EUROGROUP FOR ANIMALS

GENERAL REPORT

Improving the reporting on the implementation of Directive 2010/63/EU on the protection of animals used for scientific purposes

Under Article 54(1) of Directive 2010/63/EU (the Directive), Member States are required to submit to the European Commission (EC) information on the implementation of this Directive once every 5 years. Reports covering the first five years of the functioning of the Directive, i.e. the period 2013-2017, were submitted by EU Member States to the EC in 2018. Reporting requirements for this first submission of information on the implementation of the Directive were set out in Annex I of Commission Implementing Decision 2012/707/EU.

The second submission of information on the implementation of the Directive will cover the years 2018-2022, and is due to be submitted by the Member States to the EC by 10 November 2023. The reporting requirements for this second submission are set out in Annex II of Commission Implementing Decision 2020/569/EU, replacing Commission Implementing Decision 2012/707/EU.

The present report provides recommendations that can improve Member States' reporting on the implementation of the Directive. A better and more harmonised reporting by Member States will further increase transparency and openness, and will enable the assessment of the effectiveness of the implementation of the Directive among all Member States.

Our recommendations are based on the new reporting requirements set out in the sections of Annex II of Commission Implementing Decision 2020/569/EU, and on best practices among the replies of the Member States to the EC 2018 survey on the implementation of the Directive. Accordingly, our recommendations are divided into two subsections: legal requirements and best practices.

Competent Authorities

Section B-1

Legal requirements

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 the Directive, which states that:

- each Member State shall designate one or more competent authorities responsible for the implementation of this Directive;
- Member States may designate bodies other than public authorities for the implementation of specific tasks laid down in this Directive only if there is proof 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.

Best practices

Explain how the different **competent authorities interact** to ensure that the Directive is implemented effectively, including what **measures are in place to ensure a coherent approach and consistency of outcomes** (e.g. use of standardised forms; regular meetings, training).

Fill in the table recapitulating information on the **numbers and types of authorities per task.**

National Committee

Section B-2

Legal requirements

Explain the **structure and operation** of the National Committee.

Explain the measures taken to **ensure compliance with the requirements of Article 49(1)** of the Directive, which states that the National Committee 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.**

Examples of best practices

Specify whether **meetings, seminars, workshops and/or training sessions** are organised; as well as the topics addressed and the web-address(es) where this information can be found.

Best practices

Specify the **expertise** of the members, including in the **field of the 3Rs,** and whether they **attend training courses** related to project evaluation to provide appropriate advice on this topic, and in particular regarding the 3Rs and the use of procedures that respect the physiological and behavioural needs of animals as much as possible; cause a minimum level of pain and suffering; and use adequate research models, particularly alternative methods.

Best practices continued

Explain the measures taken to **ensure compliance with the requirements of Article 49(2)** of the Directive, which states that the National Committee shall **exchange information** on the operation of animal-welfare bodies and project evaluation and **share best practice** within the Union.

Examples of best practices

- Specify whether **reports and/or recommendations** have been disseminated in order to promote the principles of replacement, reduction and refinement.
- Indicate whether the National Committee participates in **EU National Committee meetings.**

Provide information on how the National Committee aims to address **coherent approach to project evaluation, and review strategies at national level** as provided in Recital 48 (e.g. drawing up common templates).

Animal welfare bodies

Section C-4

Legal requirements

Explain the measures taken to ensure compliance with the requirements regarding the **structure and functioning of animal welfare bodies of Articles 26 and 27,** which state that:

- Member States shall ensure that **each breeder, supplier and user** sets up an animal-welfare body;
- 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;
- 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 in these fields; (c) establish and review internal operational processes regarding 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 on 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;
- 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.

Best practices

Report the **measures implemented and/or tools provided** to ensure that members possess the **expertise** needed to advise the staff, and in particular on the application of the requirement of replacement, reduction and refinement (e.g. training; seminars).

Specify whether **animal welfare bodies are subject to controls** during inspections, and if so, describe the elements that are checked (e.g. reports; composition; monitoring of decisions; follow-up of the implemented projects).

Describe the aspects of **the work of the animal welfare bodies that function well** and that could be **improved.**

Principles of Replacement, Reduction and Refinement (3Rs)

Section D-1.1

Legal requirements

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** the Directive, which state that:

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

Examples of best practices

- Report the **information related to the 3Rs principles** that applicants need to provide in their application file (e.g. systematic literature search for alternative methods which do not involve the use of live animals; reasons for not using alternative methods when available, relevance of the animal(s) species chosen, use of appropriate statistical methods to calculate the minimal number of animals necessary to obtain scientifically relevant results, explain whether a collaboration with another laboratory is possible to reduce the number of animals used, indicate the methods used to reduce or eliminate the discomfort experienced by the animals, appropriate breeding strategies for animals with genetic modifications which cause harmful phenotypes to minimise the number of animals suffering from such phenotypes, sharing of tissue and organs either within establishments or via biobanks, information about the refinement of the conditions of accommodation and care during the projects, description of the humane end-points that were set).
- Indicate the **strategies used by the project evaluators to verify** the information submitted by an applicant, and decide whether the 3Rs principles are satisfactorily addressed (e.g. use of a standardised form or a check-list; review of the application by a statistician; use of common databases to verify whether alternative methods are available or appropriate; by staying informed on the latest technical and scientific developments in these fields).

Section D-1.2

Legal requirements

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 the Directive.

Examples of best practices

- **Specify whether it is verified that:** (a) the installations and equipment are suited to species of animals housed and to the performance of the procedures that will be carried out; (b) animals are in good health; (c) incompatible species are not housed together; (d) animal health and wellbeing is daily monitored and recorded by a competent person; (e) the transportation is adapted to the species; (f) acclimatisation and quarantine is possible; (g) animals are housed in groups when applicable; (h) animals have sufficient space and can express normal behaviour; (i) enrichment is provided as appropriate to the species; (j) the enclosures are made of non-toxic material and cannot endanger the animals; (k) the animals receive sufficient food and water; (l) bedding material and nesting material is provided and refreshed regularly; (m) the environment is suitable to the species of animals housed including ventilation, temperature, lighting, noise, and relative humidity; (n) albino animals receive special lighting conditions; (o) animals can satisfy their physiological and ethological needs; (p) animals are free of stress, anxiety, thirst, hunger, discomfort, pain, injury, illness or abnormal behaviour, and whether positive emotions are shown including playing behaviour, adaptability to situations, exploration behaviour; (q) alarm systems and active maintenance programs are in place as well as cleaning schedules for installations and equipment; (r) facilities are in place for carrying out diagnostic tests, collection of samples, housing sick animals, performing surgery, post-operative care, and post-mortem examination.
- Indicate whether **seminars, meetings, workshops and/or training days** related to the implementation of the 3Rs principles during housing and care are organised and, if so, provide information on these initiatives (e.g. frequency; topics addressed; target audience).
- Provide information on the **role of animal welfare bodies** in ensuring that the principles of the 3Rs are satisfactorily addressed during housing and care (e.g. carry out regular meetings with all persons involved in the project to advise on the implementation of the 3Rs, and verify that the 3Rs are satisfactorily addressed; ensure adequate and continuous education and training of staff).

Section D-2

Legal requirements

Explain how **duplication of procedures is avoided to comply with Article 46** of the Directive, which states that **each Member State shall accept data from other Member States** that are generated by procedures recognised by the legislation of the Union, unless further procedures need to be carried out regarding that data for the protection of public health, safety or the environment.

Examples of best practices

- Report the **information that applicants must provide in their application file** (e.g. systematic literature search; the websites, online databases, books and/or journals that were consulted as well as the time period of the search and the keywords that were used, where applicable; exchange with other research groups internally and externally; access to data within the establishment).
- Indicate the **strategy used by the project evaluators** to check this information.

Section D-1

Best practices

Submit to the European Commission a **voluntary report** regarding the Member State's activities in relation to the **development, validation and promotion of alternative approaches** at national level.

Project Evaluation & Authorisation

Section B-4

Legal requirements

Explain the **processes of project evaluation and authorisation.**

Explain the measures taken to **ensure compliance with the requirements of Article 38** of the Directive, which states that:

- 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;
- 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;

Legal requirements continued

- 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;

Examples of best practices

Report the **measures taken to consider expertise,** including for example, the obligation for the project evaluators to **provide CVs and justifications of competence** to the competent authority, obligation for the project evaluators to follow a **training programme,** and information on this (e.g. minimum duration; type of modules; training objectives; follow-ups), consultation of documents related to project evaluation by the competent authority to **ensure that the required expertise was present** during the evaluation of a project.

- subject to safeguarding intellectual property and confidential information, the project evaluation may **integrate the opinion of independent parties;**

Examples of best practices

Provide **information on the independent third parties** that may be involved in the project evaluation process (e.g. number; expertise; how often are these parties involved and under which circumstances).

- the **project evaluation process shall be transparent.**

Examples of best practices

Take measures to ensure transparency if this is not already the case, and report information on these measures. Examples include publication of the **profile and areas of expertise** of project evaluators; publication of the reasons for **rejecting project applications;** timely publication of **non-technical project summaries,** ensuring that they are clearly written and that they provide all the required information as laid down in the Directive.

Explain the measures taken to **ensure compliance with the requirements of Article 40(2) and (3)** of the Directive, which states that:

- 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;
- project authorisations shall be **granted for a period not exceeding 5 years.**

Best practices

With regard to the measures taken to **consider expertise for project evaluation,** report:

- whether there is a **training programme** for project evaluators, and information on this (e.g. minimum duration; type of modules; training objectives; follow-ups);
- the measures taken to **ensure that the project evaluators have the required expertise and skills** (e.g. providing CVs and justifications of competence to the national competent authority; consultation of documents related to project evaluation by the national competent authority to ensure that the required expertise was present during the evaluation of a project).

Best practices continued

Specify whether project applications are **discussed and reviewed by animal welfare bodies** before submitting the application to the competent authority responsible for the authorisation of projects.

Report information on the **person or body in charge** of verifying that project evaluators do not take part in the evaluation process if their own work is being assessed, and on the **strategy used** to verify this (e.g. oversight by an independent member; inspection by the national competent authority).

Explain how the **different competent authorities interact and coordinate** to ensure consistency and efficiency of the processes (e.g. regular meetings; use of standardised forms).

Section C-1.1.1

Legal requirements

In respect of each year, provide **numbers for all authorisation decisions** and authorised projects.

Retrospective Assessment

Section C-1.2.2

Legal requirements

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 the Directive and the number of projects authorised that are to undergo a retrospective assessment under Article 38(2)(f) of the Directive.

Categorise each of the projects authorised that are to undergo a retrospective assessment 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.

Section C-1.2.3

Legal requirements

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 the Directive that are not automatically subject to retrospective assessment in accordance with Article 39(2).

Enforcement

Section E-1.1

Legal requirements

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

Section E-1.2

Legal requirements

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

Section E-3

Legal requirements

Provide **summary information,** covering the five-year reporting cycle, on **reasons for the withdrawal** of project authorisations.

Section E-2.1

Legal requirements

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

Section E-2.2

Legal requirements

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

Examples of best practices

Report the **effectiveness in terms of impacts** such as declining trend in non-compliance; changes in risk profile of establishments; reduction in legal and administrative actions due to infringements.

Best practices

Regarding the **inspection process**, report:

- the **elements checked during inspections** (e.g. animal housing including ventilation, temperature, lighting, noise; housing conditions including availability of feed and water, stocking densities, bedding, hygiene, enrichment; animal health and care; reports summarising the health monitoring of laboratory animals; compliance of projects with the Directive; advice given by animal welfare bodies);
- the **number of inspectors and their expertise** and/or their (continuing) training;
- whether a **common check-list** is used during the inspection to ensure a coherent approach and to verify that all requirements are considered;
- whether **follow-up inspections** were carried out to ensure that reported deficiencies were resolved.

Indicate whether **information on inspections and enforcement** is made publicly available and, if so, provide the web-address.

Indicate whether establishments authorised to use, breed or supply **non-human primates are inspected at least once per year.**

Section E-2.3

Legal requirements

Explain the measures taken to **ensure compliance with the requirements of Article 34(2)** of the Directive, which states that the **frequency of inspections should be adapted on the basis of a risk analysis** for each establishment, taking account of the number and species of animals housed; the record of the breeder, supplier or user in complying with the requirements of the Directive; the number and types of projects carried out by the user in question; and any information that might indicate non-compliance.

Best practices

Specify the **web-address where the criteria used for risk analysis** can be found.

Section E-4.1

Legal requirements

Provide **summary information,** covering the five-year reporting cycle, on the **nature of** (a) infringements; (b) administrative actions in response to infringements; (c) legal actions in response to infringements.

Education & Training

Section B-3

Legal requirements

Provide information on the **minimum requirements referred to in Article 23(3)** of the Directive, which states that 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 (carrying out procedures on animals; designing procedures and projects; taking care of animals; or killing animals).

Examples of best practices

Specify the **web-address where this information** can be found.

Best practices

Specify the **qualifications required** for carrying out the functions set out in Article 23(2).

Indicate whether the **qualifications and training** of the persons carrying out the functions set out in Article 23(2) are **verified during inspections.**

Specify whether persons carrying out functions set out in Article 23(2) **are supervised in the performance of their tasks** until they have demonstrated the requisite competence.

Report information on the **systems required to ensure maintenance** of competence (e.g. number of mandatory training courses or other activities to maintain competence per year), and on the **person in charge** of ensuring that competence is maintained.

Provide summary information on the **mandatory and/or optional courses and training** for functions mentioned in Article 23(2), including for example, the number of courses and training per year; the minimum duration of the courses and training; and the content of the courses and training programmes.

Describe the **specific training requirements** introduced for persons mentioned in Articles 24, 25 and 38 of the Directive as recommended by the EU Guidance.

Non-human primates

Section C-2.2

Legal requirements

Explain the measures taken to **ensure compliance with the requirements of Article 10** of the Directive when sourcing non-human primates.

Explain the measures taken to **ensure compliance with the requirements of Article 28** of the Directive when sourcing non-human primates, which states that 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.

Section E-1

Best practices

Report the **number of active establishments authorised** to keep and/or to use non-human primates.

Genetically altered animals

Section D-3.1

Legal requirements

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.

Section D-3.2

Legal requirements

List the **criteria used** to ensure that the information in point D-3.1 is representative (i.e. information and numbers regarding species, methods and their related actual severity in respect of tissue sampling for the purposes of genetic characterisation carried out with and without project authorisation).

Examples of best practices

Report the **number of establishments** that were requested to provide information, as well as the **proportion that this represents** in relation to all establishments genotyping animals.

Section D-3.3

Legal requirements

Provide information on **efforts made to refine tissue sampling methods.**

Examples of best practices

List the **efforts made to refine tissue sampling methods** (e.g. use of anaesthetics; replacement of tissue sampling by fur samples, oral swabs or dry blood spot technology; optimisation of breeding programs in order to avoid genetic characterisation with invasive sampling techniques as much as possible; use of flow cytometric techniques for genetic characterisation in order to limit the amount of blood needed when blood is collected from the tail vein; use of surplus material from identification; replacement of tail biopsy by the use of tissue from identification by ear punch; use of co-expressed fluorescent markers to identify transgenic *Danio rerio* in embryonic stages).

EU Guidance and Working Documents

Section D-3.1

Best practices

Indicate if the **EU Guidance on Animal Welfare Bodies and National Committees** has been made available to the members of National Committee and establishment Animal Welfare Bodies.

Indicate if the **EU Guidance on Severity Assessment Framework** has been made available to establishments, project evaluators and inspectors.

Indicate if the **EU Guidance on Project Evaluation and Retrospective Assessment** has been made available to all project evaluators.

Indicate if the **EU Guidance on Inspections and Enforcement** has been made available to all inspectors.

Indicate if the **Working Document on Genetically Altered Animals** has been made available to establishments housing or using genetically altered animals.

Indicate if the **EU Guidance on Education and Training Framework** has been made available to those responsible for education, training and competence in establishments.

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