Answer	Required by law			Required by policy (national/regional recommendation or similar)			Not required		
Module	Count	%	Member States	Count	%	Member States	Count	%	Member States

National legislation (covering at least learning outcomes contained in Module 1)	8	29%	BG, CZ, FR, HR, IT, LT, LV, SK	7	25%	AT, DE, ES, IE, LU, PT, SE	13	46%	BE, CY, DK, EE, EL, FI, HU, MT, NL, NO, PL, RO, SI
Ethics, animal welfare and the Three Rs (level 1) (covering at least learning outcomes contained in Module 2)	7	25%	BG, CZ, FR, HR, IT, LT, LV	8	29%	AT, DE, ES, IE, LU, PT, SE, SK	13	46%	BE, CY, DK, EE, EL, FI, HU, MT, NL, NO, PL, RO, SI
Design of procedures and projects (level 1) (covering at least learning outcomes contained in Module 10)	6	21%	BG, CZ, FR, HR, LT, LV	8	29%	AT, DE, ES, IE, LU, PT, SE, SK	14	50%	BE, CY, DK, EE, EL, FI, HU, IT, MT, NL, NO, PL, RO, SI
Ethics, animal welfare and the Three Rs (level 2) (covering at least learning outcomes contained in Module 9)	6	21%	BG, CZ, FR, IT, LT, LV	8	29%	AT, DE, ES, HR, IE, LU, PT, SK	14	50%	BE, CY, DK, EE, EL, FI, HU, MT, NL, NO, PL, RO, SE, SI
Project evaluator (covering at least learning outcomes contained in Module 25)	6	21%	BG, CZ, FR, IT, LT, LV	10	36%	AT, DE, DK, FI, HR, IE, LU, SE, SI, SK	12	43%	BE, CY, EE, EL, ES, HU, MT, NL, NO, PL, PT, RO
Design of procedures and projects (level 2) (covering at least learning outcomes contained in Module 11)	5	18%	BG, CZ, FR, LT, LV	8	29%	AT, DE, ES, HR, IE, LU, PT, SK	15	54%	BE, CY, DK, EE, EL, FI, HU, IT, MT, NL, NO, PL, RO, SE, SI

Severity module	5	18%	BG, CZ, HR, LT, LV	11	39%	AT, DE, FI, FR, IE, IT, LU, PT, SE, SI, SK	12	43%	BE, CY, DK, EE, EL, ES, HU, MT, NL, NO, PL, RO

A minority of Member States require by law each of the training modules for project evaluators recommended in the Education and Training Framework document to be completed. Adding those requiring the modules by policy, approximately half of the Member States require training for project evaluators as recommended in the Education and Training Framework document.

Of the other Member States, competence is assured in different ways. Two Member States (Sweden, Norway) mentioned specific national training for project evaluators. Some project evaluators complete some training but perhaps not all modules recommended in the Education and Training Framework document (Estonia, Spain, Italy, Malta, Portugal, Finland). Competences of project evaluators are defined in legislation in some Member States (Denmark, Estonia, Poland). Some Member States reported that project evaluators (when non-public body) needed to be approved by the authority (Belgium, Cyprus). Some Member States reported the use of personnel experienced in animal experimentation as part of competent authority tasked with project evaluation (Greece, Spain, Hungary, Netherlands, Portugal, Romania, Slovenia, Finland, Sweden). One Member State (Netherlands) has specific personnel allocated to help prepare the evaluations. It seems that there may be scope for improved training specifically in project evaluation requirements to ensure that a consistent approach is taken across the Union.

Question

B - 4.2.15 What other measures are taken to ensure that project evaluators have the required expertise and skills?

Many Member States discussed the required qualifications of project evaluators but only one (Ireland) mentioned expertise in the area of alternative tests/New Approach Methodologies (NAMs).

Some examples of good practice include:

- In-house training is provided by some (Ireland) which includes shadowing of an experienced project evaluator and working under close supervision for a prolonged period (Ireland, Italy);
- Mandatory regular attendance at Three Rs continuous professional development (CPD) events/conferences to ensure evaluators are up-to-date on Three Rs developments (Ireland);
- Availability of guidance documents (Estonia);
- Dedicated working groups, discussing particular issues such as harm-benefit assessment (Finland);
- Acknowledgment that assessment know-how is constantly evolving through individual cases with sharing of the outcomes (Finland);
- Regular meetings of evaluators are conducted in order to update with current trends and legislative changes (Slovakia).

Question

B - 4.2.16 Are any projects administered according to Art 42 (Simplified Administrative Procedure)?

Answer	Count	%	Member States
Yes	12	43%	AT, BE, DE, ES, HR, IT, MT, PL, PT, RO, SI, SK
No	16	57%	BG, CY, CZ, DK, EE, EL, FI, FR, HU, IE, LT, LU, LV, NL, NO, SE

Question

B - 4.2.16.1 What types of projects are accepted under simplified administrative procedure?

A minority of Member States use simplified administrative procedures. Article 42 allows simplified administrative procedures for projects which

- contain only procedures classified as 'non-recovery', 'mild' or 'moderate', and
- do not use non-human primates,
- are necessary to satisfy regulatory requirements or
- which use animals for production or diagnostic purposes using established methods

The following Member States use all the defined criteria above: Belgium, Spain, Croatia, Austria, Poland, Slovakia.

Some Member States use narrower criteria: Slovenia did not mention non-human primates, Germany did not mention severity; Italy and Portugal only mentioned the use of simplified procedures for regulatory purposes, Romania only mentioned projects for disease diagnosis, and Malta listed regulatory projects but also nutrition and feed trial studies in fish which do not seem to fall within the categories permitted by the Directive.

Questions

B - 4.2.16.2 Are projects under simplified administrative procedure evaluated in the same way as other projects (Article 38)?

B - 4.2.16.2.bis Please explain.

Answer	Count	%	Member States
Yes	10	83%	AT, DE, ES, HR, IT, MT, PL, PT, SI, SK
No	2	17%	BE, RO

Of the 12 Member States that use simplified administrative procedures, 10 evaluate them in the same way. One Member State (Belgium) stated that the level of detail is different and different forms are used, and for Romania, a non-technical project summary is not required (as permitted in Article 37(2)).

It is important that all criteria defined in the Directive are correctly applied if simplified administrative procedures are used. It should be noted that only 12 Member States have used non-human primates in this five-year reporting period and may not have listed this criterion in their response for this reason.

Questions

B - 4.2.17 Are multiple generic projects permitted in your Member State?

B - 4.2.17.bis What types of projects are considered as a multiple generic project?

Answer	Count	%	Member States
Yes	22	79%	AT, BE, BG, CZ, DK, EL, ES, FI, FR, HR, HU, IE, IT, LU, MT, NL, NO, PL, PT, RO, SE, SI
No	6	21%	CY, DE, EE, LT, LV, SK

Most Member States permit multiple generic projects.
Article 40(4) permits authorisation of multiple generic projects if such projects

- are to satisfy regulatory requirements or
- use animals for production or diagnostic purposes using established methods.

Types of projects listed by Member States include:

1. To satisfy regulatory requirements (including quality control) (Belgium, Czechia, Denmark, Ireland, Greece, Spain, France, Croatia, Italy, Luxembourg, Malta, Netherlands, Austria, Poland, Portugal, Romania, Finland)
    - Examples of regulatory projects include: general safety studies, bioequivalence studies, potency studies for vaccines, including batch release tests, immunogenicity testing for vaccines, hormone potency testing;
    - Reported areas of work: feed stuffs or food, biocidal products, medicinal products, chemicals, plant protection products, and medical devices.
2. Production (Belgium, Czechia, Denmark, Greece, Spain, Croatia, Luxembourg, Austria, Finland, Sweden)
    - Examples of production include blood donations for blood agar production (Czechia), and production of antibodies (Denmark, Portugal, Romania, Finland, Norway);
    - Creation of genetically altered animals as a service (Netherlands, Finland, Sweden).
3. Diagnostic purposes (Belgium, Greece, Spain, Croatia, Luxembourg, Austria, Romania, Finland, Sweden, Norway)
4. Other examples included:
    - Imaging (France);
    - More complex projects (Bulgaria, Slovenia) such as multi-species and multi-procedure projects;
    - Scientifically driven studies like ecological research (Netherlands);
    - Research and development studies (Netherlands);
    - Testing of drug candidates in the pharmaceutical industry by contract research laboratories (Denmark);
    - Projects covering “same subjects” (Hungary).

Some of the reported examples would not seem to be in line with that permitted in Article 40(4). However, the provided information does not allow for a more detailed assessment.

Questions

B - 4.2.17.1 Are multiple generic projects evaluated and authorised in the same way as other projects (Article 38)?

B - 4.2.17.1.bis Describe the differences.

Answer	Count	%	Member States
Yes	17	77%	AT, BG, CZ, DK, EL, ES, FI, FR, HR, HU, IE, LU, MT, PL, PT, RO, SE
No	5	23%	BE, IT, NL, NO, SI

Most Member States use the same methods for evaluation of multiple generic projects.

The remaining Member States reported that the same process is used but project granted in two stages (Italy), level of detail is different (Belgium), two or more rapporteurs are assigned for this type of project rather than one for other types (Romania).

Question

B - 4.2.18 Where project evaluation is conducted by multiple competent authorities (e.g., local, regional), how is the Directive objective of harmonisation and a coherent approach to project evaluation ensured at the level of Member State?

Means used to achieve harmonisation when project evaluation is carried out by multiple competent authorities include:

- Project evaluation follows the procedures laid down in law or policy (Belgium, Netherlands, Austria, Poland, Slovakia, Finland, Sweden), in some cases this is regional (Belgium);
- National guidance for some types of projects (Netherlands, Poland);
- Training for project evaluators (Sweden);
- Opportunities for project evaluators to meet, discuss and/or otherwise communicate relevant issues (Belgium, Czechia, Spain, Austria, Slovakia, Finland, Sweden);
- Feedback (Netherlands) and sharing of evaluations (Sweden) between authorities.

It is surprising that there was no explanation from some Member States with large numbers of competent authorities tasked with project evaluation. It is impossible to determine if specific action is taken to promote harmonisation and a coherent approach.

Voluntary question

B - 4.2.19 If you consider that there is any room for improvement in consistency, please describe.

Suggestions provided include:

- (More frequent) meetings and improved communications between project evaluators to discuss harmonisation on methods of working (Belgium, Czechia, Portugal, Sweden);
- Development of new guidelines and recommendations (Belgium, Poland, Sweden);
- More detailed information on evaluation of harms and of benefits (Latvia);

- Continuing professional development/further specialised training in this area (Czechia, Poland);
- Discussion of complex cases e.g., 'translatability of animal models' and 'distress due to individual housing' (Netherlands);
- a single European project application and evaluation forms (Belgium).

Question

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

Number of Years	Count	%	Member States
5	26	93%	AT, BE, BG, CY, CZ, DE, DK, EE, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK
4	1	4%	NO
3	1	4%	EL

Only 2 Member States do not allow project authorisations for a full five years with 1 (Norway) permitting only four years and 1 (Greece) permitting only three years. Whilst Member States are free to determine maximum durations up to five years, shorter durations would generally create more work for both competent authorites, researchers and users, and may negatively impact on the Directive aspiration of a level playing field across the Union. However, in some specific cases, durations shorter than five years can be effective e.g., to monitor progress on transition to non-animal methods (such as testing methods linked to marketing authorisations).

Questions

B - 4.4 As part of the project evaluation process, are independent opinions sought?

B - 4.4.bis If not independent, how is impartiality achieved?

B - 4.4.tris Please explain 'Not always'

Answer	Yes			Not always		
Question	Count	%	Member States	Count	%	Member States
independent of the applicant	24	86%	AT, BE, BG, CY, CZ, EE, EL, ES, FI, HR, HU, IE, IT, LT, LU, LV, MT, NL, NO, PL, PT, RO, SI, SK	4	14%	DE, DK, FR, SE
independent of the establishment	24	86%	AT, BE, BG, CY, CZ, DE, EE, EL, FI, HR, HU, IE, IT, LT, LU, LV, MT, NL, NO, PL, PT, RO, SI, SK	4	14%	DK, ES, FR, SE

Most Member States include independent opinions during project evaluation. Four Member States selected “not always”.

Some Member States (Denmark, Germany, France, Sweden) seem to have interpreted this to mean external to the project evaluation panel where in some cases independent opinions are sought (especially when additional skills are required). These external views can be requested by the project evaluation panel whereas the intention of the question was to assess the use of the opportunity provided by the Directive to integrate views of independent parties.

One Member State (Spain) confirmed that applicants are never involved in the project evaluation of their own work.

Question

B - 4.5 The application is reviewed by:

- an individual;

- a panel of people.

Answer	Count	%	Member States
a panel of people	26	93%	AT, BE, BG, CY, CZ, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, NO, PL, RO, SE, SI, SK
an individual	2	7%	DE, PT

Only 2 Member States (Germany, Portugal) use individuals to evaluate projects.

Questions

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

B - 4.6.bis If decision is reached by "Other", please explain in more detail.

Answer	Count	%	Member States
Consensus	11	39%	CZ, EE, FI, IE, IT, LT, LU, MT, NO, RO, SK
Majority vote	11	39%	AT, BG, CY, EL, FR, HR, HU, LV, NL, SE, SI
Other	6	21%	BE, DE, DK, ES, PL, PT

Equal numbers of Member States use consensus and majority vote. Other responses included mixed approaches given that the process may not be the same when multiple competent authorities are tasked with project evaluation:

- Consensus most common but other methods are permitted (Belgium, Denmark);
- Because of regional decision making, competent authorities can decide how to make the decisions: about 50% are majority and 50% consensus (Spain);
- 2/3 majority (Poland);
- Individual project evaluator makes decision but may ask others in case of complex cases (Germany).

Voluntary questions

B - 4.7 - Are the processes for amendments to projects the same as for the initial project evaluation and authorisation (including the deadlines in Article 41)?

B - 4.7.bis If not the same, please describe the main differences.

B - 4.7.tris Please explain 'Not always'.

Answer	Yes			Not always			No		
Question	Count	%	Member States	Count	%	Member States	Count	%	Member States
the same as for the initial project evaluation	20	74%	AT, BG, CY, CZ, EE, ES, FI, FR, HU, IE, IT, LU, LV, MT, NO, PL, PT, RO, SE, SI	6	22%	BE, DE, EL, HR, NL, SK	1	4%	DK
the same as for the initial project authorisation	18	69%	AT, BG, CY, CZ, EE, ES, FR, HU, IE, IT, LU, LV, MT, NO, PL, PT, SE, SI	7	27%	BE, DE, EL, FI, HR, NL, SK	1	4%	DK

The Directive only requires an amendment to the project authorisation when a change to the project may have a negative impact on animal welfare. In such cases, a new favourable project evaluation is a prerequisite for the authorisation of the amendment.

Of those who responded, in most Member States the processes of evaluation and authorisation are the same for amendments as for original applications. In some Member States processes can be the same but are not always. No clear distinction was made between processes of project evaluation and project authorisation.

All Member States with different processes mentioned that there needs to be no negative welfare impact for it to be considered an amendment. If there is an increase in the negative impact on animal welfare, the process appears to be as for a new application. In Member States with regional structures, the alternative process may depend on regional/local competent authorities.

In one Member State (Germany) the changes are notified when there is no negative impact on animal welfare. The authorisation holder must wait two weeks before acting on the changes, unless they hear earlier that there is no objection.

In some cases, it seems the project authorisation holder alone, without any impartial input, may determine whether the changes are likely to have negative impact on animal welfare.

Two Member States (that stated that the process of project evaluation is not always the same as for initial project) mentioned extension of period of authorisation (Netherlands, Slovakia). It is not

clear whether such extensions go beyond a five-year authorisation permitted by the Directive without a full project evaluation.

Voluntary questions

B - 4.8 Has EU guidance on Project Evaluation and Retrospective Assessment been made available to competent authorities tasked with the following?:

B - 4.8.bis Please explain.

Answer	Yes			**Total**	
Question	Count	%	Member States	**Count**	**%**
project evaluation	27	100%	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LU, LV, MT, NL, NO, PL, PT, RO, SE, SI, SK	**27**	**100%**
retrospective assessment	27	100%	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LU, LV, MT, NL, NO, PL, PT, RO, SE, SI, SK	**27**	**100%**

27 Member States that responded have made the guidance on project evaluation and retrospective assessment available to competent authorities.

Voluntary question

B - 4.9 If possible, how extensively do you estimate it being used in your MS by competent authorities tasked with:

- project evaluation;

- retrospective assessment.

Answer	By all			By most			By some			**Total**	
Question	Count	%	Member States	Count	%	Member States	Count	%	Member States	**Count**	**%**
retrospective assessment	13	54%	CY, DK, EL, HU, IE, IT, LU, LV, NL, PT, SE, SI, SK	6	25%	BG, FR, HR, MT, NO, PL, SE	5	21%	BE, CZ, DE, EE, FI	**24**	**100%**
project evaluation	12	50%	CY, DK, EL, HU, IE, IT, LU, LV, NL, PT, SI, SK	7	29%	BG, FR, HR, MT, NO, PL, SE	5	21%	BE, CZ, DE, EE, FI	**24**	**100%**

Most competent authorities tasked with project evaluation and authorisation use the developed guidance. In addition, national guidance may be available.

C. OPERATION

C.1. Projects

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

Reporting obligation

"In respect of each year, provide numbers for the following: (a) all authorisation decisions and authorised projects; (b) multiple generic projects, as provided for in Article 40(4) of Directive 2010/63/EU, categorised as one of the following types:

— projects to satisfy regulatory requirements;

— projects using animals for production purposes;

— projects using animals for diagnostic purposes; (c) the authorisation decisions where the deadline of 40 days has been extended in accordance with Article 41(2) of Directive 2010/63/EU.

For the purposes of point (c), provide summary information, covering the five-year reporting cycle, on the reasons where the deadline of 40 days has been extended."

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

Questions

C - 1.1.1 Granting of project authorisations (Articles 40 and 41).

C - 1.1.1.bis Provide summary information covering the 5 year reporting cycle on the reasons why the deadline of 40 days has been extended.

Year	Number of projects authorised	Number of projects rejected	Total number of decisions (authorised and rejected)	Number of decisions >40 days	Proportion >40 days of all decisions (%)
2018	15 166	744	15 910	5 283	33%
2019	16 212	803	17 015	5 441	32%
2020	15 217	1 090	16 307	4 126	25%
2021	14 945	608	15 553	3 997	26%
2022	13 222	480	13 702	3 480	25%

Around 15 000 projects are authorised across the Union annually. Despite the disruptions due to COVID-19, the number of projects has remained reasonably constant throughout the five-year reporting period.

Each year around 4.5% of applications are rejected. In just under 30% of applications, the time for authorisation decision exceeds the 40 days stated in Article 41. However, there remain significant differences among Member States. In 2022, 4 Member States reported that more than 50% of

projects exceeded 40 days, whereas 5 Member States recorded that a decision was made on all projects in less than 40 days.

Member State	2018		2019		2020		2021		2022	
	# of decisions	% > 40 days	# of decisions	% > 40 days	# of decisions	% > 40 days	# of decisions	% > 40 days	# of decisions	% > 40 days
AT	690	11%	725	10%	682	18%	618	47%	601	13%
BE	1 350	11%	1 352	12%	1 524	8%	1 477	9%	1 459	13%
BG	40	33%	42	43%	30	33%	36	33%	10	40%
CY	10	30%	15	33%	6	83%	8	63%	11	45%
CZ	602	2%	495	1%	476	5%	493	2%	436	1%
DE	3 360	16%	3 505	14%	3 291	17%	3 041	17%	2 538	21%
DK	228	9%	224	4%	280	5%	287	7%	257	9%
EE	15	7%	20	0%	21	0%	25	0%	25	0%
EL	241	0.4%	223	9%	205	2%	236	7%	187	9%
ES	1 505	11%	1 903	24%	1 542	4%	1 960	18%	1 668	15%
FI	109	0%	128	0%	133	0%	116	0%	112	0%
FR	3 358	90%	4 515	67%	3 889	54%	3 575	51%	2 901	58%
HR	68	78%	33	18%	71	6%	44	16%	26	65%
HU	248	57%	254	41%	254	44%	234	38%	287	45%
IE	136	0.7%	118	0%	105	1%	95	0%	92	2%
IT	1 129	81%	964	80%	1 347	58%	1 012	54%	843	49%
LT	21	10%	38	8%	42	12%	35	11%	50	10%
LU	9	100%	103	97%	34	82%	26	100%	8	25%
LV	9	0%	7	0%	13	0%	9	0%	11	0%
MT	1	0%	0		0		1	0%	0	
NL	414	25%	206	40%	201	40%	209	16%	256	18%
NO	238	0%	483	0%	512	0%	468	0%	438	0%
PL	1 122	0.2%	892	0.2%	781	0.1%	873	0%	880	0%
PT	73	53%	105	59%	111	53%	126	60%	87	66%
RO	70	0%	66	0%	70	0%	58	0%	89	0%
SE	581	5%	528	4%	602	2%	402	1%	380	6%
SI	16	100%	16	88%	27	93%	25	100%	13	92%
SK	66	6%	55	4%	48	2%	64	5%	37	5%
Total	**15 910**	**33%**	**17 015**	**32%**	**16 307**	**25%**	**15 553**	**26%**	**13 702**	**25%**

Czechia, Ireland, Latvia, Poland, Romania, Finland and Norway reported that 5% or less of decisions have been extended over 40 days throughout the five-year period. During the same period, Slovenia has not achieved a single year under 88%. There are indications from reported numbers of decisons over the five-year period that there have been reductions in extended decision making in some member states e.g., France and Italy.

The responses indicated some differences in the ways that the 40 days have been calculated, which may address some of the differences seen between Member State responses. For example, one Member State has used using calendar days, rather than working days as set out in Article 41.

Another indicated that there have been occasions when reviewers included the time taken for the applicant to respond to queries on the application (Slovenia).

To improve standardisation of the operation of the Directive and of data submission, Member States should ensure that in compliance with Article 41, the decision regarding authorisation should be reported in working days from the receipt of the complete and correct application.

Questions

C - 1.1.1.bis Provide summary information covering the 5 year reporting cycle on the reasons why the deadline of 40 days has been extended.

The Directive permits, when justified by the complexity or the multidisciplinary nature of the project, the competent authority to extend the period of 40 working days (once only) by an additional period not exceeding 15 days.

A number of reasons were provided to explain why the 40 days had been exceeded. Many of these related to the complexity of the applications, including the severity of procedures and the species involved, and with very complex procedures in which the potential harms to the animals had been difficult to determine. Also, delays were attributed to common failings in the submission which required more information. These included inadequate consideration of the Three Rs, poorly drafted non-technical project summaries and their compliance with the required standard format. These latter issues may relate to project applications which are not "complete and correct" which sets the beginning for the 40-day authorisation period. After all the data had been collated at EU level for this report, following an enquiry from Commission, Slovenia reported that instead of providing timelines from when the applications were complete and correct, the times used were from the initial application.

In addition, for those Member States, where the 40-day period was extended, a lack of administrative staff to deal with applications was often cited as a cause, in addition to insufficient frequency of ethical/evaluation committee meetings, long-standing delays being slowly cleared, and delays incurred while seeking improved project submissions. Failure to pay required fees in a timely manner was also reported. During the reporting period, COVID-19 proved to have been challenging to ensure continuity for evaluation and authorisation.

Finally, it is not clear whether the authorisation period had been extended specifically in line with Article 41(2) and whether the decision was then made within 55 days, or if the 40- and 55-day target(s) were just missed. Moreover, if the 40- or 55-day period was exceeded, it is not clear how long it took to make the decision.

Question

C - 1.1.2 Have any multiple generic projects been authorised in your Member State between 2018-2022?

Answer	Count	%	Member States
Yes	21	75%	AT, BE, BG, CZ, DE, DK, EL, ES, FI, HR, HU, IE, IT, MT, NL, NO, PL, PT, RO, SI, SK
No	7	25%	CY, EE, FR, LT, LU, LV, SE

Article 40(4) allows 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 methods with established methods.

Question

C - 1.1.3 For each year, provide numbers of multiple generic projects, as provided for in Article 40(4) of Directive 2010/63/EU, categorised as one of the following types:

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	Proportion of multiple generic projects of all authorised projects (%)
2018	308	114	104	526	3%
2019	369	88	114	571	4%
2020	295	77	131	503	3%
2021	369	97	127	593	4%
2022	156	100	79	335	3%
Total	**1 497**	**476**	**555**	**2 528**	**3%**

60% of the multiple generic projects were authorised for regulatory purposes (where it is possible to specify which regulations are being complied with), 19% for routine production and 21% for diagnostic purposes. Routine production includes, for example, the manufacture of antibodies, blood-based products, bacterial growth on agar plates and genetically altered animals.

In most Member States, the percentage of all projects issued and categorised as multiple generic was less than 5%. 7 Member States reported that they have not issued multiple generic projects at all (Estonia, France, Cyprus, Latvia, Lithuania, Luxembourg, Sweden).

However, in contrast, in Slovakia 42% of all projects were reported as multiple generic projects (of which 93% for regulatory purposes; in Croatia 36% (of which 54 % for regulatory purposes) and in Hungary 27% (of which 50% for diagnostic purposes).

Malta has authorised a total of 2 projects in the five-year reporting period, both of which classified as multiple generic projects – each issued for two separate purposes – regulatory purposes and routine production. This was reported as 4 projects (2+2). As other Member States may also have had such "dual purpose" projects, the total number of projects issued as multiple generic may be inaccurate.

C.1.2. Retrospective assessment, non-technical project summaries (Articles 38, 39 and 43 of Directive 2010/63/EU)

Reporting obligation

"Explain the measures taken to ensure compliance with the requirements of Article 43(1) of Directive 2010/63/EU and indicate whether there is a requirement for non-technical project summaries to specify that a project is to undergo retrospective assessment (Article 43(2) of Directive 2010/63/EU).

In respect of each year, provide the number of projects authorised that are to undergo a retrospective assessment in accordance with Article 39(2) of Directive 2010/63/EU and the number of projects authorised that are to undergo a retrospective assessment under Article 38(2)(f) of that Directive. Categorise each of those projects as one of the following types:

(a) projects using non-human primates;

(b) projects involving procedures classified as 'severe';

(c) projects using non-human primates and involving procedures classified as 'severe';

(d) other projects that are to undergo a retrospective assessment.

Provide summary information, covering the five-year reporting cycle, on the nature of projects selected for retrospective assessment in accordance with Article 38(2)(f) of Directive 2010/63/EU that are not automatically subject to retrospective assessment in accordance with Article 39(2)."

Non-technical project summaries

Background

The 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

Voluntary questions

C - 1.2.1 Does the local Animal Welfare Body contribute to the drafting of the non-technical summary?

C - 1.2.1.bis Please explain 'Not always'.

Answer	Count	%	Member States
Yes	7	27%	BG, IT, LV, NL, NO, PL, SI
Not always	9	35%	AT, BE, CZ, DK, EL, ES, LU, PT, SE

No	10	38%	CY, DE, FI, FR, HR, HU, IE, LT, MT, SK

The local Animal Welfare Body contributes to the drafting of the non-technical project summary in some but not all cases. Such inputs can contribute to ensuring the quality of the non-technical project summaries, but it is not a legal requirement.

For those Member States who indicated that there is not always a contribution, the explanations included:

- It is optional and some Animal Welfare Bodies contribute, others do not;
- In some establishments, the Animal Welfare Body provides training for project applicants;
- It is encouraged by the competent authority for Animal Welfare Bodies to contribute but not mandated;
- One response noted that the input from Animal Welfare Bodiess contributes very positively to the quality of the non-technical project summaries.

Question

C - 1.2.2 Is the content of the non-technical summaries checked to ensure compliance with the requirements of Art 43 (1) and that they reflect the projects as authorised?

Answer	Count	%	Member States
Yes	28	100%	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, NO, PL, PT, RO, SE, SI, SK
No	0	0%	

Confirmation was received from all Member States that the content of all non-technical project summaries is checked to ensure compliance with the requirements of Article 43 (1).

Question

C - 1.2.2.1 By whom is oversight of the non-technical summaries provided to ensure they comply with the requirements of Art 43 (1) and reflect the projects as authorised?

C - 1.2.2.1.bis Specify 'Other'

C - 1.2.2.bis If not, please explain how compliance with Art 43 (1) is assured and reflect the projects as authorised.

Answer				
Member State	Competent Authority for project authorisation	Competent Authority for project evaluation	National Committee	Other
AT	✓	✓		✓
BE	✓	✓		✓
BG			✓	
CY	✓	✓	✓	
CZ	✓	✓		

DE		✓		
DK	✓	✓		
EE	✓	✓		
EL	✓	✓		
ES	✓	✓		✓
FI				✓
FR	✓	✓		
HR	✓	✓	✓	
HU	✓	✓		
IE	✓	✓		
IT	✓	✓		
LT	✓	✓	✓	
LU		✓		
LV	✓	✓	✓	
MT	✓	✓		
NL	✓			
NO	✓	✓		
PL	✓	✓	✓	✓
PT	✓	✓		
RO			✓	
SE	✓	✓		
SI		✓	✓	
SK	✓	✓		
TOTAL	**22**	**24**	**8**	**5**

In the great majority of Member States (21/28) the competent authorities responsible for project evaluation and authorisation both undertake checks to ensure that the non-technical project summary meets legal requirements and reflects the content of the authorised project. In 13 of these, all the checks are made only by the two competent authorities. In the other 8, one has appointed specific additional experts to support the process, in 1 Member State (Belgium) there is further oversight at regional level, in 1 (Spain) some non-technical project summaries may be reviewed by both competent authorities, while others may be by just one. In 5 Member States, there is additional input from the National Committee.

Of the remaining 7 Member States, 2 use exclusively the National Committee, 2 use exclusively the competent authority for project evaluation, 1 uses exclusively the competent authority for project authorisation, and 1 uses the comptent authority for project evaluation and the National Committee. In Finland, the regional state administrative agency of Southern Finland inspects and publishes non-technical project summaries.

The content of the non-technical project summary is defined by Commission Implementing Decision 2020/569/EU, and the competent authority as reported in question A.1.bis within a Member State is responsible for ensuring the quality of the non-technical project summary. Where a competent authority itself does not perform this duty, there should be clear instructions provided on compliance with requirements and oversight on delivery.

Voluntary question

C - 1.2.3.1 Has the revised EU guidance on the drafting of Non-technical Project Summaries been made available to the following:

C - 1.2.3.1.bis Please explain 'Not always'.

Answer	Yes			No			**Total**	
Question	Count	%	Member States	Count	%	Member States	**Count**	**%**
establishments	27	100%	BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, NO, PL, PT, RO, SE, SI, SK	0	0%		**27%**	**100%**
Those ensuring that NTS reflect projects as authorised	27	100%	BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, NO, PL, PT, RO, SE, SI, SK	0	0%		**27%**	**100%**

Of the 27 Member States that responded, all indicated that the guidance on the drafting of non-technical project summaries had been made available to establishments and to those responsible for ensuring that the non-technical project summaries reflect projects as authorised.

Voluntary question

C - 1.2.3.2 If possible, how extensively do you estimate it being used in your MS by:

Establishments;

Those ensuring that NTS reflect projects as authorised.

Answer	By all			By most			By some			**Total**	
Question	Count	%	Member States	Count	%	Member States	Count	%	Member States	**Count**	**%**
Those ensuring that NTS reflect projects as authorised	12	50%	DK, FI, HU, IE, IT, LU, LV, MT, NL, PT, SI, SK	8	33%	BG, CY, DE, EL, FR, HR, PL, SE	4	17%	BE, CZ, EE, NO	**24%**	**100%**

establishments	6	25%	HU, IT, LU, MT, NL, SI	9	38%	BE, BG, CY, DK, FR, LV, PL, PT, SK	9	38%	CZ, DE, EE, EL, FI, HR, IE, NO, SE	**24%**	**100%**

The responses suggested that the majority of establishments has used the guidance. It was estimated that in 20/24 Member States that responded, it has been used by all or most of those responsible for ensuring that the non-technical project summaries reflect projects as authorised.

Retrospective assessment of projects

Background

The 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

C - 1.2.4 Is the Member State legally obliged to update the non-technical summary with the outcomes of the retrospective assessment?

Answer	Count	%	Member States
Yes	16	57%	AT, BE, BG, CY, EL, FI, HR, LT, NL, NO, PL, PT, RO, SE, SI, SK
No	12	43%	CZ, DE, DK, EE, ES, FR, HU, IE, IT, LU, LV, MT

The Directive allows the possibility to update non-technical project summaries with the results of retrospective assessments. 16 Member States have transposed this requirement in their nationa legislation. The update must be published in the ALURES NTS EU database within six months from the completion of the retrospective assessment. The remaining Member States are not required to do so but are nevertheless free to upload such updates in ALURES on voluntary basis.

Question

C - 1.2.5 Provide information on the numbers and types of projects submitted for retrospective assessment (RA) under Article 39(2).

Year	Number of projects involving non-human primates (NHP), but no severe procedures	Number of projects involving severe procedures, but no NHP	Number of projects involving both NHP and severe procedures	Number of "other" projects (those involving neither NHP nor severe procedures) submitted for RA	Total number of projects submitted for RA
2018	236	2 629	28	1 524	4 417
2019	264	2 701	44	1 417	4 426
2020	200	2 949	30	1 745	4 924
2021	214	2 839	38	1 543	4 634
2022	256	2 517	40	1 249	4 062
Total	**1 170**	**13 635**	**180**	**7 478**	**22 463**

Around 30% of all authorised projects have been submitted for retrospective assessment during the reporting period. Of these, two-thirds were required for retrospective assessment by the Directive and the remaining third selected during the project evaluation.

Throughout the five-year reporting period, of those projects requiring a retrospective assessment, the majority (61%) were submitted as these projects contained severe procedures, with 5% as they authorised the use of non-human primates (without any severe procedures) and 0.8% as they authorised the use of non-human primates and severe procedures.

Question

C – 1.2.6 Provide reasons for other projects (beyond those compulsory by the Directive) being submitted for retrospective assessment covering the five-year reporting cycle.

In 12 Member States (Bulgaria, Denmark, Estonia, Greece, Croatia, Cyprus, Lithuania, Luxembourg, Malta, Netherlands, Romania, Slovenia) no additional projects have been selected for a retrospective assessment in the reporting period, although the flexibility to do so is incorporated in the national legislation.

The main “Other” reasons for selecting projects for retrospective assessment include

- requiring all projects except those containing only non-recovery procedures to be subject to retrospective assessment to ensure all outcomes are captured with regard to application of Three Rs in future projects;
- all multiple generic projects, for example regulatory toxicology;

- all projects aimed at teaching in higher education;
- where predicted harms are uncertain, e.g., some pilot studies, and where the project includes cumulative suffering;
- projects with specific exemptions, e.g., Article 10 (purpose-bred), Article 12 (use of animals outside establishments/work in the wild) or Article 33 (exemptions from animal care and accommodation standards);
- where there are ongoing concerns over the most refined methodology, for example intravenous versus retroorbital administration or sampling; use of analgesia in genetically altered animal tissue sampling;
- projects involving large numbers of animals.

One Member State uses a scoring system to assist in determining whether or not a retrospective assessment is required. Another Member State may add a requirement for a retrospective assessment during the course of a project if problems have been encountered, for example, unexpected deaths.

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

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

Reporting obligation

"Provide the species and numbers of animals that were bred and born (including by Caesarean section) for use in procedures and, having never been used in any procedures, were killed during the calendar year immediately preceding that in which the five-year report is submitted.

Include animals killed for organs or tissues and animals from the creation and maintenance of genetically altered (GA) animal lines, which are not covered in the annual statistics pursuant to Article 54(2) of Directive 2010/63/EU.

Categorise these animals as one of the following types:

(a) genetically normal animals not providing organs and/or tissues;

(b) genetically normal animals providing organs and/or tissues;

(c) GA animals providing organs and/or tissues;

(d) genetically normal animals (wild type offspring) as a result of the creation of a new GA line;

(e) animals from the maintenance of a GA line covering all GA and wild type offspring of both harmful and non- harmful phenotype.

The category referred to in point (a) excludes animals as a result of a creation of a new GA line and from the maintenance of a GA line, which are to be reported in the categories referred to in points (d) and (e) respectively;

The categories referred to in points (b) and (c) include animals as a result of creation of a new GA line and from maintenance of a GA line, when providing organs and/or tissues;

The categories referred to in points 2.1.2(d) and (e) exclude the following animals, which are to be reported in the annual statistics pursuant to Article 54(2) of Directive 2010/63/EU: (a) animals

that were genotyped using invasive methods; (b) animals from a harmful phenotype line that experienced adverse effect."

Background

The 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..."

Question

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 2022.

C - 2.1 Please attach manually filled-in excel template 'Animals bred, killed and not used in procedure' or the excel file exported from Declare report 'Animals bred, killed and not used in procedures'.

Category	1. Number of genetically normal animals (wild type offspring) produced, bred and killed as a result of a creation of a new genetically altered (GA) line			2. Number of animals bred and killed for the maintenance of an established genetically altered (GA) line			3. Number of conventional animals, bred, killed and not used in procedures (excluding those involved in the creation of maintenance of a genetically altered animal (GA) line)			
Species	Collection of organs and tissue	No collection of organs and tissue	Total	Collection of organs and tissue	No collection of organs and tissue	Total	Collection of organs and tissue	No collection of organs and tissue	Total	**Overall total 2022**
Mice	20 632	150 699	171 331	297 785	4 693 602	4 991 387	1 042 956	1 481 184	2 524 140	**7 686 858**
Zebrafish		12 139	12 139	743	491 968	492 711	41 083	136 820	177 903	**682 753**
Rats	27	1 525	1 552	5 925	163 812	169 737	113 086	212 424	325 510	**496 799**
Domestic fowl				646	14 545	15 191	21 713	115 106	136 819	**152 010**
Other fish				312	39 007	39 319	53 945	35 855	89 800	**129 119**
Sea bass					2 335	2 335	1 668	87 728	89 396	**91 731**
Guinea-Pigs					52 376	52 376	3 102	24 636	27 738	**80 114**
Rabbits				130	56 212	56 342	1 930	8 432	10 362	**66 704**
Other amphibians		716	716	23 895	20 975	44 870	7 342	3 312	10 654	**56 240**
Salmon, trout, chars and graylings					7 657	7 657	7 308	37 405	44 713	**52 370**
Xenopus	15	67	82	45	2 651	2 696	3 345	28 484	31 829	**34 607**
Guppy, swordtail, molly, platy				27	9 784	9 811	1 991	1 581	3 572	**13 383**
Other birds				138	4 258	4 396	884	3 120	4 004	**8 400**
Hamsters (Syrian)				13	482	495	884	4 691	5 575	**6 070**
Other rodents				103	542	645	2 067	837	2 904	**3 549**
Pigs		12	12		491	491	1 405	1 521	2 926	**3 429**
Turkey					318	318	840	1 074	1 914	**2 232**
Mongolian gerbil					161	161	840	640	1 480	**1 641**

Rana					618	618	565	48	613	**1 231**
Other mammals					88	88	469	75	544	**632**
Sheep					326	326	60	154	214	**540**
Cephalopods							140	325	465	**465**
Reptiles							284	104	388	**388**
Goats		10	10		230	230	62	26	88	**328**
Dogs				21	193	214	47	43	90	**304**
Horses, donkeys and cross-breeds							7	204	211	**211**
Cynomolgus monkey							11	150	161	**161**
Cattle					48	48	28	45	73	**121**
Hamsters (Chinese)					92	92				**92**
Marmoset and tamarins					1	1	51	7	58	**59**
Cats					2	2	16	33	49	**51**
Other carnivores							7	43	50	**50**
Baboons							30	14	44	**44**
Ferrets							24	6	30	**30**
Prosimians					25	25				**25**
Rhesus monkey					1	1	17		17	**18**
Total	**20 674**	**165 168**	**185 842**	**329 783**	**5 562 800**	**5 892 583**	**1 308 207**	**2 186 127**	**3 494 334**	**9 572 759**
% of animals used for collection of organs and tissues	**11%**			**6%**			**37%**			**17%**

The data to be gathered in this section was revised in line with the 2020 Commission Implementing Decision to include information on the number of animals bred and killed where organs and/or tissues were collected for scientific purposes, for example to use animal-based *ex-vivo* methods.

Animals bred, killed and not used in procedures include also breeding animals when they reach the end of their breeding life, animals which were ill and humanely killed before being used, and animals killed in order to protect the health and scientific integrity of the colony.

Most common species reported

The table shows the species used, ordered from the most common to the least common total numbers bred, killed and not used. Mice, zebrafish and rats account for more than 90% of the animals reported. The overall distribution among the species reported is similar to that reported in the first implementation report. The category "other fish" has been divided since 2017 and so some individual fish groups are shown in 2022, which did not appear in 2017. There have been other minor changes in species listing since the new Implementing Decision which have had a minor effect on this table compared to 2017. The information is now more granular.

Wild-type offspring which were not used but killed from the creation of a new genetically altered animal line

In 2022, 185 842 genetically normal (wild type) offspring were produced, bred and not used in scientific procedures as a result of creation of a new genetically altered animal line. It is inevitable that some normal animals would be produced due to Mendelian genetics. In some cases, it is more welfare-friendly to breed from heterozygotes, which produce genetically normal offspring.

Animals bred, killed and not used during maintenance of an established genetically altered line

In 2022, 5 892 583 animals were bred and killed during maintenance of genetically altered animals lines and not otherwise used for scientific purposes. This figure should include all animals bred and not used for scientific procedures from non-harmful lines and those from harmful lines not exhibiting harms.

For genetically altered animals all those tissue-sampled for the purposes of genetic chracterisation using an invasive method above minimum threshold of pain suffering and distress, and those exhibiting adverse effects from a harmful phenotype line were already reported in the annual statistics.

Animals bred and killed for the collection of organs and tissues

Organs and tissues were harvested for scientific purposes from around 17% of all the animals bred, killed and not used.

Of the conventional animals bred, killed and not used, 37% were used for collection of organs and tissues. This percentage increased for species such as marmosets (88%), baboons (68%), dogs (52%), however, it was surprising that only 11/150 (7%) Cynomolgus macaques had tissues harvested for scientific purposes. It is important that tissues and organs are utilised wherever possible.

Of the genetically normal animals ("wild type offspring") from the creation of a new genetically altered animal line, just over 11% (20 674) were used for the collection of organs and tissues. Only a small minority of 5.6% (329 783) of the genetically altered animals resulting from the

maintenance of an established genetically altered animal line, were used for the collection of organs and tissues.

All species of animals bred, killed and not used by Member State:

Category						
Country	1. Total number of genetically normal animals (wild type offspring) produced, bred and killed as a result of a creation of a new genetically altered (GA) line	2. Total number of animals bred and killed for the maintenance of an established genetically altered (GA) line	3. Total number of conventional animals, bred, killed and not used in procedures (excluding those involved in the creation of maintenance of a genetically altered animal (GA) line)	Sum of totals	# of all animals bred, killed and not used where collection of organs and/or tissues occurred	% of animals bred, killed, and not used in which collection of organs and/or tissues occurred
AT	13 834	230 695	69 084	**313 613**	50 985	16%
BE	4 066	382 616	103 086	**489 768**	142 576	29%
BG			110	**110**	0	0%
CY		1 762	10	**1 772**	10	1%
CZ		720	14 953	**15 673**	13 789	88%
DE	15 282	1 439 944	982 069	**2 437 295**	711 926	29%
DK		737 220	27 420	**764 640**	39 439	5%
EE		6 230	7 438	**13 668**	999	7%
EL	116	8 622	11 699	**20 437**	1 306	6%
ES	27 550	316 525	153 440	**497 515**	111 535	22%
FI	977	62 864	33 055	**96 896**	15 502	16%
FR	93 387	2 024 975	647 572	**2 765 934**	380 490	14%
HR		4 213	1 307	**5 520**	2 914	53%
HU	143	59 259	14 633	**74 035**	2 325	3%
IE		40	296 919	**296 959**	8 351	3%
IT	2 712	64 086	33 153	**99 951**	17 246	17%
LT			2 293	**2 293**	0	0%
LU	148	10 577	13 904	**24 629**	13 217	54%
LV	300	675	797	**1 772**	625	35%
NL	8 216	325 552	729 562	**1 063 330**	0	0%
NO	327	13 076	2 656	**16 059**	41 451	4%
PL	5 462	32 874	42 989	**81 325**	1 491	9%
PT	372	103 933	61 788	**166 093**	37 941	47%
RO		927	8 474	**9 401**	28 159	17%
SE	12 950	64 408	233 116	**310 474**	4 684	50%
SI		686	2 163	**2 849**	31 034	10%
SK		104	644	**748**	669	23%
Overall total	**185 842**	**5 892 583**	**3 494 334**	**9 572 759**	**1 658 664**	**17%**

Every Member State reported some animals bred, killed and not used. The total number of animals reported in 2022 as bred, killed and not used was 9 572 759. This includes a wide variety of species.

Although there may be a relationship between the numbers reported as used in procedures, and those reported here, it is not possible to compare between Member States, as large commercial breeders within a Member State are likely to supply animals across many Member States, and the surplus from these breeders should not be solely attributed to the Member State in which the animals are bred.

There were also wide variations between Member States of the proportion of animals that were used for the provision of organs and tissues.

In the case of genetically altered animals, often a surplus is unavoidable as the number of unsuitable animals (not being of the correct genotype) is dependent on the methodologies used and on the complexities of breeding of genetically altered animals with multiple genetic modifications.

Voluntary question

C - 2.1.bis Please provide a breakdown of 'other' species bred, killed and not used in procedures.

Animals bred, killed and not used reported under "other species" were 129 119 fish, 56 240 amphibia, 3 549 rodents, 8 400 birds and 632 mammals. The number of amphibia seems unexpectedly high.

104 different types of fish, 11 types of amphibia, 21 rodents, 14 birds, 1 reptile, 10 other mammals were reported under this question as being purpose-bred.

23 of these were used by more than 1 Member State, of which 16 were fish (including carp, catfish, stickleback, trout, tilapia, flounder, sole and sprat), 2 were amphibia (axolotl and newt), 1 was a rodent (Cairo spiny mouse), 2 birds (quail, zebra finch) and 2 mammals (opossum, bat).

Voluntary question

C - 2.2 What measures have been taken to reduce the number of surplus animals?

A large number of initiatives have been identified and introduced to manage and reduce the surplus of animals bred for scientific research. These include:

Breeding

- Optimisation of efficient breeding strategies / use of specific animal facility management software;
- Archiving of animal lines (cryopreservation of embryos and sperm).
- GA breeding
- Use of new technology e.g., Crispr-cas9;
- Breeding as homozygotes rather than heterozygotes when possible;
- Use of wild-types as controls in science;
- Sharing of Cre and Lox strains between scientists;
- Early genotyping of zebrafish (3-4 day post fertilisation).

Project

- Purchasing only the required number of animals from commercial breeders;
- Use of both sexes in procedures and single sex use must be specifically justified;
- Use of stock/surplus animals for education and training.

Establishment

- Taking all proportionate measures to avoid surplus animals, and to avoid killing any such animals
  - Animal Welfare Boby monitoring of surplus animals;
  - Appointment of breeding co-ordinator to increase the efficiency and quality of breeding within their facilities, and ensuring that everyone is aware of who is lead of breeding policies and efficiencies.
- Exchange of surplus animals between establishments;
- Encourage collaboration within and between establishments to minimise duplication and hence surplus; tissue and organ sharing, use of biobanks, both within establishments and across Member States (e.g., EUPRIM; AniMatch);
- Consolidation of breeding colonies (i.e. no duplication of lines);
- Consideration of commercial versus in-house breeding to supply animals;
- Use of killed animals as reptile/raptor food;
- Widerning of rehoming policies to also cover species such as rats, guinea pigs, llamas.

National

- Creation of national platforms and testing of already existing international platforms at a local institutional level to enable the exchange of animals, e.g., the Dutch government has provided financial support to develop a system to identify and share available lines;
- Specific focus during inspections;
- Guidance on avoidance of surplus;
- Training seminars and programmes.

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

Reporting obligation

"Explain the measures taken to ensure compliance with the requirements of Articles 10 and 28 of Directive 2010/63/EU when sourcing non-human primates."

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."

It is important to note that the Directive requires the use of F2/F2+ or those supplied from self-sustaning colonies. However, this requirement only entered into force in November 2022 whereas this report covers the entire period of 2018-2022.

Analysis

Question

C - 2.3 Were there any authorised users, breeders or suppliers of non-human primates (NHP) in your Member State between 2018-2022?

Answer	Yes			No		
Question	Count	%	Member States	Count	%	Member States
users	12	43%	AT, BE, CZ, DE, DK, EL, ES, FR, HU, IT, NL, SE	16	57%	BG, CY, EE, FI, HR, IE, LT, LU, LV, MT, NO, PL, PT, RO, SI, SK
breeders	5	18%	CZ, DE, ES, FR, NL	23	82%	AT, BE, BG, CY, DK, EE, EL, FI, HR, HU, IE, IT, LT, LU, LV, MT, NO, PL, PT, RO, SE, SI, SK
suppliers	5	18%	CZ, DE, ES, FR, NL	23	82%	AT, BE, BG, CY, DK, EE, EL, FI, HR, HU, IE, IT, LT, LU, LV, MT, NO, PL, PT, RO, SE, SI, SK

A minority of Member States, only 12, have had active users, breeders or suppliers of non-human primates. Each of the Member States which have bred and supplied also used them.

Question

C - 2.3.1 Between 2018 and 2022 have breeders and/or suppliers supplied only F2 (offspring of NHPs which have been bred in captivity) or higher generation purpose-bred NHP for use in procedures?

Answer	Count	%	Member States
Yes	3	60%	CZ, DE, NL
No	2	40%	ES, FR

Question

C - 2.3.1.bis Provide information on strategies in place to increase the proportion of animals of F2 (or higher) in line with Article 28

This question was intended specifically to address EU breeders of non-human primates, and their required strategies if not yet supplying only animals that are off-spring of parents bred in captivity, F2/F2+ animals. The responses provided may not have discriminated between EU and overseas breeders/suppliers. It was clear that the Member States not supplying only F2/F2+ animals are aware of the issue and the need to address it, and have had regular exchanges with establishments.

One Member State (Spain) reported that the first-generation purpose bred, F1 animal(s) were from a supplier only, and not a breeder, and therefore they cannot establish strategies to increase the percentage of animals that are descendants of non-human primates bred in captivity. Whilst this is true, because from November 2022 only F2/F2+ can be used, discussions with the supplier will be required.

Voluntary question

C - 2.3.2 Between 2018 and 2022 have only F2 or higher generation purpose-bred NHP been used in your Member State? (Article 10).

Answer	Count	%	Member States
Yes	7	64%	BE, CZ, DE, DK, EL, NL, SE
No	4	36%	AT, ES, FR, IT
Total	**11**	**100%**	

This voluntary question aimed to assess the situation in respect of the new requirement that took effect in November 2022 to only using F2/F2+ non-human primates in the Union irrespective of the source. Contrary to the above submission, Germany has reported the use of non-human primates of F1 generation as part of their annual statistical reports during the five-year period, between 2018 - 2022.
One Member State (France) reported that for Cynomolgus macaques (*Macaca fascicularis*) brought into the Union from Asia and Africa, the transition to F2/F2+ is taking longer than anticipated.

Furthermore, a project was carried out for the purpose of conservation of the species using F0 non-human primates in the wild, however, taking place in one of the French outermost regions. Such studies are permitted with an exemption for the requirement to use F2/F2+ when scientifically justified.

The use of animals falling under the scope of the Directive in the outermost regions must be reported in the annual statistical reports by France for Guadeloupe, French Guiana, Martinique, Réunion, Mayotte, Saint-Martin; by Portugal for the Azores and Madeira; and by Spain for the Canary Islands.

Question

C - 2.3.2.bis Provide information on the strategy to ensure the use of only F2 or higher generation purpose-bred NHP or NHP sourced from self-sustaining colonies (Article 10)

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?

The four Member States who acknowledged the continued use of F1 non-human primates between 2018-2022 provided information on their strategy to move to the use of F2+ generation animals or animals sourced from self-sustaining colonies.

Austria has performed observational behavioural studies on non-human primates which were not F2/F2+, but no procedures falling under the scope of the Directive were carried out on these animals.

In Spain, the use of F1 animals has been exceptional in the period 2018-2022 (10 uses out of the 1 404 in the period) and was necessary to meet specific scientific needs.

France, which obtains animals from Asia and Africa has encountered difficulties in sourcing animals of F2/F2+ generation due to increased demand and closure of access to Chinese suppliers. Regular exchanges with user establishments and the main breeders are underway in order to ensure a smooth transition as soon as possible.

In Italy, at present, no strategies have been developed to ensure the use of F2/F2+ non-human primates or from self-sustaining colonies. These strategies will be implemented in the course of 2024.

C.3. Exemptions

Reporting obligation

"Provide summary information, covering the five-year reporting cycle, on circumstances under which exemptions were granted in accordance with Article 10(3), the second subparagraph of Article 12(1) and Article 33(3) of Directive 2010/63/EU.

Provide information for the same period on any exceptional circumstances as referred to in Article 16(2) of that Directive where the reuse of an animal was authorised after a procedure in which the suffering of that animal was assessed to have been severe."

It is important to note that no detailed, numerical data are expected 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 voluntarily provide numerical and/or more detailed data.

In addition to exemptions detailed below, Article 55 of the Directive foresees, safeguard clauses for scientifically justified, exceptional use of great apes, the use of non-human primates for purposes other than those related to debilitating or life-threatening clinical conditions and for the use of a procedure that goes above the maximum threshold of pain, suffering and distress.
No safeguard clauses have been initiated by the Member States between 2018 - 2022.

Analysis

Article 10 - Animals bred for use in procedures

The 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."

Questions

C - 3.1 Provide summary information covering years 2018-2022 on circumstances under which exemptions were granted to the requirement to use animals (listed in Annex I) purpose bred for scientific use.

C - 3.1.bis Specify other.

Answer	Yes			No		
Question	Count	%	Member States	Count	%	Member States
investigating wild populations	18	64%	AT, BE, CZ, DE, DK, EE, FR, HU, IE, IT, LV, NL, NO, PL, PT, SE, SI, SK	10	36%	BG, CY, EL, ES, FI, HR, LT, LU, MT, RO
using pets in vet research	13	46%	AT, BE, CY, CZ, DE, DK, FI, LV, NL, NO, PL, SE, SK	15	54%	BG, EE, EL, ES, FR, HR, HU, IE, IT, LT, LU, MT, PT, RO, SI
specific breed required which are not purpose bred	11	39%	BE, CZ, DE, DK, FR, HU, NL, NO, PT, SE, SI	17	61%	AT, BG, CY, EE, EL, ES, FI, HR, IE, IT, LT, LU, LV, MT, PL, RO, SK
other	6	21%	DK, EE, ES, FI, LV, SE	22	79%	AT, BE, BG, CY, CZ, DE, EL, FR, HR, HU, IE, IT, LT, LU, MT, NL, NO, PL, PT, RO, SI, SK

In some cases, animals bred for scientific use are not suitable for the type of study being undertaken, e.g., research on wild animals, veterinary research, research on specific pet dog breeds. Therefore, the Directive foresees the possibility for an exemption on the basis of a scientific justification. The circumstances where exemptions have been granted and the Member States which have granted them are given in the table above.

There are circumstances where the environment of animals bred for scientific use makes them unsuitable, including where environmental exposure is required or a broad range of environmental conditions is required, or where a large diversity of genetic variations are required.

In two Member States an exemption was granted because there were no (available) registered breeders / suppliers of the required species (Spain: *Danio rerio*; Sweden: *specific Rana spp*). The purpose of requiring animals bred for scientific use is to improve the quality of animals used in scientific research. Care must be taken that science is not compromised by such exemptions.

Reasons other than those listed in the table above included several examples involving dogs, such as for investigation of zoonotic infections in home environment (Sweden) and the use of already trained search-dogs that did not need additional training (Sweden).

In some cases, e.g., farm animals (Estonia, Latvia) and zoo animals (Denmark) have been listed as exemptions. Farm animals are not listed on Annex I of the Directive and therefore appear to have been exempted in error.

Article 12 - Procedures

The 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."

Questions

C - 3.2 Provide summary information covering years 2018-2022 on circumstances under which exemptions were granted to the requirement to carry out a project in user's establishment.

C - 3.2.bis Specify other

Answer	Yes			No		
Question	Count	%	Member States	Count	%	Member States
work on animals in a commercial farm	22	79%	AT, BE, CZ, DE, DK, EE, ES, FI, FR, HR, HU, IE, IT, LT, LV, NL, NO, PL, PT, SE, SI, SK	6	21%	BG, CY, EL, LU, MT, RO
work on animals in the wild	22	79%	AT, BE, CZ, DE, DK, EE, EL, ES, FI, FR, HU, IE, IT, LV, NL, NO, PL, PT, RO, SE, SI, SK	6	21%	BG, CY, HR, LT, LU, MT
work in veterinary practice	15	54%	AT, BE, CY, CZ, DE, DK, ES, FI, LV, NL, NO, PL, SE, SI, SK	13	46%	BG, EE, EL, FR, HR, HU, IE, IT, LT, LU, MT, PT, RO
other	6	21%	BE, CZ, ES, FI, PL, SE	22	79%	AT, BG, CY, DE, DK, EE, EL, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, NO, PT, RO, SI, SK

A majority of Member States authorised exemptions from work being performed at an establishment for veterinary and/or agricultural research, e.g., using horses or in aquaculture research.

Research involving wild animals commonly required this exemption, or where environmental studies involving natural/usual place of habitation was critical to the science (Sweden).

Other examples of exemption included the use of specialised equipment or expertise not available at an establishment including imaging, exposure to irradiation, aquaculture expertise (Belgium, Czechia, Spain).

Article 16 - Reuse

The 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.

Questions

C - 3.3 Were any exemptions granted for the reuse of an animal after a procedure in which the actual suffering was assessed as severe (Article 16(2))?

C - 3.3.bis Describe circumstances and number of derogations granted, species and number of animals involved.

Answer	Count	%	Member States
Yes	0	0%	
No	28	100%	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, NO, PL, PT, RO, SE, SI, SK

No Member State granted exemptions for reuse after an animal had already experienced severe suffering.

Article 33 - Care and accommodation

The 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."

Questions

C - 3.4 Provide summary information covering years 2018-2022 on reasons for which exemptions were granted to the care and accommodation requirements.

C - 3.4.bis Specify other.

Answer	Yes			No		
Question	Count	%	Member States	Count	%	Member States
feeding altered diets	21	75%	AT, BE, CZ, DE, DK, EE, ES, FI, FR, HR, HU, IE, IT, LV, NL, NO, PL, PT, SE, SI, SK	7	25%	BG, CY, EL, IT, LU, MT, RO
metabolic cages	20	71%	AT, BE, CZ, DE, DK, ES, FI, FR, HR, HU, IE, IT, LV, NL, NO, PL, SE, SI, SK	8	29%	BG, CY, EE, EL, LT, LU, MT, RO
restriction of food/water	20	71%	AT, BE, CZ, DE, DK, EE, ES, FI, FR, HR, HU, IE, IT, LV, NL, NO, PL, PT, SE, SK	8	29%	BG, CY, EL, LT, LU, MT, RO, SI
other single housing to make scientific measurements	19	68%	AT, BE, CZ, DE, DK, EE, ES, FI, FR, HU, IE, IT, LV, NL, NO, PL, PT, SE, SK	9	32%	BG, CY, EL, HR, LT, LU, MT, RO, SI
disruption to normal environment as behavioural stressors	15	54%	AT, CZ, DE, DK, EE, ES, FI, FR, HU, IE, IT, NL, PL, PT, SK	13	46%	BE, BG, CY, EL, HR, LT, LU, LV, MT, NO, RO, SE, SI
other	6	21%	DK, ES, FR, IE, PL, SE	22	79%	AT, BE, BG, CY, CZ, DE, EE, EL, FI, HR, HU, IT, LT, LU, LV, MT, NL, NO, PT, RO, SI, SK

Altered and restricted diets were common exemptions to the Annex III requirements on animal care and accommodation, as were requirements for single and special housing conditions to make scientific measurements.

Using a manipulated environment to induce stress has become a scientific tool by use of small space (including restriction of movement (Spain, Sweden) and/or unenriched space, or single housing of a social species where science justifies this. In some cases, bedding was excluded as animals may eat it and this may affect nutrition studies.

Other exemptions have included exposure to cold (Ireland, France), sound (France), altered light regime (more darkness) which may be harmful (Sweden), change to substrate for domestic fowl including availability to satisfy the behavioural needs to peck, scratch and dust bath (Sweden).

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

Reporting obligation

"Explain the measures taken to ensure compliance with the requirements regarding the structure and functioning of animal welfare bodies of Articles 26 and 27 of Directive 2010/63/EU."

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."

The structure of Animal Welfare Body (Article 26)

Analysis

Question

C - 4.1 Is there a requirement to include persons in addition to the legal requirements of having a person responsible for care and welfare of animals and a scientific member?

Answer	Count	%	Member States
Yes	12	43%	EE, EL, FI, HR, IE, IT, LV, MT, PT, SE, SI, SK
No	16	57%	AT, BE, BG, CY, CZ, DE, DK, ES, FR, HU, LT, LU, NL, NO, PL, RO

Questions

C - 4.1.1 Who is included in addition to the legal requirements?

C - 4.1.1.bis Specify other

Answer	Yes			No		
Question	Count	%	Member States	Count	%	Member States
designated veterinarian	10	83%	EE, EL, FI, HR, IE, IT, LV, PT, SE, SK	2	17%	MT, SI
lay person	1	8%	PT	11	92%	EE, EL, FI, HR, IE, IT, LV, MT, SE, SI, SK
statistician	1	8%	PT	11	92%	EE, EL, FI, HR, IE, IT, LV, MT, SE, SI, SK
ethicist	0	0%		12	100%	EE, EL, FI, HR, IE, IT, LV, MT, PT, SE, SI, SK
other	3	25%	MT, PT, SE	9	75%	EE, EL, FI, HR, IE, IT, LV, SI, SK

12 Member States require additional persons on Animal Welfare Bodies beyond that required in the Directive. 10 of these require the designated veterinarian to be included in the Animal Welfare Bodies. 1 Member State (Portugal) requires a layperson and a statistician. Member States specified within the "other" answers to have required the person responsible for compliance within the establishment, an ethologist if the establishment uses non-human primates, and a person knowledgeable in replacement/alternatives.

Functioning of the Animal Welfare Body (Article 27)

Analysis

Questions

C - 4.2 Is any training required by policies (national/regional/local/establishment) and/or by law for animal Welfare Body members in your Member State?

C - 4.2.bis What training is required?

C - 4.2.tris Please explain 'Not always'.

Answer	Count	%	Member States
Yes	8	29%	CZ, EE, ES, FI, HR, IT, LV, NO
Not always	4	14%	AT, BE, IE, PT
No	16	57%	BG, CY, DE, DK, EL, FR, HU, LT, LU, MT, NL, PL, RO, SE, SI, SK

16 Member States do not have any policies requiring training for members of Animal Welfare Bodies, whereas in a further 8 Member States there are some training obligations. Some members

of Animal Welfare Bodies have training as a result of their pre-existing role (function A-D under Article 23 of the Directive). Responses from the other 4 Member States suggested that training was made available in some, but not all, establishments, and that attendance at relevant training courses covering the functions A-D may be beneficial to Animal Welfare Body members.

Question

C - 4.3 Explain the measures taken to ensure that each of the 5 tasks are completed by each Animal Welfare Body.

The requirements for Animal Welfare Bodies are set out in national legislation, and the main mechanism used by Member States to ensure compliance is through the inspection programme.

Inspections assess the suitability of structure and function of the Animal Welfare Body, and in addition ensure that the record-keeping is satisfactory and has been maintained for the required three years. The review of Animal Welfare Body performance is considered an important component of inspection, and it was noted that failure to comply with all five main tasks would be dealt with as non-compliance and subject to administrative or more punitive actions.

In one Member State, during inspections, it has been found that verbal discussions/ recommendations are not always recorded, and as a consequence the Animal Welfare Bodies have been advised to complete records more fully as difficult to determine whether or not all tasks are carried out properly. Records should contain information on how the five main tasks are being delivered.

Examples provided have been listed under the relevant tasks. In some cases, they could fit under more than one task.

a) Advise staff on welfare in relation to acquisition, care and use

- In one Member State, the Animal Welfare Bodies encourage scientists/care staff to bring issues of concern to the attention of Animal Welfare Bodies.

b) Advise staff on the Three Rs

- In one Member State, Animal Welfare Bodies are encouraged to collaborate with the national 3Rs centre, in particular when advice is required on aspects or application of the Three Rs;
- In a few Member States, the Animal Welfare Bodies have provided advice on minimising surplus;
- and promoting utilisation of any healthy surplus by sharing tissues and organs.

c) Establish and review internal operational processes for monitoring, reporting and follow up of welfare

- A number of National Committees have issued recommendations on the functioning of Animal Welfare Bodies, and together with competent authorities organise national meetings/seminars/CPD with Animal Welfare Bodiess on a variety of topics, for example the Three Rs, and to share good practices;

- A number of national networks of Animal Welfare Bodies have been established, which further facilitate exchanging and sharing of relevant information and practices. One recent theme in one Member State is to consider how best to develop and promote a culture of care.

d) Follow the development and outcome of projects

- In two Member States, as a method to review the effectiveness of Animal Welfare Bodies, project evaluators review the input of the Animal Welfare Bodies to the application;
- In one Member State, the Animal Welfare Bodies approve study plans (including individual procedures) and subsequently review the outcome of studies.

e) Advise on rehoming schemes

- No examples were provided for this task

It was reported that the national 3Rs centres can also make useful contributions at national/regional meetings of Animal Welfare Bodies.

One Member State (Malta) has yet to establish any Animal Welfare Bodies.

Question

C - 4.4 Are Animal Welfare Bodies required by law to review all project applications before submission in your Member State? The question is not about provision of local input in the application but about a formal requirement to review/evaluate all project applications.

Answer	Count	%	Member States
Yes	9	32%	CZ, EE, ES, HR, HU, IT, NL, PL, PT
No	19	68%	AT, BE, BG, CY, DE, DK, EL, FI, FR, IE, LT, LU, LV, MT, NO, RO, SE, SI, SK

Whilst Animal Welfare Bodies are required to follow development and outcome of projects, there is no requirement to review all applications. However, in nine Member States, Animal Welfare Bodies are required by law to review all project applications before submission for evaluation by the competent authority.

Question

C - 4.5 Explain the measures taken to ensure that the adequate records of advice given are kept for 3 years.

There is a legal requirement in national legislation for such records to be maintained and however, 8 Member States do not assess this during inspections/competent authority checks (Czechia, Germany, Croatia, Latvia, Hungary, Malta, Slovenia, Finland).

If there are concerns over the quality of the records, non-compliance may be reported, and advice offered on how any deficiencies be remedied. It was reported that reminders are sometimes necessary to ensure that the records include evidence that all five functions have been delivered effectively. A comment was made that records are often maintained for longer than three years.

Question

C - 4.6 Does your Member State allow achieving the tasks in Article 27(1) by other means than through establishment of an Animal Welfare Body?

C - 4.6.bis Please describe what other means are used to achieve the tasks for Animal Welfare Body as in Article 27(1).

Answer	Count	%	Member States
Yes	9	32%	AT, BE, CY, ES, FI, HR, LU, NO, RO
No	19	68%	BG, CZ, DE, DK, EE, EL, FR, HU, IE, IT, LT, LV, MT, NL, PL, PT, SE, SI, SK

Nine Member States allow other means than the establishment of an Animal Welfare Body to achieve the tasks set out in Article 27(1).

A number of different ways to achieve the tasks have been adopted by the 9 Member States.

In two Member States (Belgium, Croatia) small users, breeders or suppliers may combine with an Animal Welfare Body of another establishment, although there is no definition of "small".

One or a small number of people perform the tasks of the Animal Welfare Body in 4 Member States (Cyprus, Austria, Romania, Finland). In one Member State (Austria) this is only for smaller establishments (employing fewer than five employees and/or breeding fewer than 500 animals per year or suppliers supplying fewer than 2 000 animals per year or users using fewer than 50 animals per year).

One country (Norway) requires a description of the Animal Welfare Body be included in the application for authorisation of an establishment. Establishments are reported to have chosen different models but inspections ensure that the approved "structures" meet all the requirements of an Animal Welfare Body.

In Spain and Luxembourg, although an alternative to an Animal Welfare Body is contained in the legislation, to date this option has not been used.

Voluntary questions

C - 4.7 Has EU guidance on Animal Welfare Bodies and National Committees been made available to AWBs?

C - 4.7.bis Please explain 'Not always'.

Answer	Count	%	Member States
Yes	25	89%	AT, BE, BG, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LU, LV, NL, NO, PL, PT, RO, SE, SI, SK
No	3	11%	CY, LT, MT
Total	**28**	**100%**	

The great majority of Member States has made available the EU Guidance on Animal Welfare Bodies and National Committees[21].

[21] https://data.europa.eu/doi/10.2779/059998

It is disappointing that the guidance has not been made available to Animal Welfare Bodies or persons involved in Animal Welfare Body task delivery in three Member States, although it is possible that detailed national guidance has been developed.

Voluntary question

C – 4.8 If possible, how extensively do you estimate it being used in your MS by AWBs?

Answer	Count	%	Member States
By all	5	20%	HU, IE, IT, LU, SI
By some	10	40%	BE, CZ, DE, DK, EE, FI, HR, LT, NO, SE
By most	8	32%	BG, EL, FR, LV, NL, PL, PT, SK
Not used	2	8%	CY, MT

Of the 25 Member States that responded to this question, it is estimated that in most Member States the guidance is being used.

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

"Provide information on the measures taken to ensure that the principles of (a) replacement, (b) reduction and (c) refinement are satisfactorily addressed within authorised projects in accordance with Articles 4 and 13 of Directive 2010/63/EU.

Provide information on the measures taken to ensure that the principles of (a) reduction and (b) refinement are satisfactorily addressed during housing and care in breeding and supplying establishments in accordance with Article 4 of Directive 2010/63/EU."

Background

The 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

Questions

D - 1.1 Which of the following ensure application of Three Rs is addressed in project applications?:

D - 1.1.bis Specify other.

Answer	Yes			No		
Question	Count	%	Member States	Count	%	Member States
application includes section on reduction	28	100%	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, NO, PL, PT, RO, SE, SI, SK			
application includes section on refinement	28	100%	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, NO, PL, PT, RO, SE, SI, SK			
application includes section on replacement	28	100%	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, NO, PL, PT, RO, SE, SI, SK			

application justifies the use of each animal model to be used	28	100%	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, NO, PL, PT, RO, SE, SI, SK			
application describes animal care and housing	26	93%	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, NO, PL, PT, RO, SE, SI, SK	2	7%	FI, MT
project describes and justifies required exemptions from Annex III requirements	24	86%	AT, BE, BG, CY, CZ, DE, DK, EE, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, NL, NO, PL, PT, SE, SI	4	14%	EL, MT, RO, SK
literature review is required within application	22	79%	AT, BE, BG, CY, CZ, DE, EE, EL, ES, HR, HU, IE, IT, LT, LU, LV, NL, PL, PT, RO, SI, SK	6	21%	DK, FI, FR, MT, NO, SE
specialist on refinement involved	18	64%	AT, BE, CY, CZ, DE, DK, EE, ES, FR, HU, IE, IT, LT, LU, LV, NL, NO, SK	10	36%	BG, EL, FI, HR, MT, PL, PT, RO, SE, SI
expert statistician involved	16	57%	AT, BE, CY, CZ, DE, EE, EL, ES, HU, IE, IT, LT, LU, LV, NL, NO	12	43%	BG, DK, FI, FR, HR, MT, PL, PT, RO, SE, SI, SK
specialist on non-animal alternatives involved	15	54%	BE, CY, CZ, DE, EE, ES, HU, IE, IT, LT, LU, LV, NL, NO, SK	13	46%	AT, BG, DK, EL, FI, FR, HR, MT, PL, PT, RO, SE, SI
advice from Animal Welfare Body is mandatory	13	46%	CZ, EE, ES, HR, HU, IT, LU, MT, NL, NO, PL, PT, SI	15	54%	AT, BE, BG, CY, DE, DK, EL, FI, FR, IE, LT, LV, RO, SE, SK
other	7	25%	BE, DK, ES, FI, NL, SE, SK	21	75%	AT, BG, CY, CZ, DE, EE, EL, FR, HR, HU, IE, IT, LT, LU, LV, MT, NO, PL, PT, NO, SI

All Member States include specific sections on each R to be completed in the project application form. In addition, all Member States require that each animal model to be used is justified in the application.

26 Member States require a description of animal care and housing, and 24 Member States require a justification for any exemption from Annex III housing and care requirements. It is not clear how the other Member States justify these necessary exemptions (Greece, Malta, Romania, Slovakia), unless none have been requested.

A majority require a relevant literature review to be included in all applications.

Specialists (statistician, alternatives, refinements) are involved in the application process in many Member States. Just under half of the Member States mandate input from the Animal Welfare Bodies to the application process.

7 Member States provided additional comments regarding assurance that the Three Rs are addressed in the application process. These included the importance of training for applicants and project evaluators, the importance of a suitably detailed procedure, including animal monitoring regimens, to enable harms to be assessed, and a need to justify the use of single sex studies. 2 Member States have a requirement to state whether re-homing will occur, and one requests applicant to explain how the project contributes to sustainable agriculture, where appropriate.

1 Member State (Sweden) has produced for all personnel involved (scientists, care staff, evaluators) specific guidance on the inclusion of Three Rs in the application process.

It was noted that not all the options included would be necessary for all types of projects, for example a project only requiring simple blood sampling for *in vitro* work.

Questions

D - 1.2 What measures are in place to ensure that breeding and supplying establishment satisfactorily address the Three Rs? Please identify all measures that you have taken note of, or specifically review, during inspections.

D - 1.2.bis Specify other.

Answer	Yes			No		
Question	Count	%	Member States	Count	%	Member States
inspections of breeding and supplying establishments	28	100%	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, NO, PL, PT, RO, SE, SI, SK			
review of records of Animal Welfare Body advice	26	93%	AT, BE, BG, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, NL, NO, PL, PT, RO, SE, SI, SK	2	7%	CY, MT
review of training records of all care staff	26	93%	AT, BE, BG, CY, CZ, DE, DK, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, NO, PL, RO, SE, SI, SK	2	7%	EE, PT
regular review of care and housing practices	25	89%	AT, BG, CY, CZ, DE, DK, EE, ES, FI, FR, HR, HU, IE, IT, LT, LU, MT, NL, NO, PL, PT, RO, SE, SI, SK	3	11%	BE, EL, LV
staff feedback during inspections	22	79%	AT, CY, DE, DK, EE, ES, FI, FR, HU, IE, IT, LT, LU, LV, MT, NL, NO, PL, PT, SE, SI, SK	6	21%	BE, BG, CZ, EL, HR, RO
reporting obligation on surplus numbers	21	75%	AT, BE, BG, CY, DE, DK, EL, ES, FI, HR, HU, IE, IT, LT, LU, LV, NL, NO, PL, SI, SK	7	25%	CZ, EE, FR, MT, PT, RO, SE
written commitment to continued professional development (CPD) of all staff	17	61%	AT, BE, BG, DE, ES, FI, FR, HU, IE, IT, LT, LU, NL, NO, RO, SI, SK	11	39%	CY, CZ, DK, EE, EL, HR, LV, MT, PL, PT, SE

strategies to optimise the use of surplus animals	16	57%	AT, DE, ES, FI, FR, HR, HU, IE, IT, LT, LU, NL, PT, SE, SI, SK	12	43%	BE, BG, CY, CZ, DK, EE, EL, LV, MT, NO, PL, RO
empowerment of care staff	13	46%	CY, DE, DK, ES, FI, HU, IE, IT, LT, LU, LV, NL, PL	15	54%	AT, BE, BG, CZ, EE, EL, FR, HR, MT, NO, PT, RO, SE, SI, SK
written strategy to minimise surplus	11	39%	AT, DE, ES, HR, HU, IT, LT, LU, NL, NO, SK	17	61%	BE, BG, CY, CZ, DK, EE, EL, FI, FR, IE, LV, MT, PL, PT, RO, SE, SI
written whistle-blower policy	10	36%	AT, BE, ES, HU, IE, IT, LU, LV, NL, PT	18	64%	BG, CY, CZ, DE, DK, EE, EL, FI, FR, HR, LT, MT, NO, PL, RO, SE, SI, SK
other	3	11%	ES, NO, PL	25	89%	AT, BE, BG, CY, CZ, DE, DK, EE, EL, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, PT, RO, SE, SI, SK

All Member States agreed that having an effective inspection system is important in ensuring that reduction and refinement are fully implemented in breeding and supplying establishments.

Reviews of Animal Welfare Body advice, of housing and care practices and staff training records are considered key by the great majority of Member States in ensuring reduction and refinement practices are effectively implemented. Staff feedback during inspections is considered important by the majority.

21 Member States require information on surplus animals, and strategies to optimise the use of such animals is required by 16 Member States.

A written commitment to continued professional development for all staff is required by 17 Member States.

Just under half of the responses indicated that empowerment of care staff and a written whistleblower policy are elements utilised to ensure reduction and refinement strategies are effective.

Voluntary questions

D - 1.3 Has additional guidance or other tools on Replacement, Refinement and Reduction been developed to facilitate implementation?:

D - 1.3.bis Please provide web-address, where available.

D - 1.4 Is there a Three R center in your Member State to provide information on the application of the Three Rs?

Answer	Count	%	Member States
Yes	10	42%	AT, DE, DK, FI, IE, LU, NL, PL, SE, SK
No	14	58%	BE, BG, CY, CZ, EL, FR, HR, HU, IT, LV, MT, NO, PT, SI
Total	**24**	**100%**	

Ten Member States have developed additional guidance on the Three Rs implementation, including those detailed in the table below.

Member States	Answer
AT	https://www.bmbwf.gv.at/Themen/Forschung/Forschung-in-%C3%96sterreich/Services/TierV.html
DE	https://www.bf3r.de/de/replace__entwicklung_neuer_ersatzmethoden_zum_tierversuch-276970.html
DK	https://3rcenter.dk/forskning/forbedr-din-forskning https://en.3rcenter.dk/research/improve-your-research https://natud.dk/for-dyreteknikere https://dyreforsoegstilsynet.dk/vejledninger
FI	https://avi.fi/en/services/individuals/licences-notices-and-applications/animals/laboratory-animals
IE	The competent authority sends a quarterly newsletter ('Regulatory Update') to all stakeholders and this contains expectations regarding the implementation of the 3Rs as well as links to the latest 3Rs resources, websites, training courses and webinars.
LU	https://gouvernement.lu/fr/actualites/toutes_actualites/communiques/2022/10-octobre/19-r-r-r.html
NL	Guidance: https://www.ncadierproevenbeleid.nl/ https://www.uu.nl/en/organisation/3rs-centre Tools: https://preclinicaltrials.eu/ https://www.beyondanimaltesting.org/ Funding: https://www.zonmw.nl/nl/subsidie/publiceren-neutralenegatieve-dierexperimentele-resultaten-0 https://www.zonmw.nl/nl/subsidie/organiseren-workshop-systematisch-literatuuronderzoek-proefdieren https://www.zonmw.nl/nl/subsidie/uitvoeren-systematisch-literatuuronderzoek-dierstudies
PL	https://www.gov.pl/web/nauka/ochrona-zwierzat-wykorzystywanych-do-celow-naukowych-lub-edukacyjnych
SE	https://jordbruksverket.se/languages/english/swedish-board-of-agriculture/animals/the-swedish-3rs-center/publications
SK	https://www.snp3rs.com/

Few Member States have also voluntarily uploaded information to the EC website[22] on their work under Article 47 to contribute to the development, validation and promotion of the Three Rs.

Voluntary question

D - 1.4 Is there a Three R center in your Member State to provide information on the application of the Three Rs?

Answer	Count	%	Member States
Yes	11	46%	AT, BE, CZ, DE, DK, FI, FR, IT, NL, SE, SK

[22] https://environment.ec.europa.eu/topics/chemicals/animals-science_en#the-three-rs

No	13	54%	BG, CY, EL, HR, HU, IE, LU, LV, MT, NO, PL, PT, SI

11 Member States have developed 3Rs centres to progress Three Rs initiatives and to provide an information resource to the scientific community.

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

Reporting obligation

"Explain how duplication of procedures is avoided to comply with Article 46 of Directive 2010/63/EU."

Background

The Directive provides in its Article 4 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

Questions

D - 2 What measures have been taken to ensure there is no unnecessary duplication of procedures with project applications?

D - 2.bis Specify other.

D - 2.tris Please explain, if not always.

As pointed out by Finland, Article 46 requires Member States to accept data from other Member States that are generated by procedures recognised by legislation of the Union, unless further procedures need to be carried out regarding that data for specific purposes. However, in both the 2017 report and in responses for this report, a number of different strategies were applied to circumstances other than those specified in Article 46, to prevent or reduce unnecessary duplication across many different areas of animal use in science.

Answer	Yes			Not always			No		
Measure	Count	%	Members States	Count	%	Member States	Count	%	Member States

literature search during design of projects	26	93%	AT, BE, BG, CY, CZ, DE, EE, EL, ES, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, NO, PL, PT, RO, SE, SI, SK	1	4%	DK	1	4%	FI
competent authority reviews the arguments presented	25	89%	AT, BE, CY, CZ, DE, DK, EE, EL, ES, FR, HR, HU, IE, LT, LU, LV, MT, NL, NO, PL, PT, RO, SE, SI, SK				3	11%	BG, FI, IT
project application template includes questions about unnecessary duplication	23	82%	AT, BE, CY, CZ, DE, DK, EE, EL, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, RO, SE, SI, SK	1	4%	ES	4	14%	BG, FI, NO, PT
ensuring knowledge of unlawful nature of unnecessarily duplicating procedures	20	71%	AT, BE, CY, CZ, DE, EE, EL, FR, HR, HU, IE, IT, LT, LU, NL, PL, PT, SE, SI, SK	1	4%	ES	7	25%	BG, DK, FI, LV, MT, NO, RO
mutual acceptance of data is used where possible	19	68%	AT, BE, CY, DE, EE, FR, HR, HU, IE, IT, LT, LU, MT, NL, NO, PL, PT, SI, SK	4	14%	CZ, DK, ES, SE	5	18%	BG, EL, FI, LV, RO
key words are used by the competent authorities tasked with project evaluation to identify similar project in published papers	18	64%	AT, BE, BG, CY, DE, EE, EL, HR, HU, IT, LT, LU, LV, NL, PL, PT, SI, SK	4	14%	CZ, ES, IE, SE	6	21%	DK, FI, FR, MT, NO, RO

declaration is included that the experiment is not duplicating knowledge	16	57%	AT, BE, CZ, DE, FR, HR, HU, IE, IT, LT, LU, MT, NL, RO, SI, SK	2	7%	EE, ES	10	36%	BG, CY, DK, EL, FI, LV, NO, PL, PT, SE
checking of scientific and patent databases to assure the novelty of the research	15	54%	BE, CY, CZ, EE, HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, SK	6	21%	AT, ES, NO, PT, SE, SI	7	25%	BG, DE, DK, EL, FI, FR, RO
key words are used by the competent authorities tasked with project evaluation to identify similar project using ALURES NTS database	13	46%	BG, CY, DE, EL, HR, HU, LT, LU, LV, NL, PL, PT, SK	5	18%	AT, CZ, ES, IE, SE	10	36%	BE, DK, EE, FI, FR, IT, MT, NO, RO, SI
establishment-wide database of projects	11	39%	EE, HU, IE, IT, LT, LU, LV, NL, NO, PT, SI	5	18%	AT, CZ, DK, ES, SE	12	43%	BE, BG, CY, DE, EL, FI, FR, HR, MT, PL, RO, SK
publication of studies with negative results	10	36%	CY, EE, HR, HU, IE, LT, NL, PL, SI, SK	8	29%	AT, CZ, DE, FR, LU, LV, NO, SE	10	36%	BE, BG, DK, EL, ES, FI, IT, MT, PT, RO
other	3	11%	FI, NL, SE				25	89%	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FR, HR, HU, IE, IT, LT, LU, LV, MT, NO, PL, PT, RO, SI, SK

All but two Member States require a literature search to support the scientific application, but also to consider whether or not there are potential duplication issues.

The great majority of project application templates include questions on duplication, a reminder that avoidable duplication is not permissible, and in many cases require a declaration from the applicant that procedures will not duplicate existing knowledge.

Mutual acceptance of data is also considered an important element in minimising duplication by a majority of Member States. Checking that this occurs may not be straightforward.

Consideration of the issues around duplication is regarded as an important element of project evaluation, and in a majority of Member States an independent review of relevant databases is performed. One Member State points out that access is not always free, so this may limit the use. Keywords in the application are used to identify similar projects in the literature and through searching on the EU ALURES NTS database by around half of the Member States. There has been some criticism, that this database is not as usable as it could be. In a small number of Member States, establishments maintain in-house databases of projects.

Publication of negative results is also considered a key element to reduce duplication in about one-third of Member States. A project on this by the French 3Rs Centre is under development.

It was also reported that funding organisations should consider the potential for duplication before animal studies are funded. Sweden reported that when applying for funds, the project goes through a thorough process in which the novelty of the research is a parameter.

Dutch supported initiatives propose that study pre-registration (https://preclinicaltrials.eu) and publication of neutral or negative data of animal studies (https://www.zonmw.nl/nl/subsidie/publiceren-neutralenegatieve-dierexperimentele-resultaten-0) have the potential to reduce duplication. Both initiatives receive financial support from the Dutch government. A similar initiative was also introduced in Germany (https://www.bf3r.de/de/animalstudyregistry_org-277077.html).

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

Reporting obligation

"In respect of tissue sampling for the purposes of genetic characterisation carried out with and without project authorisation, provide representative information and numbers regarding species, methods and their related actual severity. That information shall be provided only for the calendar year immediately preceding that in which the five-year report is submitted.

List the criteria used to ensure that the information in point 3.1 is representative.

Provide information on efforts made to refine tissue sampling methods. E."

Analysis

Question

D - 3.1 Have genetically altered animals/animal lines (non-harmful and/or harmful phenotype) been genotyped between 2018 and 2022 in your MS?

Answer	Count	%	Member States
Yes	24	86%	AT, BE, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LU, NL, NO, PL, PT, RO, SE, SI, SK
No	4	14%	BG, LT, LV, MT

24 Member States indicated that genotyping had been reported between 2018 and 2022.

Question

D - 3.3 List the criteria used to ensure that the information on invasive and non-invasive genetic characterisation / tissue sampling is representative.

Member States are required to report data on genotyping which does not necessarily need to cover all establishments or the entire 12-month period provided the sub-section of data is representative of the practice in the Member State.

Of the 24 Member States which indicated that genotyping had been carried out, 22 stated that the data provided were received from all establishments for 2022. One Member State indicated that responses were received from around 40% of establishments (Germany), in another Member State (Ireland) all data was collected on invasive genotyping and data for six months on non-invasive genotyping from all establishments were received (Ireland). The tables below contain all submitted data.

Therefore, in contrast to the largely uninterpretable data received on the tissue sampling methods for the first implementation report, the data received for this report seem to include the great majority of animals genotyped for a scientific purposes in 2022 making a more complete analysis possible this time.

Question

D - 3.2.1 Mandatory question - Provide prescribed information on Genetic characterisation using non-invasive genotyping methods and surplus tissue

D - 3.2.1.bis Please provide a breakdown of 'other' non-invasive methods used for genetic characterisation including the related species

MANDATORY QUESTION if 'Other' non-invasive methods have been reported.

Method	1. Surplus tissue from the marking of an animal via ear punch	2. Surplus tissue from the marking of an animal via toe clipping	3. Non-invasive genotyping: hair sampling	4. Non-invasive genotyping: observation under special lighting	5. Non-invasive genotyping: post mortem	6. Non-invasive genotyping: other	**Total**
Species	Count	Count	Count	Count	Count	Count	**Count**
Mice	3 397 265	669 004	19 168	7 835	52 924	221 254	**4 367 450**
Zebrafish		630		148 354	35 578	98 939	**283 501**
Rats	34 455	1 956	164	400	3 164	12 493	**52 632**
Other fish				1 917	3 445	3 009	**8 371**
Domestic fowl					6 753		**6 753**
Other amphibians				3 249	2 247	638	**6 134**

Sea bass					5 153		**5 153**
Other mammals	1		3 925				**3 926**
Reptiles		2 459			29	6	**2 494**
Other birds			968	20	32	925	**1 945**
Salmon, trout, chars and graylings					669	1 068	**1 737**
Rabbits	1 423		78		15		**1 516**
Xenopus				1 094	107	159	**1 360**
Pigs	435				276	457	**1 168**
Other rodents	29		326		101	265	**721**
Mongolian gerbil	19				1	427	**447**
Hamsters (Syrian)					13	251	**264**
Cattle	79		139			3	**221**
Rana					100	30	**130**
Dogs						66	**66**
Prosimians	55						**55**
Guinea-Pigs		6			19	19	**44**
Horses, donkeys and cross-breeds			43				**43**
Ferrets					17		**17**
Cynomolgus monkey					11		**11**
Goats	6						**6**
Total	**3 433 767**	**674 055**	**24 811**	**162 869**	**110 654**	**340 009**	**4 746 165**

*Toe clipping erroneously entered as a method of obtaining tissue in zebrafish.

Information was received on 4.75 million animals which had been genotyped from tissues obtained using non-invasive methods, without any requirement for project authority. Mice accounted for 92% of the animals reported, followed by zebrafish (6%) and rats (1%).

For mice, surplus tissue from the marking of an animal via ear punch (78%) was the most common method reported, followed by surplus tissue from the marking of an animal via toe clipping (15%).

For zebrafish, observation under special lighting (52%) was the most frequently reported non-invasive method. This percentage increased to 80% in xenopus.

Surplus tissue from the marking of an animal via toe clipping was used in 99% of the 2 494 reptiles reported.

Post-mortem tissues were used in 2% of all the animals reported and this was the only non-invasive sampling method reported for domestic fowl, seabass, ferrets and cynomolgus macaques.

Other non–invasive methods reported:

Methods other than those listed were reported in 7% of the animals. The additional methods included faecal sampling (pigs/cattle/mice), feather sampling (birds), skin swabbing (zebrafish/xenopus), breeding strategy (homozygotes only, mice), expression of fluorescent/other light emitting proteins (zebrafish/mice), oral swab/ saliva sampling (mice/rana), observation when obvious phenotype (mice), sampling of umbilical cord at birth (rodents).

The numbers of animals using other methods were not recorded, but the use of breeding strategies were commonly reported. One Member State reported that the use of such breeding strategies removed the need for any tissue analysis in more than 40 000 animals.

Several Member States reported incorrectly under "Other methods", methods which were already listed in the tables resulting in under reporting of these methods. Since there was no segregation of numbers between different types of "other methods", it is not possible to estimate the extent of this error.

In addition, several Member States reported under this question invasive methods which should have been reported under question D3.2.2. Two Member States (Hungary, Poland) included fin clipping for fish, suggesting that it was not invasive as the fin regrew in time. This is an incorrect interpretation: fin clipping/sampling is an invasive method requiring project authorisation.

Questions

D - 3.2.2 Mandatory question - Provide proscribed information on Genetic characterisation using invasive genotyping methods

D - 3.2.2.bis Please provide a breakdown of 'other' invasive methods used for genetic characterisation including the related species and severities MANDATORY QUESTION if 'Other' invasive methods have been reported.

Genetic characterisation using invasive genotyping methods

Method and severity	1. Blood sampling			2. Ear biopsy			3. Tail biopsy			4. Fin biopsy			5. Toe clipping			6. Other		Total
Species	1. Non-recovery	2. Mild [up to and including]	3. Moderate	1. Non-recovery	2. Mild [up to and including]	3. Moderate	1. Non-recovery	2. Mild [up to and including]	3. Moderate	1. Non-recovery	2. Mild [up to and including]	3. Moderate	1. Non-recovery	2. Mild [up to and including]	3. Moderate	2. Mild [up to and including]	3. Moderate	
Mice	59	30 279		162	203 731	503	7	749 432	11 539		118		23	65 697	4 947	163		**1 066 660**
Zebrafish								527		2 210	152 731	7 874				407		**163 749**
Rats		2 618	51		3 145	352		8 844	333									**15 343**
Other birds		9 562	98		113													**9 773**
Other fish	30	1 105						660			7 413	87						**9 295**
Salmon, trout, chars and graylings		40								6 399	221							**6 660**
Other amphibians		10	4					3 292			8							**3 314**
Reptiles		7						2 547										**2 554**
Domestic fowl		1 821	18															**1 839**
Sheep		1 252			66	6										87	248	**1 659**
Pigs		69	43		549			582										**1 243**
Other rodents		34			65				249									**348**
Other mammals		173			60											12		**245**
Xenopus								132			99							**231**
Cattle		100			120													**220**
Hamsters (Syrian)					211													**211**
Rabbits		30			103	55												**188**
Guppy, swordtail, molly, platy											97							**97**
Goats		60																**60**
Horses, donkeys and cross-breeds		32																**32**
Dogs		20														4		**24**
Other carnivores		3																**3**
Total	**89**	**47 215**	**214**	**162**	**208 163**	**916**	**7**	**766 016**	**12 121**	**8 609**	**160 687**	**7 961**	**23**	**65 697**	**4 947**	**673**	**248**	**1 283 748**

Information was provided on the invasive genotyping methods used in around 1.3 million animals.

Mice (83%) was the most common species reported, followed by zebrafish (13%) and rats (1.2%).

None of the reported genotyping methods used in any species were considered to have resulted in "severe" severity.

Nearly 9 000 fish and mice were reported to have been genotyped using invasive methods with a severity of "non-recovery". It is possible that it may have been more refined to carry out some or all of these samplings post-mortem. It is possible that they have been misclassified.

For mice, a tail biopsy was the most common invasive method reported (72%) (used by 14 Member States), followed by ear biopsy (19%) (used by 14 Member States), toe clipping (7%) (used by 9 Member States) and blood sampling (2%) (used by 11 Member States). These proportions were very similar to those in the 2017 report: tail biopsy 65%, ear biopsy 20%, toe clipping 13% and blood sampling 2%.

Tail biopsy cannot generally be used as a method of identification, and therefore will need to be reported as a procedure when used. Use of surplus tissue from ear biopsy when marking for identification is not a procedure and would not be expected to be reported in this table. However, other marking methods may be used e.g., subcutaneous radiofrequency identification tags, in which case the tissue biopsy will require to be reported here.

In the vast majority of cases, the actual severity was reported as mild for tail biopsy (98.5%) and ear biopsy (99.5%). For toe clipping 91% were reported as mild, with 9% as moderate.

Considering the proportions of animals reported as moderate for tail biopsy and toe clipping, there may be scope for refinement or replacement of these methods in some cases. This could have a significant impact for around 25 000 animals per year.

For fish, the most commonly used invasive method was fin biopsy (97.5%), with 90% of the animals used reported as mild severity, and around 5% each as non-recovery and moderate.

In fish, the caudal fin is the fin which is attached to the tail and makes its shape. For genotyping small fish, it is most common to take a biopsy from the caudal fin. Therefore, it is possible that fin biopsy and tail biopsy are actually sampling from the same site and therefore are the same technique, particularly for zebrafish. In larger fish, other fins such as the adipose fin may be clipped/removed.

There are published recommendations for some fish species to use anaesthesia, and analgesia after fin biopsy. Without the appropriate use of anaesthesia and analgesia, the procedure is likely to result in moderate actual severity.

Some misreporting is suspected: two Member States reported the use of other invasive methods for genetic characterisation in unusual species such as skin biopsies in whales and stripping of eggs in catfish which would seem not to have been in relation to the creation or maintenance of genetically altered animal lines. Faecal sampling in cattle was reported as invasive: faecal samples can usually be obtained by stimulation of the anus which may not be considered harmful, and therefore this may represent an opportunity for refinement. 118 fin biopsies were reported for mice. The data are presented as submitted by the Member States without any corrections.

Information on genotyping methods of around 6 million animals was provided. Around 80% of the animals were genotyped using either surplus tissue from marking or non-invasive methods not requiring project authorisation.

In many Member States, there is an expectation that non-invasive methods will be used, and invasive methods are only authorised when justified and the use of non-invasive methods is not possible. One Member State indicated that only non-invasive methods were used.

There may be opportunities in some Member States to replace some invasive genotyping methods with the use of surplus tissue from marking.

Where invasive methods are used these are generally reported as of mild severity, although there are around 17 000 animals reported as having experienced moderate severity as a consequence of the tissue sampling procedure.

There may be opportunities in some Member States to refine invasive marking. With the refinements available (see below question D3.4) it would seem that the severity of invasive sampling methods should not need to exceed mild. When all refinements are applied, there should be improved consistency in severity assignment across the Union.

Question

D - 3.4 Provide information on efforts being made to refine invasive genetic characterisation / tissue sampling methods. Please indicate where more severe techniques are being replaced by less severe ones, and any other refinement efforts of specific techniques involved in GA production, and results achieved so far.

Member States provided a lot of information on the efforts being made to refine the methods used for genotyping.

Guidance has been prepared and published by two National Committees (Netherlands[23], Poland[24]).

Technology

As DNA analysis improves, the amount of tissue needed continues to reduce.

Although the use of mouth swabs and faecal material continues to show promise, there remain some technical concerns over reliability and potential for cross contamination.

It was recommended that surplus tissue be stored to obviate the need for re-sampling if there are problems with the initial analysis.

Non-invasive methods

Mice

- Breeding strategies (e.g., breeding homozygote animals) can significantly reduce the numbers of animals which need to be genotyped;
- There should be active promotion of the use of surplus tissue from identification. Although the great majority uses tissue from ear clipping, there are still significant numbers of animals where toe clipping is the identification method of choice;

[23] https://www.ncadierproevenbeleid.nl/adviezen-ncad/documenten/publicatie/20/7/30/teenknip
[24] https://www.gov.pl/web/nauka/krajowa-komisja-etyczna-do-spraw-doswiadczen-na-zwierzetach

- Dependent on scientific needs, sampling post-mortem can be used;
- Fluorescent markers can also be used in some circumstances;
- Faecal sampling is not practical in group housed animals.

Zebrafish

- Skin swabbing is considered to be a suitable non-invasive alternative to fin clipping;
- Fluorescent markers can also be used in some circumstances;
- Genotyping of zebrafish larvae (incubated in buffer to extract genetic material from skin surface) allows identification of animals at an early stage, and obviates the need for fin clipping or some other sampling method in a more mature fish.

Invasive methods

- It was noted that many establishments prohibit the use of invasive methods;
- Refinement considerations such as use of anaesthesia and analgesia;
- The importance of experienced and trained staff was often emphasised to ensure procedures are conducted effectively and efficiently;
- Instruments should be clean and of suitable design to minimise tissue damage or infection.

Mice

- Minimise the amount of tissue – for example maximum 2 mm of tail; distal phalanx only;
- Set maximum age, consider ossification and innervation – 4 weeks for tail; 7 days for toe;
- Use of local anaesthesia;
- Use of analgesia (mandated in one Member State);
- Handling – use cupping technique and rewards, such as dried fruit/sunflower seeds.

Fish

- Use of anaesthesia and analgesia for fin clipping.

In all circumstances where tissue is being removed, the methodology should be as refined as possible, taking into account the species, age, amount of tissue required and the use of anaesthesia (local or general) and analgesia to minimise pain, during and after the intervention.

Voluntary questions

D - 3.5 Has the updated Working Document on Genetically Altered animals been made available to establishments housing or using genetically altered animals?efforts of specific techniques involved in GA production, and results achieved so far.

D - 3.5.bis Please explain 'Not always'.

Answer	Count	%	Member States
Yes	22	92%	AT, BE, CY, CZ, DE, DK, EL, ES, FI, FR, HR, IE, IT, LU, LV, NL, NO, PL, PT, SE, SI, SK
Not always	0	0%	
No	2	8%	BG, MT
Total	**24**	**100%**	

All but two Member States, neither of whom has reported genetically altered animals in this reporting period, have made available the working document to establishments housing or using genetically altered animals.

Voluntary question

D - 3.6 If possible, how extensively do you estimate it being used in your MS by establishments?

Answer	Count	%	Member States
By all	4	18%	LU, NO, SI, SK
By most	9	41%	DE, EL, FR, IE, IT, LV, NK, PL, PT
By some	8	36%	BE, BG, CY, CZ, DK, FI, HR, SE
Not used	1	5%	MT
Total	**22**	**100%**	

Most Member States have made the working document on genetically altered animals available and believe that it is used. There may be value in further promotion of the document to extend uptake to encourage good practices, especially as it is available in all Member States' languages.

E. ENFORCEMENT

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

Reporting obligation

"In respect of each year, provide numbers for all active authorised breeders, suppliers and users separately.

Provide summary information, covering the five-year reporting cycle, on reasons for suspensions or withdrawals of authorisations of breeders, suppliers and users."

Background

The 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

The way in which users, breeders and suppliers are defined and authorised vary significantly between Member States. Therefore, comparisons between Member States should be discouraged.

Concerning the definition for a user, breeder and supplier, Belgium reported that establishments, as authorised, are relatively small in Belgium. This is mainly because universities are not authorised as a whole. A university has several departments which in turn are divided into several directorates/services. Usually, one or several authorisation(s) is (are) issued per directorate/service resulting in one university containing several authorised establishments, while in another Member State a university may only have a single authorisation covering all the activities of the entire university.

Concerning the types of authorisations issued, Belgium reported (under question F.5) that an establishment can hold multiple authorisations: a user may also possess an authorisation as a breeder. In such a case, the establishment has two authorisations and consequently, appears twice in the table while in another Member State such authorisations would be combined i.e. an establishment that uses and breeds animals has a single authorisation for a user-breeder.

Conversely, France reported (under question F.5) that it classifies establishments as "breeders/suppliers" or "users" according to their main activity. France does not distinguish between breeders and suppliers and counts establishments solely as "breeders/suppliers", which may include breeders, suppliers and breeders-suppliers.

These tables (E1.1 and E 1.2) should therefore be interpreted with these facts in mind.

Question

E – 1.1 Provide number of active authorised breeders and suppliers not using animals.

Year	Number of active breeding establishments (not using animals)	Number of active establishments authorised only to supply animals bred by others (not breeding/using animals)	Number of active establishments authorised to breed and supply both their own and those bred by others (not using animals)	Total number of active authorised breeders and suppliers not using animals
2018	119	188	393	700
2019	120	174	433	727
2020	118	160	386	664
2021	117	177	351	645
2022	120	170	377	667

The numbers of breeding and supplying establishments have remained reasonably static over the five-year reporting period.

The numbers of breeders and suppliers by country for 2022 are shown below:

Member States	Number of active breeding establishments (not using animals)	Number of active establishments authorised only to supply animals bred by others (not breeding/using animals)	Number of active establishments authorised to breed and supply both their own and those bred by others (not using animals)	Total number of active authorised breeders and suppliers not using animals
DE	32	149	288	469
BE	14	0	52	66
IT	27	1	8	36
FR	0	0	14	14
BG	7	3	3	13
PL	7	5	0	12
EL	7	4	0	11
SE	10	0	0	10
AT	5	0	3	8
LT	4	2	2	8
ES	3	2	1	6
CZ	0	1	4	5
SK	3	0	1	4
NO	1	2	0	3
HU	0	0	1	1
NL	0	1	0	1
CY	0	0	0	0
DK	0	0	0	0
EE	0	0	0	0
FI	0	0	0	0
HR	0	0	0	0
IE	0	0	0	0
LU	0	0	0	0
LV	0	0	0	0

MT	0	0	0	0
PT	0	0	0	0
RO	0	0	0	0
SI	0	0	0	0
Total	**120**	**170**	**377**	**667**

Question

E – 1.2 Provide the number of active users, including those also authorised to breed and/or supply.

Year	Number of active establishments authorised to only use animals	Number of active establishments authorised to use and breed animals	Number of active establishments authorised to use and supply animals	Number of active establishments authorised to use, breed and supply animals	Total number of active users, including those also authorised to breed and/or supply
2018	2 130	740	239	492	3 601
2019	2 050	738	254	613	3 655
2020	2 043	720	245	559	3 567
2021	2 058	705	263	617	3 643
2022	1 908	707	251	621	3 487

The numbers of users, including those authorised to breed and/or supply have remained reasonably static over the five-year reporting period.

The numbers of users reported in each Member State, ordered by number of users in 2022 are shown in the table below:

Member State	Number of active establishments authorised to only use animals	Number of active establishments authorised to use and breed animals	Number of active establishments authorised to use and supply animals	Number of active establishments authorised to use, breed and supply animals	Total number of active users, including those also authorised to breed and/or supply
DE	217	71	227	450	965
FR	575	0	0	0	575
IT	99	135	9	40	283
BE	244	0	0	0	244
ES	89	117	2	35	243
SE	148	57	0	0	205
PL	80	56	0	6	142
FI	63	35	0	0	98
NO	62	20	0	1	83
CZ	51	11	0	19	81
NL	33	43	0	1	77
HR	30	19	9	9	67
EL	40	11	0	11	62
AT	35	14	0	8	57
PT	20	27	0	3	50
DK	25	20	0	2	47

RO	18	20	0	8	46
SK	18	8	0	0	26
BG	13	7	2	2	24
HU	11	13	0	0	24
LT	15	5	2	2	24
IE	6	1	0	16	23
SI	3	8	0	0	11
EE	2	4	0	3	9
LV	8	1	0	0	9
CY	2	4	0	2	8
LU	0	0	0	3	3
MT	1	0	0	0	1
Total	**1 908**	**707**	**251**	**621**	**3 487**

France reported (under question F.5) that it does not distinguish separately "users" that also act as breeders and/or suppliers, and those all are reported under "users".

Question

E - 1.3 Provide number of active establishments keeping non-human primates.

Year	Number of active establishments authorised to keep and supply (but not breed) non-human primates	Number of active establishments authorised to keep, breed and supply (but not use) non-human primates	Number of active establishments authorised to use non-human primates (may also breed/supply)	Total number of active establishments keeping non-human primates
2018	9	19	73	101
2019	9	18	73	100
2020	8	19	74	101
2021	8	18	80	106
2022	8	20	80	108

Numbers of establishments with non-human primates have remained reasonably static over the five-year reporting period.

The numbers of non-human primate establishments reported by Member States in 2022 are shown in the table below:

Member State	Number of active establishments authorised to keep and supply (but not breed) non-human primates	Number of active establishments authorised to keep, breed and supply (but not use) non-human primates	Number of active establishments authorised to use non-human primates (may also breed/supply)	Total number of active establishments keeping non-human primates
DE	7	17	17	41
FR	0	1	34	35
IT	0	0	10	10
ES	0	0	8	8

BE	0	0	3	3
NL	1	0	2	3
HU	0	2	0	2
SE	0	0	2	2
AT	0	0	1	1
CZ	0	0	1	1
DK	0	0	1	1
EL	0	0	1	1
Total	**8**	**20**	**80**	**108**

In total, 12 Member States have establishments which use, supply and/or breed non-human primates.

Question

E -1.4 Were there any withdrawals or suspensions of authorisation of breeders, suppliers and/or users initiated by the competent authority between 2018 and 2022?

Answer	Count	%	Member States
Yes	9	32%	DE, DK, ES, FR, IT, LT, NL, PL, SE
No	19	68%	AT, BE, BG, CY, CZ, EE, EL, FI, HR, HU, IE, LU, LV, MT, NO, PT, RO, SI, SK

Voluntary question

E -1.4.1 Number of withdrawals or suspensions over the 5 year period, initiated by the competent authority.

Member State	Number of withdrawals or suspensions over the 5 year period, initiated by the competent authority
IT	44
DE	4
LT	4
DK	2
NL	2
PL	2
SE	2
FR	1
CZ	0
FI	0
LU	0
PT	0
SK	0
Total	**61**

Question

E -1.4.2 Reasons for suspensions or withdrawals initiated by the competent authority:

E -1.4.2.bis Specify other.

Answer	Count	%	Member States
Failing to meet the requirements of the Directive	7	78%	DE, DK, ES, FR, IT, PL, SE
Other	3	33%	IT, LT, NL

A third of all Member States have suspended authorisations, usually involving small numbers of establishments. One Member State (Italy) stands out as unusual in the numbers of suspensions that were reported (44). Italy stated that "*almost all of the withdrawals of the authorisation of users and breeders were …… at the request of the research body following the rationalisation of activities and structures.*" Lithuania also stated, "*upon the company's request*". The wording of the question "….initiated by the competent authority" was intended to exclude these reasons, however, it seems that the reported data contain withdrawals initiated by authorisation holders. Netherlands reported that if establishments are inactive for longer than two consecutive years, the competent authority can withdraw the authorisation.

Therefore, if only considering suspensions and withdrawals initiated by authorities because of failure to comply with the Directive requirements, a total of 11 in five years (total 61 minus Italy (44), Lithuania (4), Netherlands (2)) might more closely reflect the true situation.

This should be considered in the context of there being a total of 4 154 establishments across the Union in 2022 (questions E1.1 and E1.2).

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

Reporting obligation

"In respect of each year, provide numbers for inspections, broken down by announced and unannounced.

Provide summary information, covering the five-year reporting cycle, on main findings of inspections.

Explain the measures taken to ensure compliance with the requirements of Article 34(2) of Directive 2010/63/EU."

Background

The Directive provides in its Article 34 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

E - 2.1 What criteria are used to determine risk of establishments in order to design risk-based inspection programme?

E - 2.1.1 If using other criteria, select each of the below criteria that you use.

E - 2.1.1.bis Specify other

Answer	Count	%	Member States
Using all criteria listed in Appendix 1 of the endorsed EU Inspection and Enforcement guidance as the basis for risk assessment of establishments	18	64%	AT, BG, CY, CZ, DE, DK, EL, FI, HU, IE, IT, LT, LU, LV, NL, NO, RO, SK
Other	10	36%	BE, EE, ES, FR, HR, MT, PL, PT, SE, SI

Almost two-thirds of all Member States use all the criteria listed in the Inspection and Enforcement guidance document[25]. Others use various subsets of the risk criteria. Some inspect annually irrespective of risk (Croatia, regions in Spain). Ten Member States use a subset of the criteria or use other criteria.

Answer	Count	%	Member States
compliance history	8	80%	BE, ES, FR, MT, PL, PT, SE, SI
number of animals held	8	80%	BE, ES, FR, MT, PL, PT, SE, SI
species	8	80%	BE, ES, FR, MT, PL, PT, SE, SI
type and complexity of projects / procedures	7	70%	BE, ES, MT, PL, PT, SE, SI
complexity of establishment	6	60%	BE, EE, ES, FR, MT, PT
new establishment	6	60%	BE, EE, ES, FR, MT, PT
time elapsed since last inspection	6	60%	BE, EE, ES, FR, MT, PT
type of establishment	6	60%	BE, EE, ES, FR, MT, PT
Other	5	50%	BE, ES, HR, SE, SI

[25] https://data.europa.eu/doi/10.2779/143679

severity of procedures	4	40%	BE, EE, ES, PT
high staff turnover	3	30%	BE, ES, FR
staff inexperienced	3	30%	BE, ES, PT
no local animal welfare body	2	20%	FR, MT
public concern	2	20%	BE, FR
conflicts of interest	1	10%	FR
culture of care	1	10%	FR
management and communication structures	1	10%	FR

Other risk criteria used include: higher unforeseen severities (Sweden), changes to premises (Belgium), number of projects at an establishment (Spain), introduction of new animal species (Spain), changes in the composition of Animal Welfare Bodies in establishments (Spain), failure to submit statistics or reports in a timely manner (Belgium), [lack of] availability of documents related to project evaluation and project approval (Belgium).

Voluntary question

E - 2.2 Are all new establishments inspected before an authorisation is granted?

E - 2.2.1 Provide information on how the compliance with the provisions of the Directive with regards to authorisation of breeder, suppliers and users is ensured (Article 20(1))

E - 2.2.1.bis Specify other

E -2.2.2 Please explain 'Not always'

Answer	Count	%	Member States
Yes	25	93%	BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK
Not always	2	7%	FR, NO
Total	**27**	**100%**	

Of the 27 Member States that answered this voluntary question, 25 inspect before granting authorisation. In the remaining 2, it seems that such inspections are considered ideal, but in cases where there is good documentation and there are no animals on site (Norway) or where there is a shortage of inspectors (France), this does not always occur. Other answers offered were “No” and “Other”, none of these answers were chosen by any Member State.

Question

E - 2.3 Provide quantitative operational information on announced and un-announced inspections broken down by reporting year.

Year	# announced inspections	# un-announced inspections	% un-announced inspections	Total # inspections	Total # user establishments
2018	1 435	919	39%	2 354	3 553
2019	1 343	847	39%	2 190	3 604
2020	1 341	564	30%	1 905	3 513
2021	1 443	648	31%	2 091	3 590

2022	1 457	778	35%	2 235	3 431

The number of inspections has remained similar each year across the reporting period, with a small reduction in 2020. Several Member States reported reduced numbers of inspections due to COVID-19 lockdowns.

Article 34(3) requires at least one-third of users to be inspected each year. A direct comparison is not possible between the numbers of inspections and user establishments since the total number of inspections also includes repeated inspections of same establishments and inspections of breeders and suppliers. Only when the total number of inspections is less than one-third of the number of users, can firm conclusions be drawn. At the Union level, during all five years, the total number of inspections largely exceed one-third of users. Even during the COVID-19 lockdowns a total of 1 905 inspections were carried out (3 513 users).

Article 34(4) requires that an appropriate proportion of inspections shall be carried out without prior warning. At the Union level, around one-third of inspections have been unannounced, again with a small decrease in the proportions in 2020 and 2021. During the lockdowns and for some time afterwards, specific arrangements needed to be made to allow “visitors” to establishments, and non-essential visitors were prohibited.

Whether the criteria laid out in Article 34 have been met can only be determined at the level of the Member State.

	Inspection in 2018			Inspections in 2019			Inspections in 2020			Inspections in 2021			Inspections in 2022		
Member State	# announced	# un-announced	**Total**	# announced	# un-announced	**Total**	# announced	# un-announced	**Total**	# announced	# un-announced	**Total**	# announced	# un-announced	**Total**
AT	2	71	**73**	3	69	**72**	7	53	**60**	6	67	**73**	7	73	**80**
BE	96	88	**184**	148	65	**213**	134	47	**181**	145	41	**186**	129	74	**203**
BG	14	1	**15**	15	2	**17**	14	1	**15**	14	1	**15**	15	2	**17**
CY	5	0	**5**	0	0	**0**	6	0	**6**	3	0	**3**	0	0	**0**
CZ	65	28	**93**	57	10	**67**	50	11	**61**	47	11	**58**	51	10	**61**
DE	376	326	**702**	315	229	**544**	407	204	**611**	396	212	**608**	450	284	**734**
DK	11	16	**27**	17	14	**31**	14	15	**29**	27	12	**39**	7	6	**13**
EE	10	0	**10**	8	0	**8**	7	0	**7**	7	0	**7**	10	0	**10**
EL	3	0	**3**	5	1	**6**	4	1	**5**	3	0	**3**	6	0	**6**
ES	96	18	**114**	69	20	**89**	85	9	**94**	111	32	**143**	136	13	**149**
FI	37	16	**53**	24	35	**59**	8	5	**13**	35	6	**41**	36	13	**49**
FR	203	67	**270**	198	76	**274**	210	23	**233**	224	64	**288**	185	92	**277**
HR	6	0	**6**	4	0	**4**	3	0	**3**	10	0	**10**	3	0	**3**
HU	33	1	**34**	30	0	**30**	14	0	**14**	18	1	**19**	21	1	**22**
IE	14	9	**23**	21	10	**31**	16	1	**17**	17	12	**29**	12	11	**23**
IT	111	118	**229**	121	92	**213**	82	79	**161**	116	82	**198**	126	74	**200**
LT	1	0	**1**	1	10	**11**	0	8	**8**	3	7	**10**	1	16	**17**
LU	7	1	**8**	4	1	**5**	3	3	**6**	1	4	**5**	3	3	**6**
LV	4	0	**4**	0	0	**0**	0	0	**0**	0	0	**0**	0	0	**0**
MT	1	0	**1**	0	0	**0**	0	0	**0**	1	1	**2**	0	0	**0**
NL	153	72	**225**	144	85	**229**	128	18	**146**	101	12	**113**	71	11	**82**
NO	33	2	**35**	29	12	**41**	43	0	**43**	12	0	**12**	39	0	**39**
PL	72	51	**123**	64	38	**102**	53	43	**96**	77	25	**102**	80	38	**118**
PT	12	0	**12**	13	0	**13**	8	0	**8**	7	0	**7**	12	0	**12**
RO	11	17	**28**	11	20	**31**	11	23	**34**	10	11	**21**	14	19	**33**
SE	36	8	**44**	29	47	**76**	26	12	**38**	41	41	**82**	37	32	**69**
SI	2	3	**5**	2	4	**6**	1	2	**3**	0	3	**3**	1	4	**5**
SK	21	6	**27**	11	7	**18**	7	6	**13**	11	3	**14**	5	2	**7**
Total	**1 435**	**919**	**2 354**	**1 343**	**847**	**2 190**	**1 341**	**564**	**1 905**	**1 443**	**648**	**2 091**	**1 457**	**778**	**2 235**

As stated above, Article 34(3) requires that one-third of users each year should be inspected in accordance with a risk analysis.

The information on inspections does not differentiate between those carried out on users versus inspections of breeders/suppliers. However, in order for the Member State to comply with the minimum required by the Directive, the total number of inspections cannot in any case be less than 33% of the number of active authorised users.

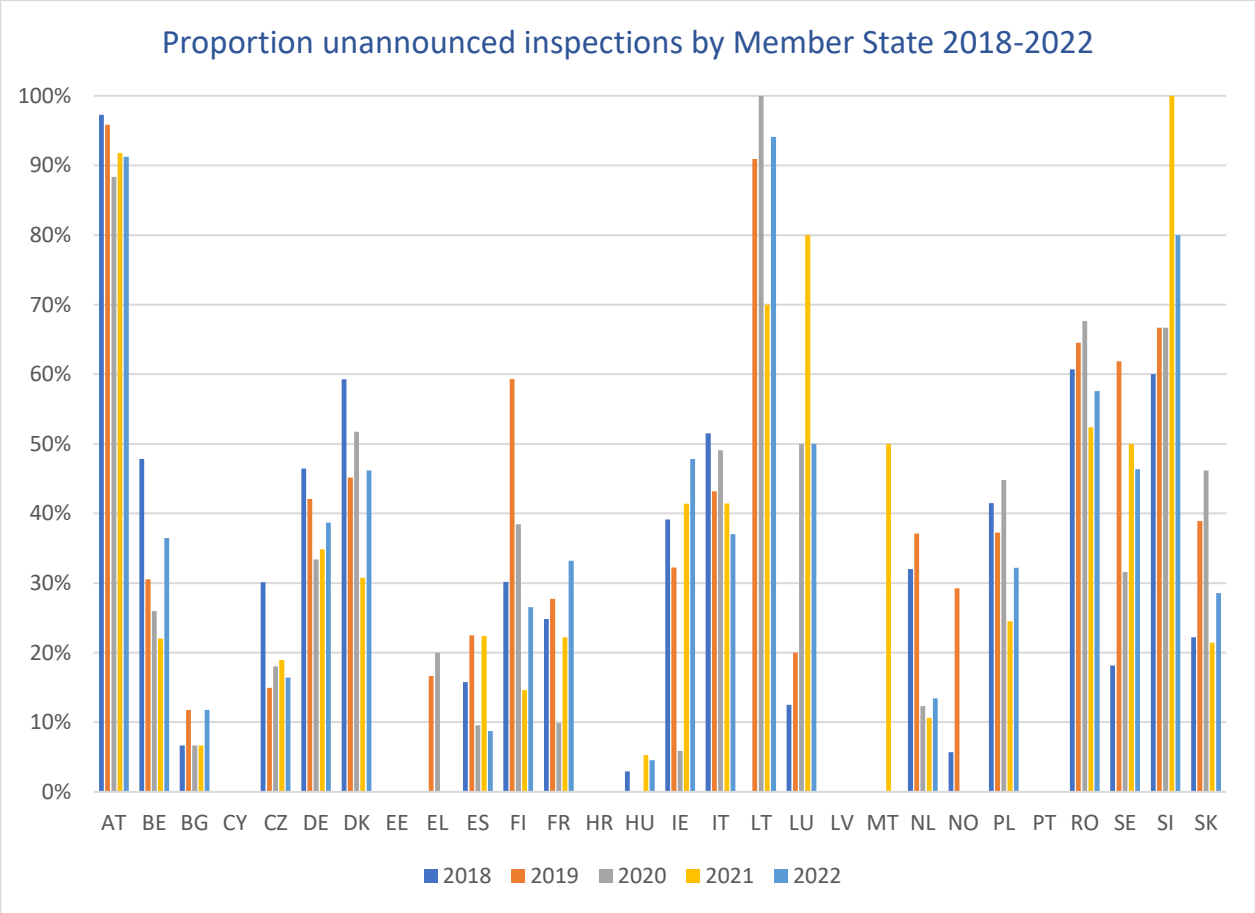
Proportion of inspections according to the total number of users by Member State by year:

Member State	2018	2019	2020	2021	2022
AT	128%	129%	109%	138%	140%
BE	68%	84%	70%	75%	83%
BG	60%	68%	75%	75%	71%
CY	83%	0%	86%	38%	0%
CZ	116%	83%	76%	73%	75%
DE	72%	53%	63%	54%	76%
DK	57%	66%	62%	83%	28%
EE	111%	89%	78%	70%	111%
EL	5%	10%	8%	5%	10%
ES	50%	35%	36%	56%	61%
FI	55%	63%	14%	41%	50%
FR	43%	44%	38%	49%	48%
HR	10%	6%	5%	15%	4%
HU	213%	158%	93%	146%	92%
IE	96%	124%	68%	126%	100%
IT	97%	93%	72%	88%	88%
LT	5%	52%	38%	45%	71%
LU	133%	125%	150%	125%	200%
LV	44%	0%	0%	0%	0%
MT	100%	0%	0%	200%	0%
NL	259%	273%	176%	145%	106%
NO	49%	58%	59%	16%	47%
PL	85%	69%	69%	73%	83%
PT	24%	26%	16%	14%	24%
RO	57%	66%	76%	46%	72%
SE	17%	31%	16%	40%	34%
SI	50%	60%	30%	27%	45%
SK	87%	50%	36%	54%	27%
Total	**66%**	**61%**	**54%**	**58%**	**65%**

The table above compares the total number of inspections (including repeated inspections and inspections of breeders/suppliers) with the total number of all users (including those also authorised to breed and supply) by Member State by year.

Three Member States appear not to have met this criterion for any of the years reported (Greece, Croatia and Portugal).

Proportion of unannounced inspections by Member State



The proportion of unannounced inspections varied between Member States from 0 to 100%. This suggests that different criteria are being applied to determine "an appropriate proportion."

Three Member States performed no unannounced inspections (Estonia, Croatia, Cyprus).

Question
E – 2.4 If you have not met the minimum requirements for inspection in any of the reporting years, please explain why this has occurred and provide information about how this is being or has been rectified.

18 Member States acknowledged that they did not meet the minimum requirements and provided explanations.

The COVID-19 pandemic has had a significant effect in many Member States in terms of ability to perform inspections (specifically reported by Italy, Latvia, Poland, Portugal, Slovenia, Slovakia, Norway). In some cases, it has affected the ability to perform unannounced inspections.

- Other reasons for not achieving the general inspection targets included: insufficient inspector resource (Greece, Croatia, Cyprus, Portugal), including inspectors covering other animal welfare issues not relating to scientific use (Croatia, Sweden);
- Risk deemed to be low (Latvia).

In some cases, actions are being taken which seem likely to resolve the issues regarding the required inspection targets. However, this was not clear in all cases.

Reasons given for low numbers of unannounced inspections included

- Research involving biosafety class II pathogens (Poland);
- Requirement for the presence of the staff member responsible for the procedures in question (Poland);
- No research in progress or no animals on site (Poland).

On general feedback, Sweden provided more detailed information on national efforts to improve inspections. Sweden stated that internal ambiguities in the interpretation and application of the Directive requirement for frequency of inspections, specifically the definition of establishment/ user/breeder/supplier had led to inconsistencies regarding how many inspections each regional board was expected to carry out. There have also been uncertainties where establishments operate in several locations in the country.

Sweden also reported that during the reporting period, there have been problems with the technical systems used by the "Boards" to record the inspection results. A lot of time and resources have been spent on improving the conditions for the inspections. However, also during the period, there have been large movements in a positive direction in the areas that have been identified as problematic by the boards. Checklists and guidelines were updated and a national system for risk based control has been developed. This is expected to lead to a higher inspection rate in the future.

Voluntary questions

E - 2.5 Is a check-list or similar document used by inspectors to assist in ensuring that a structured approach to the inspection process occurs so that all different elements are inspected?

E - 2.5.bis If no, explain how it is ensured that all different elements are inspected.

Answer	Count	%	Member States
Yes	23	85%	AT, BE, BG, CY, CZ, DK, EE, ES, FI, FR, HU, IE, IT, LU, LV, MT, NL, NO, PT, RO, SE, SI, SK
No	4	15%	DE, EL, HR, PL
Total	**27**	**100%**	

23 of the 27 Member States who responded stated that they use a checklist or similar to structure the approach and ensure that all elements are inspected.

Germany specifically stated that it aims to ensure uniform enforcement and provide country-specific guidance documents on the conduct of inspections in animal facilities and training. A group of the authorising authorities meets to exchange views on the implementation of the requirements of animal testing legislation.

Greece stated that there is a checklist but that it is being further developed and is not yet in use by all inspectors.

Voluntary questions

E - 2.6 Which issues have the competent authority instructed the inspectors to review.

E - 2.6.bis Specify other.

Answer	Yes			No		
Question	Count	%	Member States	Count	%	Member States
Records - keeping the required records (e.g., source, use, disposal, health, welfare assessments, Individual records (dog, cat, primate), scientific records	25	96%	AT, BE, BG, CY, CZ, DE, DK, EE, EL, FI, FR, HU, IE, IT, LU, LV, MT, NL, NO, PL, PT, RO, SE, SI, SK	1	4%	HR
Animal health, wellbeing, care and monitoring (e.g., daily checks, availability of feed and water, stocking densities, bedding, hygiene, enrichment)	23	88%	AT, BE, BG, CY, DE, DK, EE, EL, FI, FR, IE, IT, LU, LV, MT, NL, NO, PL, PT, RO, SE, SI, SK	3	12%	CZ,HR, HU
Facilities - environmental suitability to meet welfare and scientific needs (e.g., suitability of cages / pens, suitability and stability of ventilation, temperature, lighting, noise humidity)	23	88%	AT, BE, BG, CY, DE, DK, EE, EL, FI, FR, IE, IT, LU, LV, MT, NL, NO, PL, PT, RO, SE, SI, SK	3	12%	CZ, HR, HU
Work of Animal Welfare Bodies and the records of advice	22	88%	AT, BE, BG, CY, DE, DK, EE, EL, FI, FR, HU, IE, IT, LU, LV, NL, NO, PT, RO, SE, SI, SK	3	12%	CZ, HR, MT
Fate - killing, reuse, setting free / rehoming	22	85%	AT, BE, BG, CY, DE, DK, EE, EL, FI, FR, IE, IT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK	4	15%	CZ, HR, HU,NO
Projects in progress including implementation of Three Rs	22	85%	AT, BE, BG, CY, DE, DK, EE, EL, FI, FR, IE, IT, LU, LV, MT, NL, NO, PL, PT, RO, SE, SK	4	15%	CZ, HR, HU, SI
Personnel - education, training and competence, attitudes, Article 24/25, animal care staff, scientific staff	20	77%	BE, BG, CY, DE, EE, EL, FI, FR, IE, IT, LU, LV, MT, NL, NO, PL, RO, SE, SI, SK	6	23%	AT, CZ, DK, HR, HU, PT
Refinement of genotyping methods	13	52%	AT, BE, DE, DK, IE, IT, LU, LV, NL, NO, PT, SE, SK	12	48%	BG, CY, CZ, EE, EL, FI, FR, HR, HU, MT, RO, SI

Uptake of newly adopted alternative methods / recommendations e.g., OECD, EU Pharm, EURL ECVAM in on-going projects	10	40%	AT, DE, FR, IE, IT, LU, LV, NL, PL, SK	15	60%	BE, BG, CY, CZ, DK, EE, FI, HR, MT, NO, PT, RO, SE, SI
Management of colonies to reduce surplus animals	9	36%	AT, DE, IE, IT, LU, LV, NL, NO, SK	16	64%	BE, BG, CY, CZ, DK, EE, EL, FI, FR, HR, HU, MT, PT, RO, SE, SI
Other	7	29%	AT, BE, CZ, FR, HR, IE, SE	17	71%	BG, CY, DE, DK, EE, EL, FI, IT, LU, LV, MT, NL, NO, PL, PT, RO, SK

Most Member States have specifically requested that inspectors check the following issues:

- That records are kept correctly (e.g., source, use, disposal, health, welfare assessments, individual records for dogs, cats and primates, scientific records);
- That monitoring of animal health, wellbeing is adequate and appropriate care is being given (e.g., daily checks, stocking densities, availability of food, water and enrichment including bedding, hygiene);
- That facilities including environmental controls are suitable to meet welfare and scientific needs (e.g., suitability of cages / pens, suitability and stability of ventilation, temperature, lighting, noise, humidity);
- That fate of animals is compliant with legal requirements (killing, reuse, setting free / rehoming);
- That projects in progress include implementation of Three Rs;
- That the work of Animal Welfare Bodies complies with the legal requirements laid out in Article 27 and the records of advice are kept as required;
- That personnel is educated, trained and competent, and has appropriate attitudes.

Seven Member States check on other issues listed below:

- Whether appropriate contingency plans are in place for the protection of the animals against hazards (e.g. fire, technical failures, intrusion, breakdown of equipment) (Belgium, Ireland, Sweden);
- Whether necessary permits and project authorisations are in place and complied with (Sweden);
- Availability of sufficient animal care staff and technicians on site (Austria);
- Refinement in handling the animals (Austria);
- Assessment of culture of care (Ireland);
- Quality management systems (Ireland);
- The requirements for purpose-bred animals are met (Sweden);
- Other areas (e.g., storage, feed) comply with the facility approval and are kept satisfactorily clean (Sweden);
- Any use of animals, operative procedures and drug treatment that are not part of a project are carried out according to current regulations (Sweden);
- Whether handling and use of medicinal drugs is appropriate (France);

- Whether the legislation on transport of animals is followed (Belgium);
- Review the reports from designated experts (Belgium).

Voluntary question

E - 2.7 Is feedback from inspections given to the establishment?

Answer	Yes			No		
Question	Count	%	Member States	Count	%	Member States
Verbal	23	88%	AT, BE, CY, DE, DK, EE, EL, ES, FI, FR, HU, IE, IT, LU, MT, NL, NO, PL, PT, RO, SE, SI, SK	3	12%	CZ, HR, LV
Written	27	100%	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LU, LV, MT, NL, NO, PL, PT, RO, SE, SI, SK			

Most Member States provide feedback (written and verbal) to establishments.

Question

E - 2.8 Provide summary information on the main findings of inspections.

Several Member States (Czechia, Germany, Estonia, Ireland, Croatia, Italy, Luxembourg, Malta, Netherlands, Slovakia, Finland, Sweden, Noway) reported that findings were mostly in compliance with requirements and some stated that detected irregularities were mostly small and of minor severity.

Some reported improved enrichment and handling, housing conditions beyond the required minima, improvement in knowledge of responsibilities, and that the establishments use the findings of the inspection as an opportunity to further implement the Three Rs and correct errors and omissions quickly.

Others tended to only report negative findings covering a wide variety of topics. Examples of recurrently reported negative issues include record keeping reported as less than ideal, including Animal Welfare Body records and staff training records, fewer staff than necessary to perform all required tasks, changes to authorised projects not being notified when required, and difficulty in maintaining required standards in some facilities.

One Member State (Sweden) made the comment that the reported issues depend on the quality of the inspections, and improved quality may lead to an increase in reported deficiencies. Two Member States (Ireland, Sweden) noted that self-reporting of deficiencies occurs.

Questions

E - 2.9 As a result of an effective inspection programme, what have you identified.

E - 2.9.bis Specify other.

Answer	Yes			No		
Question	Count	%	Member States	Count	%	Member States
reduction in levels of risk at establishments	16	57%	BE, BG, DE, DK, ES, FI, HR, IE, IT, LU, LV, NL, PT, RO, SE, SK	12	43%	AT, CY, CZ, EE, EL, FR, HU, LT, MT, NO, PL, SI
decline in non-compliance	14	50%	BE, BG, DE, ES, FI, IE, IT, LU, LV, PL, PT, RO, SE, SK	14	50%	AT, CY, CZ, DK, EE, EL, FR, HR, HU, LT, MT, NL, NO, SI
reduction in legal and / or administrative actions	9	32%	BE, BG, ES, FI, HR, IE, IT, LU, RO	19	68%	AT, CY, CZ, DE, DK, EE, EL, FR, HU, LT, LV, MT, NL, NO, PL, PT, SE, SI, SK
increase of detected non-compliance	6	21%	BE, EE, IE, LT, SE, SK	22	79%	AT, BG, CY, CZ, DE, DK, EL, ES, FI, FR, HR, HU, IT, LU, LV, MT, NL, NO, PL, PT, RO, SI
other changes	5	18%	BE, DK, ES, IE, SE	23	82%	AT, BG, CY, CZ, DE, EE, EL, FI, FR, HR, HU, IT, LT, LU, LV, MT, NL, NO, PL, PT, RO, SI, SK

About half of the Member States reported lower risk and a decline in non-compliance as a result of the inspection programme.

Other issues identified include better understanding (Belgium, Spain) by stakeholders of the legislations and topics covered by (thematic) inspections, such as selection of most appropriate method of genotyping (Belgium), increased focus on animal welfare (Denmark), greater involvement of staff (Spain), improved development of standard operating protocols (Spain) and record keeping (Spain). Sweden reported that the quality of inspections has improved.

Voluntary questions

E - 2.10 Is any information (quantitative, qualitative and/or summary information) made publicly available on inspection / enforcement?

E - 2.10.bis Please provide a web-address where any published material on inspections / enforcement may be found.

Answer	Count	%	Member States
Yes	9	41%	BE, CZ, DK, FI, FR, IE, LU, NL, NO
No	13	59%	BG, CY, DE, EL, HR, IT, LV, MT, PL, PT, SE, SI, SK
Total	**22**	**100%**	

Of the 22 Member States that responded, 9 make information available to the public.

Member State	Answer
BE	In the Brussels Capital Region: https://environnement.brussels/citoyen/nos-actions/prevention-et-inspection/linspection-environnementale and https://environnement.brussels/citoyen/nos-actions/prevention-et-inspection/infractions-liees-lenvironnement-et-au-bien-etre-des-animaux In the Walloon Region: http://etat.environnement.wallonie.be/contents/indicatorcategories/gestion-environnementale/controle.html
CZ	Summary information on controls in the Information Bulletin on animal welfare surveillance activities for a given year, published on the website of the State Veterinary Administration.
DK	https://dyreforsoegstilsynet.dk/om/inspektioner
FI	https://avi.fi/en/en/about-us/our-services/animals/laboratory-animals
FR	https://agriculture.gouv.fr/animaux-utilises-des-fins-scientifiques
IE	Summary information published in HPRA Annual Report: https://www.hpra.ie/docs/default-source/publications-forms/corporate-policy-documents/annual-report-2021.pdf?sfvrsn=7
LU	https://agriculture.public.lu/de/tierhaltung/labosdeieren/genehmigungundkontrolle.html
NL	https://www.nvwa.nl/onderwerpen/dierproeven-voor-onderzoek Specific information about inspections can also be found in the annual reports, which are published on this web-address: https://www.nvwa.nl/onderwerpen/dierproeven-voor-onderzoek/jaaroverzicht-dierproeven-en-proefdieren-zo-doende
NO	www.mattilsynet.no

Voluntary questions

E – 2.11 What training is obligatory for inspectors, if any?

E – 2.11.bis Specify other.

21 Member States responded to this question.

Answer	Yes			No		
Training	Count	%	Member States	Count	%	Member States
Module 1 - National legislation	7	35%	BE, BG, FI, IE, LU, LV, SK	13	65%	CY, CZ, DE, DK, EL, FR, HR, MT, NL, PL, PT, SE, SI
Inspector module	4	20%	BG, FR, LU, LV	16	80%	BE, CY, CZ, DE, DK, EL, FI, HR, IE, MT, NL, PL, PT, SE, SI, SK
Endorsed Inspection and Enforcement document	3	16%	FI, IE, LU	16	84%	BE, BG, CY, CZ, DE, DK, EL, FR, HR, MT, NL, PL, PT, SE, SI, SK

Severity module	3	15%	IE, LU, LV	17	85%	BE, BG, CY, CZ, DE, DK, EL, FI, FR, HR, MT, NL, PL, PT, SE, SI, SK
Other	11	55%	BE, CZ, FR, HR, IE, IT, NL, NO, PT, SE, SK	9	45%	BG, CY, DE, DK, EL, FI, LU, MT, PL

Other mandated training includes:

- Specific training program for inspectors (Netherlands, Slovakia);
- Veterinary degree (Belgium, Czechia, Ireland);
- Work under supervision (Ireland, Netherlands);
- Modules for Article 23 functions A, B, C and D (Ireland);
- Project evaluation (Norway);
- Training in the use of different databases (Belgium);
- Information management (Belgium).

Voluntary question

E - 2.12 Has EU Guidance on Inspection and Enforcements been made available to inspectors?

E - 2.13 If possible, how extensively do you estimate it being used in your MS by inspectors?:

Answer	Count	%	Member States
Yes	22	88%	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, IE, IT, LU, LV, MT, NL, NO, PT, SE, SI, SK
No	3	12%	FR, HR, PL

Of the 25 Member States that responded, a large majority has made this document available, and estimated that it is used by a majority of inspectors, although 2 Member States (Croatia, France) estimated that it is not used.

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

Reporting obligation

"Provide summary information, covering the five-year reporting cycle, on reasons for the withdrawal of project authorisations."

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

The 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

Questions

E - 3.1 Were there any withdrawals of project authorisation made by the competent authority between 2018 and 2022?

E - 3.1.1 Number of withdrawals of project authorisation over the 5 year period. (voluntary question)

E - 3.1.2 Reasons for withdrawals of project authorisation made by the competent authority:

E - 3.1.2.bis Specify other.

Answer	Count	%	Member States
Yes	9	32%	BE, DE, DK, IT, LT, NL, NO, PL, SE
No	19	68%	AT, BG, CY, CZ, EE, EL, ES, FI, FR, HR, HU, IE, LU, LV, MT, PT, RO, SI, SK

Member States	Number of withdrawals of project authorisation over the 5 year period
DE	29
NL	17
SE	4
DK	2
BE	1
IT	1
LT	1
NO	1
PL	1
Total	**57**

Answer	Count	%	Member States
animal welfare issue	7	78%	BE, DE, DK, LT, NO, PL, SE
Other	6	67%	DE, DK, IT, NL, PL, SE
project altered without permission	1	11%	DE

One-third of the Member States have withdrawn project authorisations.

In the nine Member States that responded positively, there were 57 withdrawals over the five-year period. This compares with a total number of projects authorised in 2022 by those member states of 6 861.

In reference to reasons for withdrawals, in addition to animal welfare issues and alteration of project without permission, other reported reasons included failure to comply with project authorisation (Sweden) or a condition for the project approval (Denmark), lack of competence of the responsible persons (Germany), animal species not required to achieve the purpose (Italy).

One Member State (Netherlands) reported that one reason for withdrawals was a new project authorisation was granted and so the old authorisation expired. This question was intended to identify projects which were withdrawn as a result of failure of compliance, and not replacements of this type.

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

Reporting obligation

"Provide summary information, covering the five-year reporting cycle, on the nature of the following:

(a) infringements;

(b) administrative actions in response to infringements;

(c) legal actions in response to infringements."

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.

Questions

E - 4.1 Were there any infringements between 2018 and 2022?

E - 4.1.1 What is the nature of the infringements seen over the period 2018-2022?

E - 4.1.1.bis Specify other.

Answer	Count	%	Countries
Yes	20	71%	AT, BE, CZ, DE, DK, EE, ES, FI, FR, IE, IT, LT, LU, NL, NO, PL, RO, SE, SI, SK
No	8	29%	BG, CY, EL, HR, HU, LV, MT, PT

71% of Member States reported infringements.

Answer	Count	%	Member States
Incomplete or absent records	17	85%	BE, CZ, DE, DK, EE, ES, FI, FR, IE, IT, LU, NL, PL, RO, SE, SI, SK
Enclosures not conforming to legal requirements (e.g. size, lighting, noise, environmental parameters)	12	60%	BE, CZ, DE, DK, ES, FI, FR, IE, IT, PL, RO, SE
Deficiencies in hygiene	11	55%	BE, DE, DK, EE, ES, FR, IE, IT, PL, RO, SE
Failure to demonstrate daily health checks /monitoring of animals	11	55%	BE, DE, DK, ES, FR, IE, LU, NL, PL, RO, SK
Inadequate records of the animal welfare body	11	55%	BE, DK, ES, FI, FR, LU, NL, NO, PL, SI, SK

Deficiencies in alarm / backup systems or inadequate processes for emergencies	9	45%	AT, BE, DK, ES, FI, FR, PL, SE, SK
Failure to provide appropriate enrichment / bedding / nesting material	9	45%	AT, BE, DE, DK, ES, FR, IE, PL, SE
Number of animals used exceed that permitted	9	45%	BE, CZ, DE, DK, IE, IT, PL, SE, SK
Other	8	40%	AT, BE, CZ, EE, FI, IT, LT, SE
Late and/or incomplete reporting of animals used in experiments	7	35%	BE, DE, DK, ES, FR, NO, PL
Poor or inadequate cage labelling	7	35%	AT, BE, DE, DK, ES, FR, SK
Change of project without authorisation	6	30%	BE, CZ, DE, IE, NL, PL
Failure to administer pain relief for an animal experiment or failure to reduce discomfort	6	30%	BE, CZ, DE, FR, IE, NL
Performing of procedures without appropriate authorisation	6	30%	CZ, DE, ES, FR, IE, SE
Not preventing access of unauthorised persons	5	25%	AT, BE, DK, FR, SK
Failure to provide / maintain the necessary knowledge and skills	4	20%	BE, ES, FR, NO
Personnel as listed in Article 24 (named persons) and 25 (designated veterinarian) not named or not performing as required	4	20%	ES, FR, PL, SE
Health status of the animals not maintained to ensure health and defined microbiological surveillance	3	15%	BE, NO, PL
Keeping animals without appropriate authorisation	3	15%	BE, DE, ES
Killing of animals not compliant with Article 6	3	15%	DE, FR, SE

Issues not listed on table include no permission for reuse (Belgium), use of stray animals (Czechia), humane end-point reached and animal not killed (Belgium, Sweden), insufficient staff (Austria), staff not appropriately trained or supervised (Czechia, Sweden), composition of the Animal Welfare Body not as required (Belgium, Sweden), single housing exceeding permitted times (Sweden).

Question

E - 4.2 Were there any administrative actions between 2018 and 2022?:

E - 4.2.1 What is the nature of the administrative actions used in response to infringement identified over period 2018-2022?

E - 4.2.1.bis Specify other

Answer	Count	%	Member States
Yes	21	75%	AT, BE, CZ, DE, DK, EE, ES, FI, FR, HU, IE, IT, LT, LU, NO, PL, PT, RO, SE, SI, SK
No	7	25%	BG, CY, EL, HR, LV, MT, NL

Answer	Count	%	Member States
written order for improvement within a specified period	18	86%	AT, BE, DE, DK, EE, ES, FI, FR, HU, IE, IT, LU, PL, PT, RO, SE, SI, SK

performance of follow-up checks / re-inspection to verify improvements	16	76%	AT, BE, DE, DK, ES, FI, FR, IE, IT, LU, PL, PT, RO, SE, SI, SK
written warning	16	76%	AT, BE, CZ, DE, DK, ES, FR, HU, IE, IT, NO, PL, PT, TO, SE, SK
verbal order for improvement within a specified period	11	52%	AT, BE, DE, DK, EE, ES, FI, IT, PT, RO, SK
more frequent monitoring	8	38%	BE, CZ, DE, DK, ES, FI, SE, SK
ordering the operator to follow adequate training	8	38%	BE, DE, ES, FR, IT, LU, SE, SI
verbal warning	8	38%	AT, DE, DK, ES, IT, PT, RO, SK
stopping of the project	7	33%	DE, DK, ES, FR, IE, NO, SE
Other	6	29%	CZ, DK, ES, LT, PL, SE
consultation with animal welfare officers	4	19%	DK, IT, PT, SE
person not allowed to work on the project until training completed	3	14%	DE, NO, SI
imposition of veterinary measures on the operator	2	10%	DK, SE

21 Member States have used administrative actions.

Other administrative actions included: inspectorate informed the management of non-compliance (Denmark), operator voluntarily undertook to ensure measures were put in place to remedy deficiencies by agreement (Sweden), temporary ban on the introduction of new animals (Spain), refusal to authorise projects subject to the resolution of the deficiencies identified (Spain), administrative fines (Lithuania, Poland), de-registration resulting in loss of the right to continue business (Poland).

It seems that there may be varied interpretations of what constitutes administrative vs legal actions across the Union.

Question

E – 4.2.2 Provide summary information of the nature of infringements which have resulted in administrative action.

Infringements which were dealt with by administrative action were due to failings in the following areas:

- Animal welfare: humane end-point application, failure to provide analgesia, stocking density too high, insufficient monitoring at weekends, failure to perform daily checks, late/inadequate treatment of sick or injured animals;
- Staff: availability of staff, including frequency of veterinary visits; (Finland web address of resource https://avi.fi/tietoa meista/tehtavamme/elaimet/koe-elaimet - in Finnish)
- Records: on cages/pens/tanks, cards, stock animals; animal use; education and training of staff; animal health/disease; veterinary health and veterinary medicines, Animal Welfare Body advice and decisions;
- Environment: temperature, humidity, noise level and lighting, lack of/too little enrichment, ventilation, cleanliness;

- Facilities: alarm systems, lack of disaster plan, facilities not suitable/not kept in good condition, inadequate security to prevent access by unauthorised persons, equipment faulty/not maintained/replaced.

Authorisations not sufficient:

- Experiment did not comply with authorisation or there was no authorisation;
- Inadequate aseptic technique used;
- Individual housing of social species without authorisation;
- Persons not correctly listed or not correctly trained or not authorised;
- Failure to provide adequate supervision of staff ;
- Breeding occurring without authorisation;
- Use of stray animals without authorisation;
- More animals used than authorised;
- Incorrect methods of killing used;
- Significant changes occurred without authorisation, including in personnel;
- Experiment started before authorisation granted;
- Continued experiments after expiry of authorisation / renewal has not been requested;
- Late reporting of required information.

Questions

E - 4.3 Were there any legal actions taken in response to infringements in your Member State?

E - 4.3.1 What is the nature of the legal actions taken over the period 2018-2022?

Answer	Count	%	Member States
Yes	12	43%	AT, CZ, DE, ES, FI, FR, IT, LT, NL, PL, SE, SK
No	16	57%	BE, BG, CY, DK, EE, EL, HR, HU, IE, LU, LV, MT, NO, PT, RO, SI

43% of Member States used legal actions, of which two-thirds were fines.

Answer	Yes			No		
Question	Count	%	Member States	Count	%	Member States
Fines	8	67%	CZ, DE, ES, FR, IT, LT, PL, SK	4	33%	AT, FI, NL, SE
Other legal actions	4	33%	AT, DE, ES, PL	8	67%	CZ, FI, FR, IT, LT, NL, SE, SK
Referred to the competent prosecution authority and prosecuted	4	33%	DE, ES, NL, SE	8	67%	AT, CZ, FI, FR, IT, LT, PL, SK
Referred to the competent prosecution authority, but not prosecuted	3	25%	ES, FI, SE	9	75%	AT, CZ, DE, FR, IT, LT, NL, PL, SK

Voluntary question

E - 4.3.1.1 Maximum fine available in Euros to ensure that penalties provided are effective, proportionate and dissuasive (Article 60).

The range of maximum fines reported by five Member States to ensure penalties are effective, proportionate and dissuasive (Article 60) were between 150 and 40 000 Euros.

Member States	Maximum fine available in Euros to ensure that penalties provided are effective, proportionate and dissuasive (Article 60)
CZ	40 000.00
DE	25 000.00
IT	150.00
PL	11 000.00
SK	3 500.00
Total	**15 930.00**

Questions

E - 4.3.1.2 What were the reasons for not progressing to prosecution?

E - 4.3.1.3 Specify other legal actions.

Not all cases referred to prosecuting authorities were progressed and reasons for this included evidence was insufficient, the event was not considered sufficiently severe.

Other actions included temporary or permanent suspension of activity, increased inspections, written warning, educational activities to raise knowledge / awareness, written and oral improvement briefings, request for reports / documentation / records. Whilst listed as "legal" many of these seem to be administrative. Clarification of the distinction between these categories would be useful for clarity for future reports.

Question

E - 4.3.2 Provide summary information of the nature of infringements which have resulted in legal action.

The summary information on the nature of infringements having resulted in legal action includes:

- Care and handling not compliant with requirements. One Member State (Spain) qualified this "*provided that there are no permanent lesions, deformities or serious defects, or the death of the animals*", suggesting this is a lesser infringement. This is an example suggesting a lack of clear understanding and discrimination between administrative and legal actions across Member States;
- Housing: Missing or insufficient enrichment, inadequate control and monitoring of the condition of the animals, keeping animals in unsuitable enclosures, individual housing of social animals without need/justification;
- Authorisation: Experiment without authorisation, or not carried out in accordance with the authorisation (e.g., exceeding the authorised number of animals, including non-human

primates and endangered species), lack of or insufficient pain relief, use of animals after the expiry of the authorisation, unauthorised breeding of experimental animals, use of killing methods not contained in Annex IV of the Directive without appropriate derogation;

- Deficiencies in the frequency of veterinary treatments;
- Documentation: Amendments not correctly processed. Missing or incorrect certificates of competence/evidence of formal qualifications, falsification of documents (e.g., training certificates). Records not kept correctly or deficiencies in documentation;
- After an issue was identified as deficient / non-compliant and the responsible persons of the establishment pointed out this on several occasions, the issue was not resolved satisfactorily.

Voluntary question

E - 4.4 Other than information given above, please add information on the main rules and steps governing penalties in your Member State, if required for further clarification.

Further information was given by 13 Member States. There are differing systems in place across Member States, and for clarification it is necessary to view each individual Member State submission.

Article 60 states that penalties must be proportionate, effective and dissuasive. In many cases, it was reported that there was a demonstrably proportionate approach to penalties dependent on the severity of the infringement, although this was not always clear. There is a wide range of magnitudes of maximum fines (x10) across different Member States (where this is known) from question E4.3.1.1.

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, and on areas where further collaborative efforts could improve implementation. It is important to emphasise that there was no obligation to complete Section F of the questionnaire.

Voluntary question

F - 1 Do you think there are sufficient training programmes available for persons working under the Directive?

F - 1.bis If not, what problems are there?

Answer	Count	%	Member States
Yes	15	63%	BG, CY, CZ, DE, DK, EL, HR, LT, LV, NL, NO, PL, SE, SI, SK
No	9	38%	BE, FI, FR, IE, IT, LU, MT, PT, RO
Total	**24**	**100%**	

Of the 24 Member States that responded, just under two thirds thought there were sufficient training programmes available.

Several Member States (France, Italy, Luxembourg, Portugal, Finland) stated that there were insufficient programmes for less commonly used species (fish, farm animals, dogs, non-human

primates). This is particularly relevant for practical training for which there may be a prolonged time to wait for available training. However, there remains a problem in some Member States even for commonly used species (Luxembourg, Italy).

Others stated that there were no training courses for named functions other than Article 23 functions (A-D) (Romania), specifically for designated veterinarians, and inspectors (Ireland), competent authorities (Malta) and person responsible for supervising animal welfare (Portugal). [N.B. work is under way by the European Commission to make open access eModules available for designated veterinarians and inspectors by the end of 2024]

The expense of attending courses, especially when not local, was mentioned as an issue (Luxemburg). Consistency of course quality was also raised (Belgium).

Voluntary question

F - 2 Has there been an improvement in accessibility of information on alternatives e.g. databases?

Answer	Count	%	Member States
Yes	19	79%	BE, BG, CZ, DE, DK, FI, FR, IE, IT, LT, LU, LV, NL, NO, PT, RO, SE, SI, SK
No	5	21%	CY, EL, HR, MT, PL
Total	**24**	**100%**	

Of the 24 Member States that responded, 80% considered that there had been an improvement.

Voluntary question

F - 2.1 What sources of information have been helpful?

The sources indicated as helpful to support the implementation of the Directive include:

- 3Rs centre Utrecht
- ALURES Non-Technical Summary EU Database and ALURES Statistical EU Database - https://environment.ec.europa.eu/topics/chemicals/animals-science/statistics-and-non-technical-project-summaries_en
- Animal Testing Alternatives - Online Resources - https://doi.org/10.29173/istl1820
- Adverse Outcome Pathway Knowledge Base - https://aopkb.oecd.org/index.html
- Bf3R - German Centre for the Protection of Experimental Animals https://www.bf3r.de/de/ueber_das_bf3r-276226.html
- Beyond animal testing - https://www.beyondanimaltesting.org
- Bilateral communication with the EC
- DB-ALM - https://jeodpp.jrc.ec.europa.eu/ftp/jrc-opendata/EURL-ECVAM/datasets/DBALM/LATEST/online/dbalm.html
- Dutch Association for Laboratory Animal Science - www.DALAS.nl
- EU Guidance Documents – Caring for animals, aiming for better science https://environment.ec.europa.eu/topics/chemicals/animals-science_en#implementation / Guidance documents
- ECVAM Search Guide - The EURL ECVAM search guide - Publications Office of the EU (europa.eu)
- ETPLAS - https://etplas.eu

- EURL-ECVAM - https://joint-research-centre.ec.europa.eu/eu-reference-laboratory-alternatives-animal-testing-eurl-ecvam_en
- EMBASE - https://www.embase.com/
- Foetal calf serum replacement - https://fcs-free.org/
- FIN3R Centre - https://fin3r.fi/en
- FRAME - https://frame.org.uk/
- InterNICHE - https://www.interniche.org/
- ISI Web of Science
- JRC Joint Research Centre Data Catalogues on non-animal models in biomedical research - https://data.jrc.ec.europa.eu/collection/id-0088
- National Centre for 3Rs - https://nc3rs.org.uk/3rs-resources/search?topic%5B0%5D=504
- Netherlands Centre Alternatives to animal use
- Meetings of National Contact Poins under Directive 2010/63/EU
- Severity Assessment workshops
- NIH Alternatives to animal testing https://www.niehs.nih.gov/health/topics/science/sya-iccvam/index.cfm
- NORECOPA (Norway's National Consensus Platform for the evolution of the 3Rs): https://norecopa.no/alternatives
- Norecopa 3R guide - https://norecopa.no
- OECD: https://www.oecd.org
- Preclinical trails register - https://preclinicaltrials.eu/
- PubMed - https://www.ncbi.nlm.nih.gov/
- RE-Place database was created to help researchers share and find expertise on non-animal methods NAMs (New Approach Methodologies) - Belgium
- SIS
- Sweden's 3R Centre - https://jordbruksverket.se/languages/english/swedish-board-of-agriculture/animals/the-swedish-3rs-center
- Swiss3R competence centre - https://swiss3rcc.org/
- Syrf
- TPI – transition to animal free research - https://www.transitieproefdiervrijeinnovatie.nl/
- TSAR –Tracking System for Alternative Methods towards Regulatory Acceptance: https://tsar.jrc.ec.europa.eu/
- Web Of Science - https://apps.webofknowledge.com

Luxembourg stated that there are many different databases, websites or books easily accessible but despite that it is not always easy to find the appropriate alternative methods to use for a particular scientific question. Some topics are more represented in the alternatives field than others such as toxicology versus immunooncology. Luxembourg concluded that it is not easy to advise researchers on the best methods and also gave the opinion that researchers may not take enough time to investigate all the different possibilities open to them.

Voluntary question

F - 2.2 What further improvements would be helpful?

Sharing of information

Denmark, France, Luxembourg and Sweden suggested improving information sharing, communication and dissemination, including 3R centres raising awareness of the Three Rs (existing databases, websites, conferences, courses, articles, etc.).

Latvia requested identification of existing non-animal models in biomedical settings [N.B. ECVAM resources https://joint-research-centre.ec.europa.eu/eu-reference-laboratory-alternatives-animal-testing-eurl-ecvam/biomedical-research_en].

Greece wished for access to a 3Rs centre outside their Member State so that appropriate expertise could be available. Hungary hoped for a 3Rs centre within their Member State.

Luxembourg proposed databases at national level to be linked at EU level and Germany a database of available alternative methods at European level that is accessible, freely searchable and easy to understand for applicants and authorities. Other suggestions included a database of non-harmful genetically altered animal lines to avoid duplication (Spain), a database of alternatives for REACH testing (Portugal) along with action by the authorities implementing the REACH regulation[26] to promote use of alternative methods, dissemination of information and the use of databases mandatory (France) and keeping information up to date (Netherlands). Norway suggested sharing of more information with "Norecopa"[27] for a wider dissemination.

"*The more information and knowledge about Three Rs that can be shared, the faster we as a society can reach the Directive's goal regarding full replacement of procedures on live animals for scientific and educational purposes as soon as it is scientifically possible to do so.*" (Sweden).

ALURES Non-technical Summaries EU Database

Belgium and Denmark suggested modifying the ALURES non-technical summaries EU database to improve its use for searching duplicates and alternatives for animal procedures (for example possibility to search on free-text words instead of only selected keywords and information on alternatives within the Replacement field.

Transparency

Denmark stated that Member States should strive for the highest possible level of transparency in the field of experimental animals.

Animal Welfare Bodies

Spain suggested establishing a mechanisms to empower Animal Welfare Bodies.

Education and Training

Czechia suggested continuous education and awareness raising of the "professional public". Due to high staff turnover, Czechia proposed training at EU level (e.g., through the Better Training for Safer Food, BTSF Academy) for inspectors and competent authorities on topics such as statistical reporting and project evaluation to improve effectiveness. Spain suggested the development of dedicated workshops for inspectors.

[26] http://data.europa.eu/eli/reg/2006/1907/2022-12-17

[27] https://norecopa.no/

Germany suggested supplementary criteria for the assessment of the harms and Portugal proposed better monitoring schemes for the actual severity that animals experience. Latvia suggested additional resources for education and training.

Netherlands suggested harmonisation of project evaluation at the level of the Union.

Staff

Spain proposed the establishment of minimum ratios of qualified staff at the centre according to the number of animals and animal species (care staff, those carrying out procedures, designated veterinarian, person responsible for animal welfare).

Spain suggested to better determine and explain how all those involved in animal research have a unique contribution to make to the Three Rs depending on their role (Spain).

To truly achieve a culture of duty of care in each establishment that uses animals. an improved mutual understanding between the establishment's staff, animal welfare body, and researchers who use animals for scientific purposes is required (Portugal).

Voluntary questions

F - 3 Are there any other problematic areas for implementation of the Directive in your Member State?

F - 3.bis Explain problematic areas for implementation of the Directive.

Answer	Count	%	Member States
Yes	14	58%	BE, CY, CZ, DE, DK, EL, FR, HR, LU, MT, PT, SE, SI, SK
No	10	42%	BG, FI, IE, IT, LT, LV, NL, NO, PL, RO
Total	**24**	**100%**	

14 Member States raised other problem areas in the Directive including the suggestion for a regulation to replace a directive to improve consistency in implementation.

Resources

Ensuring sufficient resources for efficient implementation can be challenging, and in particular ensuring that the deadlines for project authorisation are met.

It was noted that in smaller Member States it can be challenging for every establishment to meet their obligations, in particular with Animal Welfare Bodies. However, the Directive allows small breeders, suppliers and users to fulfil the tasks of Animal Welfare Bodies by other means, e.g., by sharing resources between establishments.and also to meet the requirements in other ways (Article 26(3). It can also be difficult to contribute to national working groups when there is only a small pool of experts. In addition, retaining anonymity in project evaluation and in publication of non-technical project summaries is difficult.

Consistency

Where multiple competent authorities are involved in project evaluation and authorisation it can be challenging to ensure a harmonised and consistent approach.

One Member State noted the difficulties in ensuring all necessary information is included in project application, and indicated that improved communication on animal use is still evolving.

A suggestion was made that additional guidance on the justification for the use of and determining impacts on non-human primates would be helpful.

There are differences noted in the size and complexity of establishments, which can impact on inspection numbers, which may not then reflect risk.

Knowledge and expertise

It was noted that although there has been good progress on refinement and reduction, there are still challenges to ensure awareness of and implementation of replacement. Improved targeting of undergraduates may be helpful.

Two Member States indicated the challenges in ensuring accurate completion of the annual statistical returns and suggested further explanations of the requirements.

It was also noted that it can sometimes be challenging in farm animals to determine whether or not studies fall within the scope of the Directive.

Ensuring appropriate expertise of inspectors was noted to be a challenge, in particular where inspection of scientific establishments is only a very small part of their job.

Voluntary questions

F - 4 Are there any areas where collaborative efforts between Member States would improve implementation of the Directive?

F - 4.bis Explain areas where collaborative efforts between Member States would improve implementation of the Directive.

Answer	Count	%	Member States
Yes	15	68%	BE, CY, DE, DK, EL, FR, HR, LU, MT, NL, NO, PL, PT, SE, SK
No	7	32%	BG, CZ, FI, IT, LT, LV, RO
Total	**22**	**100%**	

15 Member States responded that there were areas where collaborative efforts between Member States would improve implementation of the Directive. However, one of the responses indicated that they didn't identify any such areas. Meetings of National Contact Points under Article 59 of the Directive are considered valuable and should continue.

The areas suggested where further collaboration would be beneficial include:

- Animal Welfare Bodies within the Member States and across the Union. National Committees have a role in promoting this and a voluntary group has been initiated at a European level (the European Network of Animal Welfare Bodies – ENAWB);
- National Committees, in particular in the development and dissemination of guidance;
- Already established 3Rs centres network for continued collaboration and educational outreach;
- Inspections.

Other suggestions for wider collaboration included:

A central European project evaluation and authorisation hub, which would improve consistency, and assist the smaller Member States who struggle having the necessary expertise. Failing a pan-European hub, as a first step, increased communication and exchanges among competent authorities responsible for project evaluation and authorisation would be beneficial, to optimise consistent approaches.

Continued efforts in harmonising severity classification and assessments due to its importance for animal welfare, science and public confidence, as there seems to remain discrepancies between establishments and also Member States.

Further reductions in animal use would benefit from increased focus on non-animal methods (NAMs) with improved collaboration on development and validation.

Work is still needed on mutual acceptance of Education and Training requirements.

Voluntary question

F - 5 Please provide here any other additional comments concerning the implementation of the Directive.

Additional comments were provided by 11 Member States.

Two Member States (Belgium, Sweden) suggested clarification and standardisation of authorisation of establishments, as there are differences among Member States – for example, an establishment authorised as a user-breeder-supplier may have one authorisation in one Member State but three in another; similarly, one academic institute may be divided into more than one user.

Consistency where there are multiple competent authorities charged with the same task can be challenging.

There is a need for training for inspectors (Greece, Cyprus), and standardised checklist for performance of inspections for all Member States, for a uniform and unitary approach (Romania) [N.B. a checklist is provided in the EU Inspections and Enforcment guidance document.] The open-access eModule currently under development will be beneficial to fill this gap. Training for project evaluators was requested. [N.B. an open-access eModule is already available (https://learn.etplas.eu/courses/eu-25-2-project-evaluation/).] Training on other less clearly specified aspects on implementation was also requested (Greece).

Concern was expressed that there remain significant differences in education and training, including CPD requirements. Further work is needed to facilitate an EU "Passport" to deliver the free movement of personnel. Increased availability of open-access eModules for all functions, and available in all community languages would be very beneficial.

Progress on international acceptance of non-animal alternatives is considered a high priority.

Finally, there was a request for Annex III standards for fish, especially zebrafish (Germany), which is now addressed through the amendment to Annex III contained in Commission Delegated Directive (EU) 2024/1262[28].

[28] *OJ L, 2024/1262, 15.5.2024*

G. COMMISSION ACTIVITIES TO FACILITATE THE IMPLEMENTATION OF THE DIRECTIVE

G.1. Transposition conformity checks

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

As reported in the first implementation report, on the basis of an in-depth assessment of the conformity (correct and complete transposition of the provisions of the Directive), the Commission had identified issues of possible incorrect or incomplete transpositions and entered into dialogue with all Member States. At the time of publishing the first implementation report in 2019, the Commission had successfully concluded discussions with the eight[29] Member States who had taken the necessary measures. With the other Member States, either the dialogue continued or a formal infringement procedure for non-conforming transposition of the Directive was opened in accordance with Article 258 of the Treaty of the Functioning of the European Union. Subsequently, several Member States amended national legislation transposing the Directive.

As a result of these efforts, between 2019 and April 2024, the Commission successfully closed cases (investigations or infringements) with an additional 15 Member States[30]. The amendments to national legislation are under assessment for the four remaining Member States[31].

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

To achieve the aims of the Directive, a uniform understanding on its obligations and objectives across the EU is needed. The European Commission continues its efforts to facilitate and support Member States and others involved in the care and use of animals in the correct implementation and application of the Directive.

The European Commission convenes twice-yearly meetings of the National Contact Points set up under Article 59 of the Directive to identify and discuss issues on implementation. The discussions focus on administrative processes and sharing of good practice among Member States, including on inspections and enforcement. Moreover, the meetings provide an opportunity to bring the latest developments on the Three Rs to the attention of Member States and key stakeholders.

In addition, the Commission has hosted expert working groups, with experts nominated by Member States, science/academia, industry, animal welfare organisations and other specialised organisations (such as laboratory animal veterinarians, laboratory animal breeders, animal technologists). The objectives of these working groups are to develop EU guidance and common lines on important topics to harmonise their implementation.

In addition to the five guidance documents developed during the first five-year period, three further guidance documents were developed covering:

- Genetically altered animals[32]

[29] BE, IE, EL, HR, CY, LT, LU and MT
[30] AT, BG, CZ, DE, EE, ES, FI, FR, HU, LV, NL PT, SI, SK and RO
[31] DK, IT, PL and SE
[32] https://data.europa.eu/doi/10.2779/499108

- Non-technical project summaries[33]
- Results of retrospective assessment[34]

Especially the guidance on genetically altered animals is expected to improve understanding and correct implementation of the rules on authorisation of the creation, maintenance and genetic characterisation of these animals. This guidance is also expected to improve reporting on this topic - where challenges had been noted in the past - in annual statistics and in the five-year implementation report. .

Following the adoption of Regulation (EU) 2019/1010[35] in June 2019, amending the Directive to improve transparency through better access to statistical data, as well as the quality and timeliness of the publication of non-technical project summaries of authorised projects, Commission Implementing Decision 2020/569/EU was adopted providing the detailed data requirements and the formats for the electronic transfer of data.

The European Commission created two public databases: one on annual statistics data on animal use and the other for the publication of non-technical project summaries. These ppen-access databases, called ALURES, were launched in 2021 making the Union the world leader in transparency on the use of animals in science. To further facilitate the implementation by Member States that did not have electronic systems available for the processing of non-technical project summaries, the complete process flow was made available through ALURES, ranging from the preparation of draft non-technical summaries, to communication between the applicant and authorities, to publication.

All Member State reporting obligations under the Directive are now centralised through ALURES, minimising administrative burden for the authorities. In addition to statistical data templates, voluntary templates were created for the five-year implementation report data collection on animals bred, killed and not used and on genetic characterisation with the aim of reducing administrative burden also for the operators.

With further funds, provided by the European Parliament, a preparatory action "Promoting alternatives to animal testing" was initiated. This builds on an earlier EP Pilot project focusing on education, training and information sharing activities on the Three Rs. The project was initiated in 2020 to deliver *inter alia* another 13 open access (on-line) e-Learning modules on areas where harmonisation of approaches is critically needed to ensure competence and implementation of the Three Rs in line with the Directive's objectives. These e-Learning modules and other assessment resources will be made available through the Education and Training Platform for Laboratory Animal Science (ETPLAS) to promote competent and continuously trained staff across the Union. In addition, material has been developed to facilitate integration of the Three Rs into curricula and teaching programmes at secondary schools and universities with the aim of equipping future generations with the Three Rs' mindset and knowledge. The project is on-going with the final deliverables expected in early 2025.

In 2023, in response to the European Citizens' Initiative "Save Cruelty-Free Cosmetics – Commit to a Europe without Animal Testing", the European Commission committed to developing a roadmap to ultimately phase out animal testing for chemical safety assessments, together with

[33] https://data.europa.eu/doi/10.2779/778680

[34] https://data.europa.eu/doi/10.2779/896767

[35] *OJ L 170, 25.6.2019, p. 115–127*

agencies, Member States, industry, and other stakeholders. The roadmap is to be finalised early in the mandate of the new Commission.