

**EUROGROUP
FOR
ANIMALS**



SUMMARY REPORT BELGIUM

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 Belgium 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 Belgium, **red crosses** (✗) correspond to elements that were required by Commission

Implementing Decision 2012/707/EU, but were not adequately reported by Belgium, 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 Belgium's 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.
- ✓ Belgium explained how the different competent authorities interact to ensure that the Directive is implemented effectively.
- ✓ Belgium reported the measures taken to ensure compliance with the requirements of Article 59(1) of the Directive.



National Committee

- ✓ Information on the structure and operation of the National Committee was reported.
- ✓ Belgium mentioned the expertise of the members, including in the field of the 3Rs.
- ✓ Information on the National Committee's task to advise the competent authorities was reported.
- ✓ Information on the measures taken to ensure compliance with the requirements of Article 49(2) of the Directive was reported.
- ✓ Belgium explained that consistency of project evaluation is ensured by drawing up a common template for project application forms.
- ✗ Belgium did not specify the web-address where the common template for project application forms can be found.
- ✗ Belgium did not indicate 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 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.

Best practices

Specify the **web-address where the common template** for project application forms can be found.

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 measures taken to ensure compliance with the requirements regarding the structure and functioning of animal welfare bodies of Articles 26 and 27 of the Directive was reported.
- ✓ Belgium 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, in particular on the 3Rs, 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 a close cooperation between animal welfare cells, ethical committees and the National Committee has been set up in all establishments, and whether measures have been taken to improve cooperation, consultation and sharing of information between establishments.



Principles of Replacement, Reduction and Refinement (3Rs)

- ✓ In accordance with Articles 4 and 13 of the Directive, information on the measures taken to ensure that the principles of the 3Rs are satisfactorily addressed within authorised projects and during housing and care was reported.
- ✓ Belgium specified the information concerning the principles of the 3Rs that is required in the common template used for project application forms.
- ✓ Belgium reported that breeders, suppliers and users are subject to inspections, and specified the elements that are verified during these inspections.
- ✓ The measures taken to ensure that there is no duplication of procedures were described.
- ✓ A voluntary report on the Member State's activities in relation to the development, validation and promotion of alternative approaches at national level was submitted.

- ✘ Information on the role of animal welfare bodies in ensuring that the principles of the 3Rs are satisfactorily addressed during housing and care was not reported.
- ✘ Belgium did not specify whether seminars, meetings, workshops and/or training days related to the implementation of the 3Rs principles during housing and care are organised.
- ✘ With regard to the avoidance of duplication, Belgium did not specify the strategy used by project evaluators to check the information submitted by the applicants.

Recommendations

Section D-1.2

Best practices

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).

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

Best practices

Regarding the **avoidance of duplication**, report the **strategy used by project evaluators** to check the information submitted by the applicants.



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 ensure impartiality and 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.
- ✔ Belgium specified the measures taken to ensure that the project evaluators have the required expertise and skills.
- ✘ Belgium did not specify whether project applications are discussed and reviewed by animal welfare bodies.
- ✘ Belgium reported that the regional public authorities can evaluate if the required expertise was present during project evaluations, but did not indicate whether this has been done.
- ✘ Belgium did not indicate whether project evaluators follow a training programme.
- ✘ Belgium did not describe how the requirements of Article 38(1), (2) and (4) of the Directive are met.
- ✘ Belgium did not specify how the requirements of Article 40(2) and (3) 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; 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

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.

Indicate whether there is a **training programme** for project evaluators, and information on this (e.g. minimum duration; type of modules; training objectives; follow-ups).

Precise whether regional public authorities have consulted project evaluation reports to **ensure that the required expertise was present during project evaluation** and, if so, report the reasons why this has happened.



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.
- ✓ Summary information, covering the five-year reporting cycle, on the nature of projects selected for retrospective assessment beyond those compulsory under Article 39(2) was reported.



Enforcement

- ✓ In respect of each year, Belgium provided numbers for inspections, broken down by announced and unannounced.
- ✓ In respect of each year, Belgium provided numbers for all active authorised breeders, suppliers and users separately.
- ✓ Belgium indicated that the endorsed EU Inspection Risk Analysis Criteria was used as the basis for risk assessment.
- ✓ Belgium reported that facilities with non-human primates are inspected on a yearly basis.
- ✓ Belgium reported that there were no suspensions or withdrawals of authorisations of breeders, suppliers and users between 2013 and 2017.
- ✓ Information on reasons for the withdrawals of project authorisation was reported.
- ✓ Information on the nature of infringements, and on the nature of legal and administrative actions as a result of infringements was reported.
- ✗ Detailed information on the inspection process, including the elements covered, was missing.
- ✗ Belgium provided a web-address where any published material on inspections and enforcement can be found, but there is no information on the web-site regarding inspections of establishments using animals for scientific and educational purposes.
- ✗ The web-address where the criteria used for risk analysis can be found was not specified.
- ✗ Qualitative operational information on the inspection process was not reported.
- ✗ Information on the criteria applied under Article 34(2) of the Directive was not reported.

Recommendations

Legal requirements

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

Section E-2.2

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.

*Recommendations continued***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.

Specify whether **information is made publicly available on inspections and enforcement** in relation to establishments using animals for scientific and educational purposes.

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

- ✓ Belgium reported that minimal requirements with regard to education and training are formulated in Articles 32 and 33, and Annexes 8 to 12 of the Royal Decree of 29 May 2013 on the protection of experimental animals.
- ✓ Belgium reported that 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.
- ✓ The qualifications required for carrying out the functions set out in Article 23(2) were specified.
- ✓ Summary information on the mandatory and/or optional courses and training for functions set out in Article 23(2) was reported.
- ✓ Belgium indicated that the qualifications and training of staff of users, breeders, and suppliers are verified during inspections.
- ✓ Belgium reported that specific training requirements have been introduced for persons responsible for the welfare and care of animals and for the designated veterinarian, but not for persons responsible for access to information, persons responsible for education, competence and training, and project evaluators.
- ✗ Belgium did not specify the web-address where the Royal Decree of 29 May 2013 on the protection of experimental animals can be found.

Recommendations

Section B-3

Best practices

Specify the **web-address where the Royal Decree of 29 May 2013** on the protection of experimental animals (including its Annexes) can be found.



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 provided.
- ✓ 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.
- ✗ Belgium did not specify the exact number of establishments genotyping animals that were asked to provide information on the efforts made to refine tissue sampling techniques for genotyping.

Recommendations

Section D-3.2

Best practices

Indicate the **exact number of establishments genotyping animals** that were asked to provide information on the efforts made to refine tissue sampling techniques for genotyping.





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 Education and Training Framework and the EU Guidance on Inspections and Enforcement have been disseminated.
- ✗ The Working Document on Genetically Altered Animals has not been made available to establishments housing or using genetically altered animals.

Recommendations

Section D-3.1

Best practices

Disseminate the **Working Document on Genetically Altered Animals** to establishments housing or using genetically altered animals.



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