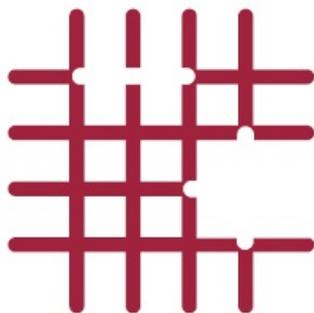


# Animal Procedures for the Livestock Farming Sector

*On the importance of animal welfare,  
sustainability and a research chain approach*



COUNCIL ON  
ANIMAL AFFAIRS

## Minister's engagement letter, 8 June 2017

Reference: DGAN-DAD / 17083493

The Central Authority for Scientific Procedures on Animals (*Centrale Commissie Dierproeven*, CCD) has written to me with a request to contact the Council on Animal Affairs (*Raad voor Dierenaangelegenheden*, RDA) and ask it to produce an advisory report on the use of research animals for the intensive livestock farming sector.

The CCD often finds itself faced with dilemmas when making ethical assessments of research proposals for animal procedures relating to intensive livestock farming. It would like to see the use of animal procedures for the livestock farming sector inserted in the context of a transition towards sustainable livestock farming.

This is why it has asked me to submit the following questions to you:

1. What can be done to ensure that animal research aimed at intensive livestock farming actually contributes to improving the health of humans and animals, without causing further distress for the animals in the longer run?
2. How can we make sure that the consideration of more fundamental changes in the farming system is embedded in the design of research into the problems that result from intensive livestock farming?
3. Are there any areas or themes where the improvement of farming conditions should be given priority from the perspective of the welfare and health of production animals?
4. In which circumstances are animal procedures justified where a solution could also be found in the provision of alternative accommodation, particularly when moderate or severe distress is involved?
5. What, in the RDA's opinion, is the target situation with regard to innovations that are free from the use of research animals? (See the opinion by the Netherlands National Committee for the protection of animals used for scientific purposes (*Nationaal Comité advies dierproevenbeleid*, NCad) on the Transition to Animal-Free Research, December 2016). In any event, it would be desirable to consult the NCad on this last question.

I wish the RDA every success in carrying out this request for opinion.

Yours faithfully,

The Minister of Agriculture

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## Procedure

This advisory report from the Council on Animal Affairs was prepared by a panel of Council members comprising Mr W.T.A.A.G.M. Van den Bergh, A.L. Ten Have-Mellema, Ms M. de Jong-Timmerman, Prof. B. Kemp, Prof. Y.H. Schukken and Dr F.L.B. Meijboom (Chair). The panel was assisted by secretary M.H.W. Schakenraad and deputy secretaries M.J.R.C. Debille and Dr B.B. Houx of the RDA team.

The forum met seven times, on one occasion with the NCad and on another in the presence of the CCD, to prepare this advisory report. In addition, the deputy secretaries held preparatory talks with the experts referred to in Appendix 5.

The draft advisory report was submitted to the entire Council for assessment. Hence, this advisory report is a product of the Council on Animal Affairs as a whole (see p. 44).

# 1. Introduction

## 1.1 Reason for this report

The Central Authority for Scientific Procedures on Animals (*Centrale Commissie Dierproeven*, CCD), the only body in the Netherlands authorised to issue licences for animal procedures (see Appendix 3, Section 10a2 for a description of its duties), has observed an ever-increasing number of complex ethical questions arising in the process of assessing animal procedures for the livestock farming sector. The then Minister took note of this fact and put five specific questions on this subject in a letter to the RDA:

1. What can be done to ensure that animal research aimed at intensive livestock farming actually contributes to improving the health of humans and animals, without causing further distress for the animals in the longer run?
2. How can we make sure that the consideration of more fundamental changes in the farming system is embedded in the design of research into the problems that result from intensive livestock farming?
3. Are there any areas or themes where the improvement of farming conditions should be given priority from the perspective of the welfare and health of production animals?
4. In which circumstances are animal procedures justified where a solution could also be found in the provision of alternative accommodation, particularly when moderate or severe distress is involved?
5. What, in the RDA's opinion, is the target situation with regard to innovations that are free from the use of research animals?

In this report, the RDA presents its opinion on these questions in order to help the CCD weigh up the legitimacy of animal procedures in a fast-moving environment. While the RDA has not included a vision for the future of livestock farming in the report, it does make recommendations for the responsible use of research animals as part of the efforts to promote sustainable livestock farming.

## 1.2 Background and conflicting interests

The subject of animal procedures for intensive livestock farming brings together two topical ethical debates: one which has to do with a vision on livestock farming and one on the responsible use of research animals. The debate on livestock farming is determined largely by a growing need for efficient and high-quality food production, greater attention to

animal welfare<sup>1</sup>, human and animal health, as well as the demand for a reduced environmental impact. It is also reflected in the new vision document 'Agriculture, nature and food: valuable and connected' (Ministry of Agriculture, Nature and Food Quality, 2018). The policy geared towards sustainable livestock farming is based on an integrated approach to meet these needs. Whereas the developments taking place in livestock farming call for assessments, often through research involving the use of animals, the use of animals for research is itself a subject of social debate.

The rules on animal procedures are laid down in the revised Experiments on Animals Act 2014 (*Wet op de dierproeven*, WOD) and European Directive 2010/63/EU. This legislation provides for assessment of the acceptability of all animal research, and for an obligation to replace, reduce and refine (the 3R's) animal procedures to the maximum extent where possible. To supplement the 'no, unless' policy for animal procedures, the Netherlands has recently focused on an accelerated transition to animal-free innovations (for example, see the Letter to Parliament dated 1 June 2018 concerning the Transition Programme for Innovation without the use of animals (*Transitie Proefdiervrije Innovatie*, TPI). This calls for especially careful consideration of the extent to which the use of research animals is actually useful or necessary. Appendix 2 provides a more detailed explanation of the definition of the term 'animal procedure' as well as the procedure for the issuing of licences.

This convergence of the debates on livestock farming and the use of research animals is at the heart of one of the dilemmas raised by the CCD, which faces the question of 'how to treat research involving the use of animals that sustains the intensive livestock farming system' (CCD, 2018: p. 11). Specifically, the CCD indicates that the application procedure and the efforts to achieve the 3R's frequently give rise to problems regarding research that potentially contributes to situations where the production capacity of animals has reached or seems likely to exceed its natural limits. Applications for research which is geared towards treating the symptoms of health and welfare problems, but which ignores or pays little attention to the underlying causes or alternative solutions, also raise concerns (see the example in Box 1).

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<sup>1</sup> The RDA uses the following working definition for animal welfare: 'Animal welfare is the quality of life as it is experienced by the animal itself. An animal will experience a positive state of well-being when it has the freedom to exhibit normal, species-specific behaviour patterns and is able to respond adequately to the challenges that the prevailing circumstances offer.' For a more wide-ranging discussion, see the Conceptual Model for Animal Welfare (*Denkkader Dierenwelzijn*, RDA, 2017).

### ***Box 1. Example: neonatal diarrhoea***

For more than two decades, research has been conducted into ways of addressing the health problems experienced by piglets. The research particularly focuses on piglets that suffer diarrhoea shortly after being weaned. A range of factors make piglets sensitive to infections, which often result in diarrhoea, during the period after weaning. Especially now that the downside of using antibiotics on livestock is known, much research has been focused on combating neonatal diarrhoea, such as by using improved feed or adjusting management and accommodation systems (see Rhouma et al., 2017 for a recent review).

Although the research has already resulted in various practical changes, neonatal diarrhoea remains a major problem for pig farmers. It has given rise to the following questions: to what extent have the animal procedures carried out so far contributed to solving the problem; is an application for research into the effects of yet another feed supplement not simply a way of treating the symptom; and are there no other, more fundamental alternatives (for example, postponing the weaning age or keeping the piglets in lower densities)? The fundamental question in practice is how new research into addressing neonatal diarrhoea should be assessed. Can the use of animal procedures to mitigate this problem within the standard farming system be justified from a social and economic point of view when another option would be to seek sustainable solutions – even if those solutions would in time require the entire sector to change?

The RDA believes that the dilemmas identified by the CCD should be addressed by:

- a) creating a clearer framework for the assessments made by the CCD, which will provide it with more guidance in licensing and will also serve as a framework for consultation with parties in the research chain;
- b) ensuring the direct involvement of partners actively engaged in livestock farming policy and research. The process of designing, applying for and implementing animal procedures tends to require many different steps in the chain. The involvement of all those parties is important if dilemmas or potential dilemmas are to be identified and discussed at an early stage, before the CCD has to decide on them in the actual licensing process. Appendix 4 provides an overview of the steps in the research chain and the partners involved in them;

- c) widening the debate beyond the area of intensive livestock farming. The question of whether and how animal research can contribute to livestock farming is at the heart of the dilemma formulated by the CCD. That question is not limited to a single livestock farming system. A wider debate on the future of livestock farming is required in order to tackle the dilemma.

The Council has answered the questions put in the engagement letter (see p. 2) with due regard for three relevant developments:

- 1) Reduction in the number of animal procedures carried out.** In 2016, the Netherlands National Committee for the protection of animals used for scientific purposes (*Nationaal Comité advies dierproeven*, NCad; see Appendix 3 for a description of its duties) published the 'Transition to Animal-Free Research' advisory report. The report contains guidelines on how best to ensure that the goal of animal-free research is achieved by 2025, by which time the Netherlands aims to become world leader in animal-free innovation (Letter to Parliament dated 1 June 2018, TPI). The NCad also mentions livestock farming in the proposal for an ambitious reduction in the number of animal procedures: 'A clear objective regularly put forward in public discussions is to no longer accept certain animal procedures, such as those involved in research into certain lifestyle-related conditions and research designed to increase the productivity of farm animals in intensive cattle farming.' (NCad, 2016a: p. 22). In addition, the NCad cites the Social Trend Analysis on Animal Procedures (*Maatschappelijke Trendanalyse Dierproeven*) (Athena Institute, 2009): 'The purpose of animal welfare research for the livestock sector – growing technologisation and the treatment of the animal as an object in business practices – may become the subject of criticism.' (NCad, 2016a: p. 48). Just like all other research fields, the livestock farming sector will have to find ways to reduce the number of animal procedures. Appendix 1 provides an overview of the number of animal procedures involving farm animals in recent years.
- 2) Transition to more sustainable livestock farming.** Since the turn of the millennium, increasing attention has been paid to the conflict between the substantial (economic) importance that livestock farming represents for the Netherlands on the one hand and the associated public concerns about its environmental impact in particular on the other. Animal welfare is a frequently mentioned factor, alongside the financial pressure on individual farms, the environmental impact and the public health risks. In the many reports and initiatives that have appeared since then, increasing the sustainability of livestock farming is seen almost unanimously as a necessary step towards an integrated solution.

The Minister's engagement letter shows that the CCD considers it desirable for the use of animal procedures for the livestock farming sector to be placed in the context of a transition towards sustainable livestock farming. Since the term 'sustainable livestock farming' covers several sub-areas and is defined in a variety of ways, the RDA has based this advisory report on a partnership known as the 'Implementation Agenda for Sustainable Livestock Farming' (*Uitvoeringsagenda Duurzame Veehouderij*, UDV), which also includes the Ministry of Economic Affairs as a participant. The various potential sub-areas of sustainable livestock farming are reflected in the 15 ambitions<sup>2</sup> which the UDV defined on 9 April 2013: 'The starting point for determining the ambitions in the sub-areas is the shared awareness that Dutch livestock farming can be sustainable as a whole if it produces animal products and all kinds of other economically or socially desirable assets in a way which is sustainable in both social and economic terms in the long run, which does not harm people and animals, and which does not produce a greater impact than the planet is able to sustain.' (Implementation Agenda for Sustainable Livestock Farming, 2011).

The question as to how animal procedures can contribute to a fundamental improvement of livestock farming is therefore connected to one or more of these sub-areas. To make them readily understood, the 15 points have been condensed here into the main aspects of the environment, animal welfare and veterinary health, public health and the economy.

- 3) **Ethics and welfare.** Welfare is an inseparable element of views on how we should treat animals. Both the revised Experiments on Animals Act 2014 and the Animals Act 2013 (*Wet dieren*) recognise animals as sentient beings that have an intrinsic value. It follows that the use of animals must be justified, and that the animals must be cared for and kept properly. Since the use of animals in animal procedures is by definition accompanied by distress<sup>3</sup>, the revised Experiments on Animals Act provides for additional requirements and supervision in relation to animal welfare and the acceptability of animal procedures, including through the establishment of the CCD.

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<sup>2</sup> The 15 ambitions of the Implementation Agenda for Sustainable Livestock Farming (2013) are Fossil energy; Climate; Biodiversity at the global level; Biodiversity at the national level; Phosphate; Soil quality; Water supply; Water quality; Animal welfare; Animal health; Public health; Local connection; Profitability; Labour; and Knowledge, learning capacity & innovation.

<sup>3</sup> Animal research which does not cause distress to the animals involved is not an animal procedure under the Experiments on Animals Act (Wod); see also Appendices 2 and 3.

However, the recognition of an animal's intrinsic value means that the care provided for animals does not entirely coincide with a focus on animal welfare. Infringing an animal's integrity<sup>4</sup> further than is reasonably necessary should also be avoided (Section 1.3 of the Animals Act). In practice, this requirement means focusing on the acceptability of standard procedures in livestock farming, including interventions such as beak-clipping or tail-docking. In 2013 the RDA published an assessment tool covering such physical interventions in respect of animals, including farm animals.

These developments show that the questions facing the CCD have brought together a number of social debates: (a) the intention to reduce the number of animal procedures, (b) the aim of making livestock farming more sustainable, and (c) the demand for a responsible balance between animal welfare and other sustainability issues.

An additional conflict (d) is the difference between the legislation applicable to research animal science and that applicable to livestock farming. In many cases, the Experiments on Animals Act sets stricter requirements for the accommodation, care and killing of animals than the Animals Act, which applies to animals that are kept for food production purposes. Ambiguities in the rules frequently emerge when animal procedures involving farm animals cause those two worlds to meet. For instance, it is often unclear whether an intervention should be seen as an animal procedure or as a necessary practical action (see also Appendix 2: The frameworks for animal procedures for the livestock farming sector).

One further conflict (e), finally, arises from the international consequences of policy proposed by the Netherlands. Research for the livestock farming sector tends to involve multiple parties, usually in public-private partnerships with an international component. As a result, research and the associated interests can move readily from and to other countries, both within the EU and beyond. Policy developments in animal procedures for the livestock farming sector could have consequences, therefore, for the Dutch economy and particularly its knowledge economy.

The five conflicting interests mentioned above were taken into account when the Council formulated its answers to the Minister's questions. Owing to the diversity among the themes, areas of expertise and interests involved, the Council interviewed a number of relevant stakeholders (see Appendix 5) to obtain a clear picture of the

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<sup>4</sup> In the Conceptual Model for Animal Welfare (*Denkkader Dierenwelzijn*, RDA, 2018), the Council elaborates on the interrelationships and definitions of the terms 'animal welfare', 'intrinsic value', 'natural behaviour', 'adaptability' and 'integrity'.

situation in the field. Those interviews and a number of meetings held by Council members produced a line of reasoning that presents the RDA's opinion on animal procedures for the livestock farming sector point by point. That line of reasoning served as a basis for answering the five questions. The line of reasoning, the answers and the debate that prompted them are at the heart of this opinion.

## 2. The debate in context

Farm animal procedures in themselves are no different from those performed on other animals that are used for research. Legislation that applies to laboratory animals such as rats and mice also applies to cattle or pigs used as research animals. The debate does not primarily concern the animal species, therefore, but rather the ultimate purpose of the research, i.e. contributing to the development of livestock farming. There are two levels to consider in procedures for the livestock farming sector: the one involves considering and assessing the welfare of the research animals, while the other entails considering and assessing the lasting impact of research on the welfare of the target animals in the livestock farming sector. This conundrum influences the assessment made when deciding whether or not to grant a licence in at least two ways. First, there may be procedures where the distress caused to the research animal during the experiment is thought to *benefit* the health and welfare of other animals in future. Humans are the primary beneficiaries in much biomedical research. In research into livestock farming, the primary beneficiaries may be animals. Second, animal research can raise questions when it focuses on aspects of livestock farming such as production efficiency while potentially causing a negative impact on the welfare of the target animals or failing to tackle existing welfare problems.

Both aspects add to the complexity of ethical assessments and lead to complex issues which, as the talks and interviews show, are also perceived as such by the CCD and the Animal Ethics Committees (*Dierexperimentencommissies*, DECs). This means that animal procedures for the livestock farming sector require a clearer vision on the treatment of farm animals as research animals. As well as the developments in livestock farming, the required approach should take account of four other factors: (1) alternatives and animal-free innovations, (2) the international context of the research, (3) the research chain's responsibility and (4) the conflict between target situations and reality. These four factors are explained below.

### 2.1 *The 3R's principle (Replacement, Reduction and Refinement)*

The 'no, unless' principle as laid down in the Experiments on Animal Act is also applied to animal procedures for the livestock farming sector. This means that animal procedures may not be carried out where alternative methods are available. As a result, researchers

first need to find out whether an alternative method is available before being given permission to start an animal procedure.

The preparatory stage presents clear opportunities as far as replacement is concerned. One example is microbiome research, where the initial phase takes place within an existing intestine model in vitro. Moreover, traditional animal models can increasingly be replaced by new techniques, such as computer models and genomics, which will mean using fewer animals in the early phase of the research.

Gains could also be achieved in the area of reduction. The RDA agrees that it is important to accelerate the reduction in the number of animal procedures as described by the NCad in the "Transition to Animal-Free Research" report (2016a). However, this aim should be understood in context. Reduction is not a goal in itself, but should rather contribute to the responsible and effective use of animals for research. In specific cases, this approach may justify allowing more rather than fewer animal procedures, especially if that will help to increase the effectiveness or feasibility of welfare improvements or other essential steps to making livestock farming more sustainable, for example. The CCD can underline the importance of this by including a question in the research application form on how the proposed research will contribute to improving welfare in potential future systems. If the researchers fail to provide a clear vision in their answers, that could be a weighty argument not to issue a licence. However, it is important to point out that even if the research does contribute to improving the welfare of the target animals, researchers are always under an obligation to aim for reduction and are bound by the legislation in force (the revised Experiments on Animals Act 2014 and European Directive 2010/63/EU).

Combining new technology with data from the field (for example, data gathered using modern sensor systems) provides opportunities for reduction as well as refinement. This option is primarily effective during the last phase before application in practice. It is conditional however on the existence of clear rules about the ownership, availability and use of the data.

Another important aspect of the reduction objective is the problem surrounding unused research data. There is still considerable room for improvement in the livestock farming sector, as elsewhere, when it comes to sharing unpublished research data according to transparent, traceable and accessible standards. Commercial research partners, in particular, could be asked to examine data sets critically in order to establish the extent to which their potential competitive sensitivity will permit their being shared. This could be an additional argument in the CCD's deliberations. At the very least, parties could be asked to share negative results. The public accessibility of all results could help to eliminate

unnecessary duplication of research. The recording at the EU level of all animal procedures, all results and humane endpoints<sup>5</sup> can make a substantial contribution to refinement as well as reduction. There is an increasing emphasis on humane endpoints for both animal procedures and veterinary medicine. Since research involving rodents and fish has already resulted in the creation of an online database (<https://www.humane-endpoints.info>), there is a similar desire as regards humane endpoints for farm animals.

Refinement is aimed at limiting distress. However, it is not easy to determine and quantify distress. While this applies to all animal research, research for the livestock farming sector carries additional complexity. Some procedures performed on animals which are regarded as standard and often not particularly taxing by a large part of the livestock farming sector, such as castration, premature weaning or accommodation in isolation, are actually viewed as being stressful for the animals concerned from the animal procedures perspective. Developing more refined techniques which are less stressful for research animals could possibly also lead to changes being made in livestock farming and therefore ultimately help to improve the welfare of the target animals. Examples include new wireless measuring systems, such as a bolus which measures the presence of substances in a cow's rumen without any stressful procedures and constant handling of the animal. Non-invasive systems such as the automatic detection of images and sound provide very promising opportunities for refinement in handling research animals and target animals. It is precisely for this reason that encouraging attention to refinement is important for animal procedures in livestock farming.

Although the research community is making great efforts in the area of refinement for research on behalf of the livestock farming sector, it is important that the entire research chain continues to take a critical and innovative approach in this area. Specifically, this means that steps pertaining to refinement must be presented explicitly in applications for an animal procedure, that the systematic exchange of possibilities is to increase (also at the international level), and that researchers and animal tenders should receive continuous education in the area of innovations relating to the 3R's.

Finally, it is important to mention a fourth 'R': the R that stands for responsibility. This responsibility is borne by all partners involved in animal research. Neither the ethical assessment nor the steps relating to the 3R's should be confined to the activities of a

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<sup>5</sup> Humane endpoints: 'the earliest indicator in an animal experiment of potential pain and/or distress that, within the context of the scientific endpoints to be met, can be used to avoid or limit pain and/or distress by taking actions such as humane killing or terminating or alleviating the pain and distress.' (humane-endpoints.info, 2010, adapted from Hendriksen & Morton, 1999)

handful of stakeholders, such as the CCD, or to a single link in the chain, such as the issuing of a licence. The responsible use of research animals and the development of livestock farming require an integrated approach, where responsibility is shared and borne by all the partners in the research chain (see Appendix 4). This aspect is elaborated in Section 2.3.

## ***2.2 The international context***

There are three reasons why research in the area of livestock farming must be regarded within its international context. First, the livestock farming sector is part of an international market, where technological or regulatory developments elsewhere in the world have an impact on local production. Second, the Netherlands is very active at the international level in research for the livestock farming sector. Dutch businesses and institutes carrying out such research often operate internationally as well, while foreign businesses are regularly successful in finding Dutch research institutes to carry out research. Third, the international context is important given the European legal framework that applies to animal research.

Since the Netherlands is a front runner in the efforts to create a society with animal-free research and sustainable livestock farming, a number of stakeholders fear that stricter procedures for animal procedures in the Netherlands will lead to research moving abroad. Although such a scenario is not improbable, its scale remains unclear. Conversely, the high standard of Dutch research also attracts assignments from abroad, often involving specific welfare or health problems which are not directly relevant to the Dutch situation. Examples include animal research directed at veterinary health problems constituting a problem mainly in Africa or Asia, or at zoonoses which are not directly relevant to the Dutch context. For instance, whereas research into an innovative treatment for *Streptococcus agalactiae mastitis* is not relevant to animal health in the Netherlands, it is hugely important to animal health and food quality in many countries where livestock farming is developing. Vigilance is required to ensure, in these types of research, that animal research animals does not result in a reduced welfare level of the target animals, or result in the preservation of sub-optimal systems. At the same time, this type of research provides opportunities for innovation in sustainable livestock farming or in the area of alternatives to animal procedures. To that end, it is important to take and maintain a leading position in these developments, without losing its connection with the international playing field.

## ***2.3 The research chain's responsibility***

Developing and using alternatives to research animals, as well as developing sustainable livestock farming systems, require an integrated approach in which the responsibility for both objectives is borne by the entire research chain, from funding and initiating research

to operationalising and implementing it (see also Appendix 4). To this end, the partners in the research chain first need to become aware of their shared responsibility. They will also be required to play an active role, partly in view of the importance attached by society to reducing the number of animal procedures and to making livestock farming more sustainable.

This cooperation between all the partners in the chain and their shared responsibility must be translated into research where existing knowledge and experience are actively used and shared, on the basis of synthesis or evidence<sup>6</sup>. Partners in the chain who are actively involved in efforts to make livestock farming sustainable will be required to ensure that research responds better to developments in areas such as animal welfare, the environment and the economy. This could be achieved if the financial backers of research take responsibility; for example, by putting additional questions to the partners involved or setting additional requirements for them as regards the contribution that the research will make to developing alternatives for animal procedures and to making livestock farming more sustainable. The current financial policy for research on behalf of the livestock farming sector through cooperation between various research institutions and private parties already provides that opportunity. In addition, participating businesses and research institutes could take steps by sharing their innovations in the use of research animals and in livestock farming with other partners, as well as by communicating them through annual reports and other CSR documents<sup>7</sup>. More space must also be included in the project applications assessed by the CCD for questions on how the research will contribute to providing alternatives for animal procedures and to making livestock farming more sustainable.

## ***2.4 The conflict between target situations and reality***

The factors referred to in the sections above influence the assessments that form part of the licensing process for every animal procedure. Every scientific research project covered by the Experiments on Animals Act must involve an assessment in which the objective of the procedure is weighed against the distress that the animals concerned are expected to suffer. There are two reasons that make such assessments especially complicated for the

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<sup>6</sup> Synthesis of evidence (SoE): 'SoE is the synthesis of relevant literature and expertise in order to arrive at scientific, well-substantiated and accessible summaries of the information that is available before research commences. This is essential for substantiating the choice of the most relevant research model. It also assists in preventing unnecessary duplication of research and in choosing the correct experimental design, particularly (though not only) in relation to animal models.' (NCad, 2016b)

<sup>7</sup> CSR instruments: standards which enable organisations to give formalised expression to corporate social responsibility focused on the 3P's: economic performances (profit) with respect for social interests (people) and the environment (planet).

livestock farming sector. First, there is no unambiguous measurement of the research purpose. While much biomedical research focuses on improving human health, research for the livestock farming sector often affects several interests at the same time, such as public health, the environment, animal welfare and production efficiency. All those interests are included in the deliberations surrounding livestock farming as the target of the procedure. How those interests are weighed, however, is in part dependent on a person's vision of the desirable development of livestock farming. This is a complicating factor, since at the moment there is no consensus on that vision in the Netherlands. Second, the assessment is not restricted simply to discussing and balancing the interests of humans against those of the research animals. Research for the livestock farming sector will often also have the objective of contributing to the current and future health and welfare of animals in that sector. In that light, the interests of the research animals will have to be weighed against those of animals in the livestock farming sector.

Things become even more complicated when the research is aimed at alleviating existing health and welfare problems on the one hand, while it is at odds with the target situation of sustainability, including animal welfare, on the other. Examples include research into animal feed to alleviate health problems which are caused in part by accommodation issues. This type of research could result in health benefits even though the underlying problem remains unsolved. More complex still is an assessment for research focusing on innovations for sustainable livestock farming which could bring about substantial improvements in the area of public health or the environment, but would cause even more harm to the interests of the animals kept. One example would be an assessment where research aimed at substantially reducing the environmental impact of, and particulate matter produced by, a livestock farming system involves little distress for the research animals but has a negative impact on animal welfare.

The Council is aware that these choices are often far from simple. However, it is important to make those trade-offs explicit at an early stage in the process when the research is agenda is set and its design laid out, rather than setting them aside until the point when the CCD has to decide whether or not to issue a licence. The objective is to optimise the interests of all those involved and to put the target animals at the forefront in the process. Active involvement of all the partners in the research chain could encourage them to look for alternatives and innovations that are also in the best interests of the target animals from the very beginning of the planning process for an animal procedure. The CCD should retain responsibility for making an independent assessment. Making deliberations explicit at an earlier stage in the chain can avoid situations where the balancing process does not take place until after many decisions, including moral decisions, have already been taken and little practical room for manoeuvre remains.

The following chapter sets out the building blocks of the Council's line of reasoning as taken in the advisory report on animal procedures for the livestock farming sector.

### 3. Building blocks of the line of reasoning

As animal procedures for the livestock farming sector require careful consideration by all parties involved, delivering an opinion is often no straightforward matter. The RDA nevertheless believes it is possible to guide the debate while doing justice to the diversity of interests and visions. The interests of the animal, in particular, should play a central part in this regard. In the following line of reasoning, there are several separate steps that combine into a coherent and integrated approach, starting from the current 'no, unless' policy with regard to animal procedures. Within the framework thus created, justice can be done to (a) the interests of the animal, (b) possibilities and developments in the livestock farming sector, and (c) the ambitions in the area of animal-free innovations. Based on the building blocks of this line of reasoning, the questions put by the Minister are answered in Chapter 4.

Animal procedures for the livestock farming sector must:

1. contribute directly to the **interests of the animal** species concerned, by improving the health and welfare of animals in the livestock farming sector.
  - In this vision, the 'no, unless' principle is used as the point of departure. If the interests of the target animals are harmed, but there are evident benefits for other sustainability objectives within livestock farming, both the applicant and the CCD must make an ethical assessment in which the interests of the target animals are weighed against the other sustainability objectives in the livestock farming sector;
2. contribute as much as possible to an optimum balance between the objectives of **sustainable livestock farming**. In addition to animal welfare and veterinary health, this involves objectives pertaining to the environment, public health, food security and the economy, among other things (see Bos, 2010, as well as the transition to circular agriculture: Ministry of Agriculture, Nature and Food Quality, 2018).
  - The mere treatment of symptoms, or an economic interest alone, is not sufficient reason to authorise an animal procedure. However, such objectives combined with other objectives could be an argument in favour of authorisation. In cases where those objectives call for an assessment, point 1 will be regarded as a minimum requirement in relation to animal welfare. The relative weight assigned to each of those objectives of sustainable

livestock farming is a matter of support and debate. By organising and encouraging such a debate with the sector and the government, the CCD will be better able to provide guidance during assessments of the various interests;

3. contribute actively to **animal-free innovations** and the **3R's** (Replacement, Reduction and Refinement).
  - Including this aspect during the research design phase and agenda-setting enables innovations to be explored and applied, while it also improves the awareness of this matter among all the parties involved.

Based on these three point of departure, the Council recognises:

4. that it takes time to develop and disseminate sustainable innovations. Given the major impact on many animals, it remains necessary to allow procedures aimed at **improving** welfare and health in the **current** (intensive) **factory farming system**. In such situations as well, applicants should demonstrate the extent of the project's contribution to sustainability in livestock farming and explain how the knowledge generated by it can and will be applied in future systems. This could ensure that research is not limited to treating symptoms but also focuses actively on the underlying issues and system innovation;
5. that animal procedures for livestock farming often imply procedures involving the **target species**. While replacement (one of the 3R's) is a guiding principle, research on the target animal can make an important contribution to improving animal welfare in sustainable livestock farming. **Accelerating** the transition towards a more sustainable livestock farming system, which also has the potential to improve animal welfare levels, will require the deployment of animal-free innovations and policy to improve the quality of procedures involving the target species itself rather than aiming for a reduction in the number of animal procedures. A strict criterion for quality improvement is that the procedure must demonstrably benefit the health and welfare of the target species (for example, see Bos et al., 2017) and at least one of the sustainable livestock farming objectives, rather than economic interests alone;
6. that the **international effects** (at least within the EU) on sustainable livestock farming and the use of research animals must also be taken into account. Among other things, this requires scope for research into innovations for sustainable livestock farming in countries outside the Netherlands and an alertness to research possibly being relocated abroad as a result of stricter regulation in the Netherlands. As a pioneer, it is important for the Netherlands to seek cooperation with other innovative international partners and not to become isolated from the international playing field.

To operationalise the line of reasoning, the Council makes the below recommendations:

1. In the application form for livestock farming projects, the CCD should include an explicit question asking the applicant to demonstrate the extent of the project's contribution to sustainability in livestock farming and to explain how the knowledge acquired can be used to improve animal welfare in future systems. This information must be included in the assessment, and may help ensure that the research is not limited to treating symptoms but also focuses actively on the underlying issues and system innovation.
2. In its assessments, the CCD should involve partners from the research chain and expert bodies on sustainable livestock farming with a view to (1) activating the debate about targets and best practices for reducing the use of research animals and promoting sustainability in livestock farming, (2) creating support, and (3) making agreements on the direction and implementation of research aimed at promoting sustainability in livestock farming.
3. The CCD should assist in making the 3R's more specific. It is especially important for research into existing systems to insist on alternatives so as to encourage innovation for both animal procedures and the system used in practice. This could be achieved by demanding this explicitly in applications. In addition to the aforementioned consultation with partners in the research chain and experts in the areas of the 3R's and sustainable livestock farming, the NCad's external contribution will be important in this context.
4. The Minister should promote the development of a clearer vision on the relationship between animal welfare and other sustainability objectives in livestock farming, by facilitating the debate on an overall vision in animal sectors where development has already begun, and initiating it where necessary. Such a vision could form the basis for a document that would offer the CCD further guidance when making its assessments.
5. The Minister should actively encourage the entire research chain for livestock farming to consider animal-free innovations. One way of achieving this would be to request more information throughout the process, from funding and initiating research to submitting an application to the CCD.
6. The entire research chain should take responsibility for developing and applying alternatives; for example, by monitoring the development of alternatives, investing in development and openly exchanging innovations. It is also important to maintain contact with the international playing field, for instance by seeking cooperation with other forward-thinking international partners.
7. The entire research chain should account in a transparent way for the contribution that it has made to a more animal-friendly and sustainable livestock farming

system. This should not only be reflected in annual reports but also in the process of setting research agendas (as part of the Top Sector policy, for example, and the agendas of the Netherlands Organisation for Scientific Research (NWO) and private parties), research design and project applications for animal procedures. The CCD could ask explicit questions about this in the assessment of applications and include the information in the assessment.

## 4. Answering the Minister's questions

Set out below are the answers to the questions put by the then Minister, based on the building blocks provided (Chapter 3) and taking the line of reasoning outlined above as a point of departure. The interests of the animal are accorded a central position in agenda setting and in research design, while the research must contribute to the objectives of sustainable livestock farming and the 3R's. This is a responsibility shared by all the partners involved in animal research. To this end, the advisory report should not be seen as an opinion for a few stakeholders such as the CCD, or being limited to a single moment in the process, such as the decision whether or not to issue a licence. The responsible use of research animals and the development of livestock farming call for an integrated approach, where responsibility is shared and borne by all partners in the chain involved in animal research in particular.

**Question 1:** *“What can be done to ensure that animal research aimed at intensive livestock farming actually contributes to improving the health of humans and animals, without causing further distress for the animals in the longer run?”*

### **Answer 1:**

Given the complexity described in the previous chapters, it is not possible to provide such assurance in every case. However, the RDA does think it desirable and possible to take several specific measures that would have animal procedures make larger and better contributions to reducing distress among animals of livestock farming species.

The starting points recommended by the RDA are as follows:

- a) Animal procedures must contribute directly to improving the health and well-being of the target animals concerned. The 'no, unless' principle is the point of departure and remains the target situation.
- b) This does not mean that a procedure could not also promote other interests related to humans or the environment (see also the answer to Question 2). If a procedure cannot contribute directly to the interests of the animal species but has evident

advantages for other sustainability objectives within livestock farming, both the applicant and the CCD must make an ethical assessment in which they weigh the interests of the target animals against the other sustainability objectives in the area of livestock farming. It is also important that both the Minister and the CCD promote the assessment frameworks that they have in mind as clearly as possible.

- c) A greater focus on innovations in the area of the alternatives (the 3R's) is required. This is not only important for the research animals themselves, but may in time also help to reduce distress among animals used in livestock farming.

The RDA makes the following recommendations on this point:

1. In the application form for projects aimed at livestock farming, the CCD should include an explicit question asking the applicant to demonstrate the extent of the project's contribution to the sustainability of livestock farming and to explain how the knowledge acquired can be used to improve animal welfare in future systems. This information must be included in the assessment and may help to ensure that the research is not limited to treating symptoms but also focuses actively on the underlying issues and system innovation.
2. The Ministry of Agriculture, Nature and Food Quality should promote the development of a clearer vision on the relationship between animal welfare and other sustainability objectives in livestock farming, by facilitating the debate on an overall vision in animal sectors where development has already begun, and initiating it where necessary. Such a vision could form the basis for a document that would provide the CCD with further guidance when making its assessments.
3. The entire research chain should account in a transparent way for the contribution that it has made to a more animal-friendly and sustainable livestock farming system. This should not only be reflected in annual reports but also in the process of setting research agenda (as part of the Top Sector policy, for example, and the agendas of the Netherlands Organisation for Scientific Research (NWO) and private parties), research design and project applications for animal procedures. The CCD should ask explicit questions about this matter in the assessment of applications and include the information in the assessment.

**Question 2:** *'How can we make sure that the consideration of more fundamental changes in the farming system is embedded in the design of research into the problems that result from intensive livestock farming?'*

**Answer 2:**

The term 'fundamental changes' is open to interpretation. The RDA interprets it as meaning 'sustainable changes', bringing the answer into line with the frameworks for the development of sustainable livestock farming.

The guiding principles recommended by the RDA are as follows:

- a) Animal procedures should contribute as much as possible to an optimum balance between the various objectives of sustainable livestock farming, such as animal welfare and animal health, the environment, food security and the economy. The treatment of symptoms or an economic interest alone is not sufficient reason to authorise an animal procedure. Such objectives can be justified only when combined with objectives of a different nature, which together would justify the authorisation of the animal procedure. The 'no, unless' principle is the point of departure, and a direct contribution to the animal species remains the target situation. While departures from this principle are possible, both the applicant and the CCD will have to make an integrated ethical assessment of the interests of the target animals as well as the evident benefits of the other sustainability objectives in the area of sustainable livestock farming to justify any such departure.

On this point, the RDA makes the following recommendations to the CCD:

- a. In its assessments, the CCD should actively involve partners from the research chain and expert bodies on sustainable livestock farming with a view to (1) activating the debate about targets and best practices for reducing the use of research animals and promoting sustainability in livestock farming, (2) creating support, and (3) making agreements on the direction and implementation of research aimed at promoting the sustainability of livestock farming.
- b. This assessment should be followed by a joint clarification on the relative weight accorded to the various objectives of sustainable livestock farming. The purpose of this debate is to provide clearer guidance during the assessment of the various interests within the research chain.
- c. In the application form for projects involving animal procedures for the livestock farming sector, the CCD should include questions on (a) the embedding of the project in the wider context of sustainable livestock farming, and (b) the use of results from previous research as well as the use of available databases containing data not published in scientific journals. This will encourage partners in the research chain to make an active

contribution, and enable the CCD to draw attention to the relationship between the proposed project and the need to promote animal-free innovations and sustainability in livestock farming.

- d. The CCD should be left with the final assessment of the distress suffered by research animals versus the importance of the procedure, also in terms of the contribution to the development of sustainable livestock farming. Given the complexity and the interests at stake, the CCD must actively use external contributions from expert bodies on sustainable livestock farming.

**Question 3:** *“Are there any areas or themes where the improvement of farming conditions should be given priority from the perspective of the welfare and health of production animals?”*

**Answer 3:**

Livestock farming research is often aimed at the ad hoc mitigation of welfare and health problems. According to the RDA, new scientific insights into animal welfare focusing on positive well-being and quality of life (see footnote 1 on page 6 and the RDA's advisory report on the Conceptual Model for Animal Welfare, 2017) should be considered a priority in the pursuit of a fundamental improvement of farming conditions, with a minimum of physical interventions and medication.

The starting points recommended by the RDA in this regard are as follows:

- a. The development of new standards for improved animal welfare and their rapid adoption in sustainable farming systems should be the main priority in research so as to increase overall welfare levels among larger numbers of animals more quickly and more effectively. Those standards should also be considered a priority when adjustments are made to existing farming systems, on the understanding that efforts to improve those systems should not detract from the urgent need to pursue more sustainable alternatives (Point 4 of the line of reasoning).

The RDA also makes the following recommendations on this point:

1. In the application form for projects aimed at livestock farming, the CCD should include an explicit question asking the applicant to demonstrate the extent of the project's contribution to increasing animal welfare and the sustainability of livestock farming and to explain how the knowledge acquired can be used to improve animal welfare in future systems. This answer must be included in the assessment, ensuring that research focuses actively on underlying issues and system innovation.

**Question 4:** *“In which circumstances are animal procedures justified where a solution could also be found in alternative accommodation, particularly when moderate or severe distress is involved?”*

**Answer 4:**

To answer this question we need to consider the difference between the debate on the future of livestock farming and the one on the responsible use of research animals. In the latter context, the existence of real and qualitatively comparable alternatives means, under the current legislation, that a procedure should not be performed. In the context of future livestock farming, alternatives to the traditional livestock farming systems are available and permitted by law. However, the question on the merits of the various accommodation systems available as a realistic target situation for livestock farming is highly complex and cannot be answered by the CCD alone. To this end, it is crucial that we have a wider-ranging debate on this subject so as to identify alternatives that could also be used within livestock farming as a benchmark for the pursuit of animal-free innovations and animal research assessments.

If there is an alternative in the form of a different livestock farming system, whether or not its use is justified will be determined by the extent to which the procedure contributes to the first two steps of the line of reasoning: the health and welfare of the animal species, and the sustainability of livestock farming. There are three possible scenarios:

1. a high score on both could justify research even if alternative systems are available;
2. a low score on both would render the research undesirable and make it difficult to justify;
3. a low score on one of the two aspects, either because the research makes a demonstrable contribution to the health and welfare of animals within an existing system, while overlooking alternative accommodation systems, or because the research largely ignores welfare problems but nonetheless make a demonstrable contribution to other sustainability objectives such as public health or the environment. In both cases, both the applicant and the CCD will have to weigh the interests of the target animals against the future gains in terms of health or welfare for the animal species.

In this regard, the RDA recommends the following:

- a) Organise a wide-ranging and critical debate within the entire chain, facilitated by the CCD and the government, with the aim of considering (1) how realistic the available alternatives are in view of the practices and objectives of the livestock

farming sector, and (2) how innovation can help to accelerate the development of alternatives.

- b) The emphasis in this debate should be on the consideration that
- animal procedures may still be necessary in the context of the efforts to develop, or accelerate the development of, sustainable systems that are based on improving the health and welfare of the animals kept. If animal procedures can help by bringing about a substantial improvement to a combination of sustainability values, it could be considered to go ahead with the procedures.
  - Where alternative farming systems are not yet available, it may be necessary to improve existing systems in the interest of the species concerned. As with the answer to the previous question, it is important in such cases to insist on alternatives (3R's), in which the distress caused by the procedure should be relieved as much as possible through optimising the refinement component. The evaluation of distress (pain and reduced welfare levels) is an important aspect in this regard.

The RDA makes the below recommendations to the Minister and the CCD on this point:

1. They should ensure that the discussions about alternative farming systems are held jointly and on an integrated basis. These discussions should be part of the development of a vision on the relationship between animal welfare and other sustainability objectives in livestock farming. This could form the basis for a document that would provide the CCD with further guidance when assessing the added value of the research objective.
2. They should assist in making the 3R's more specific. For research into existing livestock farming systems in particular, it is important to insist on alternatives (3R's) so as to encourage innovation for both the animal procedure and the system used in practice. Apart from the contribution of partners in the research chain, the external contribution of the NCad as well as experts in the areas of the 3R's and sustainable livestock farming will also be important if this aim is to be achieved.

**Question 5:** *“What, according to the RDA, is the target situation with regard to animal-free innovations? (See the opinion by the Netherlands National Committee for the protection of animals used for scientific purposes (Nationaal Comité advies dierproevenbeleid, NCad) on the Transition to Animal-Free Research, December 2016). In any event, it would be desirable consult the NCad on the last question.”*

**Answer 5:**

The RDA and the NCad have consulted to underline the importance and the necessity of actively seeking animal-free alternatives within research for the livestock farming sector as well. However, the Council notes that unlike animal research for biomedical purposes, animal experiments for the livestock farming sector do not serve as a model for a different animal species but focus on the target animal itself. Procedures involving the species itself will continue to be necessary in future for innovations aimed at improving the health and welfare of the target animals. The Council sees opportunities in the area of the 3R's by considerably reducing the number of animal procedures in the preparatory stage (Chapter 2).

On this point, the RDA makes the following recommendations:

1. The Minister should actively encourage the entire research chain in livestock farming to consider animal-free innovations. One way of achieving this would be to request more information throughout the process, from funding and initiating research to submitting an application to the CCD.
2. All partners in the chain involved in the research should take responsibility for developing and applying alternatives; for example, by monitoring the development of alternatives, investing in development and openly exchanging innovations. It is also important to maintain contact with the international playing field, by seeking cooperation with other forward-thinking international partners, for instance.

In summary, the Council believes that the pursuit of animal-free innovations should receive full attention and be given particular priority in the livestock farming sector as well. At the same time, care must be taken to avoid those efforts hampering the development of more sustainable farming systems and improvements to animal welfare and animal health in livestock farming. It is possible to conduct research using animals, but only if it contributes to sustainability improvements and the interests of the target animals.

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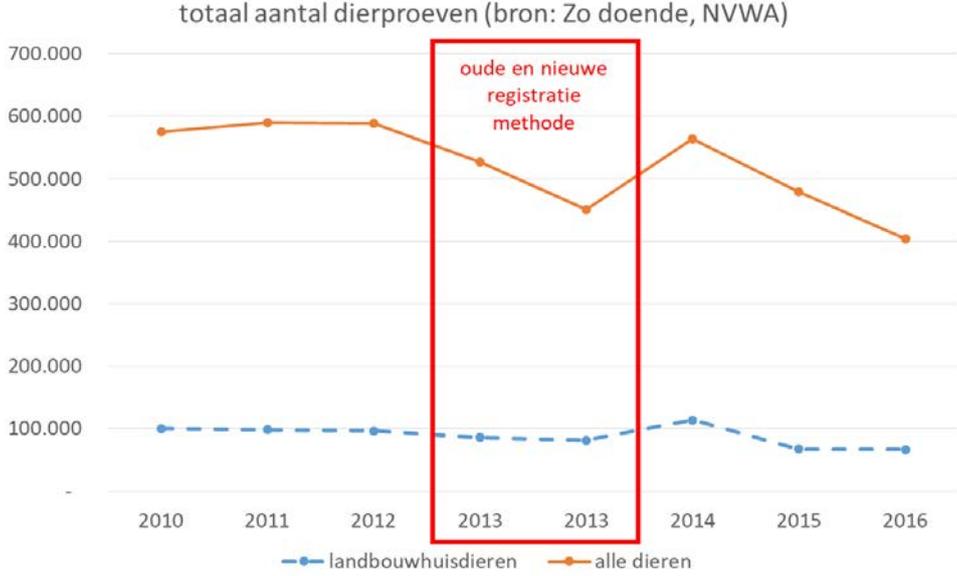
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## Appendix

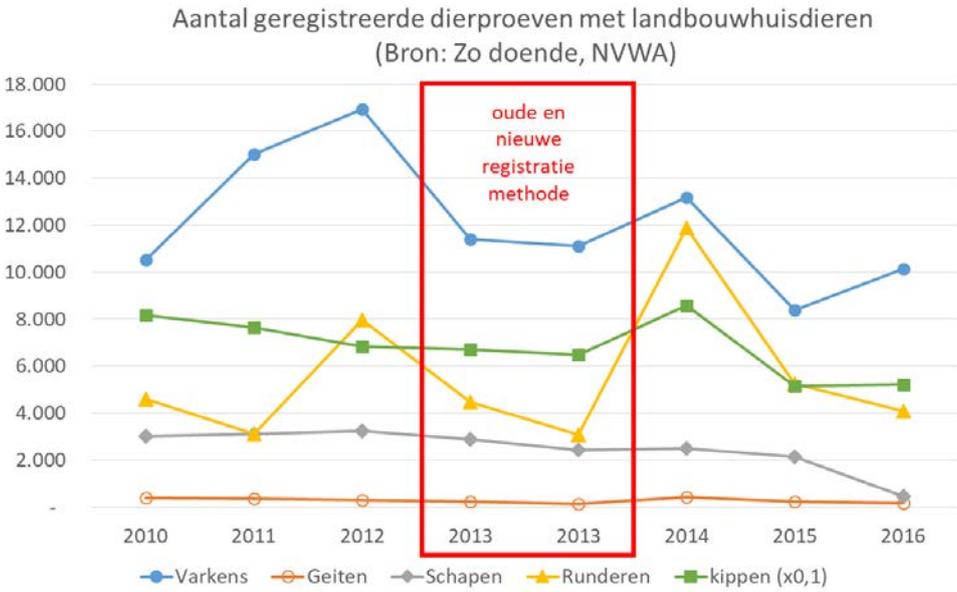
### *Appendix 1. Statistics on animal procedures for the livestock farming sector*

The number of farm animals (excluding rabbits and equidae) used annually for animal procedures fluctuated between 67,092 and 113,673 between 2010 and 2016 (Netherlands Food and Consumer Product Safety Authority (NVWA), *Zo doende*, 2010–2016; see Figure 1). They represented between 14% and 20% of the total number of research animals in the period mentioned, with the average being 17%. It should be noted that about 70% to 80% of the farm animals used for procedures were hens (see Figure 2). Although the annual figures fluctuate, particularly when the new research animal legislation was introduced in 2013, there was a decline in both the total number of research animals and the number of farm animals used in the period between 2010 and 2016 (see Figure 1). The number of research animals used for each objective fluctuates every year as well. Between 2014 and 2016 (see Figure 3), most farm animals were used for 'applied and translational research into veterinary diseases and animal welfare' (63.5%) and for 'quality control' (20.2%). In addition, 4.4% were used for 'education' and 3.1% for 'toxicology of animal feed and target animals required under the law'. The remaining 8.8% did not involve basic and applied research focused directly on the target species. In the same period, 82.7% of the animal procedures involving farm animals belonged to the 'mild distress' category; 14.1% were in the 'moderate distress' category, 2.8% in the 'severe distress' category and 0.5% involved animals that were killed under anaesthesia (see Figure 4).

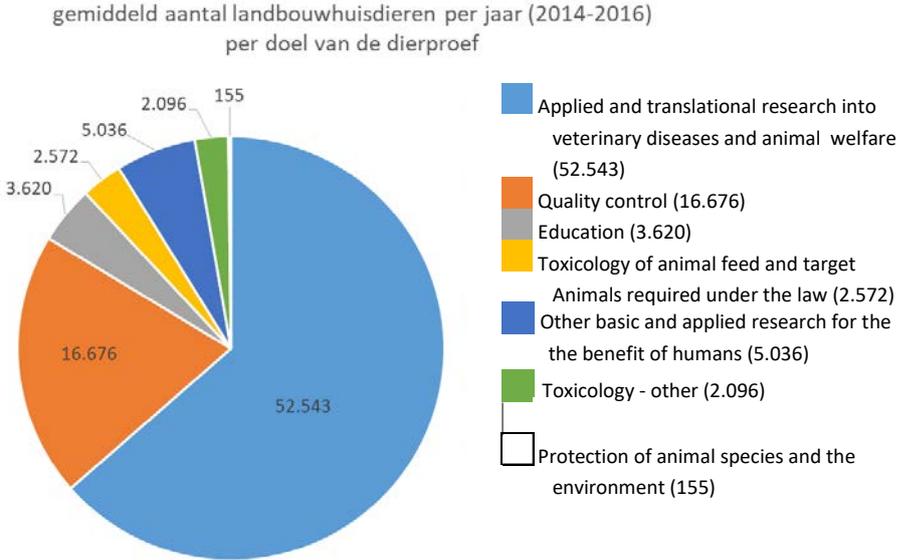
**Figure 1. The total number of animal procedures involving farm animals (dotted line) compared with the total number of animal procedures (solid line) for the years 2010 to 2016.** The number of animal procedures involving farm animals is the total of the procedures involving the different species named in Figure 2. Owing to the introduction of the new registration method in 2013, the numbers for both the old and the new method in that year are shown. Source: NVWA, *Zo doende* for the years 2010 to 2016.



**Figure 2. The number of animal procedures involving different species of farm animal for the years 2010 to 2016.** Please note: For practical reasons, the number of hens has been divided by 10. Owing to the introduction of the new registration method in 2013, the numbers for both the old and the new method in that year are shown. Source: NVWA, *Zo doende* for the years 2010 to 2016 inclusive.

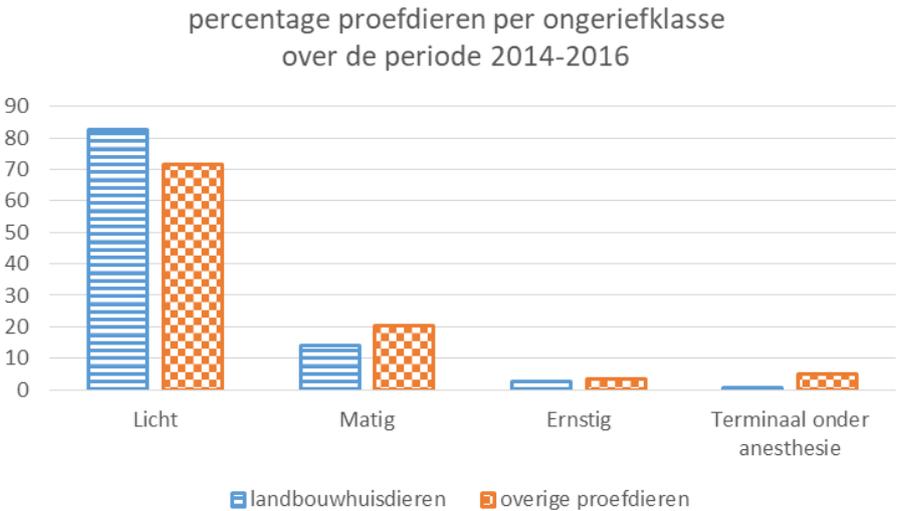


**Figure 3. The average number of farm animals (the total number of pigs, goats, sheep, cattle and domestic fowl) used for each objective in the years 2014 to 2016 (following the introduction of new research animal legislation).**



'Other basic and applied research for the benefit of humans' is the total of the following categories recorded by the NVWA: 'Basic scientific research'; 'Applied and translational research for the benefit of humans'; 'Forensic inquiries'; 'Applied and translational research – other' and 'Regulated production and breeding involving distress, not used in animal procedures'. Source: NVWA, *Zo doende* for the years 2014 to 2016 inclusive.

**Figure 4. The percentage of research animals per distress category for the period between 2014 and 2016 (following the introduction of the new research animal legislation and new requirements to record distress levels).**



The farm animals involved are the pigs, goats, sheep, cattle and domestic fowl used in animal procedures. The other research animals are all other species of animal. Source: NVWA, *Zo doende* for the years 2014 to 2016 inclusive.

## ***Appendix 2. The frameworks for animal procedures for the livestock farming sector***

The frameworks for animal procedures for the livestock farming sector

It is often difficult in livestock farming to determine whether an intervention in respect of a farm animal is an animal procedure or a necessary practical action. This concerns interventions which are frequently performed in practice but which are also covered by the definition of an animal procedure (such as tail docking). Farm animals are used for educational purposes as well, whether or not in practical situations; for example, they are used for the benefit of veterinary students or inspectors of the Netherlands Food and Consumer Product Safety Authority (*Nederlandse Voedsel- en Warenautoriteit, NVWA*). It is not always clear either when clinical diagnosis and treatment should be regarded as an animal procedure. The purpose of the following text is to provide an overview of the frameworks for animal procedures on behalf of the livestock farming sector.

### **1. The definition of an animal procedure under European and Dutch laws and regulations**

Following on from European Directive 2010/63/EU, the revised Dutch Experiments on Animals Act 2014 (*Wet op de dierproeven, WOD*) defines an animal procedure as follows:

“Any use, invasive or non-invasive, of an animal for experimental or other purposes, with known or unknown outcome, or for educational purposes, which may cause the animal a level of pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by the introduction of a needle in accordance with good veterinary practice” (see also Appendix 3, Section 1.1.a).

Three legal frameworks are especially relevant to a more detailed definition of an animal procedure. In addition to the frameworks that determine the degree of distress (Section 1.1.a), there are frameworks that determine which animals may or may not be used as research animals (Section 1b.5–6)) as well as for which purposes research animals may or may not be used (Section 1c; see Appendix 3).

### **2. The CCD's interpretation**

Although the term 'animal procedure' appears to be clearly defined in both the EU Directive and in the Experiments on Animals Act (see Appendix 3 - Section 1 and Section 1c), it often proves difficult in practice to determine unequivocally when an action constitutes an animal procedure. This is why, in 2016, the Central Authority for Scientific Procedures on Animals (CCD) provided an overview of the practical implementation of the new frameworks in the 'What is an animal procedure' memorandum (CCD, 2016). The CCD

identifies the determination of the level of distress as compared with that caused by the introduction of a needle as being particularly difficult and open to interpretation (CCD, 2016: p. 8). This is particularly true of behavioural tests and situations involving the cumulative effects of several consecutive operations.

The CCD also points out that operations preceding an animal procedure (such as catching, handling and restraining an animal) are not taken into account when determining whether or not an operation constitutes an animal procedure, even though such operations could in fact be highly invasive in certain circumstances, e.g. in the case of wild or semi-wild animals. This is why such operations are considered in the ethical assessment of the level of distress involved in a project for which a licence application has been submitted and in the recording of the distress actually experienced.

Based on the above, the CCD proposes using the following practical definition for the term "animal procedure":

'any use, invasive or non-invasive, of an animal for experimental or other purposes, with known or unknown outcome, or for educational purposes, which may cause the animal a level of pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by the introduction of a needle in accordance with good veterinary practice to the same animal concerned in the same circumstances.' (CCD, 2016: p. 10).

This definition is put into practical application using a decision tree (see Figure 5 below) and a number of sample scenarios (CCD, 2016: pp. 16–20) which can answer, or provide guidance on, the question of whether or not a particular situation constitutes an animal procedure within the framework of the revised Experiments on Animals Act 2014.

### **3. Animal procedures for the livestock farming sector**

These frameworks in the form of the decision tree (see Figure 5) can be used to determine whether an operation or treatment carried out in livestock farming should be regarded as an animal procedure.

In accordance with Step 1, all farm animals are protected under the Experiments on Animals Act.

In accordance with Step 2, operations whose principal purpose is to mark animals do not qualify as animal procedures, regardless of the accompanying distress (Section 1b.7.e of the Experiments on Animals Act; see Appendix 3, Section 1b.7).

Steps 3 to 5 inclusive concern the genetic background and any modification thereof, with a reference to a separate CCD memorandum.

Step 6 provides exceptions which are not regarded as animal procedures under Section 1b.7 of the Experiments on Animals Act (see Appendix 3, Section 1b.7). Examples of relevant exceptions include standard practices in livestock farming and clinical veterinary medicine, as well as operations which at most cause the animal a level of distress equivalent to that caused by the introduction of a needle.

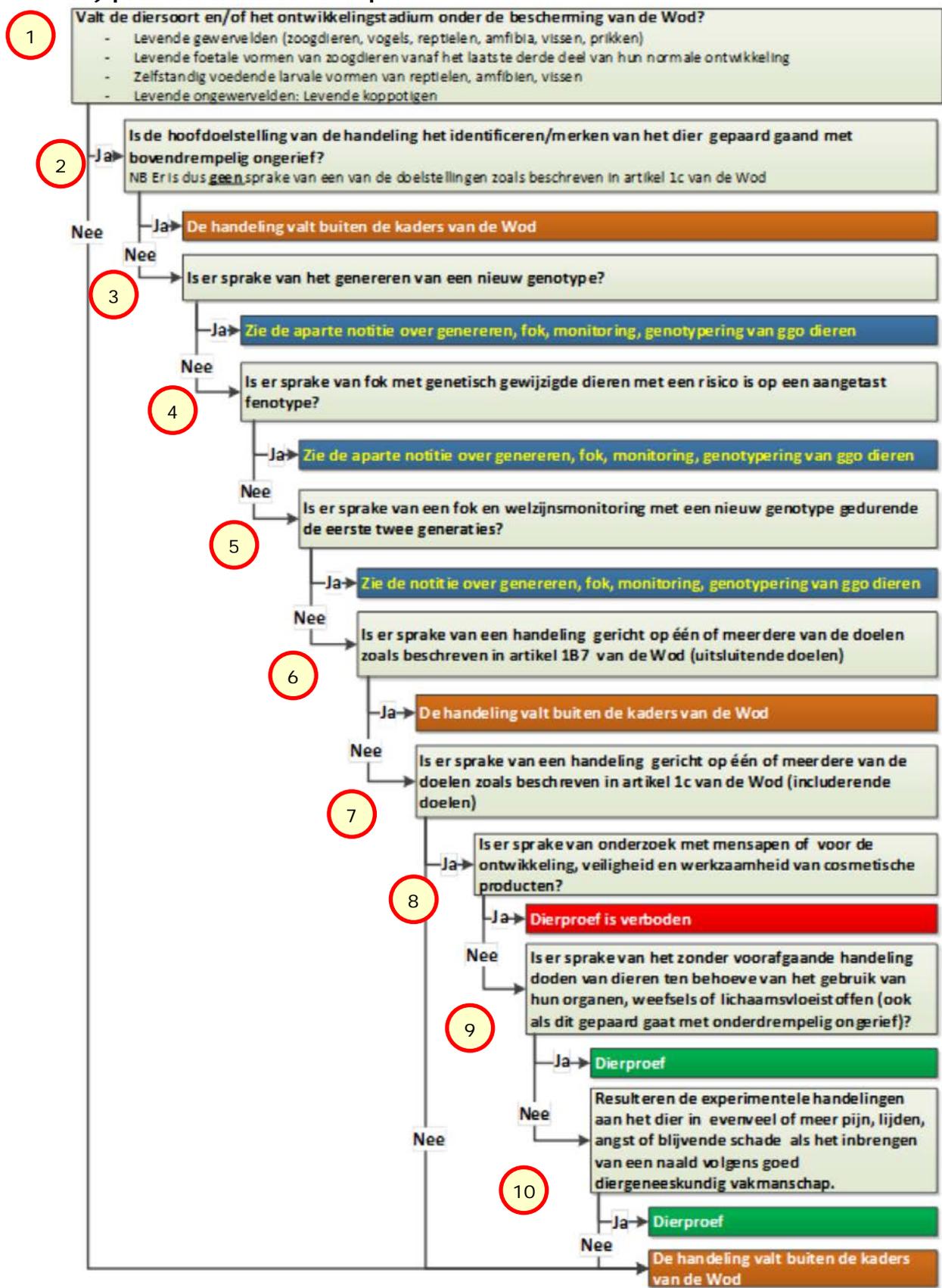
Step 7 determines for which primary purposes an animal procedure is permitted under Section 1c of the Experiments of Animals Act (see Appendix 3, Section 1c). No animal procedures may be performed for any of the other objectives. The provisions on translational or applied research (1c.b), development of medicines, food and animal feed (1c.c), and protection of the environment in the interest of the health or welfare of humans or animals (1c.d) are especially relevant to animal procedures.

Step 8 is irrelevant to livestock farming; it prohibits animal procedures that involve the use great apes or are performed on behalf of the cosmetics industry.

Step 9 provides that animals bred specifically for the scientific use of their organs, tissues or bodily fluids (Experiments on Animals Act, Sections 1.1.a and 1b.1.b) shall also be regarded as research animals.

Step 10 concerns the level of intensity of the operation or treatment. While this is already a source of contention according to the CCD memorandum, it is made even more fraught in the case of livestock farming because of the occasional need to perform operations in the course of animal procedures which are more intensive than the introduction of a needle but which are standard for all animals of that species kept, e.g. castrating pigs or burning the beaks off hens. The degree of pain, suffering and distress as well as the assessment thereof can also vary depending on the farming conditions, which are often less standardised than laboratory conditions.

Figure 5. The CCD's 'What is an animal procedure' decision tree (CCD, 2016: p. 14) plus the numbered steps.



#### 4. Permission for an animal procedure

The above decision tree determines only whether the operation or treatment should be regarded as an animal procedure. Before a licence is issued for the procedure actually to be performed, a number of the aspects referred to in the Experiments on Animals Act require careful consideration:

- possible alternatives (Section 1d.1);
- weighing the importance against the distress (Sections 10c and 10a2.1.b; see also Appendix 3, Section 10a2);
- institutional licences (paragraph 2, in particular Section 21; see also Step 7);
- whether use is made of animals bred specifically for animal procedures (Section 11);
- whether the persons responsible for the procedure meet the requirements for expertise (pursuant to the Order in Council) and the persons concerned are qualified to ensure proper care for the animals (pursuant to the Order in Council) (Section 13f);
- the fate of the animals once the procedure has been completed. At the end of a procedure, a decision on the endpoint is taken by a veterinary surgeon or by another competent person (Section 13a.2). The laboratory animals are killed in the institution (Section 13c.1), unless they are released for adoption or otherwise under the provisions of Section 13d.

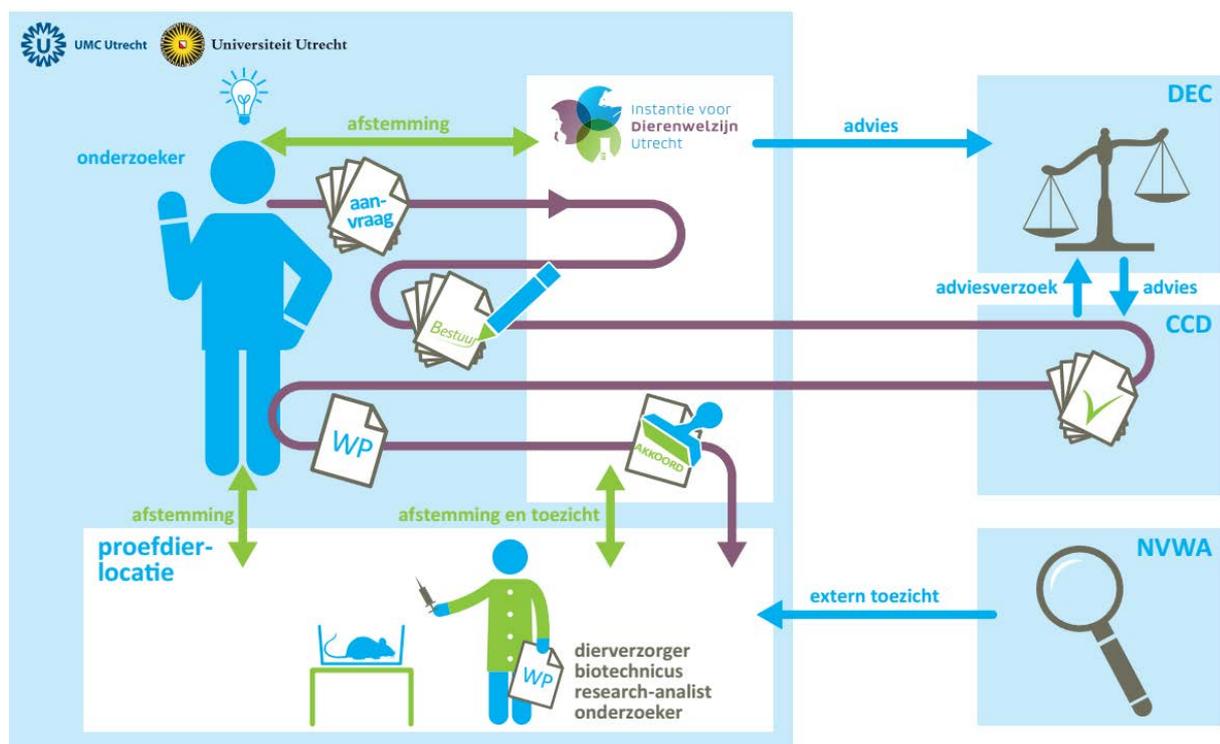
Various bodies mentioned in the Animal Experiments Act are involved in those assessments (see Figure 6). To apply for an animal procedure, a researcher must submit a proposal for a research project in accordance with a fixed protocol. The proposal must explain the following: purpose; necessity; design; method; animal species required; number of animals and their ages; possibilities for reduction, replacement or refinement of animal procedures (3R alternatives); accommodation and care; degree of distress; pain relief and, if applicable, method of killing.

Following consultation with the Animal Welfare Body (*Instantie voor Dierenwelzijn*, IvD) of the research institute concerned (Experiments on Animals Act 2014, e.g. Section 14), the proposal is submitted to the Central Authority for Scientific Procedures on Animals (*Centrale Commissie Dierproeven*, CCD). The CCD asks an Animal Ethics Committee (*Dierexperimentencommissie*, DEC) for its opinion. As part of that opinion, the DEC assesses the scientific quality of the procedure and the ethical consideration of its necessity relative to the distress caused to the research animals concerned. The DEC presents its opinion to the CCD as a recommendation. The CCD is the only body with the authority ultimately to issue a project licence based on the considerations mentioned above. In line with the project licensing procedure, the researcher then draws up a work protocol (WP)

for each element of the project, which records and accounts for the operations involved in each animal procedure. This process is monitored by the IvD. The Netherlands Food and Consumer Product Safety Authority (NVWA) checks the institutes, animal procedures and research animals. In addition, the NVWA records the numbers of animal procedures and publishes them in its *Zo doende* annual report.

Prior to an application for a project licence, though often running in parallel, the researcher will usually have to arrange funding and facilities for the animal procedure. This usually involves the same considerations as at the project application stage. Appendix 4 provides an overview of the various steps in the chain involved in designing and carrying out experimental research on animals for the livestock farming sector and the partners involved.

**Figure 6: Example of the various steps in the chain that a proposal for an animal procedure must go through in order to ultimately obtain permission.**



DEC = Animal Ethics Committee; CCD = Central Authority for Scientific Procedures on Animals; WP = work protocol; NVWA = Netherlands Food and Consumer Product Safety Authority Source: Animal Welfare Body, Utrecht University

## ***Appendix 3. Relevant legislative texts***

### **Experiments on Animals Act 2014 (Wod), Section 1**

1. For the purposes of the provisions under or pursuant to this Act, the following definitions shall apply:
  - a. animal procedure: any use, invasive or non-invasive, of an animal for experimental or other purposes, with known or unknown outcome, or for educational purposes, which may cause the animal a level of pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by the introduction of a needle in accordance with good veterinary practice. This includes any course of action intended, or liable, to result in the birth or hatching of an animal or the creation and maintenance of a genetically modified animal line in any such condition, including the killing of animals solely for the use of their organs, tissues or bodily fluids for a purpose specified in Section 1c.

### **Experiments on Animals Act 2014 (Wod), Section 1b.7**

This Act shall not apply to:

- a. non-experimental agricultural practices;
- b. non-experimental clinical veterinary practices;
- c. veterinary clinical trials required for the marketing authorisation of a veterinary medicinal product;
- d. practices undertaken for the purposes of recognised animal husbandry;
- e. practices undertaken for the primary purpose of identification of an animal;
- f. practices not likely to cause pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by the introduction of a needle in accordance with good veterinary practice.

### **Experiments on Animals Act 2014 (Wod), Section 1c**

Notwithstanding Section 2.2 and Section 2.3, animal procedures may be carried out for the following purposes only:

- a. basic research;
- b. translational or applied research with any of the following aims:
  - the avoidance, prevention, diagnosis or treatment of disease, ill-health or other abnormality or their effects in human beings, animals or plants;
  - the assessment, detection, regulation or modification of physiological conditions in human beings, animals or plants; or
  - the welfare of animals and the improvement of the production conditions for animals reared for agricultural purposes;

- c. for any of the aims in point (b) in the development, manufacture or testing of the quality, effectiveness and safety of drugs, foodstuffs and feed-stuffs and other substances or products;
- d. protection of the natural environment in the interests of the health or welfare of human beings or animals;
- e. research aimed at preservation of the species;
- f. higher education, or training for the acquisition, maintenance or improvement of vocational skills;
- g. forensic inquiries.

### **Experiments on Animals Act 2014 (WOD), Section 10a2**

1. The Central Authority for Scientific Procedures on Animals shall issue a project licence for a project only where:
  - 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;
  - c. the project is designed so as to enable procedures to be carried out in the most humane and environmentally sensitive manner possible; and
  - d. the project is designed in accordance with Section 9.
  
2. The project evaluation shall consist in particular of the following:
  - a. an evaluation of the objectives of the project and the predicted scientific benefits or educational value;
  - b. an assessment of the compliance of the project with Section 10;
  - c. an assessment 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 the reasons for deviating from the provisions under or pursuant to Section 1e.1, 10e.2–4 inclusive, Section 10f.1 and 4, Section 10g.1, Section 10h.1, Section 11.1, Section 13.3 and Section 13c.2, or of the reasons referred to in Section 13f.2.f;
  - f. a determination as to whether and when the project should be assessed retrospectively.
  
3. When it is determined in accordance with Section 10a1.1 and 3 that the project shall be assessed retrospectively, the Central Authority for Scientific Procedures on Animals, after consultation of the ethical review committee which has given prior

advice on the project proposal and on the basis of the necessary documentation submitted by the user as indicated by the Central Authority for Scientific Procedures on Animals, shall assess the following aspects:

- a. whether the objectives of the project were achieved;
- b. the harm inflicted on animals, including the numbers and species of animals used, and the severity of the procedures; and
- c. any elements that may contribute to the further implementation of Section 10.

### **Experiments on Animals Act 2014 (Wod), Section 19**

1. There shall be a national committee for the protection of animals used for scientific purposes.
2. The national committee shall perform the following tasks:
  - a. advising Our Minister, the Central Authority for Scientific Procedures on Animals and the animal welfare bodies on matters dealing with the acquisition, breeding, accommodation, care and use of animals in procedures;
  - b. ensuring sharing of best practices;
  - c. exchanging information with national committees of other Member States on the operation of animal welfare bodies and evaluation of project licence applications and sharing best practices within the European Union;
  - d. other duties assigned by Our Minister.

## Appendix 4. Overview of chain steps

Overview of the steps involved in an animal procedure using farm animals and the chain partners involved:

Step	Action	Chain Partner
1	Research terms of reference	<ul style="list-style-type: none"> <li>• research institute</li> <li>• company</li> <li>• government</li> <li>• consortium</li> </ul>
2	Research plan	<ul style="list-style-type: none"> <li>• Researcher (Principal Investigator, PI)</li> </ul>
3	Secondary cooperation partners (not originally included in the terms of reference)	<ul style="list-style-type: none"> <li>• Facilities department of the research institute</li> <li>• External research institute</li> <li>• Commercial farm, non-scientific</li> <li>• Private individuals/patient owners</li> </ul>
4	Funding	<ul style="list-style-type: none"> <li>• Research institute – first flow of funds</li> <li>• Public money – second flow of funds</li> <li>• contract/project funding – third flow of funds</li> </ul>
5	3R's & scientific assessment	<ul style="list-style-type: none"> <li>• IVD</li> </ul>
6	Ethical assessment of the application	<ul style="list-style-type: none"> <li>• DEC</li> </ul>
7	Administrative assessment of the application	<ul style="list-style-type: none"> <li>• Faculty/research institute/company</li> </ul>
8	Permission for the animal procedure	<ul style="list-style-type: none"> <li>• CCD</li> </ul>
9	Origin of animals	<ul style="list-style-type: none"> <li>• Bred in-house</li> <li>• Bred externally</li> <li>• Available in-house</li> <li>• Available externally</li> </ul>
10	Animal accommodation	<ul style="list-style-type: none"> <li>• Laboratory</li> <li>• Applied research</li> <li>• External commercial farms</li> </ul>
11	Care for animals	<ul style="list-style-type: none"> <li>• Staff trained pursuant to the Experiments on Animals Act</li> <li>• in derogation of the Experiments on Animals Act, external staff</li> </ul>
12	Performing animal procedures	<ul style="list-style-type: none"> <li>• researchers or animal tenders certified pursuant to the Experiments on Animals Act</li> </ul>
13	Endpoint of the procedure/animals (killing, reuse or return to the Commercial farm pursuant to the Experiments on Animals Act/Animals Act)	<ul style="list-style-type: none"> <li>• research insitute</li> <li>• researcher (PI)</li> <li>• animal tenders</li> </ul>
14	Assessment of implementation pursuant to the Experiments on Animals Act	<ul style="list-style-type: none"> <li>• NVWA</li> </ul>
15	Scientific accountability	<ul style="list-style-type: none"> <li>• Client/PI's employer</li> <li>• Publisher, peer review</li> </ul>
16	Financial accountability	<ul style="list-style-type: none"> <li>• Financial backer → annual overview, accountant</li> </ul>

## *Appendix 5. Stakeholders interviewed*

1. General secretaries of the CCD and the NCad
2. CCD implementation expert
3. Senior policy officer at the Ministry of Agriculture, Nature and Food Quality
4. Head of Utrecht University's IVD
5. Senior policy officer at the Ministry of Agriculture, Nature and Food Quality
6. WUR IVD and Livestock & Environment project manager, WUR
7. Chair of the CVI-WUR IVD
8. Professor of Animal Welfare and Research Animal Science, Utrecht University, and researcher of farm animal behaviour and welfare, WUR
9. Professor of Farm Animal Health, Utrecht University
10. Nutreco Director of R&D and Quality Affairs and Professor by special appointment of Sustainable Animal Nutrition in Production Chains, WUR

## Publication details

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