



SUMMARY REPORT ITALY

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 Italy 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 Italy, **red crosses** (✗) correspond to elements that were required by Commission Implementing Decision 2012/707/EU, but were not adequately reported

by Italy, 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 Italy'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 tasks of the competent authorities was reported.
- ✗ Italy did not explain how the different competent authorities interact to ensure that the Directive is implemented effectively.
- ✗ Information on the framework for competent authorities, including the numbers and types of authorities was incomplete.

Recommendations

Section B-1

Legal requirements

Explain the framework for competent authorities, including the **numbers and types of authorities**.



Examples of best practices

- Provide the number of local **competent authorities**.
- **Specify whether** the Technical Scientific Bodies only have an advisory role, or whether they are the competent authority for project evaluation.
- Fill in the table recapitulating information on the **numbers and types of authorities per task**.

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 how the National Committee aims to address coherent approach to project evaluation, and review strategies at national level was missing.
- ✗ Information on the expertise of the members, including in the field of the 3Rs, was missing.

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.

Best practices

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

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 structure of animal welfare bodies was reported.
- ✓ Italy reported that there are additional permanent members beyond those listed in Article 26(2), and provided information on this.
- ✗ The aspects of the work of the animal welfare bodies that function well and that could be improved were not 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.
- ✗ Information on the functioning of animal welfare bodies was missing.

Recommendations

Section C-4

Legal requirements

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

- Member States shall ensure that **each breeder, supplier and user** sets up an animal-welfare body;
- the animal welfare body shall, as a minimum, **carry out the following tasks**: (a) advise the staff dealing with animals on matters related to the welfare of animals, in relation to their acquisition, accommodation, care and use; (b) advise the staff on the application of the requirement of replacement, reduction and refinement, and keep it informed of technical and scientific developments in these fields; (c) establish and review internal operational processes regarding monitoring, reporting and follow-up in relation to the welfare of animals housed or used in the establishment; (d) follow the development and outcome of projects, taking into account the effect on the animals used, and identify and advise on elements that further contribute to replacement, reduction and refinement; and (e) advise on rehoming schemes, including the appropriate socialisation of the animals to be rehomed;
- Member States shall ensure that the **records of any advice given by the animal-welfare body** and decisions taken regarding that advice are kept for at least 3 years.

*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).

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).

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.
- ✓ Italy reported the criteria that are discussed and verified during the technical-scientific evaluation.
- ✓ 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.
- ✓ Italy reported that the advice provided by the animal welfare body is verified during the inspections.
- ✓ Italy explained that applicants must declare in their project application form that the experiments have never been carried out, and that project evaluators carry out appropriate verifications to exclude any duplication.
- ✓ 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 Italy's activities up to 2015.
- ✗ Information on the strategies used by project evaluators to ensure that there is no duplication of procedures was missing.

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;

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

Recommendations continued

- Member States shall ensure that the number of animals used in projects is **reduced to a minimum** without compromising the objectives of the project;
- Member States shall ensure refinement of breeding, accommodation and care, and of methods used in procedures, **eliminating or reducing to the minimum** any possible pain, suffering, distress or lasting harm to the animals;
- without prejudice to national legislation prohibiting certain types of methods, Member States shall ensure that a procedure is **not carried out if another method** or testing strategy for obtaining the result sought, not entailing the use of a live animal, is recognised under the legislation of the Union;
- in choosing between procedures, those which to the **greatest extent meet the following requirements shall be selected:** (a) use the minimum number of animals; (b) involve animals with the lowest capacity to experience pain, suffering, distress or lasting harm; (c) cause the least pain, suffering, distress or lasting harm; and are most likely to provide satisfactory results;
- **death as the end-point of a procedure shall be avoided** as far as possible and replaced by early and humane end-points. Where death as the end-point is unavoidable, the procedure shall be designed so as to (a) result in the deaths of as few animals as possible; and (b) reduce the duration and intensity of suffering to the animal to the minimum possible and, as far as possible, ensure a painless death.

the minimal number of animals necessary to obtain scientifically relevant results, explain whether a collaboration with another laboratory is possible to reduce the number of animals used, indicate the methods used to reduce or eliminate the discomfort experienced by the animals, appropriate breeding strategies for animals with genetic modifications which cause harmful phenotypes to minimise the number of animals suffering from such phenotypes, sharing of tissue and organs either within establishments or via biobanks, information about the refinement of the conditions of accommodation and care during the projects, description of the humane end-points that were set).

- Indicate the **strategies used by the project evaluators to verify** the information submitted by an applicant, and decide whether the 3Rs principles are satisfactorily addressed (e.g. use of a standardised form or a check-list, review of the application by a statistician; use of common databases to verify whether alternative methods are available or appropriate; by staying informed on the latest technical and scientific developments in these fields).

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;

Recommendations continued



(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) that 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).

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.

Best practices

Submit to the European Commission an updated **voluntary report** regarding Italy's activities in relation to the **development, validation and promotion of alternative approaches** at national level since 2015.



Project Evaluation & Authorisation

- ✓ The processes of project evaluation and authorisation have been published.
- ✓ The processes of project evaluation and authorisation were described.
- ✓ Italy specified that project applications are discussed and reviewed by animal welfare bodies before submitting the application to the competent authority responsible for the authorisation of project.
- ✓ Information on how the opinions of independent parties are integrated was provided.
- ✓ In regard to the measures taken to consider expertise for project evaluation, Italy reported that the expertise of project evaluators is evaluated based on their CVs and scientific activities.
- ✗ A login is required to get access to the web-site where the processes of project evaluation and authorisation have been published.
- ✗ Italy did not specify whether there is a training programme for project evaluators.
- ✗ Italy did not explain how the different competent authorities interact and coordinate to ensure consistency and efficiency of the processes.
- ✗ Italy did not describe how the requirements of Article 38 of the Directive are met.
- ✗ Italy did not specify 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;

Recommendations continued

- the competent authority carrying out the project evaluation shall **consider expertise in particular in the following areas**: (a) the areas of scientific use for which animals will be used including replacement, reduction and refinement in the respective areas; (b) experimental design, including statistics where appropriate; (c) veterinary practice in laboratory animal science or wildlife veterinary practice where appropriate; (d) animal husbandry and care, in relation to the species that are intended to be used;
- 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; reasons that explain why **project applications have never been rejected**; 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

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

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).

Provide an open access **web-address where published information regarding the processes** of project evaluation and authorisation can be found.

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



Enforcement

- ✓ In respect of each year, Italy provided numbers for inspections, broken down by announced and unannounced.
- ✓ In respect of each year, Italy provided numbers for all active authorised breeders, suppliers and users separately.
- ✓ Qualitative operational information on the inspection process, including on the effectiveness in terms of impacts, was provided.
- ✓ Italy indicated that the endorsed EU Inspection Risk Analysis Criteria was used as the basis for risk assessment.
- ✓ Italy reported that there were no suspensions or withdrawals of authorisations of breeders, suppliers and users between 2014 and 2017.
- ✓ Italy reported that there were no withdrawals of project authorisation between 2014 and 2017.
- ✓ Italy reported that there were no infringements between 2014 and 2017.
- ✗ Italy did not specify whether information on inspections and enforcement is made publicly available.
- ✗ Detailed information on the inspection process, including the elements covered, was missing.
- ✗ Italy 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.
- ✗ Information on the criteria applied under Article 34(2) of the Directive was not reported.

Recommendations

Section E-2.2

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

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

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

- ✘ The qualifications required for carrying out the functions set out in Article 23(2) were not specified.
- ✘ Italy 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.
- ✘ Italy reported that, at the time of submitting the report (2018), no ministerial decree was issued with regard to the requirements for obtaining, maintaining and demonstrating requisite competence, and the minimum requirements introduced for education and training for functions in Article 23(2).

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).

Examples of best practices

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

*Recommendations continued***Best practices**

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

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

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.
- ✗ Italy mentioned that there are no authorised users, breeders or suppliers of non-human primates, but then reported the number of active establishments using 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 missing.

Recommendations

Section C-2.2

Legal requirements

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

Best practices

If Italy has active establishments keeping non-human primates, then **answer positively** to the question "Do you have any authorised users, breeders or suppliers of non-human primates (NHP) in your Member State?"





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.
- ✗ Italy 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

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 Education and Training Framework, the EU Guidance on Inspections and Enforcement and the Working Document on Genetically Altered Animals have been disseminated.



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© Eurogroup for Animals, June 2022

PUBLISHED BY

Eurogroup for Animals in June 2022

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