



SUMMARY REPORT CZECHIA

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

Implementing Decision 2012/707/EU, but were not adequately reported by Czechia, 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 Czechia'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.
- ✗ Czechia reported that eight competent authorities are responsible for project authorisation. However, it only indicated the areas of research or the type of research institutions submitting project applications that are approved by the Ministry of the Environment, the Ministry of Agriculture and the Academy of Sciences of the Czech Republic. Information on the areas of research or the type of research institutions submitting project applications that are approved by each of the other five competent state authorities in charge of project authorisation was missing.
- ✗ Czechia did not explain how the different competent authorities interact to ensure that the Directive is implemented effectively.

Recommendations

Section B-1

Best practices

Report the **areas of research or the type of research institutions** submitting project applications that are approved by each of the competent state authorities in charge of project authorisation.

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.
- ✓ General information on the expertise of the members was reported.
- ✓ Information on the National Committee's tasks to advise competent authorities and animal welfare bodies on matters dealing with the acquisition, breeding, accommodation, care and use of animals in procedures was reported.
- ✓ Information on the National Committee's tasks to share best practice was reported.
- ✓ The web-address where reports on the activities of the National Committee can be found were indicated.
- ✗ Czechia reported that details on the information structure and operation of the National Committee are laid down in the Act on the Protection of Animals Against Cruelty, but the web-address where this Act can be found was missing.
- ✗ Information on the expertise of the members in the field of the 3Rs was missing.
- ✗ Czechia reported that the National committee produces documents for expert commissions in charge of project authorisation, but information on these commissions was missing.

Recommendations

Section B-2

Best practices

Provide the **web-address where the Act on the Protection of Animals Against Cruelty** can be found.

Specify the expertise of the members 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.

Provide information on the **expert commissions in charge of project authorisation**, including their composition, expertise and tasks.



Animal welfare bodies

- ✓ General information on the structure and functioning of animal welfare bodies was reported.
- ✓ The animal welfare bodies' tasks were described.
- ✓ Czechia reported that there are no additional permanent members beyond those listed in Article 26(2).
- ✗ 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.

Recommendations

Section C-4

Legal requirements

⚠ Explain the measures taken to ensure compliance with the following requirements regarding the **structure and functioning of animal welfare bodies of Articles 26 and 27** of the Directive:

- 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.

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).

Indicate 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).

Recommendations continued

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)

- ✓ 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.
- ✓ Czechia specified the information regarding the 3Rs that applicants need to provide in their project application form.
- ✓ Czechia reported that compliance with the requirements of the 3Rs is verified during project evaluation, and that the competent authority responsible for project evaluation takes into account expert opinions including in the field of the 3Rs.
- ✓ 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. However, this report relates Czechia's activities up to 2017.
- ✗ Czechia did not specify the strategies used by the project evaluators to verify the information submitted by an applicant, and decide whether the 3Rs principles are satisfactorily addressed.

Recommendations

Best practices

Section D-1.1

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).

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

Recommendations continued

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-1**Best practices**

Submit to the European Commission an updated **voluntary report** regarding Czechia's activities in relation to the **development, validation and promotion of alternative approaches** at national level since 2017.



Project Evaluation & Authorisation

- ✓ The processes of project evaluation and authorisation were described.
- ✓ Czechia explained that project applications are discussed and reviewed by animal welfare bodies before submitting the application to the competent authority responsible for the authorisation of projects.
- ✓ The measures taken to integrate the opinion of independent parties were described.
- ✓ General information on how expertise for project evaluation is considered was reported.
- ✗ The processes of project evaluation and authorisation have been published, but the web-address is no longer accessible.
- ✗ Czechia reported that, in some cases, the opinion of independent third parties is integrated, but information regarding the involvement of these third parties was missing.
- ✗ Czechia did not specify which body or person is in charge of verifying that project evaluators do not take part in the evaluation process if their own work is being assessed, and how this is verified.
- ✗ Czechia did not explain how the different competent authorities interact and coordinate to ensure consistency and efficiency of the processes.
- ✗ Information on the annual number of projects authorised was not reported.
- ✗ Czechia did not describe how the requirements of Article 38(3) and (4) of the Directive are met.
- ✗ Czechia did not specify how the requirements of Article 40(2) and (3) of the Directive are met.

Recommendations

Section B-4

Legal requirements

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

Explain the measures taken to **ensure compliance with the requirements of Article 38(3) and (4) of the Directive**, which states that:

- 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 national 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

- 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 number and 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

Provide the **correct web-address where information on the processes** of project evaluation and authorisation can be found.

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

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, as well as the strategy used to check 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).

**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, Czechia provided numbers for inspections, broken down by announced and unannounced.
- ✓ In respect of each year, Czechia provided numbers for all active authorised breeders, suppliers and users separately.
- ✓ General information on the inspection frequency was reported.
- ✓ Czechia reported that facilities with non-human primates are inspected on a yearly basis.
- ✓ Czechia indicated that the endorsed EU Inspection Risk Analysis Criteria was used as the basis for risk assessment.
- ✓ Czechia 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.
- ✗ Czechia did not specify whether information on inspections and enforcement is made publicly available.
- ✗ 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

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.

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

- ✓ Czechia reported that minimal requirements with regard to education and training are laid down in the Act on the Protection of Animals Against Cruelty.
- ✓ Czechia 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.
- ✗ The web-address where information on the training institutes in Czechia can be found is no longer accessible.
- ✗ Information on specific training requirements for persons mentioned in Articles 24, 25 and 38 was missing.

Recommendations

Section B-3**Best practices**

Provide the correct **web-address where information on the training institutes** in Czechia can be found.

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

- ✓ 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.
- ✗ The number of active establishments authorised to keep and to use non-human primates was missing.

Recommendations

Best practices

Section E-1.1

Report the **number of active establishments authorised** to keep and to use 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.
- ✗ Czechia reported that information on the efforts made to refine tissue sampling techniques for genotyping was obtained from all user establishments, but the exact number of establishments was not specified.

Recommendations

Best practices

Section D-3.2

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

Recommendations

Section D-3.1

Best practices

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



EUROGROUP FOR ANIMALS

EUROGROUP FOR ANIMALS

Rue Ducale 29 – 1000 Brussels

Tel: +32 (0)2 740 08 20

info@eurogroupforanimals.org

eurogroupforanimals.org

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AUTHOR

Dr Luísa Bastos
Laurence Walder

EDITOR

Marie Cochet

DESIGN

Blush design agency

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 @eurogroup-for-animals

 @eurogroupforanimals

