Nationaal Comité
advies dierproevenbeleid

# Codes of Practice working methods – Research report

OF CURRENT RELEVANCE, KNOWN, AND SUPPORTED BY EXPERTS

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# 1 SUMMARY FOR THE GENERAL PUBLIC

The Dutch Codes of Practice (CoPs) have generated a great deal of debate, revolving around questions such as 'Are these CoPs compulsory?', 'How much weight should we attach to these recommendations?' and 'Are we allowed to deviate from the code?'. Through this study, the Netherlands National Committee for the protection of animals used for scientific purposes (NCad) aims to provide answers to these and other questions and perform the tasks for which it is responsible more effectively.

***A CODE OF PRACTICE CREATES OBLIGATIONS***

The principal features of CoPs are that they are (or should be) of current relevance, known, and supported by experts. A CoP is a document which, at the time of its publication, presents the practices that experts believe are the best available in dealing with laboratory animals and the 3Rs principles. The CoP also provides concrete guidelines which every person dealing with laboratory animals should abide by.

A CoP should be seen, first and foremost, as a moral appeal. In addition, once experts have formulated such a best practice and all parties concerned can reasonably be expected to be aware of it, compliance with the CoP is required by law. This means that such best practices cannot be deviated from at will, but only if there are sound reasons for doing so.

***A CODE OF PRACTICE MUST CONTINUALLY BE UPDATED AND MUST BE GENERALLY KNOWN***

The CoPs issued by the precursors of the Netherlands Food and Consumer product Safety Authority (NVWA) need to be updated. The best known CoPs in this domain are those relating to the immunisation of laboratory animals, animal procedures in cancer research and laboratory animal welfare monitoring. When CoPs become obsolete, their value diminishes. Even if the main argument remains valid, the details of the CoP will no longer reflect optimal working practices. The NCad will endeavour to update obsolete CoPs, in collaboration with players in the field.

Many CoPs, and particularly those of the NCad, should be made easier to find. Not all public authorities and parties in the field are currently aware of them. This does not apply to the most relevant older CoPs of the NVWA and its precursors, however; awareness of these CoPs is higher.

***THE NCAD AND PARTIES IN THE FIELD JOINTLY PREPARE CODES OF PRACTICE***

One important aspect of a CoP is it that it is written by an expert working group that assumes much of the responsibility for its content. This should preferably also involve experts from outside the domain of animal testing who have relevant expertise in the field of the CoP concerned.

The NCad drafts new CoPs in collaboration with the IvD Platform, the umbrella forum for animal welfare bodies. The NCad has a strong network within the Dutch government and the European Union. In addition, it has the resources and leeway needed to perform a coordinating role and support players in the field through the IvD Platform or other relevant parties. In doing so, moreover, the NCad is able to monitor the level of continuity and quality in the drafting process.

***THE NCAD COLLABORATES WITH OTHER NATIONAL COMMITTEES***

Other national committees also issue CoPs. The NCad may choose to taken them into account in its own CoPs, or use them as a basis for reviewing or drafting its own CoPs. It may also decide simply to disseminate the CoPs from other national committees. Another potentially interesting option is to actively seek collaboration with the NCs of other Member States with regard to CoPs that are relevant to multiple NCs.

To facilitate collaboration with other Member States, in international consultations the NCad could use digital resources that have gained widespread acceptance since the COVID-19 pandemic, allowing all NCs to join in, including those whose travel options are restricted.

# 2 INTRODUCTION

## 2.1 BACKGROUND

The sharing of best practices is a statutory duty of the Netherlands National Committee for the protection of animals used for scientific purposes (NCad) that arises from the associated European directive.[1] According to various stakeholders, it is important for the NCad to draft or at least facilitate the creation of Codes of Practice (CoPs) to ensure that best practices are applied on as wide a scale as possible. Discussions with parties in the field have shown that the status of individual CoPs is not always clear to them. In addition, there is some confusion as to the extent to which CoPs from other countries could potentially also apply to the Netherlands, and about the level of support in the field for Dutch CoPs.

The NCad's responsibilities include sharing best practices with other national committees (NCs) within the European Union (EU) and disseminating,, in the Netherlands, guidelines or best practices developed in other Member States.[2] In its interim evaluation, the European Commission pointed out that on the whole, progress on this issue is not yet sufficient (European Commission, 2020).

## 2.2 OBJECTIVE

The objective of this project is to identify (1) the status that is or ought to be attached to CoPs, (2) whether specific types of CoPs can or ought to be distinguished, (3) how CoPs are used and how their use can be encouraged, both nationally and internationally, and more specifically (4) what role the NCad and its partners could potentially play in the creation and implementation of CoPs.

This involves both CoPs issued by the NCad itself and CoPs which are used in practice but were not issued by the NCad.

[1] Directive 2010/63/EU, Article 49(1)

[2] Experiments on Animals Act, Section 19(2)(c) and 2014 Experiments on Animals Regulations, Article 10.

# 3 DESIGN

## 3.1 DESK RESEARCH

As regards desk research, this project comprised the following activities.

First of all, all the information previously collected by the NCad secretariat was gathered and compiled. This concerns the input and results of a session of the NCad and the IvD Platform during the Biotechnician Days in 2017; the internal debate from 2019 regarding and the conclusion on whether the NCad's CoPs qualify as detailed specifications of Article 10(1); the outcome of a discussion between the Netherlands Food and Consumer Product Safety Authority (NVWA), the responsible policy department of the Ministry of Agriculture, Nature and Food Quality (*Landbouw, Natuur en Voedselkwaliteit*, LNV) and the NCad in April 2019; and the NCad's earlier inventory (2016) of CoPs that need updating.

In addition to that, a theoretical framework was put in place that makes it possible to approach CoP-related challenges from various different perspectives, devise alternative solution strategies and draft evidence-informed deliverables (in particular, the guidance and tool) (Annex C).

A comparison was made of all CoPs issued by the NCad and the most commonly used CoPs written by the NVWA and its precursors. A CoP from the United Kingdom was also examined, as were the responses of the responsible member of government in the House of Representatives to the NCad's recommendations that were accompanied by a CoP.

Finally, the project involved the study of a report written by the Amsterdam Public Health Research Institute EMGO+ and the VU University Medical Centre (VUmc) on the translation of field norms to inspection norms in the practices of the Inspectorate for Health and Youth Care. This was the subject of a meeting with a senior coordinating inspector from the Inspectorate.

See Annex B for the results of this part of the study.

## 3.2 INTERVIEWS AND QUESTIONNAIRES

In order to gain an up-to-date picture of attitudes to CoPs among a variety of stakeholders, interviews were held with staff of the NVWA, IvD members and chairs, a licence holder, chairpersons of professional associations in the field of animal testing, NCad members and staff member of the NCad and staff members of the Central Authority for Scientific Procedures on Animals (CCD). In addition, consultations were held with the responsible policy official at LNV and, briefly and in writing, with a member of staff of the European Commission who is involved in the EC's policy on laboratory animals.

A survey was held among other NCs. Twelve NCs responded: nine in writing and three by taking part in an interview. In 2017, these countries jointly represented around two-fifths of the total number of laboratory animals used in the EU.

See Annex A for the results of this part of the study.

# 4 CONCLUSIONS AND RECOMMENDATIONS

The objective of this project was to achieve the four sub-targets mentioned above in section 2.2. For each of those targets, the conclusions are presented below. Section 4.5 presents the conclusions regarding international collaboration. Chapter 4 ends with several recommendations, subdivided into quick wins and long-term recommendations, and a brief note on the study.

## 4.1 THE STATUS OF CODES OF PRACTICE

Parties in the field are often unclear about the status of a CoP. While some believe CoPs are compulsory, others tend to regard them as little more than a tool - or an obstacle. The idea that CoPs lay down compulsory working practices is to be attributed to the fact that according to some CoPs issued by the NVWA, the Inspectorate assumes that the methods described in the CoP are adhered to.

The government parties involved (LNV, NVWA) are clear however on how the CoPs are to be used in the context of inspection. The NVWA uses CoPs as guidelines, in line with the responsible member of government's remarks in her policy response to one of the NCad's CoPs. In practice, this means that a licence holder needs to have sound reasons for deviating from any CoP that is still applicable. The NVWA itself indicates that it uses CoPs in applying statutory open standards in its inspection activities.[3] Many interviewees say that when designing working practices with laboratory animals and assessing such practices for licensing purposes, they - potentially - use CoPs as important sources of information. This includes CoPs from the Netherlands and guidelines issued by leading international organisations.

It has been stated that a CoP serves as a detailed specification of open standards in the law. Reference is made to the 'generally knowable view prevalent among experts' as referred to in Section 10(1), Part A of the WOD, which rules that animal procedures are prohibited when common opinion holds that such procedures could be performed by alternative means according to the 3Rs principle.[4] To qualify as a 'specification' of this open standard, the views in the CoP must be generally knowable and reflect common consensus among experts. The NCad's CoPs do not always fulfil the former requirement, because they are not always sufficiently knowable and findable.

### 4.1.1 Reflection on the status of Codes of Practice

Given the nature of the questions that this project aims to answer, this report may create the impression that a CoP principally serves to impose additional regulations on licence holders. This is incorrect. First of all, a CoP is a document which indicates (or ought to indicate) the best practice currently available, according to a group of experts, for working with laboratory animals within a specific domain. The purpose of the CoP is to make this knowledge available to all professionals in the field who work with laboratory animals so as to enhance animal welfare and promote the application of the 3 Rs in daily practice.

The question about status supports this purpose. Under a CoP, researchers may be required to put in an extra effort to promote animal welfare. While researchers who use laboratory animals should feel a moral commitment to observing the highest animal welfare standards, it appears that in a number

[3] There are existing agreements on this subject between the NCad and the NVWA; see Annex B, section 7.2.7.3.
[4] It is prohibited to conduct an animal procedure for a purpose which, according to the generally knowable view prevalent among experts, may also be achieved by means other than animal procedures, or through an animal procedure that involves the use of fewer animals or causes less discomfort to the animals than the procedure in question.

of practical situations there is a need for a specific legal status to be attributed to those ‘best practices’ so as to facilitate their implementation, and to support animal welfare bodies in this regard as required. Animal welfare will of course remain open to innovation, so no CoP should prevent any professional from adopting more animal-friendly practices than those prescribed by it. It is also conceivable that the same results can be achieved in ways other than those described in the CoP. Every CoP should be clear about this. The overriding attention in this report to the 'status’ issue mainly springs from the fact that this is the area that generates the most uncertainty.

## 4.2 Code of Practice types

Except for the distinction between the NCad's CoPs and those of the NVWA, there are no clearly distinct types of CoP. It is possible however to distinguish between the various types of *information* presented in CoPs. Some include clear minimum requirements (e.g., an animal should not lose more than x% of its body weight), others prescribe specific working processes (e.g., for each laboratory animal, the following data must be recorded) or recommendations for specific situations (e.g., if, following the experiment, the animal receives such and such treatment, bear in mind that...). Individual CoPs may contain various types of information, in varying proportions, which makes it difficult to distinguish them on this basis. The format of an CoP will influence the way in which it is (or can be) applied and monitored in practice.

## 4.3 The use of Codes of Practice

A Code of Practice is a best practice drawn up by experts for dealing with laboratory animals and applying the 3Rs principle. As such, it is inherently subject to obsolescence. CoPs are sources of information on such best practices for animal welfare bodies, DECs and all other parties involved in the domain of animal testing. In practice, CoPs are used in various ways. Some animal welfare bodies use CoPs as input for implementing Standard Operations Procedures (SOPs), others as a basis for internal discussion on current practices, or as input for junior researchers or new research programmes so as to prevent them from having to reinvent the wheel in establishing responsible practices for working with laboratory animals. Not all licence holders actually use all CoPs. This is because not all CoPs apply to their work within the faculty concerned, or because their own standards are equivalent or even better that those described in the CoP.[5]

## 4.4 The role of the NCad

There is room for improvement in the communication by the NCad about CoPs and in their findability. Parties in the field have no clear view of which CoPs were issued by the NCad, nor of how they are expected to deal with CoPs.

The NCad is regarded as the party that is best positioned to facilitate and encourage the drafting of CoPs, as it is able to safeguard quality throughout the process and boasts a network that strongly supports a coordinating role. Dissemination of CoPs is viewed as another important task for the NCad. While the NCad is by no means the only party in the Netherlands to be authorised to draw up CoPs, those that it produces should have particular authority by reason of their quality.

[5] The suggestion that better working practices are conceivable than the ‘best practices’ contained in a CoP may sound like a contradiction in terms. However, if the assumption is that a CoP represents the generally knowable view prevalent among experts, individual licence holders may, within their specific situation, still seek to observe higher animal welfare standards than those contained in the CoP.

## 4.5 INTERNATIONAL COLLABORATION

While other National Committees have also drawn up CoPs or guidelines, international collaboration in this regard is still in the process of development. Some NCs are already actively seeking to forge bilateral contacts. At the same time, not all NCs appear to have the resources required for active participation in an international context. Indeed, the limited availability of resources is an important reason why many NCs feel the need for collaboration in a variety of fields. This would enable them to share resources while also encouraging harmonisation within the EU, particularly as regards guidelines and CoPs on the use of animals. The latter is also an important consideration for internationally operating organisations based in the Netherlands, due to the level playing field that exists within the EU, especially in terms of statutory regulations and enforcement.

# 4.6 RECOMMENDATIONS

### 4.6.1 Quick wins

- Publish all of the NCad's recommendations that contain a CoP on the best practices page of the NCad website. This page was found to be the first source of CoP-related information consulted by the parties interviewed. Make sure that this web page contains the latest version of the NCad's CoPs, with the correct publication details.
- Encourage international partners to hold international consultations in a blended format (offline, with sections of participants being able to join specific components online), or fully online. This will make it easier for smaller NCs to join in.

### 4.6.2 Considerations for the longer term

- Provide clarity regarding the NCad's position to CoPs and regarding the status of CoPs. Further recommendations in this regard are given in the chapter on scenarios.
- In each CoP, include a chapter on how it came about, how it is to be applied in practice and how other parties (such as the NVWA, CCD and ministry of LNV) responded to it. It is recommended to consult with these parties so as to arrive at a shared vision and approach.
- Clearly formulate your CoPs and provide justification for requirements and guidelines where possible. Clearly differentiate between requirements and guidelines.
- Make sure that the CoP can be read and used as a stand-alone document, so that its value is evident even to those who have not read the associated recommendation (if applicable).
- Invest in collaborating on best practices with other NCs that are willing to join forces, and make sure to benefit from existing guidelines in other countries when drafting Dutch CoPs.
- Regularly evaluate the use of CoPs and their current relevance as a standard activity in the working process. Include these considerations (evaluation method, frequency) in the process of drafting the CoP. Allow your choices in this regard to benefit from subsequent publications from other organisations.
- Accept the NVWA's offer to submit new or updated CoPs to a version of the HUF test (assessing the feasibility, practicability and fraud-sensitivity of laws and regulations). Evaluate the test, especially the first few rounds, and determine the practical value of the results.

# 5 THE NCAD'S ROLE IN DRAWING UP CODES OF PRACTICE: FIVE SCENARIOS

Put briefly, the question underlying the present project can be worded as follows: 'What exactly is the best line of action for the NCad to take regarding CoPs?'. The information gathered within the context of this project provides no easy answers to this question, due to the interdependencies of the many aspects involved. This makes it impossible to pinpoint an answer somewhere on the line between ‘no action’ and ‘far more action than at present’. There are many aspects which each call for specific decisions to be made.

To ensure a meaningful discussion despite these complexities, we have developed five obvious scenarios for the NCad's potential approach to CoPs, based on the interviews held. Each scenario presents its own advantages and disadvantages; none of them provides a fully independent, comprehensive solution. The five scenarios were discussed for the first time during the NCad's meeting of July 2020; this discussion and its further development form the basis for section 5.2.

Each scenario is introduced with a brief statement, followed by a more detailed description. The table provides an overview of key aspects to take into account in each scenario. While the scenarios have been designed for new, relatively large CoPs, they can also be used for updating existing CoPs and for translating foreign CoPs and guidelines into Dutch guidance.

While not entirely uniform, the views among parties in the field on what a CoP is are largely consistent in outline, as indicated in the previous chapter. This is why it is important for the NCad to select a single basic concept to inform its further approach.

## 5.1 SCENARIOS

A. Not a party in the development of CoPs

*The NCad is a strategic body; due to their practical orientation, CoPs offer no added value to enhance the NCad's impact.*

In this scenario, there is no role for the NCad in connection with CoPs, with respect to parties in the field or the Minister. The statutory task of sharing best practices in a national and international context will be assigned and performed in other ways as yet to be determined.

B. Disseminator

*The NCad actively pursues its statutory task of disseminating best practices by gathering CoPs and best practices in the field and sharing them at the national and international level. This will enhance the NCad's impact on working practices in the Netherlands and elsewhere in the EU.*

This scenario specifies the ways in which various statutory tasks are to be fulfilled. It remains to be seen, however, whether this role will eventually provide sufficient added value. If the NCad is to share CoPs and best practices, it will first have to find them somewhere. Several parties in the field, and animal welfare bodies in particular, have stressed the importance they attach to support from the NCad in the formulation of CoPs, and also that after a promising start, initiatives in the field tend to grind to a halt due to time constraints or lack of motivation. Since any CoPs or guidelines shared by the NCad implicitly bear the NCad's stamp of approval, it needs to thoroughly assess products from the field before disseminating them. The greater its distance to the authors, the more difficult it will be for the NCad to perform this assessment. If the NCad elects to issue recommendations on a

largely strategic level, this scenario will probably suffice to enable it to fulfil its statutory duties. It is expected to be less effective in meeting the expectations of the Minister, who has asked for CoPs in a number of specific cases.

C. Process supervisor and disseminator

*After initiating the CoP drafting process, the NCad remotely monitors progress to maintain momentum while conceding the initiating role for further steps to the parties in the field. The NCad does take an active part in disseminating the CoP at the national and international level, ensuring additional impact on working processes in the Netherlands and the rest of the EU.*

In this scenario, the NCad provides the minimum level of 'secretarial' support required to maintain momentum in the drafting of CoPs. Responsibility for the quality of the deliverable and for coordination with all the key partners rests with the parties in the field that have initiated the CoP or other best practices document. In this arrangement, the NCad drives the process, allowing the experts to devote most of their efforts to drafting the document and waste no time on designing consultation structures and booking meeting venues. In this role, the NCad clearly supports the field.

It enables the NCad to fulfil its statutory task of sharing best practices and eliminates the risk of losing momentum in the drafting process. In addition, in this scenario the NCad is better positioned to monitor quality and meet the Minister's expectations. It does however call for greater involvement of the NCad and, in particular, of its secretariat, whose activities will be mainly of a secretarial nature.

D. Network partner and process manager

*The NCad performs a network partner role, joints parties in the field in producing and sharing CoPs and, as such, will become a major player in the 3Rs policy in the Netherlands and the EU at large.*

In this scenario, although the players in the field will actually draft the CoPs, the NCad will play an important role in creating them. Thanks to its excellent contacts with the CCD, NVWA and LNV, the NCad will be able to contribute to the favourable reception of CoPs in each of these bodies. In this scenario, moreover, the NCad is in an even better position to monitor the quality of the documents drafted; indeed, effective performance of its role means that the NCad could become a crucial factor for government bodies and players in the field in the context of 3Rs policy.

The NCad will serve as a liaison between parties in the field and the Minister. It will be able to provide the Minister with clear advice on best practices in animal procedures, through the CoPs. As such, it will be able to safeguard the quality of those CoPs thanks to its intimate involvement in drafting them.

As co-owner of the CoP, in this scenario the NCad will commit to keeping the documents concerned up to date following their publication and, as such, will have a long-term involvement with those documents. It will provide periodic updates of the CoPs in its care, in conjunction with players in the field. The updating process should be carefully scheduled so as to prevent CoPs from losing their relevance (as some obsolete CoPs issued by (precursors of) the NVWA have). A modular design for the CoPs will make it easier to update them.

This role could potentially increase the NCad's impact over the longer term, as well as its long-term obligations, for instance in the field of updating CoPs and monitoring the quality of published documents. As such, this role will entail additional responsibility and burden for the NCad, some great opportunities as well as a number of risks.

E. CoP producer

*The NCad itself produces Codes of Practice and also disseminates them. It hires the requisite expertise for a number of specific tasks.*

In this scenario, the NCad will itself draw up the CoPs and may hire additional expertise in the process. To perform this task effectively and meet the needs of the field players and other partners involved, good contacts and communication are crucial. The NCad itself does the actual drafting of the CoP, possibly assisted by hired experts. This means the NCad itself is the full owner of each CoP and, as such, responsible for its content and continued relevance. As a result, this is the scenario that involves the highest level of risk. The risks involved concern such issues as acceptance of a CoP among parties in the field and by the supervisory authority, and the NCad's reputation among its stakeholders. Also note that this scenario is very labour-intensive.

The NCad presents the CoPs it has produced to the responsible member of government , who may or may not have commissioned it.

| SCENARIO | A | B | C | D | E |
|---|---|---|---|---|---|
| **NCAD'S DUTIES** | None | Disseminate | Disseminate, secretarial | Disseminate, monitor, co-draft, evaluate, update | Disseminate, draft, evaluate, update |
| **DUTIES OF PARTIES IN THE FIELD** | Disseminate, draft, evaluate, update | Draft, evaluate, update | Draft, evaluate, update | Co-disseminate, co-draft, update | None |
| **COP OWNER** | Field | Field | Field | Field, NCad | NCad |
| **NCAD'S IMPACT** | None | Low | Low | Potentially large | Potentially large |
| **RISK** | Practically nil | Low | High | Substantial | Very high |
| **TIME INVESTMENT** | None | Low | Substantial | High | Very high |
| **IMPLEMENTATION OF STATUTORY DUTY** | No | Possible | Yes | Yes | Yes |
| **SUPPORT* AMONG PARTIES IN THE FIELD** | Low | Low | Yes | Yes | No |
| **SUPPORT* AMONG POLICY OFFICIALS** | No | Unknown | Yes | Yes | Unknown |

*) based on information obtained from the interviews No concrete scenarios were submitted.

## 5.2 RECOMMENDATION

The talks and interviews held plead against scenarios A and B. Both players in the field and LNV believe there is a more substantial role for the NCad to play in the area of CoPs than merely sharing them after the field has produced them. The NCad has the time and resources required for promoting the sharing of best practices and monitoring their quality. In addition, its position and network of contacts enable it to play a more significant role than envisaged in either scenario A or B.

Scenario E, at the other end of the spectrum, shifts the entire burden of responsibility for CoPs to the NCad. In this scenario, parties in the field have no role to play other than possibly being hired as experts by the NCad. One view however that consistently emerges from the interviews and talks held is that CoPs should be drafted by the field. This seems to disqualify scenario E, which, moreover, incurs the risk of an unfavourable reception of CoPs ('Who do they think they are at the NCad, trying to tell us what to do?'). This is a real risk: in the interviews, several parties expressed their annoyance over NCad publications that had been produced without sufficient involvement from the field.

Scenarios C and D are closely interrelated. In scenario C, the NCad provides a minimum level of support to enable the field to draft a CoP, but has very limited possibilities to influence the drafting process. Given its limited influence, the NCad would run a risk by attaching its name to a CoP produced under this scenario. After all, if the CoP fails to meet the expectations of parties in the field or the Minister, they will tend to hold the NCad responsible. Scenario D offers better opportunities for the NCad to influence the quality and consistency of CoPs as co-author. What is more, collaboration with parties in the field could potentially enhance the NCad's reputation among them as well as improve its ability to keep in touch with the field. One drawback of scenario D is that it calls for a larger time investment from the NCad than scenario C. Even so, given the express desire for more impact, scenario D would be the more logical choice. The NCad itself also prefers scenario D, which offers the possibility to intelligently increase or decrease its involvement in accordance with the other scenarios.

### 5.2.1 Scenario D, with the option to move to other scenarios

The NCad prefers scenario D, as long as it is able to deviate from it if the situation so demands. This part of the report provides some explanation of the potential use of other scenarios alongside scenario D. In many cases, deviation from scenario D will effectively mean that the NCad is not a party itself in drafting the CoP, or that a CoP is not an appropriate means for what the NCad is trying to achieve. It is worth noting here that frequent deviation from a standard working method will create confusion and could potentially diminish the value of other, existing NCad CoPs.

That standard approach would be for the NCad to publish a CoP on the basis of scenario D, drafting the document jointly in collaboration with the field and becoming its co-owner. 'Jointly' in this context means that the CoP is the result of contributions based on the parties' respective strengths. One important characteristic of the CoP is that it is drafted by experts from the field, with the NCad playing a largely facilitating role.

Any deviation towards scenario E, which eliminates involvement from the field, would be ill-advised, in view of the attitude of parties in the field towards NCad documents in which they had not (or not sufficiently) been involved. If the NCad nevertheless wishes to produce a document without involvement from the field, it would be better advised to opt for another format, such as guidance or an opinion, rather than a CoP.

Deviation from scenario D in favour of scenario A can only be an active decision by the NCad in a situation in which another party has initiated the development of a CoP and the NCad, in response to a request by that party, decides not to collaborate. In that case, the NCad would have no role to play and is not a party to that CoP. Needless to say, every party is free to publish a CoP under its own management without involving the NCad.

Deviation in favour of scenario B will be largely limited to situations involving documents that have been published abroad by experts and are already of good quality. In such a case, the obvious choice would be to share the document through social media and other channels, rather than for the NCad

to publish its own CoP. Note that such documents are not usually published as 'CoPs'. If they are, the NCad might consider attaching a disclaimer stating that the CoP concerned was not drafted under the management of the NCad. It is also possible, however, that documents published by other organisations give cause for the NCad to review its own existing publications. That could be done with relatively little effort, in accordance with scenario D.

Deviation in favour of scenario C is a realistic option if the party drafting the document enjoys the NCad's confidence. In practice this will most commonly apply to cases of collaboration with the IvD Platform (the Dutch umbrella organisation of AWBs). If the NCad is co-owner/co-publisher, it is important to ensure effective monitoring of the quality of both the document and the process.

The guidance will offer a more detailed description of the design of the drafting process, and how this may be influenced by the topic of or reason for the CoP or when a CoP (or a part of it) is revised. Generally speaking, when the NCad issues a CoP it should do so on the basis of scenario D. In that case, the NCad would publish a document, in collaboration with the field, that meets the standard of quality to be expected from the NCad, with the expert working group being responsible mainly for the content of the document. It the NCad is unable or unwilling to adopt this approach for a document on a particular subject, then it should consider a different publication format (opinion, letter, recommendation or news message).

# 6 DELIVERABLES OF THE RESEARCH PROJECT

Scenario D (the preferred scenario) has produced the following deliverables:

- a report with information gathered during the process, to be further processed by the NCad, including a summary for the benefit of the general public;
- a description of the process that results in a CoP highlighting all the key issues, in the form of guidance and a tool for use by those involved in the creation of CoPs, and of the underlying information derived from the research and the theoretical framework.

# Annexes

## A SUMMARY OF THE RESULTS OF INTERVIEWS AND SURVEYS

### A.1 INTERVIEWS

For each objective, relevant insights obtained through the interviews have been summarised. These insights reflect the content of the interviews and talks and, as such, are representative of the interviewees' opinions. They do not however necessarily reflect reality in a strictly formal sense.

*(1) What status is or ought to be assigned to CoPs?*

CoPs - provided they are of current relevance and suitable - can be used as tools that provide detailed specifications of open standards. Such open standards are important as a means of providing the research community with the space it needs to innovate. CoPs are not necessarily applied in supervisory practice in an integral fashion. They may have grown obsolete; indeed, parts of a CoP may already be outdated by the time the document is published. However, provided that they have current relevance and are widely supported, CoPs can be used quite effectively in supervisory practice. In such cases, licence holders should adhere to them or else provide very good reasons if they intend to deviate.

Any deviations from a CoP in a negative sense, i.e. to the detriment of animal welfare, are only permitted if they are supported by solid arguments. If a particular procedure is covered by a CoP, adherence to that CoP does not by definition reflect current best practice, as the CoP may have become obsolete. Neither is adherence to a CoP necessarily the only possible way of meeting the 3 Rs principle. Also note that it may not be possible to apply a CoP in particular situations. Researchers should apply the 3Rs principle to always remain alert to alternative methods that are more conducive to animal welfare. In many cases, however, CoPs may serve as minimum requirements. The use of CoPs in supervisory practice was discussed only in general terms.

Parties in the field tend to regard CoPs as mandatory guidelines. This explains why some CoPs that are clearly obsolete are still being used in practice. In other cases, a reference to more recent literature is added, for example in project applications. The notion that CoPs are mandatory tools stems from specific phraseology, particularly in CoPs drawn up by the then Inspectorate for Health Protection, Commodities and Veterinary Public Health, in which adherence to the methods laid down in them was taken for granted. While ways have likely been found of circumventing obsolete CoPs, it does not feel right to have to avoid application of a CoP whose very purpose it was to promote the 3 Rs principle.

Parties that tend to regard CoPs as recommended practices which they invariably adopt (if they did not already apply them) said that they would appreciate more clarity as regards the status of a CoP.

Since new CoPs are not ratified by the Minister LNV or by the NVWA, it is not clear what their status is. In addition, due to the way they are formulated not all new CoPs are entirely suitable as detailed specifications of the law.

The status of the NCad's recommendations and guidelines is similarly unclear. In terms of communication, there is considerable room for improvement here.

*(2) Can different types of CoPs be distinguished?*

The picture has thus far remained obscure. Sometimes it is difficult to determine whether a NCad publication is a CoP or a recommendation. Some recommendations have extremely practical and concrete content, while some CoPs have the nature of recommendations. We also note issues regarding the findability of CoPs. The NCad website only lists two CoPs, but many more must have been written.

A distinction is made between guidelines, guidance, recommendations, target visions (*streefbeelden*) and CoPs. The level of acceptance appears to depend on the name of the document, as does the willingness to include ambitious targets.

Thus far, only government-related institutions appear to distinguish between CoPs by reference to their origin (published by the NCad or by another party?); this seems to be much less of an issue among parties in the field. As soon as a document bears the name 'CoP', it is used as a CoP.

*(3) How are CoPs being used and how could their use be promoted, nationally and internationally?*

CoPs - but some more than others - are being used as arguments in discussions with researchers, both in supervisory practice and by some animal welfare bodies. For the time being, there seems to be no need to promote their use. To ensure that CoPs can be used in practice, however, it is important that they are of current relevance and that they are regularly reviewed or supplemented. Another aspect that should be given more attention is publication. Some parties say that they wish to remain informed, but are unable to find the relevant CoPs.

Many institutions use SOPs (Standard Operations Procedures). Some animal welfare bodies say that they use the CoPs to update their SOPs in accordance with new standards laid down by the CoP. Laboratories that adhere to the Good Laboratory Practice guidelines review their SOPs at least once every three years.

CoPs are also used in the design of new research programmes, for example when these concern animal species that have not previously been used, or new types of research. The use of specific relevant CoPs, e.g. for accommodation and animal welfare, prevents the organisation concerned from having to reinvent the wheel. In this regard, it is pointed out that CoPs and guidelines tend to devote little attention to farm animals, forcing the parties concerned to either rely on in-house knowhow or obtain relevant expertise from other bodies.

Despite the fact that science is international, many interviewees indicate that variations in working practices per country are such that most CoPs cannot readily be shared. Some use that as an excuse for exempting themselves from the obligation to apply CoPs. Even so, CoPs are useful in terms of indicating desirable approaches. To promote their international exchange, it might be worthwhile to formulate CoPs in collaboration with other countries.

One point for attention that emerged in connection with the need for international collaboration and enforcement of equal standards is the notion of legal equality within the EU. While the relevant legislation applies across the EU, its implementation nevertheless appears to vary.

*(4) What is the potential role of the NCad and its partners in the creation and implementation of a CoP?*

One important statutory task for the NCad is to share best practices. It is important for field experts to be actively involved in the formulation of CoPs. In this connection, it is crucial to ensure that all parties in the field are represented in the working group of experts for a particular CoP. The drafting

of a CoP entails a variety of risks. For example, a party may feel 'ownership' of the CoP to such an extent that it will not accept any changes; or the working group may formulate relatively conservative standards that are too liberal to prevent serious degradation of animal welfare. Conflicts of interests may also arise.

Parties that have been involved in the formulation of CoPs have identified possible ways of improving the process; the overall impression if positive. One priority emphasised by many is the need for a person who is able to facilitate the process and keep it going. The scientific community also sees regular initiatives to arrive at a joint, uniform approach. However, many of those initiatives fail to come to fruition, due to a lack of momentum among the initiators, a lack of time and/or a lack of funds. When this happens, those who joined the initiative may be less inclined to participate a second time.

The NCad could take up this facilitating role and serve as a liaison between parties in the field, policymakers and international organisations. The respondents also feel that the NCad has the right network and the best position to facilitate the production and dissemination of CoPs. Potentially there is also a role to play for the IvD Platform from the world of practice, although they lack the capacity to be able to work on multiple CoPs at the same time. They are currently dealing with two CoPs and feel their capacity is already being stretched to the limit. For animal welfare bodies, formulating CoPs is an additional task on top of their existing heavy workload. There is also a widespread view that the NVWA should be involved for content-related issues. The NVWA could submit a CoP to a version of the HUF test, which could or should also involve a substantive check.[6] This is because the NVWA has intimate knowledge of a variety of parties, which places it in a good position to assess whether a particular CoP indeed reflects the best practices for a particular sector.

As regards the updating of documents, there is general consensus that the NVWA and the IvD Platform should play a signalling role, in view of their wide networks and intimate connections in the field. Parties are strongly inclined to regard others as being better positioned to assume final responsibility for documents.

All interviewees agree that a CoP should be drawn up by the players in the field. In addition, they agree that the working groups should be made up of scientists and other subject-matter experts.

In one interview, an animal welfare body offers a clear picture of the desired approach: the discussion should not be restricted to animal welfare bodies or policymakers. We need a transparent process which should not be too lengthy, which leaves room for parties to have their say and also involves the NVWA. If compliance with the document is to be subject to formal inspection, we should make sure it can be enforced. The NCad, CCD and NVWA should get together and decide who is to take responsibility. We need them to agree on that. The field is quite active, but much of the work is done by volunteers and you cannot leave it all to them.

#### *(5) Other insights*

The CoPs of the former Inspectorate for Health Protection, Commodities and Veterinary Public Health are held in high regard, but they urgently need updating. However, it seems to have become impossible to identify their owners.

[6] The HUF test involves an assessment of the feasibility, practicability and fraud-sensitivity of laws and regulations.

It is hard to say at what frequency CoPs should be updated. This strongly depends on their subject-matter, on the nature of the activity, and on the rate of developments in that particular area of science.

Some interviewees argue that CoPs are often too specific to be of much use to the CCD and DECs. Even so, some CoPs have influenced CCD policies quite directly.

CoPs tend to end up in working protocols and only rarely in licence applications. Some licences or applications list activities or situations which, strictly speaking, are permitted under the licence but fail to meet the minimum requirement of the CoP.

Generally speaking, the level of regulatory compliance among parties in the field is very high.

Drawing up a CoP is not always necessarily the best choice. As mere checklists, CoPs will defeat their purpose and can never give rise to a real culture of care.

## A.2 National Committee survey

In all, twelve national committees filled in the survey. Together, these NCs represent approximately two-fifths of the total number of laboratory animals used within the EU in 2017. The respondents included both the NCs of countries that used fewer than 5,000 animals and NC of countries that used the highest numbers of animals. Below is a summary of the responses per question.

The survey comprised three sections. Section I is about best practices in the Member State concerned, section II about best practices at EU level and section III about the NCad's CoPs.

### A.2.1 Best practices

The first question of section I invites respondents to describe exactly what a 'best practice' actually is. The common denominator in these responses is that best practices concern animal welfare, the 3 Rs and the need to safeguard scientific quality. In addition, best practices represent the best approaches that can practically be achieved. They are also identified as a means of communicating and sharing the necessary knowledge about the 3 Rs. One NC said it prefers the term 'good practices', so as to leave room for further improvements.

Next, the respondents were asked how best practices are monitored in the Member State concerned. Five NCs explicitly stated that they did not do this themselves. Others said they had assigned the monitoring task to their secretariats, or that the scientists or a 3R centre were responsible for monitoring. A number of NCs organise meetings for the purpose of sharing best practices, or share them through a 3Rs centre or a government body.

The third question in the survey concerned the approach to formulating and drafting best practices in the individual Member States. Six NCs indicate that they did not have any specific arrangements for this. One NC said they did not do this themselves, but that this was a task for groups of specialists in their Member State and elsewhere in the EU. Six NCs issued guidelines on best practices; two have also issued guidelines on the situation regarding the COVID-19 pandemic.

Further in-depth questions were asked to specifically identify the role of each NC in formulating best practices. Some of the NCs which in the previous question said that they did not have any specific arrangements for this, now described their own roles surrounding best practices and knowledge sharing in a wider sense. Three NCs stated they did not have any role at all in this regard; of these, one indicated that they did actually discuss best practices when called upon to do so in a project

evaluation exercise. Four NCs organise meetings and eight NCs share information via the Internet with references to other parties or (in five cases) to themselves as co-authors.

In the last question of section I, the NCs were asked about the sharing of best practices, and their own role in this, within their Member State. Three NCs said they did not perform any role in this regard, mainly due to a lack of resources. Most NCs share best practices through meetings or through their own website, a government website or the website of a 3Rs centre. One NC also publishes documents in scientific journals such as *Nature*, *Plos Biology* or *EMBO Reports*.

### A.2.2 International collaboration

The second section contained questions on collaboration and the sharing of best practices among the NCs themselves. They were asked to present a picture of the current situation, ideas on the sharing of best practices and suggestions on how collaboration might be improved. Not all NCs feel a need to intensify collaboration at this point in time. Of all NCs that responded, one explicitly says so while several others mainly focus on collaboration efforts already taking place and potential improvements.

One medium that is often mentioned is CIRCABC. Three NCs state that they have no access to this platform for document sharing. Others point out that the document sharing process is slow, that CIRCABC is not particularly user-friendly and that the EC is not very dynamic in this field either. Some NCs mention a shared online platform as a potential solution for the future. That will only work, they add, if such a platform is properly structured and organised, and allows for more effective searches.

The respondents' views on NC meetings are mixed. While most believe those meetings are useful, not all NCs have the resources they need to attend; according to some, the meetings should be more frequent to be really effective. Some NC say they would be happy to participate online if they are unable to attend physically, largely due to a lack of resources. One NC adds that the EC might take up the responsibility for ensuring that all NCs are able to attend in person. Another NC believes that commercial parties could be involved by means of a sponsorship system.

Other collaboration options mentioned are more frequent video conferences and workshops, standard publication in English, joint contributions from NCs to international conferences (such as the FELASA congress) and a joint NC website to facilitate collaboration. In addition, an effort could be made to identify common themes relevant to multiple NCs. An echo of this is found in a remark by one NC on the idea to ensure continuous investment in a network of NCs and 3Rs centres, in which National Contact Points (NCPs) should also be involved.

### A.2.3 Dutch Codes of Practice

The last section of the survey was about the extent to which other NCs are aware of, and able to apply, the Dutch CoPs issued by the NCad. To this end, the NCs were presented with the recommendations and the associated CoPs on relocation and motivation by restriction. As the CoPs are only available as appendices to the recommendations rather than as stand-alone documents, below the reference is to the recommendations as a whole, including the relevant CoPs. Nine (out of a total of twelve) NCs said they were familiar with those recommendations. Those NCs that explained how they became aware of the recommendations mainly referred to the NC meetings, followed by the NCad website and CIRCABC. Eight NCs said they were able to use these types of documents, for a variety of reasons. While minor adaptations were required for some countries, other NCs stated they could always find something useful in the documents. A number of CoPs are about cats, dogs and non-human primates (NHPs), and since these animals are not used in all countries, the CoPs concerned are not relevant everywhere. One obstacle mentioned in promoting the use of the

recommendations is the fact that since each country has its own structure, there are differences in how the European directive is implemented. One NC said it would need to study the CoPs in further detail before it could make any statements on the matter.

Ten out of the total of twelve NCs called for collaboration on CoPs on issues that are important for multiple NCs. One NC was more reserved, stating that the CoPs would have to be highly practical, without further discussing their desirability. According to another NC, collaboration on best practices might not be very useful, and collaboration at the strategic level might be more relevant to all parties involved. One NC failed to respond explicitly to this particular question.

#### A.2.4 Final comments

At the end of the survey the NCs were invited to leave any comments. These did not generate a great many new insights. One NC said that the division of tasks between the NC, the 3Rs centre, animal welfare bodies and other organisations in each country should be carefully taken into account, as this is likely to influence the survey results.

One NC submitted a substantive question regarding a consideration in licence applications that it found particularly problematic, and another NC proposed to consult with the NCad on future collaboration. These comments seem to stem from a broader need among NCs for more accessible or practical channels for contact and collaboration.

# B SUMMARY OF INFORMATION FROM THE DESK RESEARCH

## B.1 CODES OF PRACTICE TIMELINE

Around ten CoPs are currently in force in the Netherlands. The first ones were issued by the precursors of the NVWA (including the Inspectorate for Health Protection, Commodities and Veterinary Public Health). References to the supervisory authority or the NVWA are given below in this annex. The first CoPs were issued between 1989 and 1993. These are now largely regarded as superfluous (see 7.2.2 on the results of a comparison of CoPs). In 1999 and 2000, some of the CoPs from this first period were revised and a few new ones were published.

In 2010, the European Union published a directive with stricter requirements regarding the use of animals for scientific purposes. In the Netherlands, these European rules were laid down in the new Experiments on Animals Act. That act also provided for the establishment of the NCad, which published its first CoPs as part of a recommendation in 2016, which also included the advice to review some of the supervisory authority's CoPs. After that the CoPs issued several more CoPs. In 2019, it started work on another two CoPs in collaboration with the IvD Platform.

## B.2 RESULT OF A COMPARISON BETWEEN DUTCH CODES OF PRACTICE

| | |
|---|---:|
| Framework for motivation by restriction | 2018 |
| Motivation by restriction – rodents | 2018 |
| Motivation by restriction – NHP | 2018 |
| Creation of GM animals | 2018 |
| Breeding models for GM animals | 2018 |
| Relocation of dogs | 2016 |
| Relocation of cats | 2016 |
| Relocation of NHP | 2016 |

| | |
|---|---|
| Relocation framework | 2016 |
| Preventing, recognising and combating pain | 2016 |
| Welfare monitoring | 2000 |
| Immunisation of laboratory animals | 1993 (reviewed in 2000) |
| Cancer research in laboratory animals | 1999 |

The above CoPs of the NCad (from 2016 and after) and the supervisory authority (up until 2000) were considered in an attempt to find out whether different types of CoPs can be distinguished.

One clear finding is that the NCad is more likely than the supervisory authority to divide its CoPs into smaller sections for specific animals. This is also reflected in the length of the documents: the NCad's CoPs are considerably shorter. Not all of the NCad's CoPs explicitly mention the experts involved in compiling them. The experts' names can be found however on the last page of the recommendation to which the CoP belongs. In the CoPs issued by the supervisory authority, the experts' names can always be found in the document itself. Since their focus is confined to separate animal species, the NCad's CoPs appear to have a narrower scope of application than those issued by the supervisory authority. The NCad's frameworks are not referred to as CoPs and, for that reason, are more likely to be overlooked by superficial readers.

Further comparison reveals that the supervisory authority's CoPs and most of the NCad's CoPs include clear guidelines with obligations on parties involved in the use of laboratory animals, while the NCad's CoPs on relocation only offer guidance. Also note that as regard the CoPs on motivation by restriction, the framework appears to be essential for understanding the arguments supporting the CoP.

*Findability*

The findability of Cops was also examined. For the NCad's CoPs, findability on Google was studied using the website and (part of) the title of the document as the search term. For CoPs issued by the NVWA's precursors, only their findability on Google was studied. In principle, all CoPs can be found on Google, with the exception of de 'Creating GM animals' and ‘Breeding models for GM animals'. The latter are unfindable. For the 'Motivation by restriction' and 'Relocation of former laboratory animals' CoPs, both issued by the NCad, the title of the recommendation suffices to find the recommendation with the associated CoPs in the annex. The CoP on 'Preventing, recognising and combating pain' can be found using 'combating pain' as a search term. The supervisory authority's CoPs can be found quite easily on Google through a variety of websites. On the NCad website, some CoPs are easier to find than others. Those on 'Preventing, recognising and combating pain in laboratory animals' and 'Relocation of former laboratory animals' can be found on the best practices page. To find the other CoPs, the user will have to know to which recommendation they belong. That is relatively easy to find out as regards 'Motivation by restriction', where the title of the CoP is the same as the name of the recommendation. However, the CoPs entitled 'Generating GM animals' and 'Breeding models for GM animals' belong to the second part of 'Genetically modified animals killed in stock'. A search for 'CoP' on the NCad website only produces those entitled 'Preventing, recognising and combating pain in laboratory animals' and 'Relocation of former laboratory animals'.

Incidentally, according to the NCad website the publication date of one of the CoPs on GM animals is in 2015, while in fact it was published in 2018. Such a discrepancy in publication dates affects the assessment of the current value of the CoP concerned, especially in view of the rapid developments in molecular biology. There are also discrepancies in the publication dates of other CoPs, although none are as large (and potentially as significant).

*Reviewing CoPs*

One further objective of this study was to identify the CoPs in need of a review. A previous recommendation from the NCad in 2016 and an earlier study by the NCad had already singled out 'Welfare monitoring', 'Cancer research using laboratory animals' and 'Immunisation of laboratory animals' as CoPs to be revised. Information from the interviews suggests that most of the NCad's CoPs do not need to be revised, with the possible exception of 'Motivation by restriction', on which there is no consensus in this regard. Given the rapid progress in CRISPR-Cas technology and other developments in molecular biology, it could be useful to also evaluate the current relevance of CoPs concerning genetic modification in laboratory animals. As regards the CoPs of the supervisory authority that are not mentioned in this section, earlier studies by the NCad found them to have become obsolete to such an extent that there was no point in updating them. They concerned types of research using laboratory animals that are no longer performed. Revision of the supervisory authority's other CoPs is regarded as a high priority, except for the one on immunisation of laboratory animals, where the level of urgency is moderate.

*Status claim*

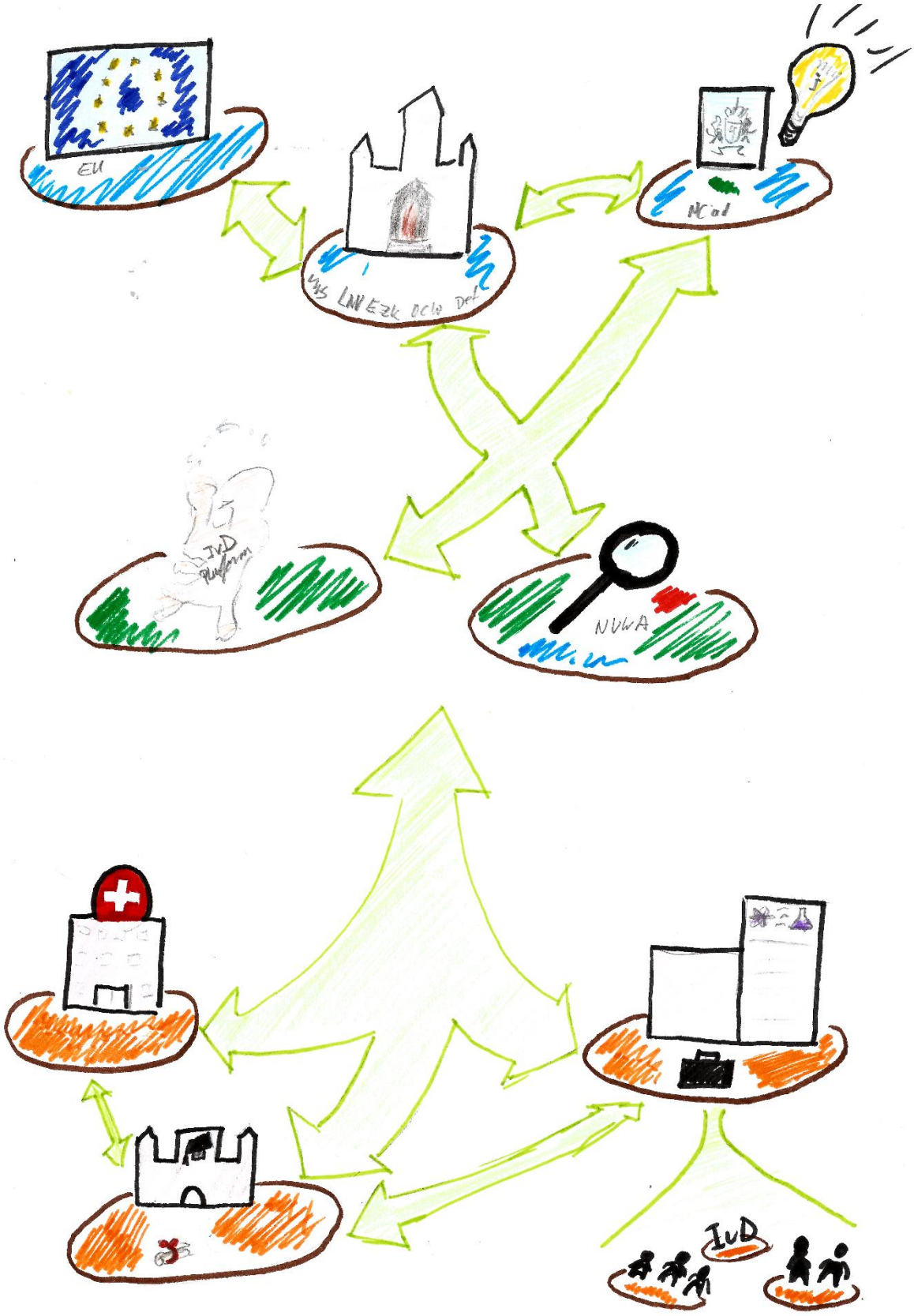
The interviews suggest that perhaps the greatest need for clarification concerns the issue of CoP status. The CoPs issued by the supervisory authority contain an explanation of behaviours and actions expected from the sector. As regards welfare monitoring, researchers are expected to adhere to working practices; in cancer research deviations from prescribed practices must be explained, and the CoP on immunisation of laboratory animals is expressly labelled for use in the field. A number of the NCad's CoPs contain no such explanatory notes. In the CoP on 'Motivation by restriction', the NCad states that it can be regarded as an interpretation of Article 10, and in 'Preventing, recognising and combating pain' that it is intended to serve as a point of departure for animal testing policy and supervision. The section on the formal responses to CoPs also contains the relevant government member's response to the CoP concerned.

## B.3 NCAD FINDINGS ALREADY AVAILABLE

CoPs were also the subject of an earlier study by the NCad, which resulted in a session organised by the NCad in collaboration with the IVD Platform during the Biotechnology Days. In addition to the comments in B.2 above about updating CoPs, in its own overview the NCad refers to the possibility of revising the CoP entitled 'Grading discomfort levels'. At the time of the study, the NCad was drafting a CoP on pain control and an international working group was working on the same subject. This is why a 'Yes, unless' approach was adopted for revision, with 'unless' being understood to mean 'unless the other two documents have eliminated the need for reviewing this CoP'.

It is difficult to assess the practical gains achieved during the Biotechnology Days workshop, but it seems clear that those gains largely overlap with the results of the interviews. In addition, part of the input already seems to have been incorporated into the NCad's working practices. For these reasons, the gains from the workshop are not discussed in further detail.

## B.4 THEORETICAL FRAMEWORK



The theoretical framework has not been integrated into the conclusions. It has been included in this report on account of the fact that the theory described has served as input for the guidance and the tool.

The black/brown circles represent the 'community of practice' within an organisation. The green arrows symbolise the exchange of knowledge and represent the major connections between the parties.

A community of practice is a group of individuals who have a specific skills set, are part of a community and have jointly developed a specific background (a common tone of voice, shared routines, stories, sensitivities etc.). Communities of practice arise from the interplay of skills and experience that is required for a shared commitment. Such communities are elements within a larger system of social learning mechanisms. Many academic institutions or businesses constitute communities of practice. They often have a shared institutional or company history and work according to internally aligned practices, which tend to deviate slightly - but significantly - from those of others. Even within organisations, separate communities of practice can be identified, such as research groups, functional clusters or departments. While some of the learning takes place within such communities of practice, most actually results from their interaction with other communities. However, this can only happen if individuals are prepared to look beyond the boundaries of their own community of practice or move between different communities. Objects or other types of interaction may facilitate this. Indeed, many CoPs could be seen as objects whose significance transcends the boundaries of separate communities. In addition, organisations such as the NVWA and the IvD Platform (and possibly the NCad itself) could be regarded as entities that operate in between the various communities of practice (Wenger 2000).

The notion of communities of practice also lends particular significance to the theory on cross-disciplinary collaboration (Pennington 2008). This theory may serve as a useful source of input for the process associated with the drafting of CoPs in contexts where experts or participants from a range of backgrounds are required to deliver a single end product. The theory concerns the conditions that need to be fulfilled for cross-disciplinary collaboration. If the further stages of the project incorporate this type of collaboration, this part of the theoretical framework will be developed in further detail, also in conjunction with the theory on intrinsic and extrinsic motivation, with insights possibly provided by a paper on the subject (Ryan and Deci 2000).

Colours have been added to identify the theories associated with the various parties. Blue represents the various methods of government direction (Peeters, Schultz et al. 2011, van der Steen, van Twist et al. 2013) and the connections with the open policy approach (Herold 2017). This theory could be useful in analysing the various positions of government ministries, the NCad and the NVWA as regards animal procedures and determining the roles that could be invited to issue CoPs. It could help to identify the parties likely to qualify as driving forces of CoPs - in other words, bring into view the parties most suitable, from an administrative point of view, to initiate CoPs and identify the conditions that need to be fulfilled. The insights currently available lack the level of detail required to merit a further discussion of this topic here.

The colour red, which is reserved for the supervisory authority (NVWA), represents the theory on street-level bureaucracy. Identified as public-sector professionals, street-level bureaucrats have frequent contacts with citizens as part of their regular duties, while being required to adhere to hierarchic structures. They decide on whether or not a particular service is to be provided to citizens, and make that decision with due observance of statutory rules and policies. At the same time, those rules and especially the policies leave room for personal interpretation and implementation. Street-

level bureaucrats apply a variety of mechanisms to cope with the stress resulting from this paradox. This part of the theoretical framework needs to be developed in further detail in a process that may offer useful clues as regards the role of CoPs in the NVWA's monitoring task (Huibers, Kunst et al. 2019).

Dark green is reserved for players that typically serve as 'knowledge brokers' between the various parties, or for players that move between the various communities of practice as referred to above. A considerable amount of work has been published about the category of knowledge brokers. They translate and coordinate the dissemination if knowledge across the range of perspectives involved. In addition, the theory explains why knowledge brokers are invisible and the effect of their potentially marginal presence in two different knowledge domains (Meyer 2010).

Finally, orange/yellow is a colour mostly found among parties that produce knowledge. CoPs mainly describe know-how as a form of knowledge. The theory provides insights into this form of knowledge, and contains a description of the relationship between knowledge on the one hand, and the individual and identity on the other (Boshoff 2014).

### 6.1.1 Experiences of the Inspectorate for Health and Youth Care with field standards

While the experiences of the Inspectorate for Health and Youth Care have not been incorporated into the conclusions, they did serve as input for the guidance and the tool.

In the performance of its supervisory duties, the Inspectorate applies norms drawn up by parties in the field and laid down in quality standards. Similarly, CoPs could be seen as norms drafted by the field and laid down in quality standards. The supervisory authority's CoPs are used in supervisory practice, while the NVWA uses several of the NCad's CoPs as guidelines. So there are parallels between the Inspectorate's working methods and the role of CoPs. Those working methods have been the subject of a study by Academic Workplace Supervision (AWT). The associated report and an interview with one of the Inspectorate's coordinating inspectors form the basis of this part of the project.

In its study, AWT focused on three cases. These cases provided input for the formulation of criteria on the matter of enforceability and of guidance on the development of supervision. The following enforceability criteria were given:

1. The norms should, in unambiguous terms, describe the 'desired behaviour' and the characteristics that distinguish it from 'undesired behaviour'.
2. It should be possible to test the norms.

As regards quality standards, the report provides the following general criteria:

1. There should be clarity as regards the basic conditions, and a plan on meeting those conditions so as to satisfy the quality standard.
2. There should be a clear distinction between norms and target values. As for the target values, a schedule should be available identifying the points in time at which, and the extent to which, each target value needs to be achieved. This should give both the parties in the field and the Inspectorate a clear overview of when a target value can be converted into a norm that can be monitored.
3. The components of a quality standard that are priority areas for monitoring should be clearly identified.

While serving as tools enabling a supervisory authority to assess the enforceability of a standard, in the context of CoPs these criteria will also help the group of experts draft a CoP that can be used in supervisory practice.

The guidance drawn up by the AWT researchers mainly focuses on the inspector in translating field norms to supervisory practice. In contract, the present project mainly focuses on the other actors. As such, the guidance has a somewhat narrower range of application. Even so, it does contain some useful aspects. The guidance is based on the analysis of the study results using the 'collaborative governance' model. The principal conclusion is that the success of translating field norms into supervisory practice depends, to a very large extent, on open communication and collaboration. The systematic and explicit involvement of actors promotes the level of support for supervision and the degree of transparency and predictability of the Inspectorate's activities (Voordouw, van Dijk et al. 2016).

The importance of open communication and collaboration also emerges from the consultation with the Inspectorate, which identified different categories of norms. One of those categories is formed by the statutory norms and rules, which are drawn up by the legislator and are absolute in nature. These should be distinguished from the quality framework and the field norms. They converge in a monitoring instrument. The quality frameworks and field norms are from the world of practice; the Inspectorate does not draft them itself. The Inspectorate does however put them under a magnifying glass when preparing the supervisory objects. It is important for the various parties involved to keep discussing these norms, for example on how to use them and where assistance is needed. Dialogue is also essential when things get difficult; after all, no-one benefits from conflict. For the rest, it is important for the Inspectorate to remain transparent and autonomous. Everybody should be able to decide upon their own approach to the norms with due regard for their specific role.

Those charged with drawing up a CoP are advised to adopt the NVWA's perspective; try to imagine what the NVWA needs in order to be able to make steps forward. What would make a CoP truly valuable? Is there any common ground to build on? This may demand more time; sometimes it is best to settle for a minor step forward rather than risking a deadlock in the process. A relatively mild norm that can count on some support is preferable to a strict norm without any support at all. People will be more inclined to adapt their behaviour to a new norm if it takes less of an effort to satisfy that norm.

### 6.1.2 The European Union's perspective on Codes of Practice

Upon introducing the European directive, the European Commission commissioned a group of experts to prepare a document on the functioning of the animal welfare platforms and national committees. That document includes detailed descriptions of the NC's tasks in accordance with the directive, and examines the ways in which the NCs could implement those tasks. One important role of NCs is to advise animal welfare centres on the functioning of the centres themselves and on developments in animal welfare and the 3 Rs. As regards the sharing of good practices[7], it is crucial for this to be initiated from within the animal welfare bodies. NCs can contribute to the sharing of good practices by setting up a national system for gathering, storing and disseminating information about such practices. Respondents also refer to the importance of personal contacts, as well as non-personal communication (through newsletters), to drive the sharing of practices.

[7] 'Good practice' is the term used in the document produced by the working group.

There are various comments about collaboration and exchanging information at EU level. Since these comments largely echo the feedback given by the Member States in the survey, they are not repeated here.

Brief email correspondence with a staff member of the EC has revealed that during their first meeting, the NC chairpersons developed a form to keep each another abreast of the projects they are doing, so as to prevent double efforts and encourage collaboration. So far, it appears that the NCs have failed to use this instrument in actual practice. They also used the meeting to share ideas. The EC has created a page on its website to promote the dissemination of national guidelines. There are no statistics on how often this page is consulted. Given the scarcity of resources, collaboration is of the essence, also as a means to promote harmonisation.

### 6.1.3 Legal frameworks, formal responses and agreements

#### 6.1.3.1 *The NCad's statutory duties*

Pursuant to the Experiments on Animals Act (WOD), the NCad's duties are as follows:

- advising Our Minister, the Central Authority for Scientific Procedures on Animals and the animal welfare bodies on matters concerning the acquisition, breeding, accommodation, care and use of animals in procedures;
- ensuring the sharing of best practices;
- exchanging information with national committees of other Member States on the operation of animal welfare bodies and evaluation of project proposals and sharing best practices within the European Union.

These duties are assigned to the NCad pursuant to Directive 2010/63/EU of the European Parliament and of the Council. In the Experiments on Animals Regulations, the Minister added the following duties:

- promoting the development, validation, acceptance and application of alternatives to animal procedures, at the national and international level;
- advising the government, the Central Authority for Scientific Experiments on Animals, the animal welfare bodies and the individuals referred to in Section 13f(3)(a) of the Act on alternatives to animal procedures;
- compiling and coordinating contributions from international bodies;
- supporting communication among and with professionals in the field of (alternatives to) animal procedures and arranging communication with the general public on (alternatives to) animal procedures.

#### 6.1.3.2 *Legal advice: Implementation of open standards and their use in licence applications*

This study involved an analysis of the status of CoPs. One suggestion made is that a CoP could serve to reflect the 'generally knowable view prevalent among experts' as referred to in Section 10(1), Part A of the WOD, which rules that animal procedures are prohibited when common opinion holds that such procedures could be performed by alternative means according to the 3Rs principle.[8] The NCad previously solicited advice on this from legal experts at the Netherlands Enterprise Agency (RVO). Following consultation with the NVWA, they concluded that the way the current CoPs have been

[8] It is prohibited to conduct an animal procedure for a purpose which, according to the generally knowable view prevalent among experts, may also be achieved by means other than animal procedures, or through an animal procedure that involves the use of fewer animals or causes less discomfort than the procedure in question.

drafted, structured and published is inconsistent with the 'generally knowable view prevalent among experts' referred to above. The legal experts mentioned three reasons for this:

1) Due to the way in which CoPs are currently shared, they are not generally knowable.
2) It is not clear how it is ensured that the group of experts represents the 'view prevalent among experts'.
3) It is not clear what purpose CoPs are intended to serve.

This conclusion dates from April 2019. Interviews with parties in the field do not suggest that the situation has changed significantly since then.

Around the time of publication of this report, moreover, a request for advice was submitted concerning the use of a CoP in licence applications, since that was one issue mentioned in a number of interviews with animal welfare bodies. The question was to identify the demands that a CoP needs to fulfil in order to be used in a licence application to demonstrate compliance with specific requirements. First of all, the CCD will need to introduce a separate policy rule for this. Second, a CoP must be knowable and understandable, and be in accordance with the law. Finally, it must be possible for the CCD to apply the CoP to individual cases.

#### 6.1.3.3 *Agreements with the NVWA regarding Codes of Practice*

The approach to CoPs has also been the subject of consultation between the NCad and NVWA and LNV policy staff. The parties agreed on the following arrangements:

- The NVWA does not approve CoPs.
- The NVWA does not act as co-author of a CoP.
- At the request of the relevant expert group, the NVWA will submit a CoP drafted by an expert group (with guidance from the IvD Platform in collaboration with the NCad) to a version of the HUF test (assessing the feasibility, practicability and fraud-sensitivity of laws and regulations; standard test of the NVWA) before the CoP has been adopted by the NCad.
- The NVWA will enforce compliance with the provisions of the Act.
- The NVWA uses CoPs as detailed specifications of the open standards referred to in the Act.
- Peer feedback from NVWA inspectors on the content of draft CoPs (for example, by referring to the relevant literature) is greatly appreciated by the NCad and the IvD Platform.

The NCad could consider including the following text in a CoP:

*'This Code of Practice (CoP) includes views prevalent among experts on (x=subject). This CoP is regarded as a detailed specification of the regulatory norms. The NVWA has not co-authored the CoP and is not responsible for the views included in it. Within the framework of its supervision of the WOD, the NVWA enforces compliance with regulatory norms and, at the authors' request, has tested the CoP for enforceability, practicability and fraud-sensitivity.'*

When this report was written, the NCad had not yet used the option of conducting a version of the HUF test.

#### 6.1.3.4 *Response by the relevant members of government to the NCad's Codes of Practice*

Since it was founded, the NCad has issued various CoPs as part of its recommendations. The responsible government member responds to those recommendations in the Letters to the House of Representatives (*Kamerbrieven*) in which he or she submits them to the House. In some of these letters, the member of government also included responses to CoPs.

The first of the NCad's recommendations that included a CoP were 'Relocation of former laboratory animals' and 'Preventing, recognising and combating pain in laboratory animals'. The latter recommendation centres around a CoP. In his response to the House, the State Secretary of Economic Affairs said he expects this particular CoP to become part of the Culture of Care and to serve as a guideline for the NVWA's supervision. He also expects the NCad to share this CoP with the NCs of the other Member States. In its recommendation, the NCad incorporated a range of support measures, including an effort to update CoPs previously published by the NVWA. In this regard, the State Secretary emphasises the important role for parties in the field to ensure that CoPs remain living and relevant documents at all times and that knowledge on pain control remains easily accessible to users. He also stresses that the institution that holds the licence is responsible for ensuring the availability of knowledge on methods to recognise and combat pain (House of Representatives, 2015-2016, 32 336 No. 61).

The State Secretary calls on parties in the field of animal procedures to implement the CoPs for 'Relocation of former laboratory animals' and assign a leading role for the animal welfare bodies in this regard. In doing so, he emphasises the shared responsibility for the relocation process and the importance of coordination and collaboration among the parties involved. (House of Representatives, 2015-2016, 32 336 No. 61)

In 2018, the NCad published its 'Motivation by restriction' recommendation, with the associated CoPs. In the ministers  response to the House, she refers to the CoPs as part of the recommendation and asks the CCD and the NVWA to take this recommendation into account in the performance of their licensing and supervisory duties. She also asked the NCad to draw attention to the recommendation in a European context (House of Representatives, 2017-2018, 32 336 No. 70)

The NCad also issued CoPs accompanying the second part of its recommendation on genetically modified animals killed in stock. According to the Minister, the CCD is using those CoPs as a central criterion in licensing. In addition, she points out that a consultation platform for breeding coordinators has been established, on the initiative of the Dutch Association for Laboratory Animal Science. It has been agreed with the group of largest users that the CoP will be implemented in the near future (House of Representatives, 2018-2019, 32 336 No. 89)

# 7 LIST OF ABBREVIATIONS

CCD: Central Authority for Scientific Procedures on Animals

LNV: Ministry of Agriculture, Nature and Food Quality

NVWA: The Netherlands Food and Consumer Product Safety Authority (*Nederlandse Voedsel en Warenautoriteit*)

NCad: The Netherlands National Committee for the Protection of Animals Used for Scientific Purposes

NC: National Committee for the protection of animals used for scientific purposes

EC: European Commission

CoP: Code of Practice

SOP: Standard Operation Procedure

IvD: Animal welfare body

DEC: Animal Experiments Committee

RVO: Netherlands Enterprise Agency

3 Rs: Replacement, Reduction and Refinement

WOD: The Experiments on Animals Act: (*Wet op de dierproeven*)

OBDA: Support Office for Animal Procedures and Alternatives

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