

# Legislation and administrative procedures for biomedical research involving laboratory animals

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**Baden-Württemberg**

MINISTERIUM FÜR LÄNDLICHEN RAUM  
UND VERBRAUCHERSCHUTZ

Animal welfare officer =  
Competent authority

Preliminary remark:



my duty as „**animal welfare commissioner**“:

- no competent authority
- **advisory function / contact**
  - for the federal government,
  - for animal welfare organisations or farmers' associations
  - for everybody, who has to look after animals



## Topics:

### Legislation (by):

Council of Europe (47 member states)  
European community (27 member states)  
Germany



### Legal preconditions for research involving lab animals

### Administrative procedures:

Authorisation (projects, users etc.)  
statistics



# European Convention for the Protection of Vertebrate Animals used for Experimental and Other Scientific Purposes (ETS 123)

Strasbourg, 18.III.1986

(Selected important contents)



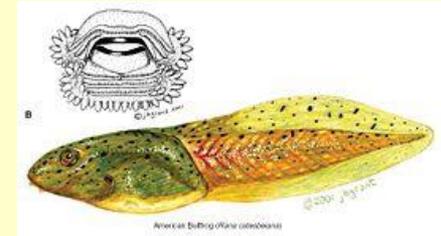
## Preamble:

- Man has a **moral obligation** to respect all animals and to have due consideration for their capacity for suffering and memory;
- Man in his quest for knowledge, health and safety has a **need** to use animals where there is a reasonable expectation that the result will be to extend knowledge or be to the overall benefit of man or animal, just as he uses them for food, clothing and as beasts of burden;
- ...to **limit the use of animals** for experimental and other scientific purposes, with the aim of replacing such use wherever practical, in particular by seeking alternative measures and encouraging the use of these alternative measures



important framework / main conflict

## European Convention ...(ETS 123): (Continuation) defines



### Art. 1:

**“*animal*”** , unless otherwise qualified, means any live non-human vertebrate, including free-living and/or reproducing larval forms, but excluding other foetal or embryonic forms

**"*procedure*"** means any experimental or other scientific use of an animal which may cause it pain, suffering, distress or lasting harm, including any course of action intended to, or liable to, result in the birth of an animal in any such conditions, but excluding the least painful methods accepted in modern practice (that is "humane" methods) of killing or marking an animal.

## European Convention ...(ETS 123): (Continuation) describes



Art. 2: purposes for procedures

Art. 5: general care and accommodation → **Appendix A**

Art. 6: A procedure shall not be performed, if another scientifically satisfactory method, not entailing the use of an animal, is reasonably and practicably available  
**= “priority of alternative methods”**

Art. 7: ....in a choice between procedures, those should be selected which use the **minimum number of animals**, **cause the least pain, suffering, distress or lasting harm** and which are **most likely to provide satisfactory results**.



## European Convention ... (ETS 123): (Continuation) describes

Art. 6 + 7 represent the so called “3 R”:

to **replace**, to **reduce**, to **refine**

first described by

Russell & Burch, 1959, in

„The Principles of Humane Experimental Techniques“



W.M.S. Russell and R.L. Burch





## European Convention ...(ETS 123):

(Continuation) makes clear

**Art. 8: priority for general or local anaesthesia or analgesia**

**Art. 13: procedures have to be authorised**

**Art. 21/22: In user establishments, only animals supplied from registered breeding or supplying establishments shall be used**

**(no straydogs etc. !)**

**Furthermore: Education and training of involved persons  
Statistical information, that has to be collected (App.B)**



### **Appendix A: Guidelines for accomodation and care of animals (Art. 5 of the convention), revised 2006**

#### **General section - general requirements**

Adequate facilities (holding room etc.)

Adequate ventilation (15-20 air changes per hour)

Adequate temperature/lighting/humidity/avoidance of noise

Health strategy and daily control of animals

Quarantine, Acclimatisation

Enrichment, socially housing in stable groups

Handling with a caring and respectful attitude

Humane killing



## European Convention ... (ETS 123):

### **Appendix A: Guidelines for accomodation and care of animals (Art. 5 of the convention)**

#### **Species-specific section,** concerning

rodents, rabbits, cats, dogs, farm animals, minipigs, non-human primates, reptiles, fishes etc.

**Including species specific data for  
space allowences,  
temperature etc.**



- **has been transferred to national legislation by several legislative acts**
- **is taken as a most important advisory opinion !**
- **has to be fulfilled as soon as possible**



## Directive 2010/63/EU on the protection of animals used for scientific purposes (22.09.2010):

### Whereas I (reasons) :

Animals have an intrinsic value which must be respected. There are also the ethical concerns of the general public as regards the use of animals in procedures.

Therefore,

animals should always be to treated as **sentient creatures** and their use in procedures should be restricted to areas which may ultimately benefit human or animal health, or the environment.





## Directive 2010/63/EU on the protection of animals used for scientific purposes (22.09.2010)

### Whereas II (reasons) :

- To eliminate disparities between laws, regulations and administrative provisions of the Member States
- To improve animal welfare due to new scientific knowledge
- To include fetal forms of mammals et al.
- To restrict the use of non-human primates
- to facilitate and promote the advancement of alternative approaches
- the principles of replacement, reduction and refinement should be considered systematically when implementing this Directive





## Directive 2010/63/EU on the protection of animals used for scientific purposes (22.09.2010)

### Therefore the new directive emphasizes/ introduces rules for:

- 3 R-principles (**Art. 4**)
- the origin, breeding, marking, care and accommodation and killing of animals;
- the operations of breeders, suppliers and users
- the evaluation and authorisation of projects involving the use of animals in procedures.





## Directive 2010/63/EU on the protection of animals used for scientific purposes (22.09.2010)

**Therefore the new directive reforms /introduces/emphasizes –  
Examples:**

Authorization for every breeder or supplier by competent auth.

Authorization for every user by competent auth.

Introduction of an animal-welfare-body

Designated veterinarian

} every breeder, supplier, user

Priority of anesthesia / analgesia (as before)





## Directive 2010/63/EU on the protection of animals used for scientific purposes (22.09.2010)

**Therefore the new directive reforms /introduces/emphasizes –  
Examples:**

Authorization of every procedure by comp.auth., including

- **Publication of non technical reports of procedures !**
- Obligatory **retrospective assessment** in the case of severe procedures or the use of non human primates !

**Annex IV:** appropriate killing methods

**Annex VIII:** severity classification of procedures **with examples**  
(mild, moderate, severe, non-recovery)



Implementation of EU-directive 2010/63/EU  
is in progress just now:



New german „Tierschutzgesetz“: principles (decided 1.2.13)



(delegated act)

New german „Tierschutz-Versuchstier-Verordnung“: details (?)





## Tierschutzgesetz (“Animal protection law”) (new version)

- § 7 (1): Animal experiments/procedures on animals have to be restricted to an **undispensable degree** (number of animals, suffering, pain, lasting harm)
- § 7 (2): definition: experimental procedures, that may lead to suffering, pain and lasting harm
- § 7a (1): purposes for procedures
- § 7a (2): preconditions for authorization of procedures:
- experiment has to be undispensable/essential in this scientific context
  - suffering, pain and lasting harm must be **ethically justified** by the purpose / expected scientific progress





## Tierschutzgesetz (“Animal protection law”) (new version)

- § 8a:** announcement instead of authorization:
- regulatory projects (i.e. obligatory testing)
  - projects using animals for educational purposes
  - some other exemptions
- § 9 :** right for delegated legislative acts concerning
- authorization procedure
  - competence/expertise
- § 10:** “**Tierschutzbeauftragter**” and animal-welfare body:  
details in delegated act
- § 11:** authorization for breeder, supplier and user



## Delegated legislative act (Tierschutz-Versuchstier-Verordnung):

- many details still open !
- Discussion in the federal assembly of Germany in the next weeks

although there are many details missing,  
let's try to find some “take home messages”



# I. Summary of legislative documents:

European convention:

- basic principles (3R etc.)
- specific requirements for the care and accomodation of lab animals (Appendix A)

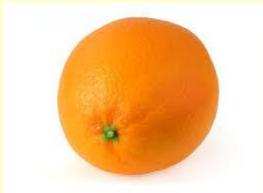
EU-Directive and national legislation:

- including contents of European convention
- predominantly regulating administrative procedure details



## II. Most important legal preconditions for research involving lab animals

- Procedure has to be indispensable/essential
- Procedure has to be restricted to the indispensable degree
- Procedure has to be ethically justified



Burdens to animals is justified by scientific benefit/results/progress



### III. Resulting administrative steps for researcher:

- Verify, that your project is (scientifically) essential (no other means to answer your question)
- Verify, that the 3R have been considered seriously (incl. biostatistics, housing conditions etc.)
- Prepare the ethical appreciation of values as essential part of the authorization procedure

then:

- Write your application
- in contact with the „Tierschutzbeauftragter“





Thank you for  
your attention!

