



SUMMARY REPORT SPAIN

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 Spain 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 Spain, **red crosses** (✘) correspond to elements that were required by Commission Implementing Decision

2012/707/EU, but were not adequately reported by Spain, 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 Spain'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.
- ✓ Spain explained how the different competent authorities interact to ensure that the Directive is implemented effectively.
- ✗ Spain reported that there are 17 Autonomous Communities in charge of the implementation of the Directive, but that one of the regions has three competent authorities. So, it is unclear whether Spain has 17 or 20 competent authorities in charge of the authorisation of establishments; inspections and project authorisation.

Recommendations

Section B-1

Legal requirements

⚠ Explain the measures taken to **ensure compliance with the requirements of Article 59(1)** of the Directive, which states that Member States may designate bodies other than public authorities for the implementation of specific tasks laid down in this Directive only if there is proof that the body: (a) has the **expertise and infrastructure required** to carry out the tasks; and (b) is **free of any conflict of interests** as regards the performance of the tasks.

Best practices

Precisely report the **number of competent authorities**.



National Committee

- ✓ Information on the structure of the National Committee was reported.
- ✓ Information on the expertise of the members, including in the field of the 3Rs, was reported.
- ✓ General information on the National Committee's tasks to advise competent authorities, to advise animal welfare bodies and to share best practice was reported.
- ✗ Information on how the National Committee aims to address coherent approach to project evaluation, and review strategies at national level 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.
- Indicate whether **reports and/or recommendations are disseminated** in order to promote the principles of replacement, reduction and refinement, and provide the web-address(es) where this information can be found, if applicable.

⚠️ 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 the National Committee **participates in EU National Committee meetings**.

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).



Animal welfare bodies

- ✓ Information on the structure and functioning of animal welfare bodies, including their tasks, was reported.
- ✓ Spain 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

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.
- ✓ Regarding the avoidance of duplication, Spain reported the information that applicants must provide in their project application form.
- ✗ Spain reported that an important effort has been made in training, but detailed information on this training was missing.
- ✗ With regard to the avoidance of duplication, Spain did not specify the strategy used by project evaluators to check the information submitted by the applicants.
- ✗ A voluntary report on the Member State's activities in relation to the development, validation and promotion of alternative approaches at national level was not submitted.

Recommendations

Section D-1.1

Legal requirements

⚠ Provide information on the measures taken to ensure that the **principles of (a) replacement, (b) reduction and (c) refinement are satisfactorily addressed within authorised projects** in accordance with Articles 4 and 13 of the Directive, which state that:

- Member States shall ensure that, wherever possible, a **scientifically satisfactory method** or testing strategy, not entailing the use of live animals, shall be used instead of a procedure;

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

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.

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; and (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.

- 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).

Best practices

Provide information on the **training** related to the implementation of the 3Rs principles during housing and care (e.g. frequency; topics addressed and content; 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.

Section D-1

Best practices

Submit to the European Commission a **voluntary report** regarding Spain'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 for 9 Autonomous Communities.
- ✓ The processes of project evaluation and authorisation were described.
- ✓ Spain indicated 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.
- ✓ Spain reported that the impartiality of the evaluation is ensured by a statement from the members involved in the process.
- ✓ Spain indicated that the expertise of project evaluators is assessed from their curriculum vitae.
- ✗ Spain indicated that the information that must be included in project applications is listed in Annex X of Royal Decree 53/2013, but did not specify the web-address where this Annex can be found.
- ✗ Spain reported that, in some cases, the opinion of independent third parties is integrated, but detailed information on this was missing.
- ✗ Spain 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.
- ✗ Spain differentiated the number of project authorisations and the number of procedure authorisations, but did not explain why and how this distinction is made.
- ✗ Spain did not specify whether there is a training programme for project evaluators.
- ✗ Spain did not explain how the different competent authorities interact and coordinate to ensure consistency and efficiency of the processes.
- ✗ Spain did not describe how the requirements of Article 38 of the Directive are met.
- ✗ Spain 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** 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 web-address(es) where the **identity and profile of project evaluators** can be found; 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

Publish the processes of project evaluation and authorisation for all Autonomous Communities, and provide the web-address(es) where this information can be found.

Specify the **web-address where Annex X** of Royal Decree 53/2013 can be found.

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

Report information on the **person or body in charge** of verifying that ethics committee members do not take part in the evaluation process if their own work is being assessed, and on the **strategy used** to verify this (e.g. oversight by an independent member; inspection by the national competent authority).

Explain the **difference between project authorisations and procedure authorisations**, and why this distinction is made.

Report 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).



Retrospective Assessment

- ✓ 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.
- ✗ Information on the proportion and types of projects submitted for retrospective assessment under Article 38(2)(f) of the Directive beyond those compulsory under Article 39(2) of that Directive was missing.

Recommendations

Section C-1.2.2

Legal requirements

In respect of each year, provide the **number of projects authorised** that are to undergo a retrospective assessment in accordance with Article 39(2) of Directive 2010/63/EU, and the number of projects authorised that are to undergo a retrospective assessment under Article 38(2)(f) of that Directive.

⚠ **Categorise each of the projects authorised that are to undergo a retrospective assessment** as one of the following types: (a) projects using non-human primates; (b) projects involving procedures classified as 'severe'; (c) projects using non-human primates and involving procedures classified as 'severe'; (d) other projects that are to undergo a retrospective assessment.



Enforcement

- ✓ In respect of each year, Spain provided numbers for inspections, broken down by announced and unannounced.
- ✓ In respect of each year, Spain provided numbers for all active authorised breeders, suppliers and users separately.
- ✓ Qualitative operational information on the inspection process was reported, including the criteria applied under Article 34(2) of the Directive.
- ✓ Spain reported that follow-up inspections were carried out to ensure that reported deficiencies were resolved.
- ✓ Spain indicated that the endorsed EU Inspection Risk Analysis Criteria was used as the basis for risk assessment.
- ✓ Information on suspensions or withdrawals of authorisations of breeders, suppliers and users, and the reasons therefore was reported.
- ✓ Spain reported that there were no withdrawals of project authorisation between 2013 and 2017.
- ✓ Information on the nature of infringements, and on the nature of legal and administrative actions as a result of infringements was reported.
- ✗ Detailed information on the inspection process, including the elements covered, was missing.
- ✗ Spain did not specify whether facilities with non-human primates are inspected on a yearly basis.
- ✗ Spain 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.

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.

Specify whether facilities with **non-human primates are inspected on a yearly basis**.

Indicate whether **information on inspections and enforcement** is made publicly available and, if so, provide the web-address.

Section E-2.3

Best practices

Specify the **web-address where the criteria used for risk analysis** can be found.



Education & Training

- ✓ Spain mentioned that information on the minimum requirements for education and training for functions in Article 23(2) is set out in Order ECC/566/2015.
- ✓ Information on the requirements for obtaining, maintaining and demonstrating requisite competence for functions referred to in Article 23(2) was provided.
- ✓ Spain reported that persons carrying out functions referred to 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.
- ✓ Spain reported that specific training requirements have been introduced for persons mentioned in Articles 24 and 25.
- ✗ The web-address where Order ECC/566/2015 can be found was missing.
- ✗ Spain did not provide information on the minimum requirements referred to in Article 23(3) on the basis of the elements set out in Annex V of the Directive.

Recommendations

Section B-3

Legal requirements

Provide information on the **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) **on the basis of the elements set out in Annex V** of the Directive.

Best practices

Indicate the **web-address where Order ECC/566/2015** can be found.



Non-human primates

- ✓ Information on the strategies in place to increase the proportion of non-human primates of F2 or higher was reported.
- ✓ Information on how the requirements of Article 10 of the Directive are being met was reported.
- ✗ The number of active establishments authorised to keep and/or to use non-human primates was missing.
- ✗ Information on the sourcing of non-human primates was missing.

Recommendations

Section C-2.2

Legal requirements

Provide information on the **sourcing of non-human primates**.

Section E-1

Best practices

Report the **number of active establishments authorised** to keep and/or 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.
- ✗ Spain reported that information on the efforts made to refine tissue sampling techniques for genotyping has been requested from all user establishments, but the exact number of establishments was not specified.

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



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