



Centrale Commissie Dierproeven

# Revised Animal Procedures Act: the effects on animal procedures in the Netherlands

Central Authority for Scientific  
Procedures on Animals (CCD)

December 2nd 2016,  
Soesterberg

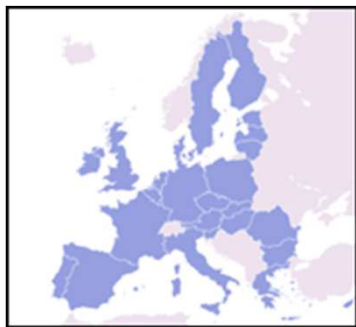


## Background

- 2010: Directive 2010/63/EU on the protection of animals used for scientific purposes
- 18 december 2014: Directive implemented in the Dutch revised Animal Procedures Act (Wod)
- Because of this Wod, establishment of:
  - › National Committee for the protection of animals used for scientific purposes (Ncad)
  - › Central Authority for Scientific Procedures on Animals (CCD)



## Which players are involved?



### *Each European member state*

National Contact Point

National Committee

Competent Authority

Awb



### *The Netherlands*

NCP

NCad

zbo CCD

NVWA

### *Each licenced establishment*

Awb

DEC



## NCad

- Advisory body, established by the Ministry of Economic Affairs
- No hierarchical position compared to CCD, DECAs, Animal welfare bodies or establishments performing animal experiments
- Independent and impartial
- Contribute to minimalisation of animal use in experiments by advise, exchange of knowledge and (inter)national networks



## Legal tasks NCad

- Advise Minister Economic Affairs, CCD, Animal welfare bodies and others about purchase, breeding, housing, care, and use of animals in experimenta and alternatives.
- Spread best practices
- Exchange of information with NC's of other member states
- Stimulate development, validation, acceptance and use of alternatives (both national and international)
- Support communication with and between professionals and inform the public about animal experiments and alternatives



## Animal welfare body (Awb) legal tasks

- Advises performers of animal experiments on animal welfare concerning purchase, housing, care and use
- Advises performers of animal experiments on 3 Rs and informs on technical and scientific developments
- Establishes and controls internal procedures to secure welfare of animals in the institution
- Advises on continuation of projects, based on the results of the project
- Advises on adoption of animals



## Animal Experiments Committee (DEC)

- Advises the Central Authority for Scientific Procedures on Animals on project licence applications



## Central Authority for Scientific Procedures on Animals

- Independent governing body (ZBO)
- 5 members + Secretary
- Distant from the licence holders / centralised
- The only body for project licencing
- Recognises/recalls Animal Experiments Committees
- Delivers guidelines for DEC advise
- NTS will be published on the website of the CCD





## Animals that are protected by the Wod

- a) Live non-human vertebrate animals, including:
  - i) Independently feeding larval forms; and
  - ii) foetal forms of mammals as from the last third of their normal development
- b) Live cephalopods

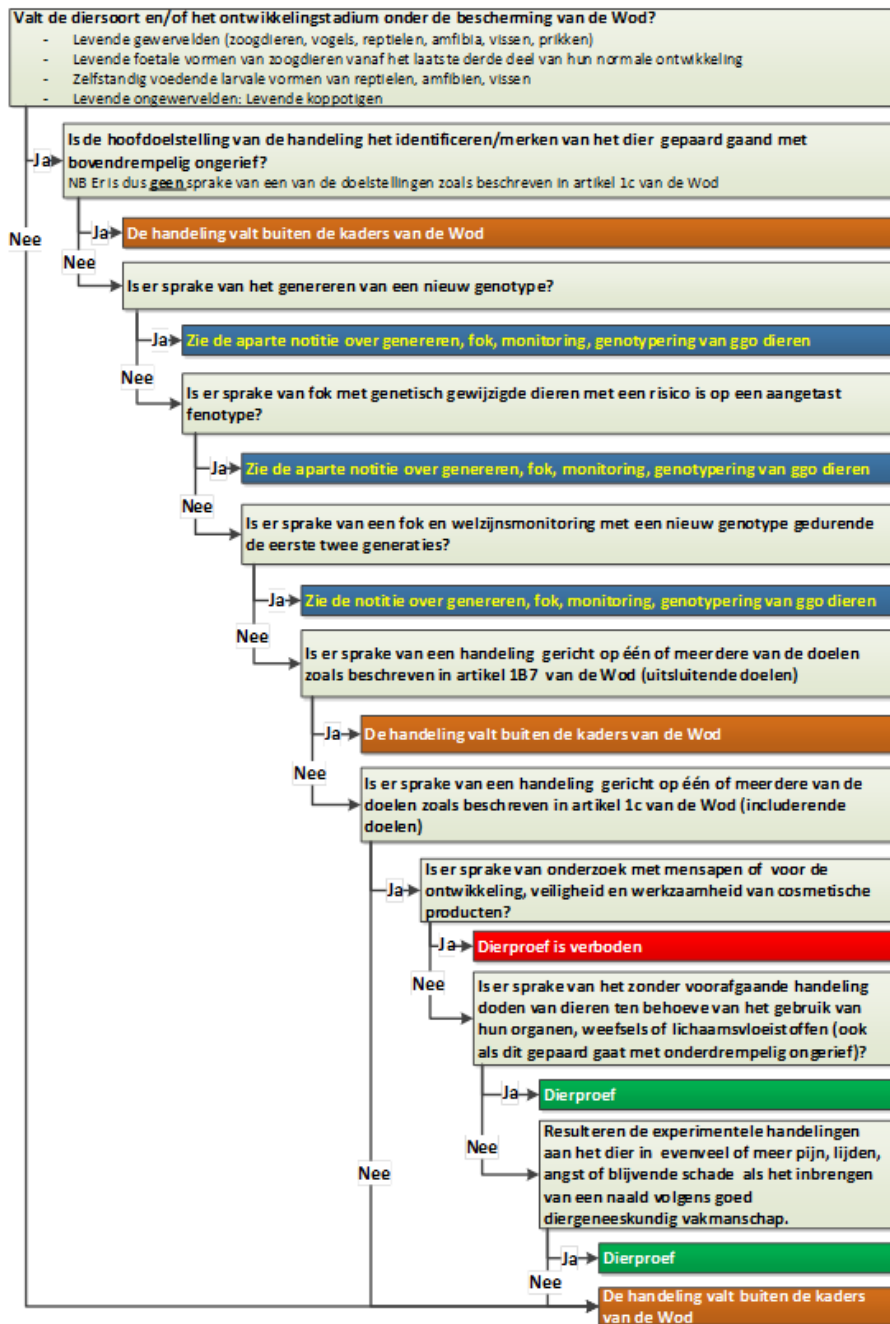


## When do you need a licence?

Definition of a procedure:

any use, invasive or non-invasive, of an animal for experimental or other scientific purposes, with known or unknown outcome, or 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 or tissues**;



See document “Herziene Wet op de dierproeven: Wanneer is er sprake van een dierproef in de zin van de Wet?” published on the website of the CCD.



## Types of applications

- Project licence application: new project
- Amendment: when the project alterations will adversely affect the welfare of the animals or affect the basic principles of the project licence
- Notification\*: when the proposed alternations do not adversely affect the welfare of the animals it is sufficient to notify the CCD

\* The policy guideline for notifications will be published in the Staatscourant soon



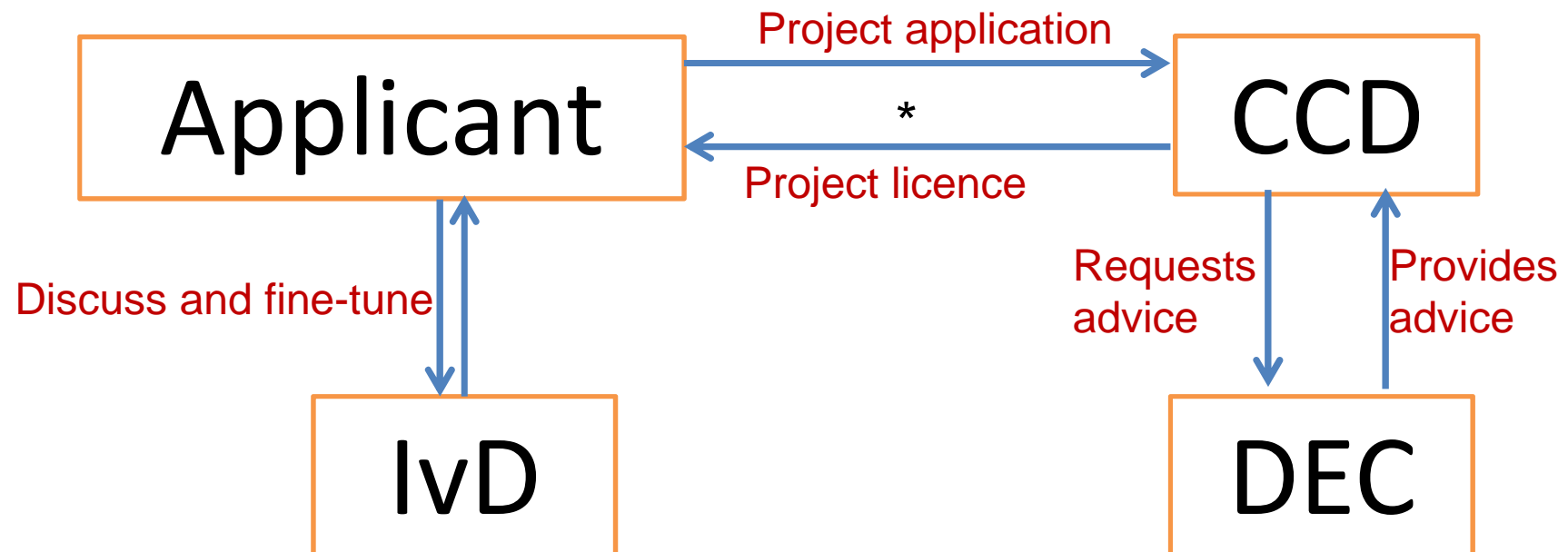
## Application for a project licence

- Non technical summary (in Dutch)
- Project licence application for animal procedures (in Dutch)
- Project proposal
- Appendix – Description animal procedures
- Optional:
  - › Form ‘melding machtiging’ (in Dutch)
  - › DEC advice

All these forms can be downloaded from  
[www.centralecommissiedierproeven.nl](http://www.centralecommissiedierproeven.nl)



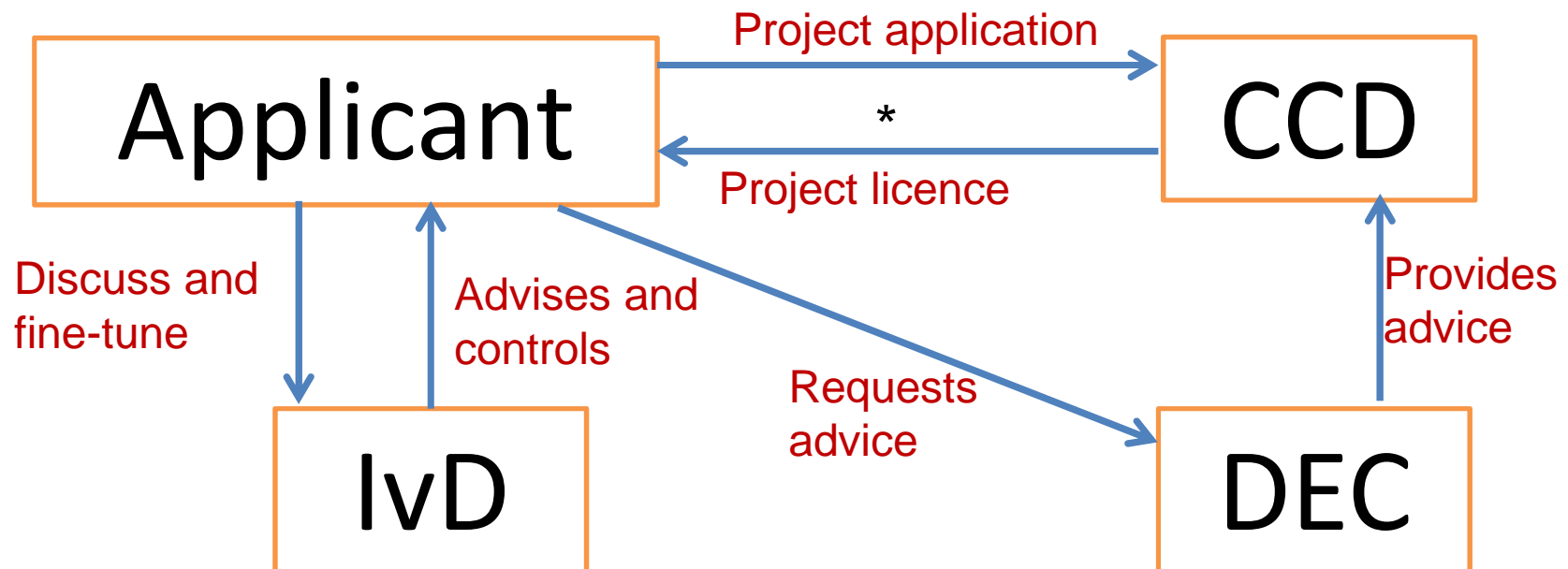
## Route 1: Apply directly to the CCD



\* Max. 40 days, possibility to be extended with 15 days.



## Route 2: Apply with a DEC advice included



\* Max. 40 days, possibility to be extended with 15 days.



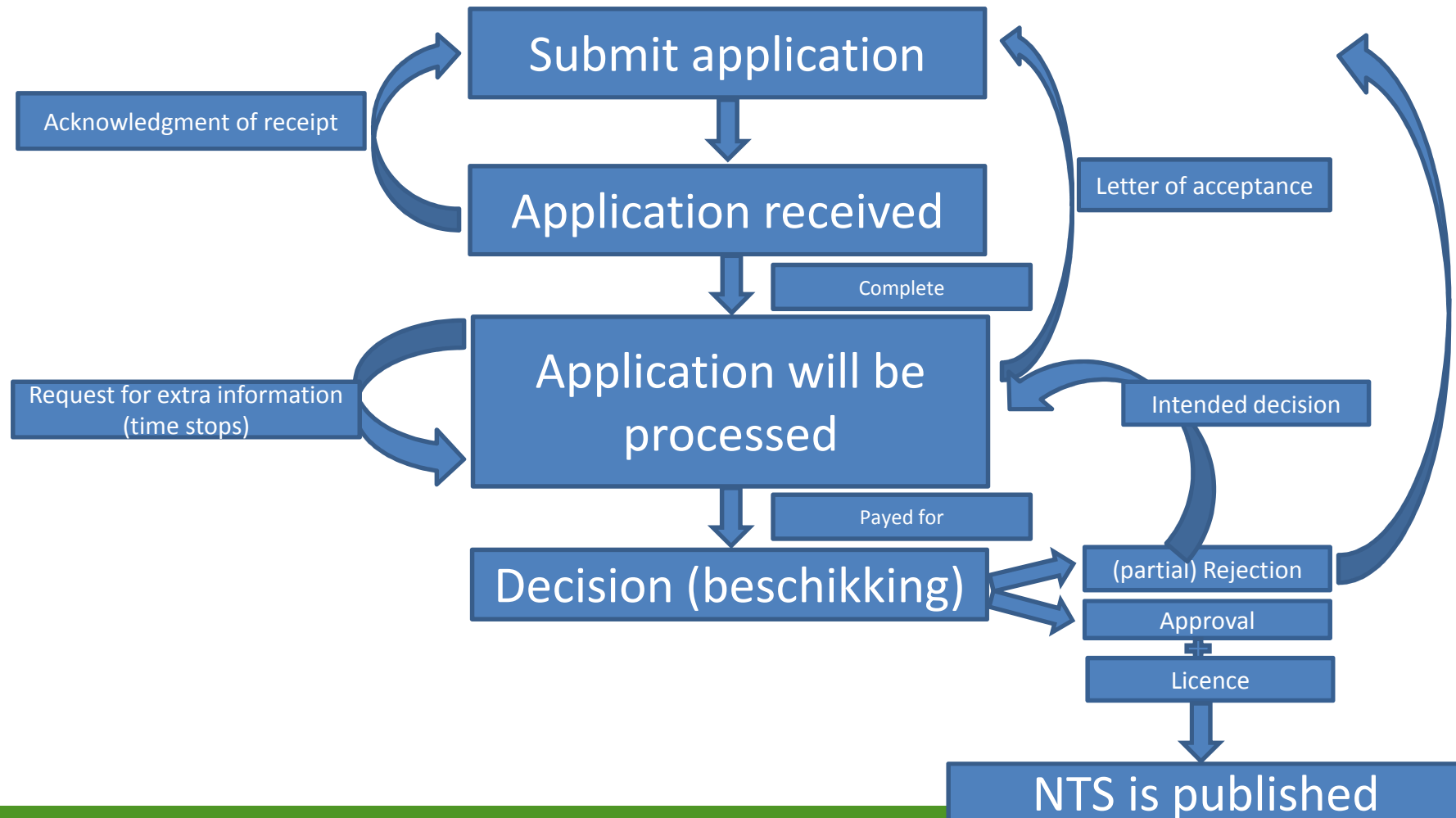
## Path for project application

- Application complete, signed, and paid for
- Total time from receiving application to decision CCD is max. 40 working days
- This deadline can be extended with max. 15 working days
- When extra information is requested from the applicant the clock will be temporarily stopped. The process will continue when the required information is received by the CCD
- In certain cases there is an option for urgency





## Path for project application





*One needs to apply for a project licence at the CCD before one is allowed to perform any study or project which involves the use of laboratory animals (Wod art. 10a)*

### The CCD only approves an application when:

- The purpose of the project is relevant from a scientific or educational viewpoint, or is legally required;
  - The objective(s) of the project justify the use of animals;
  - The project is designed in a way that makes the animal experiments as humane as possible.
- 
- Most important part of the Dutch legislation: No, unless...



## From procedure to project level

Project: a programme of work with a well-defined goal which entails one or more animal procedures\*

- › Animal experiments with a logical coherence
- › Serving a common, well-defined purpose
- › The sub-goals each contribute to the main purpose
- › Impact for each animal is clear
- › Feasible to achieve this purpose within the authorisation period of max. 5 years

\* See also “Handreiking ‘Invulling definitie project’ on the website of the CCD (English version in progress)



## Project evaluation by CCD includes especially

- Evaluation of the goals and expected results or educational value
- Information on the positioning of the research
- Evaluation of assigned severity classifications
- Harm-benefit analysis: is the harm to the animals (suffering, pain, distress) justified by the expected outcome? (Ethical considerations)
- Evaluation of feasibility (realistic goals, animal model)
- 3 R's
- Animals bred but not used “in voorraad gedood”
- Advice of DEC carries great weight



- Special emphasis

- Endangered species
- Non-human primates
- Animals taken from the wild
- Animals not bred for use in procedures (Annex 1)
- Stray and feral animals of domestic species
- Re-use
- No anesthesia/analgesia when applicable
- Method of killing deviating from guideline (Annex 4)



## What is the maximum size of a project proposal?

- No maximum number of animals
- No maximum number of animal procedures (appendices)
- Limit complexity
- Goal should be feasible within 5 years
- Steps to take / choices to be made should be clear
- Links and relations between different animal procedures should be clear
- Go / no-go moments and criteria should be clear
- Proposal should be clear without background knowledge



## Animal procedures / level of detail

- Clearly describe how you have made certain that you have researched all aspects properly
- Provide a description of i.e. types of pain medication, but not in detail
- What treatments affect animal welfare?
- Experimental design is more important than individual experiments.
- Describe type, frequency and duration of procedures
- Describe read-outs
- Explain choices



## 3 R's

- In the new legislation there is a lot of emphasis on the 3R's - the golden rule is : NO, unless.....
- Therefore it is of great importance to explain:
  - › Why you need to use animals?
  - › What do you do to minimize distress and pain?
  - › What is the decision making process for welfare indicators and optimal housing conditions?





## Description Animal procedures at D. Replacement, Reduction, Refinement

- Address the 3R's on a more “animal model” level:
  - › Why you need to use laboratory animals?
  - › What do you do to minimize distress and pain?
  - › What is the decision making process for welfare indicators and optimal housing conditions?



## After evaluation by the CCD

- The applicant receives the decision of the CCD, if positive, including the license.
- Publication of NTS on website CCD
- CCD is a Independent Governing Body, therefore all communication with the CCD can be requested under the Freedom of Information Act (Wob)
- Objection and appeal is possible, but only for people with a clear interest in the matter.



## Non Technical Summary

- Is a mandatory part of the project application
- Should be in Dutch (EU requirement)
- Approximately 500 words
- Important to:
  - Consider the content carefully
  - Ensure the meaning and relevance of the content
  - Suitable for a broad audience
  - No privacy sensitive information, i.e. names and addresses
- Goal: to provide transparency



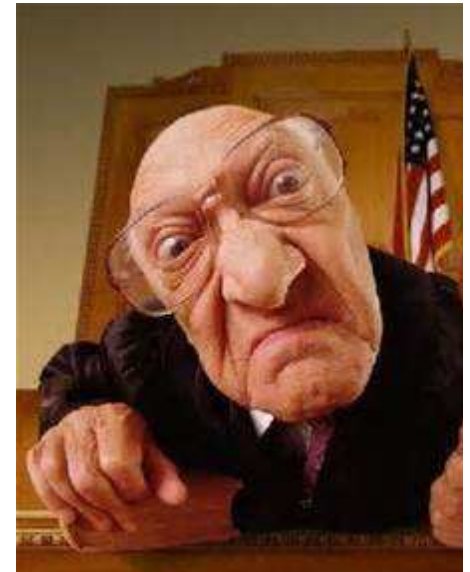
## Freedom of information act (WOB)

- Stakeholders are asked for their vision
- Strong arguments necessary for refusing
  - privacy, company secret, safety
- CCD decides whether or not to reveal information



## Objection and appeal

- Objection at CCD
- Appeal at court of justice





## Summary

- Animal Welfare Bodies, NCad and CCD
- New role for the Animal Experiments Committees
- Evaluation of animal procedures take place on a different (project) level
- Further information can be requested under the Freedom of Information Act
- Society will be critical on the work we all do
- This requires clear and well defined project proposals and well motivated and carefully considered descriptions



## Help when applying for a project licence

- Several tools are available on the CCD website
  - Guidelines to the project license application form
  - Manual for applying for a project licence for animal procedures
  - Q&A
  - Examples (Wob)
  - Guidances



## Questions?

- <http://www.centralecommissiedierproeven.nl/>
- [info@zbo-ccd.nl](mailto:info@zbo-ccd.nl)
- T: 0900 2800028

