EUROGROUP FOR ANIMALS

SUMMARY REPORT SWEDEN

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 Sweden 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 Sweden, **red crosses** (✗) correspond to elements that were required by Commission Implementing Decision 2012/707/EU, but were not adequately reported by Sweden, 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 Sweden'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.
- Sweden explained how the different competent authorities interact to ensure that the Directive is implemented effectively.

National Committee

- Information on the structure and operation of the National Committee was reported.
- Sweden mentioned the expertise of the members, including in the field of the 3Rs.
- Sweden reported that, as contribution to the harmonisation of the ethical evaluation process, the National Committee is involved in the education of the members of the regional ethics committees and in the development of guiding instructions for the committees.
- Sweden reported that the National Committee holds meetings with the animal welfare bodies in order to support them in their role, analyse difficulties and to harmonise their work.
- Information on the National Committee's task to share best practice was reported.
- Sweden did not indicate whether the members of the National Committee attend training courses related to project evaluation to provide appropriate advice on this topic.
- The web-address(es) where the guiding instructions for the ethics committees can be found were not specified.

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.

Best practices

Specify whether the members of the National Committee **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 the **web-address(es) where the guiding instructions** for the ethics committees can be found.

Animal welfare bodies

- Information on the structure and functioning of animal welfare bodies, and on additional permanent members beyond those listed in Article 26(2) was reported.
- The aspects of the work of animal welfare bodies that function well and that could be improved were 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.

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:

- 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.

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).

Specify whether concrete measures have been taken since 2018 to **improve the aspects of the work of animal welfare bodies that could be ameliorated,** including measures taken to improve the animal welfare body's task to 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.

Principles of Replacement, Reduction and Refinement (3Rs)

- The general measures taken to ensure that the principles of replacement and reduction are satisfactorily addressed during housing and care were described.
- Information on the role of animal welfare bodies in ensuring that the principles of the 3Rs are satisfactorily addressed within authorised projects and during housing and care was reported.
- Sweden reported that applicants need to specify in their application form how they have ensured that there is no duplication of procedures.
- 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 Sweden's activities up to 2017.
- Sweden reported that the implementation of the 3Rs needs to be specified in the application for project authorisation in accordance with Annex VI of the Directive, but detailed information on the data regarding the 3Rs that applicants need to provide in their application file was missing.
- Sweden reported that the regional ethics committees control the compliance of the application with the principles of the 3Rs, but did not specify the strategies used by project evaluators to verify the information submitted by an applicant.
- Detailed information on the avoidance of duplication was missing, including the information that applicants need to provide in their project application form, and the strategies used by the regional ethics committees to verify this.

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;

Recommendations continued

- **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.

Best practices

Report the **information related to the 3Rs principles** that applicants need to provide in their application file (e.g. systematic literature search for alternative methods which do not involve the use of live animals; reasons for not using alternative methods when available, relevance of the animal(s) species chosen, use of appropriate statistical methods to calculate the minimal number of animals necessary to obtain scientifically relevant results, explain whether a collaboration with another laboratory is possible to reduce the number of animals used, indicate the methods used to reduce or eliminate the 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 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).

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

Recommendations continued

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).

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.

Section D-1

Best practices

Submit to the European Commission an updated **voluntary report** regarding Sweden'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 have been published.
- The processes of project evaluation and authorisation were described.
- Sweden reported that, in order to promote consistency in the project evaluation process, the Swedish Board of Agriculture holds training for the members in the committees, and arranges meetings on a regular basis.
- The measures taken to integrate the opinion of independent parties were described.
- Sweden reported that ethics committees are composed of scientists, animal technicians and laypersons as well as a chair with relevant judicial experience, and that designated veterinarians as well as the county board may attend the ethics committees plenary meetings to offer further advice.
- Sweden did not specify whether project applications are discussed and reviewed by animal welfare bodies.
- Sweden reported that researchers in the ethics committees who are involved in a project are not allowed to handle that project or take part in its evaluation process and decision-making, but did not specify who is in charge of verifying that project evaluators do not take part in the evaluation process if their own work is being assessed.
- Sweden did not describe how the requirements of Article 38 of the Directive are met.
- Sweden 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;

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.

- 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 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.

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, as well as 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.
- In some cases, Sweden only provided the title of the project submitted for retrospective assessment and not the reason for its submission.

Recommendations

Section C-1.2.2

Best practices

Specify the **reasons for submitting projects** for retrospective assessment (beyond those compulsory).

Enforcement

- In respect of each year, Sweden provided numbers for inspections, broken down by announced and unannounced.
- In respect of each year, Sweden provided numbers for all active authorised breeders, suppliers and users separately.
- Qualitative operational information on the inspection process was reported.
- Sweden indicated that the endorsed EU Inspection Risk Analysis Criteria is not used as the basis for risk assessment.
- The criteria used for risk analysis as mentioned in Article 34(2) of the Directive, as well as the web-address where this criteria can be found were reported.
- Sweden reported that no information concerning the outcome of inspections and enforcement is made publically available, but the public is allowed to ask for this information from the County Administrative Boards.
- Sweden reported that there were no suspensions or withdrawals of authorisations of breeders, suppliers and users between 2013 and 2017.
- Sweden 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.
- Sweden did not specify whether breeders, suppliers and users of non-human primates are inspected at least once a year.

Recommendations

Section E-2.2

Best practices

With regard to 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 breeders, suppliers and users of **non-human primates are inspected at least once a year.**

Education & Training

- Sweden reported that the minimum requirements referred to in Article 23(3) are laid down in the provisions on Laboratory Animals, are conform to all of the demands in Annex V in the Directive, and refer to the EU guidance document on Education and Training.
- Sweden specified the person in charge of ensuring that personnel is sufficiently educated and trained.
- Sweden reported that specific training requirements for persons mentioned in Articles 24, 25 and 38 have not been introduced.
- Sweden did not specify the web-address where the provisions on Laboratory Animals (SJVFS 2017:40) can be found.
- The qualifications required for carrying out the functions set out in Article 23(2) were not specified.
- Sweden 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.

Recommendations

Section B-3

Best practices

Specify the **web-address where the provisions on Laboratory Animals** (SJVFS 2017:40) can be found.

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.

Recommendations continued

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).

Non-human primates

- The number of active establishments authorised to keep and to use non-human primates was reported.
- 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.
- Information on the sourcing of non-human primates was confusing. On the one hand, Sweden indicated in its 2018 Implementation Report that "the animals are sourced from Asia" (Section C-2. ii.tris), but on the other hand, Sweden indicated in its 2017 annual submission of statistical data on the use of animals for scientific purposes that 19 non-human primates used for the first time were born in America.

Recommendations

Section C-2.2

Best practices

Specify the **origin of non-human primates** (Asia, America or both continents) in accordance with the annual submission of statistical data on the use of animals for scientific purposes.

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.
- Sweden indicated that the questionnaire on the efforts made to refine tissue sampling techniques for genotyping was sent to all establishments working with animals used for scientific purposes, but did not specify the exact number of establishments that this represents.

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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