



Central Authority for Scientific
Procedures on Animals

Implementation policy for livestock licence applications

*Guideline issued by the Central Authority for Scientific
Procedures on Animals*



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Introduction

One of the Central Authority for Scientific Procedures on Animals' (CCD) key responsibilities is to determine whether project licence applications for animal procedures comply with applicable legislation. This assessment includes an ethical review, weighing the benefit of the research against the harm it causes. The ethical review considers whether the project's objective and achievability justify the harm caused to the animals. All possible interests are taken into account, such as those of the laboratory animal, the target animal, patients, science, society, the economy and the environment.

Since the establishment of the CCD, a number of research proposals aimed at (intensive) livestock farming has been submitted. The Animal Ethics Committee (DEC) and/or the CCD quickly identified recurring dilemmas in this type of application. These particular research projects focused on dealing with negative side-effects of livestock farming, but made little or no contribution to eliminating the underlying causes of those effects. The CCD and DEC's also faced a dilemma when reviewing project proposals focused on optimising the current production systems and making them more efficient. This was especially true for research in areas where the animal's productive capacity had reached its natural limits or was in danger of being exceeded. Both dilemmas relate to the desire to make livestock farming more sustainable, a desire that is increasingly important to society as a whole.

On 18 December 2015, the CCD brought the aforementioned dilemmas to the attention of the then State Secretary of the Ministry of Economic Affairs. In response, the State Secretary requested the [Council on Animal Affairs](#) (RDA) on 8 June 2017 to draft an advisory report to help the DEC's and CCD conduct their ethical review of project licence applications relating to livestock farming.

Disclaimer: This document may contain translations of Dutch legal texts. These are unofficial and for informational purposes only. In case of discrepancies, the original Dutch legislation prevails.

Council on Animal Affairs advisory report

The Council on Animal Affairs (RDA) presented its advisory report (RDA.2018.239 'Animal Procedures in Livestock Research') on 12 October 2018.

In its opinion, the RDA states, based on the 'No, unless' principle as formulated in the Dutch Animals Act (Wet op de dierproeven, Wod), that animal procedures aimed at livestock farming:

1. must contribute directly to the interests of the target animals themselves in the form of improved animal health and welfare;
2. must contribute as far as possible to achieving the best possible balance as regards the objectives of sustainable livestock farming;
3. must contribute actively to finding animal free research models and promoting the 3Rs (Replacement, Reduction and Refinement) of animal procedures.

In CCD's opinion, the advisory report provides valuable support to the entire research chain to ensure that the use of animal procedures for the livestock farming sector is viewed more in the context of a transition towards sustainable livestock farming. The report provides clear recommendations for the assessment of project applications for livestock farming: the CCD can consider whether alternative methods exist outside the context of the project, such as adapting current livestock farming systems. The CCD can also look at how the project application relates to making livestock farming more sustainable. Finally, the RDA clarified the importance that can be assigned to project applications that focus exclusively on symptom management or economic benefits. The recommendations made by the RDA for the assessment of project licence applications are helpful to the CCD in evaluating such projects.

The CCD has therefore taken the RDA's opinion as the basis for formulating its own perspective on the assessment of project licence applications related to livestock farming. This has been translated by the CCD into the implementation policy outlined below.

CCD Implementation Policy

The Act (Wod) holds to the principle that animals have intrinsic value that should be respected. This principle leads to the use of a 'No, unless...' policy when dealing with laboratory animals: animal procedures may not be conducted for a purpose that could also be achieved by means other than animal procedures, or by using an animal procedure that involves fewer animals or causes less discomfort (Article 10(1a) of the Act). Moreover, animal procedures may not be carried out if the importance of the objective does not outweigh the harm experienced by the laboratory animal (Article 10(1c) of the Act). The assessment of project licence applications for animal procedures must therefore include a harm-benefit analysis (Article 10a2(2d) of the Act). In conducting these analyses, the CCD and the DEC's follow the *ethical review framework for the use of laboratory animals*. As a rule, the CCD and the DEC's ask the following question: is the harm caused to animals justified by the immediate objective, (where relevant) the ultimate objective' and the feasibility of the project? To answer this question, it is necessary to identify the project's stakeholders and establish which values it affects positively (benefit) or negatively (harm). This process considers various interests, including those of the laboratory animal, the target animal, patients, science, society, the economy and the environment.

Subsequently, the potential harm and benefits are evaluated and weighed against each other. However, the harm-benefit analysis is not limited to a consideration of different interests. It also includes factors such as the special animal categories and origin of the animals, the 3Rs, discomfort of the animals, the knowledge and expertise of the people concerned, the achievability of the objectives and relevant legislation (as set out in the *ethical review framework for the use of laboratory animals*). If the outcome of the harm-benefit analysis is negative, no licence will be granted for the proposed animal procedures.

In the case of animal procedures for the purposes of livestock farming, it is important to the CCD that the animal procedures contribute directly to improving the health and welfare² of the target animals,³ or that the project contributes to other aspects of increasing sustainability in livestock farming.⁴ For this reason, the CCD assigns only limited importance to economic interests.

In the CCD's view, applications should ideally not focus exclusively on symptom management, as such symptoms can often be addressed more effectively by modifying current livestock farming systems. Consequently, the CCD assigns only limited weight to symptom-oriented approaches.

Symptom management alone may result in a negative harm-benefit analysis, due to the limited weight assigned to such interests. This depends on the level of discomfort experienced by the laboratory animals, the achievability of the objectives and any additional benefits. Additional benefits, such as those listed below, can still generate a positive outcome from the harm-benefit analysis.

1. Contributing to animal-free innovations and/or more refined techniques for current and/or future research.
2. Contributing to sustainable livestock farming, for example in terms of animal health and welfare, public health, nature, the environment and the climate.

The CCD considers these types of benefits to be of significant importance

¹ Both the immediate objective and the ultimate objective are emphasised in the ethical review (see the ethical review framework for the use of laboratory animals). Before an assessment can be made, it must be clear that there is a real, direct relationship between the immediate objective and the ultimate objective: it is likely that the ultimate objective will be achieved in the near future. In the case of fundamental research, however, the relationship between the immediate and ultimate objectives is generally less clear. It is not possible to determine in advance whether the ultimate objective will in fact be achieved. In such cases, the CCD and the DEC's will consider whether the fundamental research may in itself provide sufficient justification for the use of laboratory animals.

² The CCD uses the concept described by D. Fraser (Acta Veterinaria Scandinavica, 2008, 50) to assess animal welfare and considers the broader implications of the concept when making assessments. This consideration includes the following aspects: 1) Health and biological functioning; 2) Affective state of the animal; 3) Expression of natural behaviour.

³ The species used as a laboratory animal does not necessarily have to be the target animal. Where the species used as a laboratory animal is not the target animal, an assessment is made as to whether the use of a different species can generate information that is relevant to the target animal.

⁴ The CCD's definition of sustainability is based on the ambitions mentioned in the Uitvoeringsagenda Duurzame Veehouderij 2023 (Implementation Agenda for Sustainable Livestock Farming) regarding people, animals, nature, the environment and the climate.

Guide for Animal Ethics Committees

When assessing a project licence application, the CCD places great importance on the DEC's advice. The DECs use the ethical framework developed jointly by the CCD and the DECs to perform the ethical evaluation and formulate their advice. In addition to the ethical framework, DECs may consult this guideline when advising on project applications relating to livestock farming. To further support the DECs in this regard, sections of the DEC advice template are explained in more detail below.

In the case of animal procedures for the purposes of livestock farming, the CCD's assessment considers not only whether the project's immediate and ultimate objectives are justified, but also whether the objectives could be achieved by other methods, such as by adapting current livestock farming systems. The CCD expects DECs to consider potential alternatives when assessing livestock farming-related applications, and to include this consideration in their ethical review. It is important to the CCD that a DEC advice makes clear whether this broader context has been considered and, if so, how.

The following section outlines how DECs can make this clear using the DEC advice format.

question C4 - Is the objective of the research justified within the context of the research field?

If the DEC finds that it is possible to assess the application according to a different context, it can also state whether the immediate objective is justified in that other context.

question C5 - Who are the stakeholders in the project?

Here, the DEC identifies the project stakeholders and, for each stakeholder, describes the moral values that are positively or negatively affected. The ethical review framework names some potential stakeholders and identifies values that are positively or negatively affected. Stakeholders can include target groups, laboratory animals and other interest groups or entities that are relevant to the project, such as the environment and society as a whole. It is important to the CCD that animal procedures carried out for the purposes of livestock farming contribute directly to improving the health and welfare of the target animal. For this reason, when assessing applications relating to livestock farming, the CCD asks the DEC to identify the target animal as a stakeholder and to state which of that animal's values are positively or negatively affected. In addition, the CCD asks the DEC to state whether and, if so, how and to what extent the project promotes sustainability in livestock farming. Society in general can also be named as a stakeholder.

question C8 - How realistic is the described feasibility of the project?

Here, the DEC determines whether, as a result of the chosen strategy, the objective can be achieved within the framework of the project. If the applicant lists secondary objectives, such as making livestock farming more sustainable or developing animal-free and/or more refined techniques, the DEC can determine whether the chosen strategy could lead to these secondary objectives being achieved during the course of the project. The DEC can also indicate whether the applicant is in a position to use the knowledge gained from the project to improve animal welfare in future livestock farming systems, or whether other actors would be needed to achieve this goal.

questions C14-C16 - Are the principles of Replacement, Reduction, and Refinement adequately ensured?

Here, the DEC determines whether the applicant has argued convincingly that no suitable alternative methods exist (C14) and that there is a clear strategy to ensure that the project will involve the lowest possible number of animals necessary to achieve a reliable result (C15), and whether the project complies with the requirement to refine animal procedures and is set up in such a way as to prevent or minimise every form of pain, suffering, fear and lasting harm the animals could experience (C16). If the project focuses to any degree on developing animal-free innovations and/or more refined techniques, and if the applicant indicates that the knowledge gained can be applied during the course of the project itself, the CCD asks the DEC to consider this when answering questions C14, C15 and C16.

question D2 - Evaluation of the most important values at stake and the rationale behind this evaluation

Here, the DEC considers whether the social and moral values of each stakeholder, as described in C5, will be positively or negatively affected, relative to each other. It is important to the CCD that animal procedures carried out for the purposes of livestock farming contribute directly to improving the health and welfare of the target animals. For this reason, the CCD assigns only limited importance to symptom management and economic interests. The CCD assigns significant importance to contributions to animal-free innovations and/or more refined techniques for current and/or future research, and to sustainable livestock farming, for example in terms of animal health and welfare, public health, nature, the environment and the climate.

The CCD explicitly **does not** give DECs any instructions as to how the interests and associated values of the various stakeholders should be evaluated and weighed against each other. The DECs use their own ethical considerations to produce their independent advice. However, the CCD does ask the DEC to explain why it has chosen to prioritise a positive effect (benefit) on one stakeholder's values over a negative effect (harm) on those of another.

question D3 - Answering the central moral question

Here, the DEC answers the central moral question, weighing up moral values as described in question D2. In addition, the DEC uses the morally relevant facts assessed in section C, such as the importance of the research (C4), the achievability of the objectives (C8) and the 3Rs (C14, C15, C16).

As stated above, when assessing applications relating to livestock farming, the DEC can indicate whether the immediate objective is justified in a different context (C4); any secondary objectives are achievable (C8); other actors are needed to apply the knowledge gained from the project in practice; and the knowledge gained during the project will lead to replacement and/or refinement (C14/C16). The CCD asks the DEC to explain how all these elements contributed to answering the central moral question, in such a way that the reasoning can be clearly followed without requiring detailed knowledge of the project proposal. The CCD also asks the DEC to show whether it considered the question of whether alternative methods exist outside the context of the project.

question E3 Dilemma's

Here, the DEC can mention any difficulties/dilemmas that arose while assessing the application and preparing the advice, giving sufficient emphasis to whether and, if so, how the DEC examined the application in a broader context. The DEC is requested to provide more explanation on this point.

This is a publication of the Central Authority for Scientific Procedures on Animals (CCD).

The CCD is the sole competent authority in the Netherlands authorised to grant and issue project licences for conducting animal procedures.

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