



SUMMARY REPORT HUNGARY

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

Implementing Decision 2012/707/EU, but were not adequately reported by Hungary, 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 Hungary'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 was reported.
- ✗ Hungary did not specify which competent authority is responsible for the authorisation of establishments.
- ✗ Hungary 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 framework for competent authorities, including the **numbers and types of authorities** as well as **their respective 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

- ✓ 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 missing.
- ✗ Hungary reported that the National Committee's task to share best practice has not been fulfilled because of a lack of resources.

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 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.

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 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**.

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.



Animal welfare bodies

- ✓ Information on the tasks of the animal welfare bodies was reported.
- ✓ Hungary reported that there are no additional permanent members beyond those listed in Article (26).
- ✗ 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.
- ✗ The aspects of the work of the animal welfare bodies that function well and that could be improved were not reported.
- ✗ Information on the structure and functioning of animal welfare bodies was missing.

Recommendations

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(2)**, 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;
- 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.

*Recommendations continued***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)

- ✓ Hungary mentioned that the 3Rs principles are verified during project evaluation, inspections and retrospective assessment.
- ✗ 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.
- ✗ The general measures taken to ensure that the principles of replacement, reduction and refinement are satisfactorily addressed within authorised projects as well as during housing and care, also in breeding and supplying establishments, were not described.
- ✗ The measures taken to ensure that there is no duplication of procedures were not described.

Recommendations

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;

Section D-1.1

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

Recommendations continued

- 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.

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 National Committee 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).



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.

Section D-1.2

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

Recommendations continued

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).

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.

Section D-2

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 National Committee** to check this information.

Best practices

Submit to the European Commission a **voluntary report** regarding Hungary's 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.
- ✗ Hungary did not specify whether project applications are discussed and reviewed by animal welfare bodies.
- ✗ Hungary did not describe how the requirements of Article 38 of the Directive are met.
- ✗ Hungary did not describe how the requirements of Article 40(2) and (3) of the Directive are met.

Recommendations

Legal requirements

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;
- 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, 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.

Recommendations continued

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

Since the **reasons for rejecting project applications** are made publicly available by Hungary, report the web-address where this information can be found.

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.

**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, Hungary provided numbers for inspections, broken down by announced and unannounced.
- ✓ In respect of each year, Hungary provided numbers for all active authorised breeders, suppliers and users separately.
- ✓ Hungary indicated that the endorsed EU Inspection Risk Analysis Criteria was not used as the basis for risk assessment.
- ✓ Hungary reported that there were no suspensions or withdrawals of authorisations related to animal welfare issues.
- ✓ 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.
- ✗ Hungary did not specify whether information on inspections and enforcement is made publicly available.
- ✗ Hungary did not specify whether facilities with non-human primates are inspected on a yearly basis.
- ✗ The web-address where the criteria used for risk analysis can be found was not specified.
- ✗ Qualitative operational information on the inspection process was missing.
- ✗ 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

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.

Recommendations continued

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.



Education & Training

- ✓ General information on the minimum requirements referred to in Article 23(3) of the Directive was reported.
- ✗ The qualifications required for carrying out the functions set out in Article 23(2) were not specified.
- ✗ Hungary did not 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.
- ✗ Summary information on the mandatory and/or optional courses and training for functions set out in Article 23(2) was missing.
- ✗ Information on specific training requirements for persons mentioned in Articles 24, 25 and 38 was missing.
- ✗ Hungary did not indicate whether it has published, on the basis of the elements set out in Annex V, the minimum requirements referred to in Article 23(3) of the Directive.

Recommendations

Section B-3**Legal requirements**

Indicate whether the **minimum requirements referred to in Article 23(3)** of the Directive has been published on the **basis of the elements set out in Annex V**.

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).

Recommendations continued

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.

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

- ✓ The number of active establishments authorised to use non-human primates was reported.
- ✗ Information on how the requirements of Articles 10 and 28 of the Directive are met was missing.

Recommendations

Legal requirements

Section C-2.2

Explain the measures taken to **ensure compliance with the requirements of Articles 10 and 28** of the Directive when sourcing non-human primates.



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.
- ✗ Only the largest genetically modified mouse breeding facility had been requested to provide information on the efforts made to refine tissue sampling techniques for genotyping.

Recommendations

Best practices

Section D-3.2

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

- ✘ Hungary did not specify whether 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 and the Working Document on Genetically Altered Animals have been disseminated.
- ✘ The EU Guidance on Education and Training Framework has not been made available to those responsible for education, training and competence in establishments.

Recommendations

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.

Disseminate the **EU Guidance on Education and Training Framework** to those responsible for education, training and competence in establishments.



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© Eurogroup for Animals, June 2022

PUBLISHED BY

Eurogroup for Animals in June 2022

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