

Animal Department
Laboratory Animal Unit

Impact assessment proposal for the Swedish Board of Agriculture's Regulations and general guidelines on ethical evaluation of animal experiments

According to the Ordinance (2024:183) on impact assessments, an authority that is considering new or amended rules shall investigate the economic and other impacts of the rules to the extent needed for the particular case and document the investigation procedure in an impact assessment.

Summary of the proposal

Table 1: Table with paragraphs that are contained in the current regulations and which are being amended.

Chapters and sections in the current regulations	Chapters and sections in the new regulations	Amendments with regard to
Chapter 1, Section 8	Chapter 1, Section 3	Updated definitions are proposed.
Chapter 7, Section 2;	-	Repealed ¹ .
Chapter 7, Section 3	-	Repealed.
Chapter 7, Section 7	Chapter 2, Section 5	The requirement for the regional animal experiment ethics committee to check whether there is a relevant operating authorisation is repealed.
Chapter 7, Section 10	Chapter 2, Section 8	An amendment with regard to who is called upon and who is allowed to express their opinion. The inspection authority is removed.
Chapter 7, Section 12	Chapter 2, Section 10	It is proposed that all recipients, except the Swedish Board of Agriculture (SJV), be removed.
Chapter 7, Section 27	Chapter 3, Section 15	Addition of a copy recipient is proposed, the Swedish National Board on research animal ethics is proposed to be added in cases where an animal experiment is to be evaluated retrospectively.

¹ In this context, repeal means that the paragraph is not transferred to these regulations.

Table 2: Table with sections that are new.

Chapters and sections in the new regulations	New section without previous equivalent as regards:
Chapter 1, Section 2	New reference section.
Chapter 2, Section 11	Introduces requirements for the composition of a processing group.
Chapter 2, Section 12	Introduces a requirement for a processing group to prepare a reasoned proposal for a decision.
Chapter 2, Section 13	Introduces a requirement for members who are to serve at a relevant meeting to have access to the processing group's proposal for a decision.
Chapter 2, Section 14	New requirement for the regional animal experiment ethics committees to inform the Swedish Board of Agriculture of matters of fundamental importance.
Chapter 3, Section 17	Allows the chairperson to make decisions alone in cases where no ethics review is carried out.
Chapter 4, Section 6	The proposal allows the regional animal experiment ethics committees to grant exemptions from the keeping rules for the new animal species mentioned in Directive 2010/63/EU.

Table of paragraphs contained in current regulations and relating only to editorial changes; see Table 3 under 1.1.

Background to the draft amendments

The Swedish Board of Agriculture's Regulations and general advice (SJVFS 2019:9) on laboratory animals contain sections on laboratory animals, animal experiments and the ethical evaluation of animal experiments. It is proposed that these regulations be repealed and replaced by two new regulations. This impact assessment examines the proposal for the Swedish Board of Agriculture's Regulations and general guidelines on animal experiment ethics.

The regulations are part of the transposal of Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes.

These regulations are addressed to the regional animal experiment ethics committees (the committees) and their processing of applications for ethical approval of animal experiments. The animal experiment ethics committees are part of the Swedish Board of Agriculture and constitute what is referred to as special branches of activity.

According to the Swedish Board of Agriculture's assessment, the draft regulations have no direct impact on companies, other individuals, municipalities and regions.

1 General

When preparing the impact assessment, account should be taken of the guidance provided by the Swedish National Financial Management Authority. If any part of the analysis cannot be carried out, this must be justified.

The proposal concerns

Companies Other individuals Municipalities Regions The State

1.1 Description of the problem and the change sought, as well as the consequences that arise if no action is taken

The ethical evaluation of animal experiments

The current regulations contain sections on laboratory animals, animal experiments and the ethical evaluation of animal experiments carried out by the committees. Since the regulations are already extensive with many chapters and sections, we propose that the part relating to the animal experiment ethics evaluation be removed and instead be regulated in our own regulations. We believe that this has several positive effects. Among other things, that we can add further sections without the regulations being too extensive. We also raise the status of the committees' ethics evaluation by giving them their own regulations.

Definitions

The definitions have been updated. In the proposal, the terms defined in the sections have also been removed and moved to the section containing definitions. This is to increase readability. If the proposal is not implemented, the opportunity to make the regulations clearer for readers will be missed.

Sections without substantive changes

The sections that follow from Table 3 below have been examined by the Board of Agriculture without finding any reason to change the substance. These sections have only undergone editorial changes and clarifications.

Table 3: Table with sections that are contained in the current regulations and which refer only to editorial changes.

Chapters and sections in the current regulations	Chapters and sections in the new regulations	Editorial changes.
Chapter 2,	Chapter 3,	Editorial change.

Section 16	Section 16	
Chapter 7, Section 1	Chapter 1, Section 1	Editorial change.
Chapter 7, Section 4	Chapter 2, Section 1	Editorial change, the general advice has been removed.
Chapter 7, Section 5	Chapter 2, Sections 2-3.	Editorial change, the general advice has been removed.
Chapter 7, Section 6	Chapter 2, Section 4	Editorial change.
Chapter 7, Section 7	Chapter 2, Section 5	Editorial change.
Chapter 7, Section 8	Chapter 2, Section 6	Editorial change.
Chapter 7, Section 9	Chapter 2, Section 7	Editorial change.
Chapter 7, Section 11	Chapter 2, Section 9	Editorial change.
Chapter 7, Section 13	Chapter 3, Section 1	Editorial change.
Chapter 7, Section 14	Chapter 3, Section 2	Editorial change.
Chapter 7, Section 15	Chapter 3, Section 3	Editorial change.
Chapter 7, Section 16	Chapter 3, Section 4	Editorial change.
Chapter 7, Section 17	Chapter 4, Section 1	Editorial change.
Chapter 7, Section 18	Chapter 3, Section 5	Editorial change.
Chapter 7, Section 19	Chapter 3, Section 6	Editorial change.
Chapter 7, Section 20	Chapter 3, Section 7	Editorial change.
Chapter 7, Section 21	Chapter 3, Sections 8-9.	Editorial change.
Chapter 7, Section 22	Chapter 3, Section 10	Editorial change.
Chapter 7, Section 23	Chapter 3, Section 11	Editorial change.
Chapter 7, Section 24	Chapter 3, Section 12	Editorial change.
Chapter 7, Section 25	Chapter 3, Section 13	Editorial change.
Chapter 7, Section 26	Chapter 3, Section 14	Editorial change.
Chapter 7, Section 28	Chapter 3, Section 18	Editorial change.
Chapter 7, Section 29	Chapter 3, Section 19	Editorial change.
Chapter 7, Section 30	Chapter 3, Section 20	Editorial change.

Chapter 7, Section 31	Chapter 3, Section 21	Editorial change.
Chapter 7, Section 32	Chapter 3, Section 22	Editorial change.
Chapter 7, Section 33	Chapter 3, Section 23	Editorial change.
Chapter 7, Section 34	Chapter 3, Section 24	Editorial change.
Chapter 10, Section 2	Chapter 4, Section 1	Editorial change.
Chapter 10, Section 4	Chapter 4, Section 2	Editorial change.
Chapter 10, Section 5	Chapter 4, Section 1	Editorial change.
Chapter 11, Section 8	Chapter 4, Section 3	Editorial change.
Chapter 12, Section 10	Chapter 4, Section 1	Editorial change.
Chapter 14, Section 6	Chapter 4, Section 4	Editorial change.
Chapter 14, Section 10	Chapter 4, Section 5	Editorial change.
Chapter 15, Section 28	Chapter 4, Section 6	Editorial change.
Chapter 16, Section 10	Chapter 4, Section 6	Editorial change.
Chapter 20, Section 9	Chapter 4, Section 7	Editorial change.
Chapter 24, Section 6	Chapter 4, Section 8	Editorial change.

1.2 Description of the proposed regulation and options considered. Description of the advantages and disadvantages of the different options, and why the proposed regulation is considered most appropriate

Chapter 1. Introductory provisions

Section 2. Reference section to a new regulation on the animal experiment ethics evaluation.

Section 3. The proposal means that the definitions have been collected and adapted to the content of the sections in order to facilitate understanding. The Swedish Board of Agriculture has considered not compiling and

adapting the definitions. The advantage of the proposal is that it makes the sections easier to understand. The disadvantage is that the reader needs to scroll down in the regulation in order to find the definitions. The Swedish Board of Agriculture believes that the proposed alternative is most appropriate as it contributes to increased readability of the sections while at the same time clearly defined concepts facilitate understanding of the sections.

Chapter 2. Organisation and working methods of the regional animal experiment ethics committees

Section 5. The proposal removes the requirement that the committees check the existence of a relevant operating permit. The Board of Agriculture considers that the committees do not need to check whether there is a valid operating permit. It is the responsibility of the experiment manager to ensure that there is a relevant operating permit. This shall be done no later than when an application is made in the Swedish Board of Agriculture's e-service. The Swedish Board of Agriculture has considered not removing the requirement. The advantage of the proposal is that it reduces the administrative burden for the committees. The Swedish Board of Agriculture sees no disadvantages to the proposal. The Board considers that the proposal is the most appropriate as it reduces the administration of the committees.

The Swedish Board of Agriculture estimates that it takes the committee an estimated 15 minutes per application to check that there is a relevant operating permit. In 2024, 344 cases were received, which would yield a time gain of 86 hours per year combining all the committees.

Section 8. The proposal means that the requirement that the inspection authority be notified of the time, has the right to attend and comment at the meetings of the committees has been removed. The Swedish Board of Agriculture has considered not removing the requirements. An inspection authority shall be impartial in its exercise of public authority and the Swedish Board of Agriculture estimates that if an inspection authority takes part and submits opinions in the meetings of the committees, the impartiality may be questioned. The advantage of the proposal is that it reduces the risk of the impartiality of the inspection authority being called into question. The disadvantage of the proposal is that the committees lose the competence that the inspection authority has. The Swedish Board of Agriculture considers that the proposal is the most appropriate as it promotes the impartiality of the inspection authorities.

Section 10. The proposal means that the requirement to send a copy of the minutes of the committee's meetings has been removed for all, except that the minutes must be sent to the Swedish Board of Agriculture. The

inspection authorities already receive a copy of the decisions for the cases handled by the committees and the Swedish Board of Agriculture therefore considers that they do not need to send the minutes. Permit holders also receive the copies of ethical approval decisions that they are affected by and therefore do not need to obtain a copy of the minutes. The Swedish Board of Agriculture believes that this will be an administrative relief for the committees. The Swedish Board of Agriculture has considered not removing the requirements. The advantage of the proposal is that the administrative requirements of the committees are reduced. The Swedish Board of Agriculture sees no disadvantages to the proposal. The Board considers that the proposal is the most appropriate as it reduces the administration of the committees.

Section 11. The proposal reintroduces a previously deleted section on the composition of the processing groups in the committees. The Swedish Board of Agriculture has considered not reintroducing the section. The advantage of the proposal is that the relationship between laypersons and researchers/representatives of those who care for the animals in the preparation group is maintained. The Swedish Board of Agriculture sees no disadvantages to the proposal. The Board considers that the proposal is the most appropriate since the relationship between laymen and researchers/representatives of those who take care of the animals in the processing group is maintained.

Section 12. The proposal entails the reintroduction of a previously deleted section requiring the processing groups of the committees to produce a reasoned proposal for a decision or decision-making documentation. The Swedish Board of Agriculture has considered not reintroducing the section. The advantage of the proposal is that a reasoned proposal for a decision or decision-making documentation is prepared before the decision is taken. The Swedish Board of Agriculture sees no disadvantages to the proposal. The Board of Agriculture considers that the proposal is the most appropriate because a reasoned proposal for a decision or decision-making documentation is created to assist in decision-making.

Section 13. The proposal entails the reintroduction of a previously deleted section stating that the members who are to serve at decision-making meetings shall have access to the reasoned proposal for a decision or decision-making documentation drawn up by the processing group. The advantage of the proposal is that the other members of the committee who did not attend the preparatory work receive a reasoned proposal for a decision or decision-making documentation to study in advance of the decision-making. The Swedish Board of Agriculture sees no disadvantages to the proposal. The Board considers the proposal to be the most appropriate since other members of the committee who did not attend the preparation

process receive a reasoned proposal for a decision or decision-making documentation to consult before taking a decision.

Section 14 The proposal means that a previously deleted section requiring the committees to send decisions on ethical approval of animal experiments that are of principle significance to the Swedish Board of Agriculture is reintroduced. The Swedish Board of Agriculture has considered not reintroducing the requirement. The advantage of the proposal is that the Swedish Board of Agriculture is notified when decisions are made in the committees that are important for the Swedish Board of Agriculture to be informed of. The disadvantage of the proposal is that the administration increases. The Swedish Board of Agriculture considers the proposal to be the most appropriate because it ensures that the Board is informed of decisions of principle significance. The Swedish Board of Agriculture considers that the requirement will entail negligible costs for the committees because these are isolated cases of which the committees need to inform the Board of Agriculture.

Chapter 3. Evaluation by the regional animal experiment ethics committee

Section 15. The proposal means that decisions to be evaluated retrospectively shall be sent to the Swedish National Board on research animal ethics to facilitate their processing. The Swedish Board of Agriculture has considered not introducing the requirement. The advantage of the proposal is that it makes it easier for the Swedish National Board on research animal ethics to obtain the information they need without having to request it at a later stage. For the committees, this should also mean a simplification, as the processing takes place when the case is up-to-date and accessible. The Swedish Board of Agriculture sees no disadvantages to the proposal. The Board considers that the proposal is the most appropriate as it facilitates compliance with the requirements of Directive 2010/63/EU concerning retrospective evaluation.

Section 17. The proposal entails the introduction of a new section to facilitate the administration of the committees by ensuring that cases that are to be dismissed, written off or rectified by clerical errors or the like can be made by the committee's chairperson and do not need to be decided by the committee. The Swedish Board of Agriculture has considered not introducing the requirements. The advantage of the proposal is that the chairperson can make these decisions himself/herself and that the entire committee does not need to meet. The Swedish Board of Agriculture sees no disadvantages to the proposal. The Board considers that the proposal is the most appropriate as it facilitates the administration of the committees.

Chapter 4. The regional animal experiment ethics committee's ability to grant exemptions

Section 6 The proposal provides for the possibility for the committees to grant exemptions from keeping rules for those animal species where new keeping requirements are added in accordance with Directive 2010/63/EU. These species are octopus, zebrafish, sparrow, starling, blue tit and great tit. It is up to the Member States to transpose EU directives. If this is not the case, the Commission may initiate infringement proceedings against the Member State. The proposed amendment must therefore be implemented.

Sections repealed

Chapter 7, Section 2. The proposal removes the information clause concerning animal experiments which are exempt from the requirement for ethical approval of animal experiments. The Swedish Board of Agriculture has considered not removing the informative section. The advantage is that a section that is not relevant to the work of the committees is removed. The Swedish Board of Agriculture sees no disadvantages to the proposal. The Board considers that the proposal is the most appropriate because it removes an unnecessary section.

Chapter 7, Section 3. The proposal means that the informative section stipulating that there is a specific decision regulating, inter alia, how many committees there should be is removed. The Swedish Board of Agriculture has considered not removing the informative section. The advantage of the proposal is that requirements that are not relevant to the work of the committee are removed. The Swedish Board of Agriculture sees no disadvantages to the proposal. The Board considers that the proposal is the most appropriate because it removes an unnecessary section.

Clarification or editorial changes

The following sections in the table below have been examined by the Swedish Board of Agriculture without finding any reason to change the substance. These sections have thus only undergone editorial changes or clarifications.

For the requirements transposed in 2012 which are not currently subject to any substantive change, see the attached Impact Assessment (Annex 1).

Chapter 1. Introductory provisions

Section 1. Editorial change.

Chapter 2. Organisation and working methods of the regional animal experiment ethics committees

Sections 1-3. Editorial change.

Section 4. Editorial change.

Section 6. Editorial change.

Section 7. Editorial change.

Section 9. Editorial change.

Chapter 3. Evaluation by the regional animal experiment ethics committee

Section 1. Editorial change.

Sections 2-7. Editorial change.

Section 8. Editorial change.

Sections 9-12. Editorial change.

Sections 13 and 14. Editorial change.

Section 16. Editorial change.

Section 18. Editorial change.

Sections 19-21. Editorial change.

Section 22. Editorial change.

Sections 23 and 24. Editorial change.

Chapter 4. The regional animal experiment ethics committee's ability to grant exemptions

Sections 1-5. Editorial change.

Sections 7-9. Editorial change.

2 The State

2.1 Description of who is affected by the regulation and how many they are

The six regional animal experiment ethics committees that evaluate applications for ethical approval of animal experiments are affected by these

regulations. The animal experiment ethics committees are part of the Swedish Board of Agriculture and constitute what is referred to as special branches of activity. In addition to the committees, there is also the Swedish National Board on research animal ethics that handles appeals of cases that have been decided by the committees. In addition to appeals, the Swedish National Board on research animal ethics also conducts retrospective evaluations of animal experiments.

There are also 21 county administrative boards that are inspection authorities in the field of animal welfare. For the Swedish Armed Forces, the inspection authority is the Defence Inspector for Health and Environment.

2.2 Description and estimate of the costs and benefits of the draft regulations for

An analysis of the currently applicable sections in the Swedish Board of Agriculture's Regulations and general advice (SJVFS 2019:9) on laboratory animals is set out in Annex 1. An analysis of the new sections and the costs they entail is set out in Chapter 1.2.

2.3 Description and, if possible, a calculation of other relevant impacts

See previous Chapter 2.2.

2.4 Outline of the measures taken to ensure that the draft regulations do not entail costs or restrictions that go beyond what is deemed necessary to achieve the objective

An analysis of the currently applicable sections of the Swedish Board of Agriculture's Regulations and general advice (SJVFS 2019:9) on laboratory animals is set out in Annex 1. An analysis of sections that are new is shown in Section 1.2.

3 Authorisations, etc.

3.1 Information about the authorisations on which the HaV's decision-making power is based

These regulations are prescribed pursuant to Chapter 4, Section 2; Chapter 5, Section 3; Chapter 7, Sections 2, 10, 12 and 18; and Chapter 11, Section 2 of the Animal Welfare Ordinance (2019:66).

3.2 Assessment of whether the regulation is in line with or exceeds Sweden's obligations as a Member State of the European Union

The regulations are part of the transposal of Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes.

In the opinion of the Swedish Board of Agriculture, the proposal does not conflict with the obligations which result from Sweden's accession to the European Union.

3.3 Please state the reasons if the proposal aims at transposing EU directives into national law that go beyond the minimum level of the directive

See above under Section 3.2.

3.4 Assessment as to whether special consideration must be given to the date of entry into force and whether special information initiatives are required

The Swedish Board of Agriculture considers that a transitional period is not necessary.

Specific information activities will be carried out according to a specific communication plan.

3.5 Description of how and when the impact of the draft regulations can be evaluated

Evaluation of the impact of the proposal should be carried out in dialogue with the committees, the experimental animal industry and the inspection authorities. The regulations proposed to enter into force at the end of 2025 will be evaluated in 2027.

4 Consultation

Description of early consultation

Representatives from the following bodies have participated in early consultations in various parts of the regulatory process: the regional animal experiment ethics committees.

Contact

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