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Challenges regarding the implementation of 2010/63 in The Netherlands

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History of the legislation > 2010

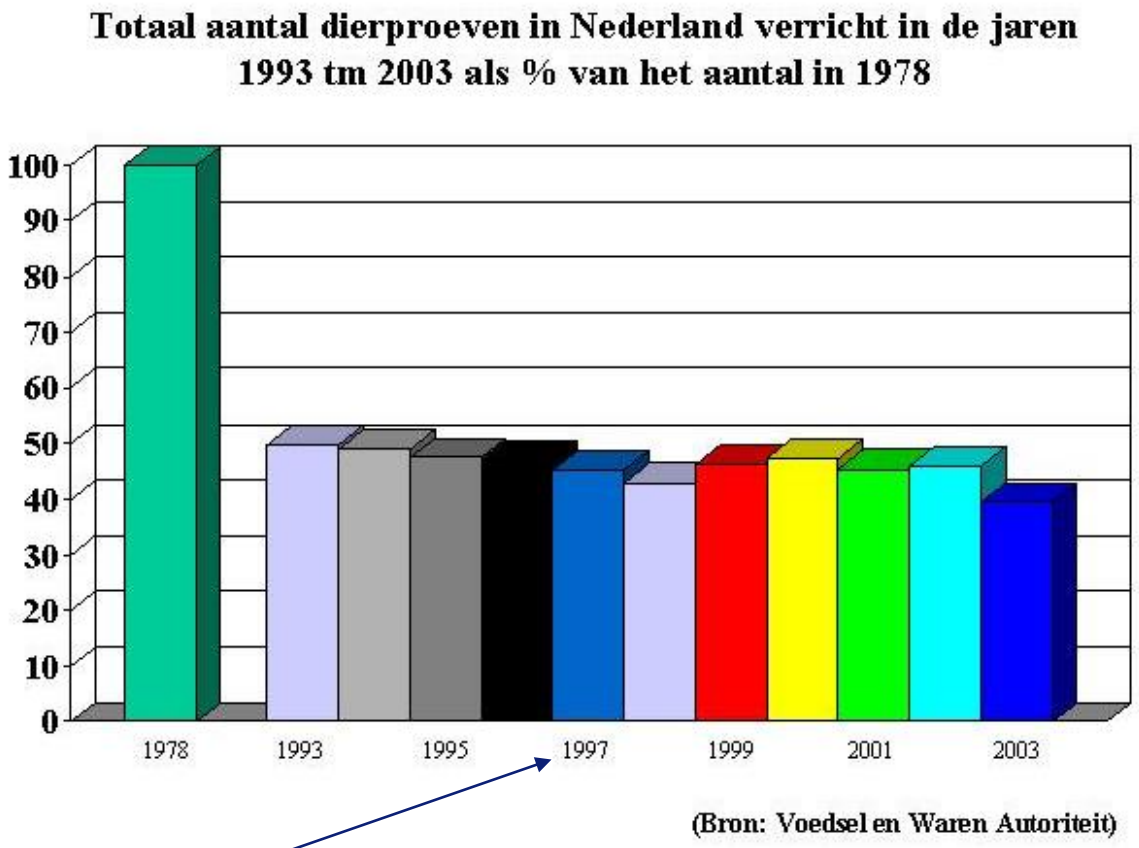
- 1977: Law on animal experimentation (lex specialis, in addition to the Law on the protection of animals), *Ministry of Public Health*
- 1986 European legislation for the protection of animals used for scientific or other experimental procedures, *European Commission*
- 1996 Renewal of domestic Law on animal experimentation, *PH*:
  - Implementation of European law (86/609), some additions:
    - institutional ethical review required, committees to be recognized – about 20 served 60 licensed institutions;
    - some possible offenses classified as criminal (never applied)
- 1997 Legislation on biotechnology in animals, *Ministry of Agriculture*
  - Additional ethical review (biosafety in other framework)
  - Embryo's and invertebrates all included
  - License procedure w. public hearings, appeals, et cetera
- 2010: License requirement revoked for biomedical applications

Bull Herman (16 December 1990 –2 April 2004) transgenic for human lactoferrin, moving targets:

- Prevention of mastitis in dairy cows (public)
- Use in baby food formulas (private enterprise)
- Pharmaceutical (public)

Herman became iconic and was kept and finally humanely put down in *a museum of natural history*

Statistics on animal use for research



Ethical review
legally required

1997 Special license for GM

EU Directive 2010/63

- Best protection of animals used for research, worldwide
- 3Rs-alternatives (Relacement, Reduction, Refinement)
- Transparency
  - Non-Technical Summaries project licenses
  - Statististical reporting
- Level playing field (w/i Europe)
  - Academy
  - Institutions
  - Industry
- No ‘gold plating’:

  No further restrictive rules to be added relative to Directive and national legslation in 2009

Transposition of 2010/63 to NL law policy and political approaches

Old law (1977!) was amended, despite the outcome of evaluations done in 2005

This was wrong in the opinion of all societal stakeholders (this was reviewed in several MSc studies)

- All ‘old rule’ was maintained
- Structure is increasingly unclear, also real mistakes
- MPs saw room for more political ambition, were told that the Directive was less restrictive than what we had before (this was not what the professional field observed)
- 2 years overdue, first Ministry of public health
- starting 2013: Economic affairs

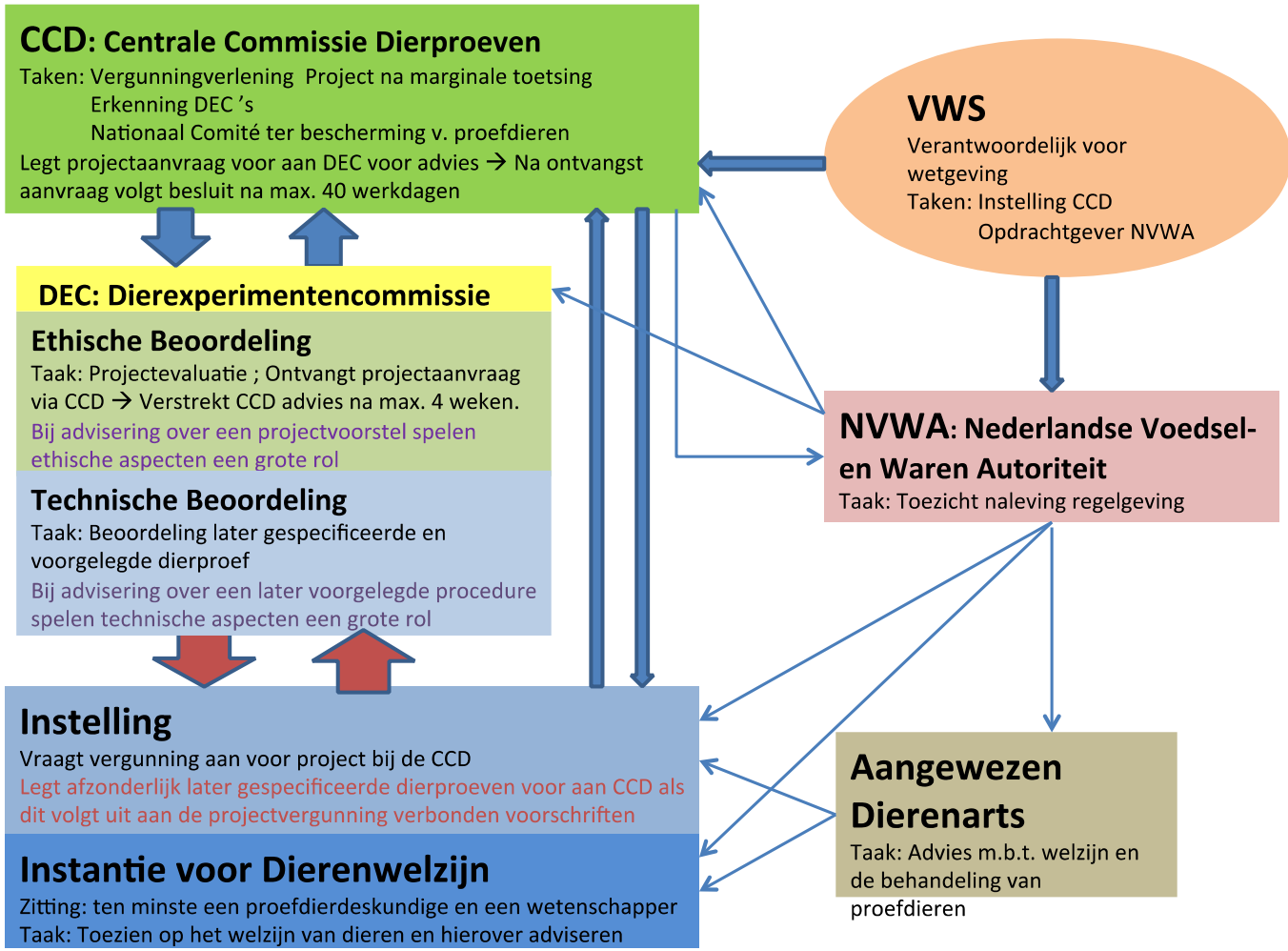
Gold plating

The overall risk is that the European Directive has direct legal power in case it is not or not correctly implemented in national legislation, European court will overrule

- The law requires that licence applications are first submitted to the Animal Welfare Body *(oversight staff has been doubled or tripled and spends all time on this, not on other AWB tasks)*
- Minor adaptations during the use of a project licences that have no impact on animal welfare must be reported to the CA *(even more bureaucracy but also the risk that adaptations in favor of animal welfare will not be made because of this)*
- Misinterpretation that an internal oversight person must be responsible for the project rather than the PI *(which weakens the much wanted concept that the PI will be responsible to manage the project in detail)*

How ‘simple’ it was meant to be

Taken & Verantwoordelijkheden Herziene Wet op de Dierproeven



Instead

- The CA (tasked to issue project licenses) also issues novel and additional rulings
- The National Committee (second official body per Directive, advising the Minister)
  - is not consulted on novel rulings
  - produces lots of additional reports
- All of this is done with very limited transparency and input from experts
- On transparency: FOIA (Freedom of information act) is ineffective because everything is claimed to be ‘internal deliberations’

Practice …..

The elephant in the room

FOIA

- Project licenses, and the elaborate advices from Ethical Review bodies, and all further correspondence, is published upon request
- Before that is done, parties in the process are to give their opinion
- Typically, when not everything, including names of institutions and persons, is published, appeals by the requester follow
- Parties are again to respond to this and loose their anonymity in the process
- Next follow court procedures

The triple cost of FOIA

- Financial cost (labour, legal expenses)
  - To the applicant (institute)
  - To the ERB
  - To the CA

- Premature disclosure of IP/ loss of competitiveness
  - Industry (strategy and product development)
  - Academia (strategy and creative products)

- A lot of pressure on the entire process
  - Limits sharing of information

Risks of FOIA

- Animal rights extremism
- Research is moved abroad
- Animals suffer more outside EU

BUT THERE IS HOPE

- Three recent decisions of high court recognise the risks of extremism and imply that
  - statistical information from individual institutions is not to be published
  - the identity of institutions and persons must be withheld
  - public servants must be anonymous
- Regarding project license files, appeal procedures to high court are anticipated

The European landscape:

- EU: 28 countries, different organization, different guidance, ?
- Numbers of evaluations range from 1 – 3 (3 in Czech republic and …. The Netherlands)
- Only in The Netherlands, entire application files are made public based on FOIA
  - Costly procedures
  - Threat to IP
  - Threat to people
  - Inhibitory to free exchange of information in the review process
- Other differences regard:
  - Fees from applicants (most countries: none)
  - When the NTS is published (delays)
  - Appeal procedures (Possible? Who and where?)
  - Time delays

FP7 ANIMPACT consortium has done active comparisons

More differences – statistics are not what they seem

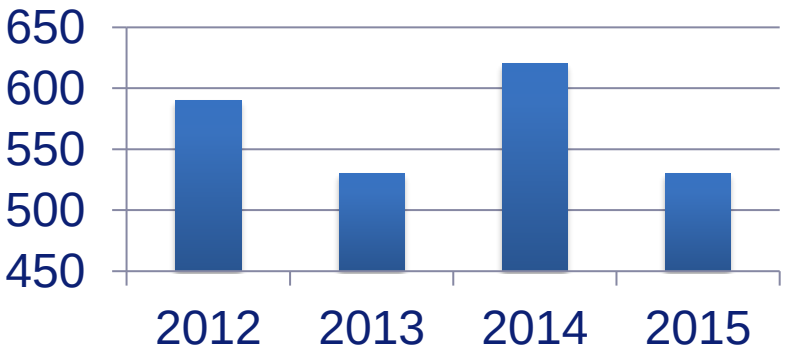
NUMBERS

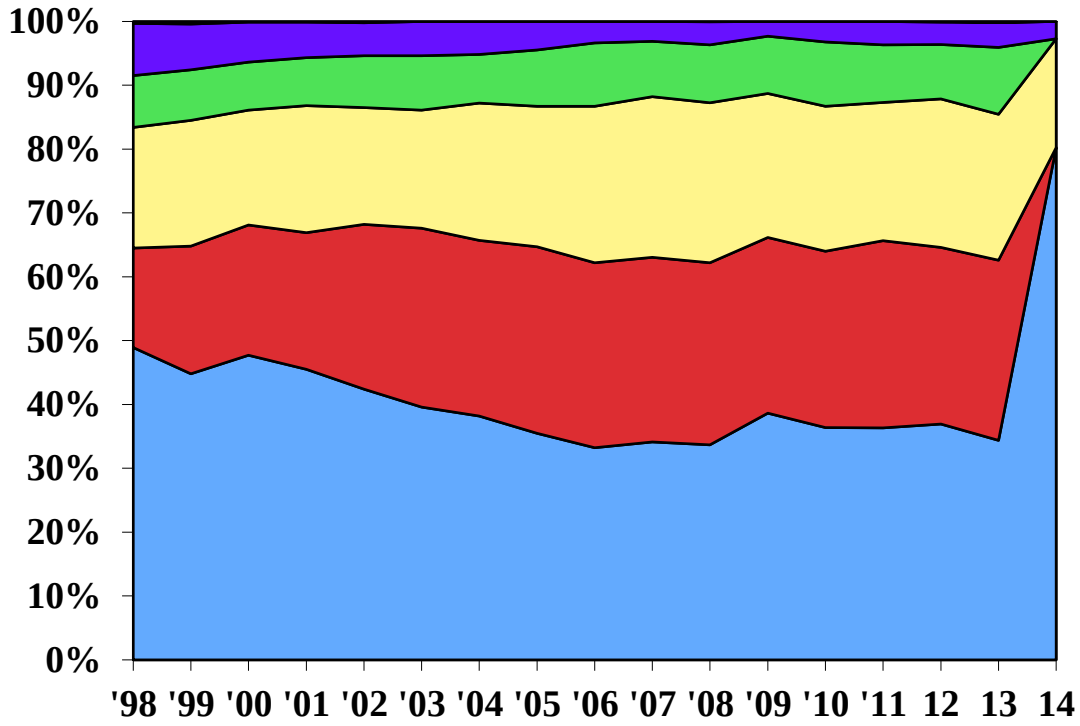
SEVERITY

- No annual comparisons are made any more
- Categories to be reported vary

European statistics by 2017

Harmonized?

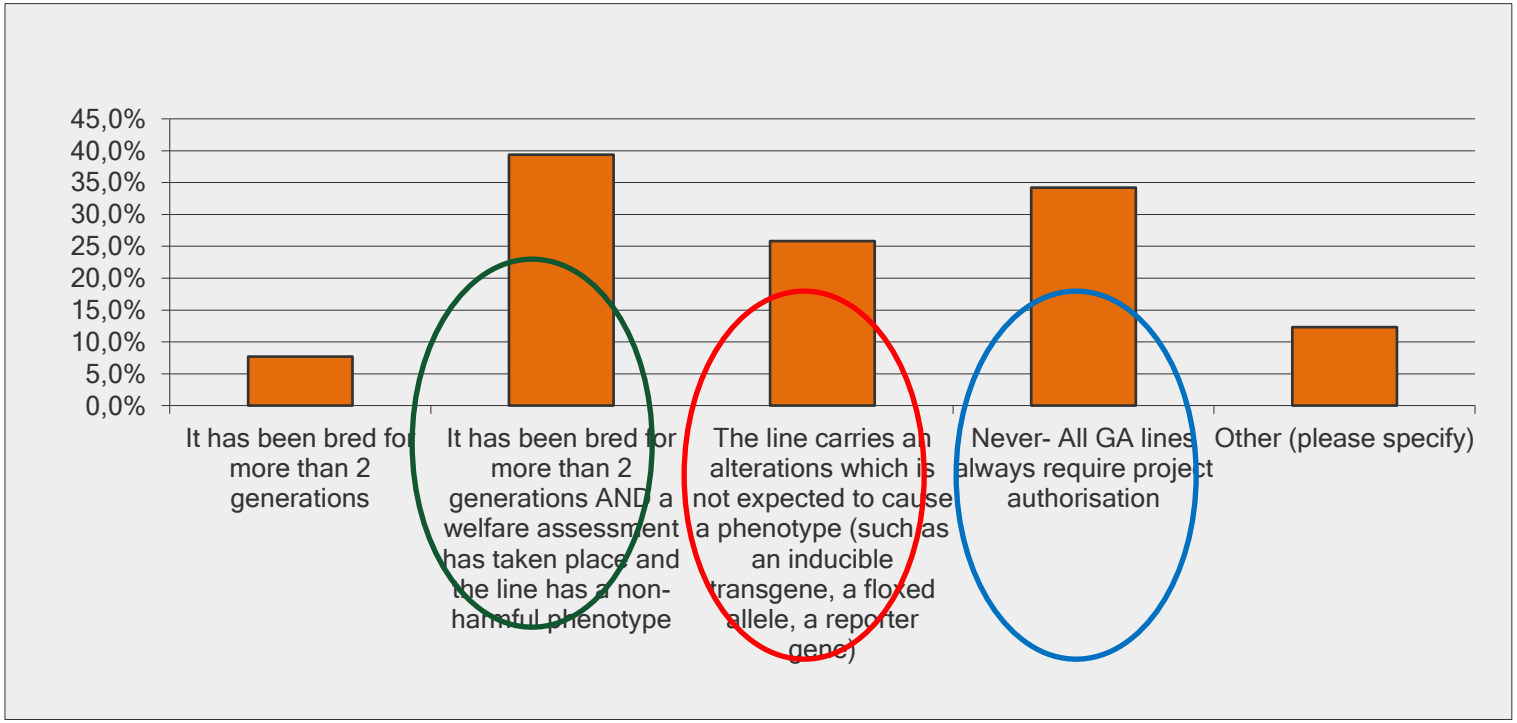




More differences

Question:

The breeding and maintenance of newly generated genetically altered animals DO NOT require project authorisation at your facility when



In NL, animals from newly generated lines are not reported as regulated procedures while under welfare impact assessment (in deviation from EC Implementing Decision on reporting by the MS)

Conclusive (ambitions)

- The Parliament asked the Minister for a plan to end animal use in 10 years

- After extensive deliberations, the outcome was:

To be World Leader in Alternatives by 2025

- Some people think: replacement; others: all 3 Rs

- Focus on regulatory testing and quality control in pharmaceutical industry

Conclusive: questions

HOW TO MEASURE ‘SUCCESS’?

- If numbers of animals used go down, what proportion will be due to export (and ever changing definitions for statistical reporting)?
- Should this be related to scientific output and R&D in LSH?
- How would we evaluate the development and adoption of Replacement alternatives? (we can evaluate Refinement!)
- What technological drivers will there be, e.g. stem cells and regenerative medicine?
- What could be the impact on, e.g. (bio)medicine?
- Will scientific talent go adrift?

A plead for a healthy and sustainable research climate!