EUROGROUP FOR ANIMALS

SUMMARY REPORT
THE NETHERLANDS

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.

Based on the answers provided by the Netherlands and other Member States to the EC 2018 survey on the implementation of the Directive, the present summary report provides the following information: **blue check marks** (✓) correspond to elements that were adequately reported by the Netherlands, **red crosses** (✗) correspond to elements that were required by Commission Implementing Decision 2012/707/EU, but were not adequately reported by the Netherlands, and **yellow crosses** (✗) correspond to elements that were not explicitly required by law, but were reported by other Member States or requested by the EC to help clarify any concerns from users and other stakeholders.

In line with this analysis, this report provides recommendations that can improve the Netherlands' 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.** Recommendations under legal requirements will be preceded by a **warning sign** (⚠) for elements that were adequately reported, but where supplementary information is now required by the new Commission Implementing Decision 2020/569/EU.

Competent Authorities

- Information on the framework for competent authorities, including the numbers and types of authorities as well as their respective tasks was reported.
- An organogram summarising the different competent authorities was attached.
- The Netherlands did not explain how the different competent authorities interact to ensure that the Directive is implemented effectively.

Recommendations

Section B-1

Legal requirements

⚠ Explain the measures taken to **ensure compliance with the requirements of Article 59(1)** of the Directive, which states that 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).

National Committee

- Information on the structure and operation of the National Committee was reported.
- Information on the expertise of the members, including in the field of the 3Rs, was reported.
- The Netherlands mentioned that the National Committee fulfils its task to advise the competent authorities and the animal welfare bodies.
- Information on the National Committee's task to share best practice was reported.
- The Netherlands explained how it aims to address coherent approach to project evaluation.
- The Netherlands did not specify whether the members of the National Committee attend training courses related to project evaluation to provide appropriate advice on this topic.

Recommendations

Section B-2

Legal requirements

⚠ 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.

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.

Recommendations 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.

Best practices

Specify whether the members of the National Committee **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.

Animal welfare bodies

- Information on the structure and functioning of animal welfare bodies, including their tasks, was reported.
- The Netherlands reported that there are no additional permanent members beyond those listed in Article 26(2).
- The aspects of the work of animal welfare bodies that function well and that could be improved were reported.
- Information on the measures implemented to ensure that members possess the expertise needed to advise the staff, and whether animal welfare bodies are subject to controls during inspections was missing.

Recommendations

Section C-4

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).

Specify whether concrete measures have been taken since 2018 to **improve the aspects of the work of animal welfare bodies that could be ameliorated,** including whether all categories of breeders, suppliers and users have set up an animal welfare body.

Principles of Replacement, Reduction and Refinement (3Rs)

- General information on the measures taken to ensure that the 3Rs principles are satisfactorily addressed within authorised projects and during housing and care was reported.
- The information that applicants need to provide in their application file regarding the 3Rs principles was mentioned.
- Information on the role of animal welfare bodies in ensuring that the principles of the 3Rs are satisfactorily addressed during housing and care was reported.
- The Netherlands reported that inspectors verify compliance with the codes of practices elaborated by the National Committee.
- In regard to the measures taken to avoid duplication of procedures, the Netherlands reported that the applicant must provide information on this in the project application file.
- The Netherlands did not explain the strategies used by the project evaluators to verify the information submitted by an applicant.
- With regard to the avoidance of duplication, the Netherlands did not specify the information that must be provided by the applicants, and the strategy used by project evaluators to check this information.
- A voluntary report on the Member State's activities in relation to the development, validation and promotion of alternative approaches at national level was not submitted.

Recommendations

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;

Recommendations continued

- **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.

Best practices

Explain 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.

Recommendations continued

- 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).

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.

Best practices

Regarding the **avoidance of duplication,** 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);
- the **strategy used by project evaluators** to check this information.

Section D-1

Best practices

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

Project Evaluation & Authorisation

- ✓ The processes of project evaluation and authorisation have been published.
- ✓ The processes of project evaluation and authorisation were described.
- ✓ The measures taken to integrate the opinion of independent parties were described.
- ✓ Information on how expertise for project evaluation is considered in accordance with Article 38(3) was reported.
- ✗ 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 was missing.
- ✗ Information on the measures taken to ensure that the project evaluators have the required expertise and skills, and whether there is a training programme for project evaluators was missing.
- ✗ The Netherlands did not explain how the different competent authorities interact and coordinate to ensure consistency and efficiency of the processes.

- The Netherlands did not describe how the requirements of Article 38(1), (2) and (4) of the Directive are met.
- The Netherlands did not specify how the requirements of Article 40(2) of the Directive are met.

Recommendations

Section B-4

Legal requirements

Explain the measures taken to **ensure compliance with the requirements of Article 38(1), (2) and (4)** 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;
- 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; 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.

Also, since the **reasons for rejecting project applications** are made publicly available by the Netherlands in the CCD's annual reports, report the web-address where this information can be found.

Explain the measures taken to **ensure compliance with the requirements of Article 40(2)** 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.

Recommendations continued

Best practices

Provide 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 that impartiality is correctly maintained, as well as the **strategy used to check this** (e.g. oversight by an independent member; inspection by the national competent authority).

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).

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).

Retrospective Assessment

- The number of projects submitted for retrospective assessment was reported in respect of each year.
- Information on the types of projects submitted for retrospective assessment was reported in respect of each year.

Recommendations

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 Directive 2010/63/EU that are not automatically subject to retrospective assessment in accordance with Article 39(2).

Enforcement

- In respect of each year, the Netherlands provided numbers for inspections, broken down by announced and unannounced.
- In respect of each year, the Netherlands provided numbers for all active authorised breeders, suppliers and users separately.
- The Netherlands indicated that information on inspections and enforcement is made publicly available.
- Qualitative operational information on the inspection process was reported, including the number of inspectors.

- The Netherlands indicated that the endorsed EU Inspection Risk Analysis Criteria was used as the basis for risk assessment.
- Information on suspensions or withdrawals of authorisations of breeders, suppliers and users, and the reasons therefore was reported.
- The Netherlands reported that there were no withdrawals of project authorisation between 2013 and 2017.
- Information on the nature of infringements, and on the nature of legal and administrative actions as a result of infringements was reported.
- The Netherlands reported that follow-up inspections were carried out to ensure that reported deficiencies were resolved.
- Detailed information on the inspection process, including the elements covered, was missing.
- The Netherlands did not indicate whether establishments authorised to use, breed or supply non-human primates are inspected at least once per year.
- The web-address where the criteria used for risk analysis can be found was not specified.
- Information on the criteria applied under Article 34(2) of the Directive was not reported.

Recommendations

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

With regard to 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);
- whether a **common check-list** is used during the inspection to ensure a coherent approach and to verify that all requirements are considered.

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

Recommendations continued

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.

Education & Training

- The qualifications required for carrying out the functions set out in Article 23(2) were specified.
- The Netherlands indicated that each licence holder must have several persons on site who are responsible for ensuring that the staff are adequately educated, competent and continuously trained, including in the 3Rs, and that they are supervised until they have demonstrated the requisite competence.
- The Netherlands reported that specific training requirements are not introduced for persons mentioned in Articles 24, 25 and 38 of the Directive.
- Summary information on the mandatory and/or optional courses and training for functions set out in Article 23(2) was missing.
- The Netherlands did not provide information on the minimum requirements referred to in Article 23(3) on the basis of the elements set out in Annex V.

Recommendations

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 Article 23(2).

Best practices

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; the content of the courses and training programmes; and the type of training (accredited and/or Member State approved, local or establishment training, other).

Non-human primates

- The number of active establishments authorised to keep and to use non-human primates was reported.
- Information on the measures taken to ensure compliance with the requirements of Articles 10 and 28 of the Directive when sourcing non-human primates was reported.

Genetically altered animals

- The number of animals bred, killed and not used in procedures including genetically altered animals not otherwise reported in the annual statistics was reported.
- Representative information on the efforts made to refine the methods of tissue sampling for the purposes of genetic characterisation carried out with and without project authorisation was reported for toe and ear clipping.
- Information on the criteria used to ensure that the information on the efforts made to refine the methods of tissue sampling for the purposes of genetic characterisation is representative was reported.
- Information on the efforts made to refine tissue sampling techniques for genotyping for methods other than toe and ear clipping was missing.
- For methods other than toe clipping, the Netherlands reported that only the largest users of genetically modified animals were approached in 2017 to provide information on the efforts made to refine tissue sampling techniques for genotyping.

Recommendations

Section D-3.2

Best practices

Report information on the efforts made to **refine tissue sampling techniques for genotyping** for methods other than toe and ear clipping (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).

Request **information on the efforts** made to refine tissue sampling techniques for genotyping from **all establishments** genotyping animals to obtain a comprehensive and accurate dataset.

EU Guidance and Working Documents

- The EU Guidance on Animal Welfare Bodies and National Committees, the EU Guidance on Severity Assessment Framework, the EU Guidance on Project Evaluation and Retrospective Assessment, the EU Guidance on Inspections and Enforcement, the EU Guidance on Education and Training Framework and the Working Document on Genetically Altered Animals have been disseminated.

EUROGROUP FOR ANIMALS

EUROGROUP FOR ANIMALS
Rue Ducale 29 – 1000 Brussels

Tel: +32 (0)2 740 08 20

info@eurogroupforanimals.org

eurogroupforanimals.org

PUBLISHED BY
Eurogroup for Animals in June 2022

AUTHOR
Dr Luísa Bastos
Laurence Walder

EDITOR
Marie Cochet

DESIGN
Blush design agency

@Act4AnimalsEU
@eurogroupforanimals
@eurogroup-for-animals
@eurogroupforanimals