



# **SUMMARY REPORT AUSTRIA**

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

Implementing Decision 2012/707/EU, but were not adequately reported by Austria, 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 Austria'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.
- ✓ Austria mentioned that the competent authorities meet about once a year to share experiences and information on the 3Rs, and that they are supported by official experts in the field of the 3Rs, experimental design, veterinary practice and animal husbandry and care.
- ✗ It is difficult to assess whether all competent authorities (BMBWF + Länder) are in charge of project evaluation, project authorisation, inspection, retrospective assessment and authorisation of establishments, or whether these five tasks are only carried out by the provincial competent authorities (Länder).
- ✗ Austria did not explain how the different competent authorities interact to ensure that the Directive is implemented effectively.

### Recommendations

#### Section B-1

#### 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.
- ✓ Austria reported that the National Committee issued recommendations to the competent authorities and animal welfare bodies on the functioning of animal welfare bodies.
- ✓ Information on the National Committee's task to share best practice was reported.
- ✗ Information on the expertise of the members in the field of the 3Rs was missing.
- ✗ 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.

#### 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 project evaluation**.

**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 whether the members of the National Committee possess **expertise 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 and functioning of animal welfare bodies, including their tasks, was reported.
- ✓ Austria reported that there are no additional permanent members beyond those listed in Article 26(2).
- ✓ The aspects of the work of animal welfare bodies that function well were reported.
- ✗ Information on the measures implemented to ensure that members possess the expertise needed to advise the staff, in particular on the 3Rs, and whether animal welfare bodies are subject to controls during inspections was missing.
- ✗ The aspects of the work of animal welfare bodies 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 could be **improved**.



## Principles of Replacement, Reduction and Refinement (3Rs)

- ✓ Information on the general measures taken to ensure that the principles of the 3Rs are satisfactorily addressed within authorised projects as well as during housing and care was reported.
- ✓ Austria listed the elements that may be requested by project evaluators to provide additional information on methods to replace, reduce and refine the use of animals in projects.
- ✓ Austria reported that animal welfare bodies advise on the implementation of the 3Rs, and ensure adequate and continuous education and training of staff by internal and external training programs.
- ✓ Austria reported that compliance with the use of the 3Rs principles is subject to inspections.
- ✓ The measures taken to ensure that there is no duplication of procedures were described.
- ✗ With regard to the avoidance of duplication, Austria 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;
- 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.

## Recommendations continued

## Section D-1.2

**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.

***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 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.

## 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 an updated **voluntary report** regarding Austria'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.
- ✓ Austria reported that the project evaluation verifies that the project is scientifically or educationally justified, and that the expected harm to the animals is justified by the expected benefit taking into account ethical considerations.
- ✓ The measures taken to integrate the opinion of independent parties were described.
- ✗ Austria did not specify whether project applications are discussed and reviewed by animal welfare bodies.
- ✗ Austria reported that a common check-list is available to ensure that all requirements are considered during project evaluation, but did not specify which criteria is included in this common check-list.
- ✗ Austria did not specify which body or person is responsible for verifying that ethics committee members do not take part in the evaluation process if their own work is being assessed, and how this is verified.
- ✗ The description of how the requirements of Article 38 of the Directive are met was incomplete.
- ✗ Austria 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 following requirements of Article 38** of the Directive:

- 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**: (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; (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***

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.

***Examples of best practices***

**Take measures to ensure transparency** if this is not already the case, and report information on these measures. Examples include publication of the **profile and areas of expertise** of project evaluators; publication of the reasons for **rejecting project applications**; timely publication of **non-technical project summaries**, ensuring that they are clearly written, and that they provide all the required information as laid down in the Directive.

Explain the measures taken to **ensure compliance with the requirements of Article 40(2) and (3)** of the Directive, which states that:

- the **project authorisation shall specify** the following: (a) the user who undertakes the project; (b) the persons responsible for the overall implementation of the project and its compliance with the project authorisation; (c) the establishments in which the project will be undertaken, where applicable; and (d) any specific conditions following the project evaluation, including whether and when the project shall be assessed retrospectively;
- project authorisations shall be **granted for a period not exceeding 5 years**.

**Best practices**

Specify whether project applications are **discussed and reviewed by animal welfare bodies** before submitting the application to the competent authority responsible for the authorisation of projects.

Specify the **criteria included in the common check-list** that is used by the official experts to ensure that all requirements are considered during project evaluation.

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).

## 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, Austria provided numbers for inspections, broken down by announced and unannounced.
- ✓ In respect of each year, Austria provided numbers for all active authorised breeders, suppliers and users separately.
- ✓ Qualitative operational information on the inspection process was reported, including the elements covered during inspections.
- ✓ Austria indicated that the endorsed EU Inspection Risk Analysis Criteria was not used as the basis for risk assessment.
- ✓ Austria reported that there were no suspensions or withdrawals of authorisations of breeders, suppliers and users between 2013 and 2017.
- ✓ Austria 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 number of inspectors and their expertise, was missing.
- ✗ Austria reported that a common check-list is available to ensure that all requirements are considered during inspections, but did not specify which criteria is included in this common check-list.
- ✗ Austria reported that information on inspections and enforcement is not 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 **number of inspectors and their expertise** and/or their (continuing) training;
- whether **follow-up inspections** were carried out to ensure that reported deficiencies were resolved.

Specify the **criteria included in the common check-list** that is used to ensure that all requirements are considered during inspections.

Make information on inspections and enforcement **publicly available**.

### 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

- ✓ Austria reported that persons carrying out functions referred to in points (a), (c) or (d) of 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.
- ✓ Austria reported that the qualifications of all persons involved in a project are checked by the competent authority.

- ✘ 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.
- ✘ Austria 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.

## 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).

#### Best practices

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.



## 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.
- ✘ Austria reported that all users, breeders and suppliers were requested to submit information on the efforts made to refine tissue sampling techniques for genotyping, 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 and the EU Guidance on Project Evaluation and Retrospective Assessment have been disseminated.
- ✗ The EU Guidance on Inspections and Enforcement has not been made available to all inspectors.
- ✗ The EU Guidance on Education and Training Framework has not been made available to those responsible for education, training and competence in establishments.
- ✗ The Working Document on Genetically Altered Animals has not been made available to establishments housing or using genetically altered animals.

### Recommendations

Section D-3.1

#### Best practices

Disseminate the **EU Guidance on Inspections and Enforcement** to all inspectors.

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

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



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