

Application of Animal Studies

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Animal Studies





A thought experiment



Utilitarianism



Jeremy Bentham (1748–1832) and John Stuart Mill (1806–1873)

Normative Law



Legal Framework

DIRECTIVE 2010/63/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 22 September 2010 on the protection of animals used for scientific purposes

is transferred into German law:

Tierschutzgesetz in der Fassung der Bekanntmachung vom 18. Mai 2006 (BGBl. I S. 1206, 1313), das zuletzt durch Artikel 4 Absatz 90 des Gesetzes vom 7. August 2013 (BGBl. I S. 3154) geändert worden ist

Tierschutz-Versuchstierverordnung vom 1. August 2013 (BGBl. I S. 3125, 3126), die durch Artikel 6 der Verordnung vom 12. Dezember 2013 (BGBl. I S. 4145) geändert worden ist

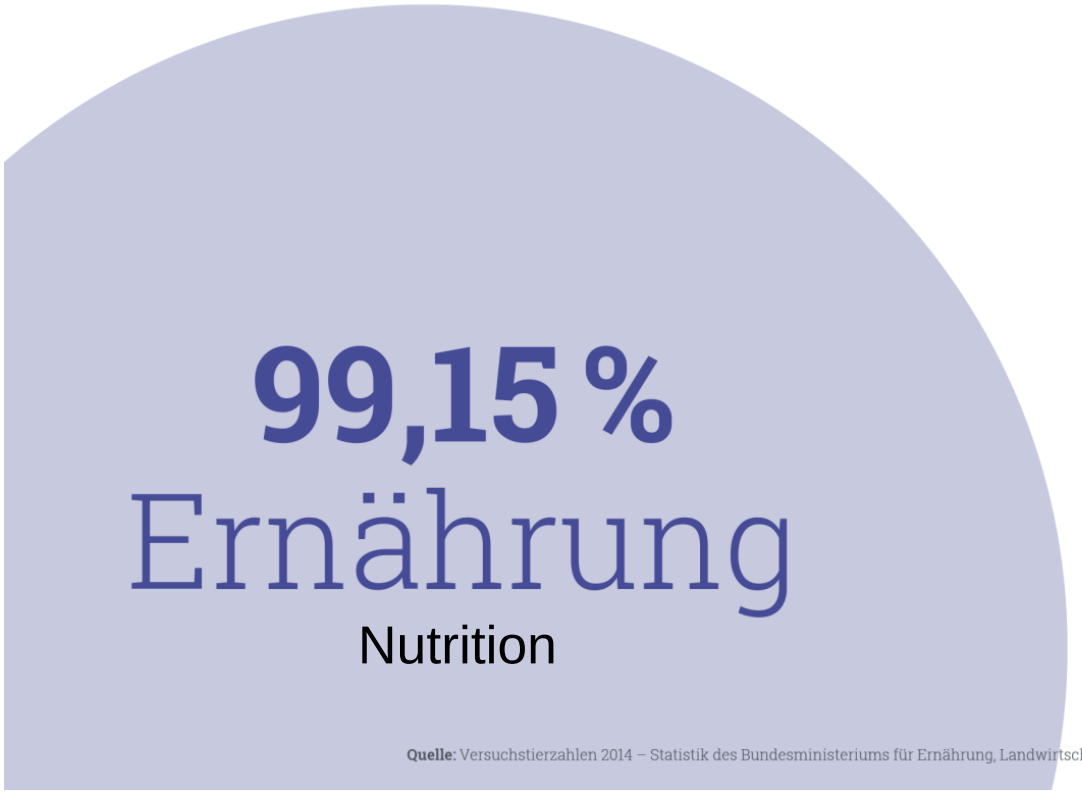
General Principles

§ 1 TierSchG

Zweck dieses Gesetzes ist es, aus der Verantwortung des Menschen für das Tier als Mitgeschöpf dessen Leben und Wohlbefinden zu schützen.
Niemand darf einem Tier ohne vernünftigen Grund Schmerzen, Leiden oder Schäden zufügen.

Nobody is allowed to inflict harm, suffering or injuries to an animal without a reasonable motive.

Why are animals sacrificed?



Hunting

- 0,5 %
  Jagd

- 0,09 %
  Pflichtversuche u.a.

Madatory Experiments

- 0,26 %
  Forschung

Research

Quelle: Versuchstierzahlen 2014 – Statistik des Bundesministeriums für Ernährung, Landwirtschaft und Verbraucherschutz (BMEL)

Reasonable Motive



Meat Production



Cheap Eggs

DIRECTIVE 2010/63/EU

Article 1 Subject matter and scope

1. This Directive establishes measures for the protection of animals used for scientific or educational purposes.

To that end, it lays down rules on the following:

(a) the replacement and reduction of the use of animals in procedures and the refinement of the breeding, accommodation, care and use of animals in procedures;

(b) the origin, breeding, marking, care and accommodation and killing of animals;

(c) the operations of breeders, suppliers and users;

(d) the evaluation and authorization of projects involving the use of animals in procedures.

2. This Directive shall apply where animals are used or intended to be used in procedures, or bred specifically so that their organs or tissues may be used for scientific purposes.

This Directive shall apply until the animals referred to in the first subparagraph have been killed, rehomed or returned to a suitable habitat or husbandry system.

The elimination of pain, suffering, distress or lasting harm by the successful use of anaesthesia, analgesia or other methods shall not exclude the use of an animal in procedures from the scope of this Directive.

DIRECTIVE 2010/63/EU



3. This Directive shall apply to the following animals:

(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.

4. This Directive shall apply to animals used in procedures, which are at an earlier stage of development than that referred to in point (a) of paragraph 3, if the animal is to be allowed to live beyond that stage of development and, as a result of the procedures performed, is likely to experience pain, suffering, distress or lasting harm after it has reached that stage of development.

5. This Directive shall not apply to the following:

(a) non-experimental agricultural practices;

(b) non-experimental clinical veterinary practices;

(c) veterinary clinical trials required for the marketing authorisation of a veterinary medicinal product;

(d) practices undertaken for the purposes of recognised animal husbandry;

(e) practices undertaken for the primary purpose of identification of an animal;

(f) practices not likely to cause pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by the introduction of a needle in accordance with good veterinary practice.

6. This Directive shall apply without prejudice to Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (8).

Non-experimental agricultural practices



Horse walkers

DIRECTIVE 2010/63/EU

Article 2 Stricter national measures

Article 3 Definitions

Article 4 Principle of replacement, reduction and refinement

Article 5 Purposes of procedures

Procedures may be carried out for the following purposes only:

(a) basic research;

(b) translational or applied research with any of the following aims:

(i) the avoidance, prevention, diagnosis or treatment of disease, ill-health or other abnormality or their effects in human beings, animals or plants;

(ii) the assessment, detection, regulation or modification of physiological conditions in human beings, animals or plants; or

(iii) the welfare of animals and the improvement of the production conditions for animals reared for agricultural purposes;

(c) for any of the aims in point (b) in the development, manufacture or testing of the quality, effectiveness and safety of drugs, foodstuffs and feed-stuffs and other substances or products;

(d) protection of the natural environment in the interests of the health or welfare of human beings or animals;

(e) research aimed at preservation of the species;

(f) higher education, or training for the acquisition, maintenance or improvement of vocational skills;

(g) forensic inquiries.

General Principles

The 3 „R“s

- **Replacement**

which refers to the preferred use of non-animal methods over animal methods whenever it is possible to achieve the same scientific aims.

- **Reduction**

which refers to methods that enable researchers to obtain comparable levels of information from fewer animals, or to obtain more information from the same number of animals.

- **Refinement**

which refers to methods that alleviate or minimize potential pain, suffering or distress, and enhance animal welfare for the animals used.

Russell, W.M.S. and Burch, R.L., (1959). The Principles of Humane Experimental Technique, Methuen, London.

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(e) research aimed at preservation of the species;

(f) higher education, or training for the acquisition, maintenance or improvement of vocational skills;

(g) forensic inquiries.

DIRECTIVE 2010/63/EU

Article 6 Methods of killing

1. Member States shall ensure that animals are killed with minimum pain, suffering and distress.
2. Member States shall ensure that animals are killed in the establishment of a breeder, supplier or user, by a competent person.

However, in the case of a field study an animal may be killed by a competent person outside of an establishment.

3. In relation to the animals covered by Annex IV, the appropriate method of killing as set out in that Annex shall be used.
4. Competent authorities may grant exemptions from the requirement in paragraph 3:

(a) to allow the use of another method provided that, on the basis of scientific evidence, the method is considered to be at least as humane; or

(b) when, on the basis of scientific justification, the purpose of the procedure cannot be achieved by the use of a method of killing set out in Annex IV.

5. Paragraphs 2 and 3 shall not apply where an animal has to be killed in emergency circumstances for animal-welfare, public-health, public-security, animal-health or environmental reasons.

DIRECTIVE 2010/63/EU

Animals-remarks/methods	Fish	Amphibians	Reptiles	Birds	Rodents	Rabbits	Dogs, cats, ferrets and foxes	Large mammals	Non-human primates
Anaesthetic overdose	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)
Captive bolt	X	X	(2)	X	X		X		X
Carbon dioxide	X	X	X		(3)	X	X	X	X
Cervical dislocation	X	X	X	(4)	(5)	(6)	X	X	X
Concussion/percussive blow to the head				(7)	(8)	(9)	(10)	X	X
Decapitation	X	X	X	(11)	(12)	X	X	X	X
Electrical stunning	(13)	(13)	X	(13)	X	(13)	(13)	(13)	X
Inert gases (Ar, N2)	X	X	X			X	X	(14)	X
Shooting with a free bullet with appropriate rifles, guns and ammunition	X	X	(15)	X	X	X	(16)	(15)	X

1. Shall, where appropriate, be used with prior sedation.
2. Only to be used on large reptiles.
3. Only to be used in gradual fill. Not to be used for foetal and neonate rodents.
4. Only to be used for birds under 1 kg. Birds over 250 g shall be sedated.
5. Only to be used for rodents under 1 kg. Rodents over 150 g shall be sedated.
6. Only to be used for rabbits under 1 kg. Rabbits over 150 g shall be sedated.
7. Only to be used for birds under 5 kg.
8. Only to be used for rodents under 1 kg.
9. Only to be used for rabbits under 5 kg.
10. Only to be used on neonates.
11. Only to be used for birds under 250 g.
12. Only to be used if other methods are not possible.
13. Specialised equipment required.
14. Only to be used on pigs.
15. Only to be used in field conditions by experienced marksmen.
16. Only to be used in field conditions by experienced marksmen when other methods are not possible.

DIRECTIVE 2010/63/EU

Article 7 Endangered species

Article 8 Non-human primates

Article 9 Animals taken from the wild

Article 10 Animals bred for use in procedures

Article 11 Stray and feral animals of domestic species

1. Stray and feral animals of domestic species shall not be used in procedures.
2. The competent authorities may only grant exemptions from paragraph 1 subject to the following conditions:

(a) there is an essential need for studies concerning the health and welfare of the animals or serious threats to the environment or to human or animal health; and

(b) there is scientific justification to the effect that the purpose of the procedure can be achieved only by the use of a stray or a feral animal.

DIRECTIVE 2010/63/EU

Article 12 Procedures

1. Member States shall ensure that procedures are carried out in a user's establishment.

The competent authority may grant an exemption from the first subparagraph on the basis of scientific justification.

2. Procedures may be carried out only within the framework of a project.

Article 13 Choice of methods

1. Without prejudice to national legislation prohibiting certain types of methods, Member States shall ensure that a procedure is not carried out if another method or testing strategy for obtaining the result sought, not entailing the use of a live animal, is recognised under the legislation of the Union.

2. In choosing between procedures, those which to the greatest extent meet the following requirements shall be selected:

(a) use the minimum number of animals;

(b) involve animals with the lowest capacity to experience pain, suffering, distress or lasting harm;

(c) cause the least pain, suffering, distress or lasting harm;

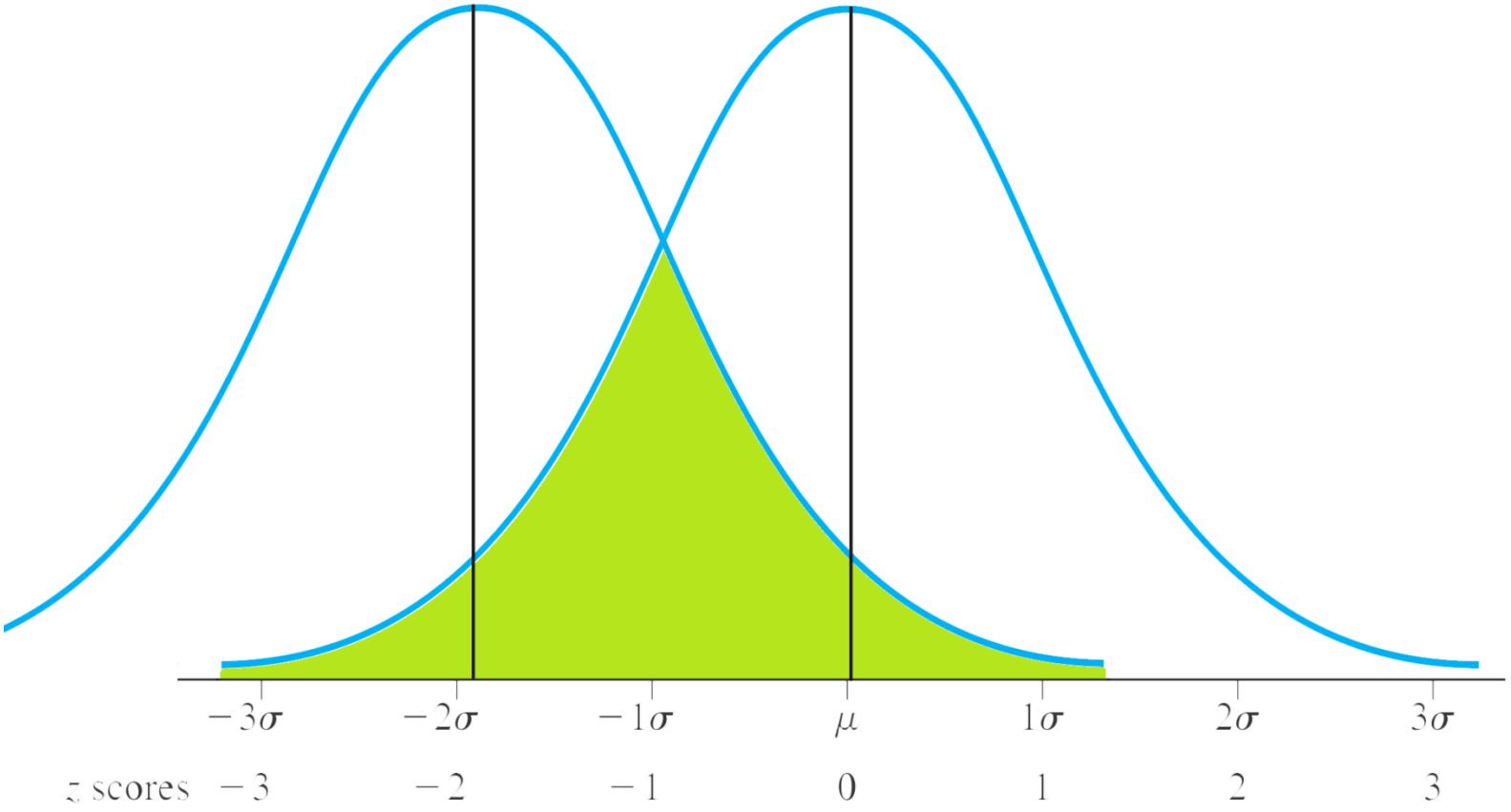
and are most likely to provide satisfactory results.

3. Death as the end-point of a procedure shall be avoided as far as possible and replaced by early and humane end-points. Where death as the end-point is unavoidable, the procedure shall be designed so as to:

(a) result in the deaths of as few animals as possible; and

(b) reduce the duration and intensity of suffering to the animal to the minimum possible and, as far as possible, ensure a painless death.

The Biometry Problem



The Biometry Problem

Sample number estimation:

- Hypothesis
- Primary Target Parameter
- Standard Deviation of Measurement
- Effect Size
- Acceptable Error Type I
- Acceptable Error Type II

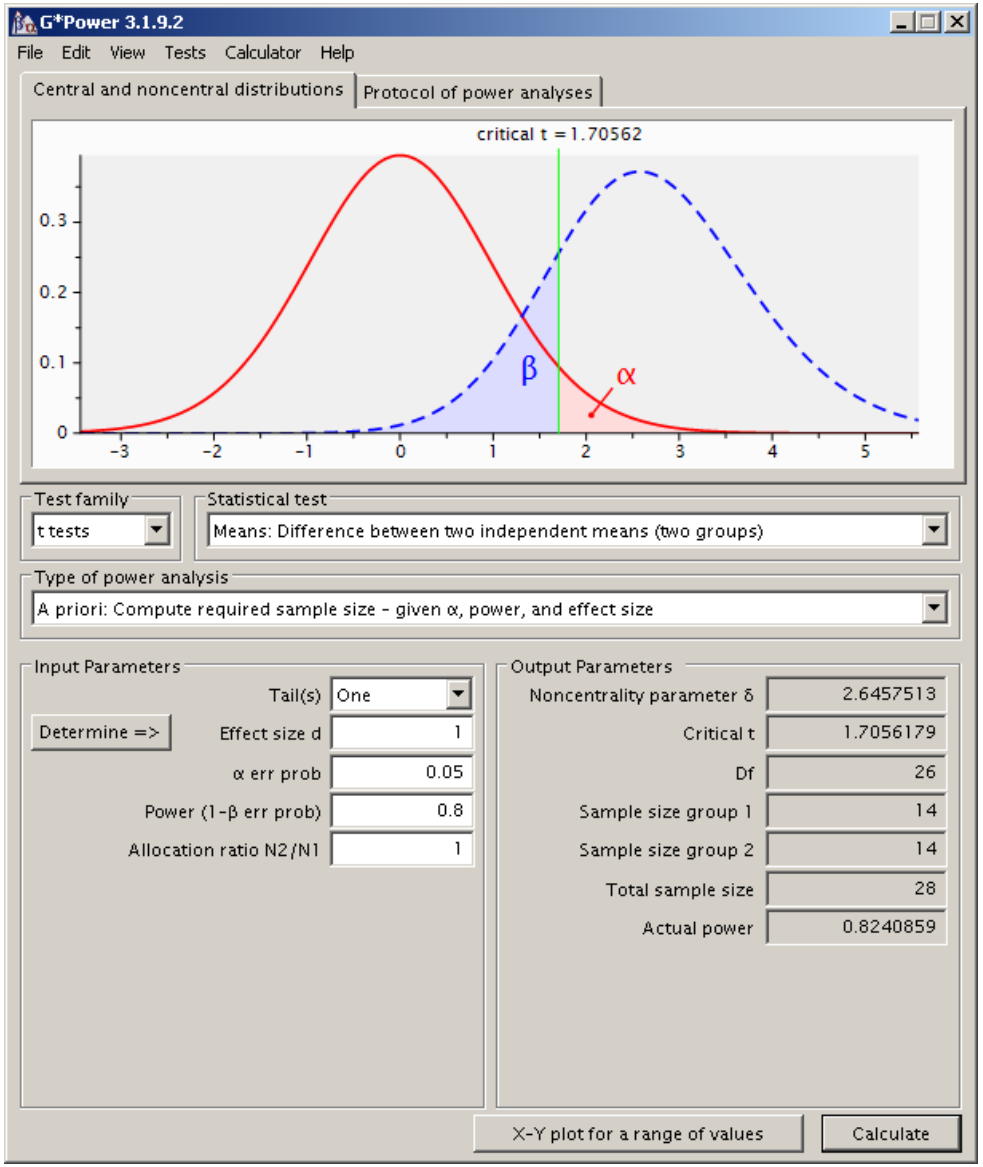
The Biometry Problem

Table of error types

Tabularised relations between truth/falseness of the null hypothesis and outcomes of the test:

Table of error types		Null hypothesis (H_0) is	
		True	**False**
Decision About Null Hypothesis (H_0)	**Reject**	Type I error (False Positive)	Correct inference (True Positive)
	Fail to reject	Correct inference (True Negative)	Type II error (False Negative)

The Biometry Problem



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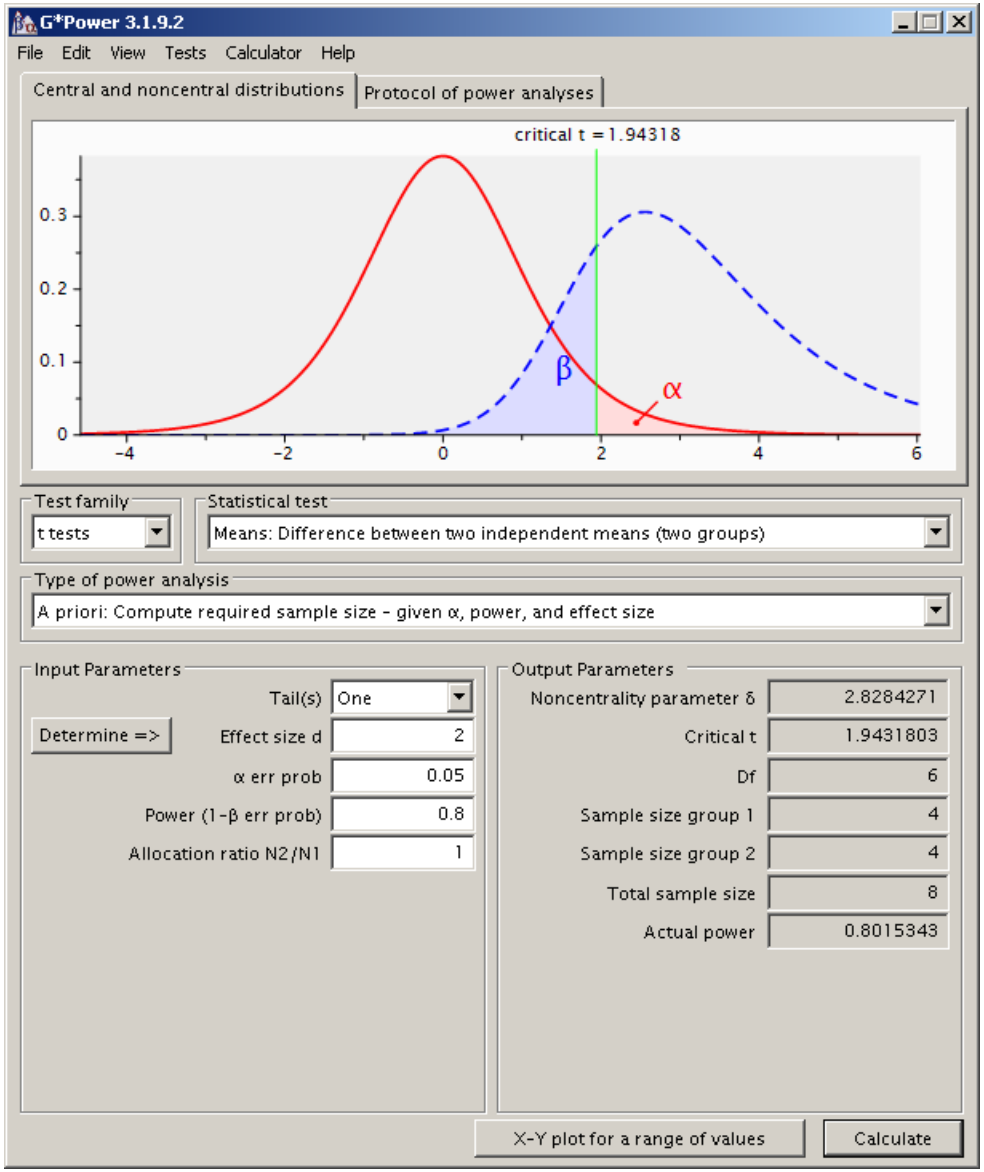

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Least Animal Suffering



Least Animal Suffering

Professionality

- Infrastructural
- Experimentators
- Animal Keeping

Continuous Monitoring

- Health status
- Expected and unexpected suffering

Appreciation

- The most valuable team members

DIRECTIVE 2010/63/EU

Article 14 Anesthesia

Article 15 Classification of severity of procedures

1. Member States shall ensure that all procedures are classified as 'non-recovery', 'mild', 'moderate', or 'severe' on a case-by-case basis using the assignment criteria set out in Annex VIII.
2. Subject to the use of the safeguard clause in Article 55(3), Member States shall ensure that a procedure is not performed if it involves severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated.

Article 16 Reuse

Article 17 End of the procedure

1. A procedure shall be deemed to end when no further observations are to be made for that procedure or, as regards new genetically modified animal lines, when the progeny are no longer observed or expected to experience pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by the introduction of a needle.
2. At the end of a procedure, a decision to keep an animal alive shall be taken by a veterinarian or by another competent person. An animal shall be killed when it is likely to remain in moderate or severe pain, suffering, distress or lasting harm.
3. Where an animal is to be kept alive, it shall receive care and accommodation appropriate to its state of health.

Article 18 Sharing organs and tissues

Member States shall facilitate, where appropriate, the establishment of programmes for the sharing of organs and tissues of animals killed.

Article 19 Setting free of animals and rehoming

DIRECTIVE 2010/63/EU

1. Mild:

(b) pharmacokinetic study where a single dose is administered and a limited number of blood samples are taken

(c) non-invasive imaging of animals (e.g. MRI) with appropriate sedation or anaesthesia;

(d) superficial procedures, e.g. ear and tail biopsies

2. Moderate:

(c) surgery under general anaesthesia and appropriate analgesia, associated with post surgical pain, suffering or impairment of general condition. Examples include: thoracotomy, craniotomy, laparotomy,

(d) models of induction of tumours, or spontaneous tumours, that are expected to cause moderate pain or distress or moderate interference with normal behaviour;

(e) irradiation or chemotherapy with a sublethal dose

3. Severe:

(a) toxicity testing where death is the end-point

(c) vaccine potency testing characterised by persistent impairment of the animal's condition, progressive disease leading to death, associated with long-lasting moderate pain, distress or suffering;

(g) organ transplantation where organ rejection is likely to lead to severe distress or impairment of the general condition of the animals (e.g. xenotransplantation);

(h) breeding animals with genetic disorders that are expected to experience severe and persistent impairment of general condition, for example Huntington's disease, Muscular dystrophy, chronic relapsing neuritis models

DIRECTIVE 2010/63/EU

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DIRECTIVE 2010/63/EU

Article 20 Authorisation of breeders, suppliers and users

Article 21 Suspension and withdrawal of authorisation

Article 22 Requirements for installations and equipment

Article 23 Competence of personnel

1. Member States shall ensure that each breeder, supplier and user has sufficient staff on site.
2. The staff shall be adequately educated and trained before they perform any of the following functions:

(a) carrying out procedures on animals;

(b) designing procedures and projects;

(c) taking care of animals; or

(d) killing animals.Persons carrying out the functions referred to in point (b) shall have received instruction in a scientific discipline relevant to the work being undertaken and shall have species-specific knowledge.

Staff carrying out functions referred to in points (a), (c) or (d) shall be supervised in the performance of their tasks until they have demonstrated the requisite competence.

Member States shall ensure, through authorisation or by other means, that the requirements laid down in this paragraph are fulfilled.

3. Member States shall publish, on the basis of the elements set out in Annex V, minimum requirements with regard to education and training and the requirements for obtaining, maintaining and demonstrating requisite competence for the functions set out in paragraph 2.

Article 24 Specific requirements for personnel

DIRECTIVE 2010/63/EU

1. National legislation in force relevant to the acquisition, husbandry, care and use of animals for scientific purposes.
2. Ethics in relation to human-animal relationship, intrinsic value of life and arguments for and against the use of animals for scientific purposes.
3. Basic and appropriate species-specific biology in relation to anatomy, physiological features, breeding, genetics and genetic alteration.
4. Animal behaviour, husbandry and enrichment.
5. Species-specific methods of handling and procedures, where appropriate.
6. Animal health management and hygiene.
7. Recognition of species-specific distress, pain and suffering of most common laboratory species.
8. Anaesthesia, pain relieving methods and killing.
9. Use of humane end-points.
10. Requirement of replacement, reduction and refinement.
11. Design of procedures and projects, where appropriate.

TierSchVersV

§ 16 Anforderungen an die Sachkunde

(1) Tierversuche an Wirbeltieren und Kopffüßern dürfen nur von Personen durchgeführt werden, die über die Kenntnisse und Fähigkeiten nach Anlage 1 Abschnitt 3 verfügen. Darüber hinaus dürfen Tierversuche nur

1. von Personen mit abgeschlossenem Hochschulstudium der Veterinärmedizin, der Medizin oder der Zahnmedizin,
2. von Personen mit abgeschlossenem naturwissenschaftlichen Hochschulstudium, sofern sie nachweislich die erforderlichen Kenntnisse und Fähigkeiten haben, oder
3. von Personen, die nachweislich im Rahmen einer abgeschlossenen Berufsausbildung die erforderlichen Kenntnisse und Fähigkeiten erworben haben,

durchgeführt werden. Tierversuche mit operativen Eingriffen an Wirbeltieren dürfen unbeschadet des Satzes 1 nur

1. von Personen mit abgeschlossenem Hochschulstudium der Veterinärmedizin, der Medizin oder der Zahnmedizin oder
2. von Personen mit abgeschlossenem naturwissenschaftlichen Hochschulstudium oder einer Weiterbildung im Anschluss an ein naturwissenschaftliches Hochschulstudium, sofern sie nachweislich die erforderlichen Kenntnisse und Fähigkeiten haben,

durchgeführt werden. Die Sätze 2 und 3 gelten nicht für Tierversuche nach § 7 Absatz 2 Satz 2 Nummer 1 des Tierschutzgesetzes, die nach bereits erprobten Verfahren vorgenommen werden. Die zuständige Behörde genehmigt Ausnahmen von den Sätzen 2 und 3, wenn der Nachweis der erforderlichen Kenntnisse und Fähigkeiten auf andere Weise erbracht ist.

(2) Tierversuche, die Aus-, Fort- oder Weiterbildungszwecken dienen, dürfen abweichend von § 7 Absatz 1 Satz 3 des Tierschutzgesetzes und Absatz 1 Satz 1 bis 3 auch von Personen, die die dort genannten Anforderungen nicht erfüllen, durchgeführt werden, soweit dies in Anwesenheit und unter Aufsicht einer Person erfolgt, die die jeweiligen Anforderungen erfüllt.

(3) Tierversuche dürfen nur durchgeführt werden, wenn die Personen, von denen das Versuchsvorhaben und die beabsichtigten Tierversuche geplant worden sind, über die hierfür erforderlichen Kenntnisse und Fähigkeiten einschließlich der Kenntnisse und Fähigkeiten nach Anlage 1 Abschnitt 3 verfügen und diese der zuständigen Behörde auf Verlangen nachweisen.

DIRECTIVE 2010/63/EU

Article 25 Designated veterinarian

Article 26 Animal-welfare body

Article 27 Tasks of the animal-welfare body

Article 28 Breeding strategy for non-human primates

Article 29 Scheme for rehoming or setting free of animals

Article 30 Animal records

1. Member States shall ensure that all breeders, suppliers and users keep records of at least the following:

(a) the number and the species of animals bred, acquired, supplied, used in procedures, set-free or rehomed;

(b) the origin of the animals, including whether they are bred for use in procedures;

(c) the dates on which the animals are acquired, supplied, released or rehomed;

(d) from whom the animals are acquired;

(e) the name and address of the recipient of animals;

(f) the number and species of animals which died or were killed in each establishment. For animals that have died, the cause of death shall, when known, be noted; and

(g) in the case of users, the projects in which animals are used.

2. The records referred to in paragraph 1 shall be kept for a minimum of 5 years and made available to the competent authority upon request.

DIRECTIVE 2010/63/EU

Article 31 Information on dogs, cats and non-human primates

Article 32 Marking and identification of dogs, cats and non-human primates

Article 33 Care and accommodation

1. Member States shall, as far as the care and accommodation of animals is concerned, ensure that:

(a) all animals are provided with accommodation, an environment, food, water and care which are appropriate to their health and well-being;

(b) any restrictions on the extent to which an animal can satisfy its physiological and ethological needs are kept to a minimum;

(c) the environmental conditions in which animals are bred, kept or used are checked daily;

(d) arrangements are made to ensure that any defect or avoidable pain, suffering, distress or lasting harm discovered is eliminated as quickly as possible; and

(e) animals are transported under appropriate conditions.

2. For the purposes of paragraph 1, Member States shall ensure that the care and accommodation standards set out in Annex III are applied from the dates provided for therein.

3. Member States may allow exemptions from the requirements of paragraph 1(a) or paragraph 2 for scientific, animal-welfare or animal-health reasons.

DIRECTIVE 2010/63/EU

Article 34 Inspections by the Member States

Article 35 Controls of Member State inspections

Article 36 Project authorisation

1. Member States shall ensure, without prejudice to Article 42, that projects are not carried out without prior authorisation from the competent authority, and that projects are carried out in accordance with the authorisation or, in the cases referred to in Article 42, in accordance with the application sent to the competent authority or any decision taken by the competent authority.

2. Member States shall ensure that no project is carried out unless a favourable project evaluation by the competent authority has been received in accordance with Article 38.

Article 37 Application for project authorisation

1. Member States shall ensure that an application for project authorisation is submitted by the user or the person responsible for the project. The application shall include at least the following:

(a) the project proposal;

(b) a non-technical project summary; and

(c) information on the elements set out in Annex VI.

DIRECTIVE 2010/63/EU

Article 38 Project evaluation

1. The project evaluation shall be performed with a degree of detail appropriate for the type of project and shall verify that the project meets the following criteria:

(a) **the project is justified from a scientific or educational point of view or required by law;**

(b) **the purposes of the project justify the use of animals; and**

(c) **the project is designed so as to enable procedures to be carried out in the most humane and environmentally sensitive manner possible.**

2. The project evaluation shall consist in particular of the following:

(a) an evaluation of the objectives of the project, the predicted scientific benefits or educational value;

(b) an assessment of the compliance of the project with the requirement of replacement, reduction and refinement;

(c) an assessment and assignment of the classification of the severity of procedures;

(d) a harm-benefit analysis of the project, to assess whether the harm to the animals in terms of suffering, pain and distress is justified by the expected outcome taking into account ethical considerations, and may ultimately benefit human beings, animals or the environment;

(e) an assessment of any justification referred to in Articles 6 to 12, 14, 16 and 33; and

(f) a determination as to whether and when the project should be assessed retrospectively.

DIRECTIVE 2010/63/EU

3. The competent authority carrying out the project evaluation shall consider expertise in particular in the following areas:

(a) the areas of scientific use for which animals will be used including replacement, reduction and refinement in the respective areas;

(b) experimental design, including statistics where appropriate;

(c) veterinary practice in laboratory animal science or wildlife veterinary practice where appropriate;

(d) animal husbandry and care, in relation to the species that are intended to be used.

4. The project evaluation process shall be transparent.

Subject to safeguarding intellectual property and confidential information, the project evaluation shall be performed in an impartial manner and may integrate the opinion of independent parties.

DIRECTIVE 2010/63/EU

Article 39 Retrospective assessment

Article 40 Granting of project authorisation

Article 41 Authorisation decisions

Article 42 Simplified administrative procedure

Article 43 Non-technical project summaries

1. Subject to safeguarding intellectual property and confidential information, the non-technical project summary shall provide the following:

(a) information on the objectives of the project, including the predicted harm and benefits and the number and types of animals to be used;

(b) a demonstration of compliance with the requirement of replacement, reduction and refinement.The non-technical project summary shall be anonymous and shall not contain the names and addresses of the user and its personnel.

2. Member States may require the non-technical project summary to specify whether a project is to undergo a retrospective assessment and by what deadline. In such a case, Member States shall ensure that the non-technical project summary is updated with the results of any retrospective assessment.

3. Member States shall publish the non-technical project summaries of authorised projects and any updates thereto.

www.animaltestinfo.de

FAQ Benutzungshinweise Rechtliche Grundlagen

BfR Bundesinstitut für Risikobewertung

AnimalTestInfo

Datenbank zu Tierversuchsvorhaben in Deutschland

Was finden Sie in der Datenbank und wer steht dahinter?
Der Gesetzgeber hat dem Bundesinstitut für Risikobewertung (BfR) den gesetzlichen Auftrag erteilt, allgemein verständliche, nichttechnische Projektzusammenfassungen von genehmigten Tierversuchsvorhaben in Deutschland anonym zu veröffentlichen. Die Datenbank AnimalTestInfo enthält für die Öffentlichkeit verständliche Projektzusammenfassungen der Tierversuchsvorhaben, deren Durchführung von wissenschaftlichen Forschungsinstituten der Universitäten, der Industrie und des Bundes beantragt und von den zuständigen Behörden der Bundesländer genehmigt wurden. (mehr)

Die Suche nach „Tierart(en) Schweine, alle Zwecke, Jahr(e) 2017, Titel enthält Stichwort bei Nur-Titel-Dokumenten“ ergab 97 relevante Tierversuchsvorhaben (10 Seiten):

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	Titel/Beschreibung	Zweck	Tierart	Tierzahl	Jahr	htm	pdf
51	Detektion von Blutgefäßen im Gehirn	Grundlagenforschung; Translationale und angewandte Forschung	Schweine	10	2017		
52	Evaluation von Medizinprodukten	Translationale und angewandte Forschung	Schweine	30	2017		
53	Medizinprodukte Minipig	Translationale und angewandte Forschung	Schweine	470	2017		
54	Kardioprotektion und neuronaler Signaltransfer	Grundlagenforschung	Ratten; Schweine	1014; 280	2017		
55	Pharmakokinetik - Nager/Nichtnager	Translationale und angewandte Forschung; Verwendung zu regulatorischen Zwecken und Routineproduktion	Ratten; Meerschweinchen; Hunde; Schweine; Mäuse	750; 250; 20; 2000	2017		
56	Zelluloseüberzug von	Translationale und angewandte Forschung	Schweine	18	2017		

Evaluation von Medizinprodukten; Quelle: www.animaltestinfo.de

(Kurz-)Titel bzw. Bezeichnung des Versuchsvorhabens

Evaluation von Medizinprodukten

Zweck des Versuchsvorhabens

- Translationale und angewandte Forschung

Zu erwartender Nutzen des Versuchsvorhabens

Die präklinische Evaluation von innovativen Medizinprodukten stellt eine essentielle Brücke zwischen der rein technischen Entwicklung und der klinischen Erprobung am Menschen dar. Die Medizinprodukte sollen nach dem Ausschöpfen aller Möglichkeiten in-vitro im beantragten Projekt am lebenden Tier in Einsatz kommen. Schwerpunkte der Evaluation sind Handhabbarkeit, Wirksamkeit und Sicherheit. Eine Evaluation im Rahmen einer klinischen Erprobung würde die behandelten Patienten einem nicht verantwortbaren Risiko aussetzen. Die breite präklinische Evaluation von Medizinprodukten dient der Sicherheit der Patienten.

Schäden

Alle in diesem Projekt durchgeführten Versuche weisen gemäß Anhang VIII der Richtlinie 2010/63/EU den Schweregrad "Termialversuch, ohne Wiederherstellung der Lebensfunktion" auf. Die Tiere werden nach Prädikation lege artis in den OP transferiert, die Narkose wird vertieft, das Tier wird intubiert, die Versuche werden unter angemessenen starker Analagsie durchgeführt und das Tier ohne Erwachen aus der Narkose getötet.

Tiere

Tierart	Tierzahl	Freiwillige Ergänzungen
Schweine	30	

Anwendung der 3R

Replacement/Vermeidung

Die Fragestellung, wie ein Medizinprodukt sicher, handhabbar und wirksam an vitalem Gewebe eingesetzt werden kann, kann nur an diesem erprobt werden. Die Möglichkeit der Arbeiten an isoliert perfundierten Organen werden voll ausgeschöft. Der Erkenntnisgewinn aus Terminalversuchen ist hinsichtlich der nur geringfügig höheren Belastung jedoch dem aus zur Organentnahme getöteten Tieren überlegen, so dass beim Einsatz der gleichen Tierzahl eine Erprobung in Terminalversuchen ethisch angezeigt ist.

Reduction/Verminderung

Die Studie untersucht in Einzeltieren oder kleinen Serien (n < 5) begleitend den Fortschitt in der Entwicklung eines Medizinprodukts. Eine Anwendung einer Technologie in einer größeren Serie z.B. für Zulassungszwecke wird gesondert beantragt.

Refinement/Verbesserung

Das Schwein ist ein akzeptiertes Modell in der präklinischen Evaluation von Medizinprodukten, da es in Größe, Anatomie und physiologischer Funktion den Menschen über weite Strecken gut abbildet. Durch die Beschränkung des Projekt auf Terminalversuche werden Schmerzen und Leiden des Tiers auf ein Minimum reduziert.

Gesetzlicher Auftrag des BfR

Der Gesetzgeber hat dem Bundesinstitut für Risikobewertung (BfR) den gesetzlichen Auftrag erteilt, allgemein verständliche, nichttechnische Projektzusammenfassungen von genehmigten Tierversuchsvorhaben in Deutschland anonym zu veröffentlichen. Die Datenbank AnimalTestInfo enthält für die Öffentlichkeit verständliche Projektzusammenfassungen der Tierversuchsvorhaben, deren Durchführung von wissenschaftlichen Forschungsinstituten der Universitäten, der Industrie und des Bundes beantragt und von den zuständigen Behörden der Bundesländer genehmigt wurden.
Die Tierversuchsvorhaben müssen in Deutschland von den zuständigen Behörden der jeweiligen Bundesländer genehmigt werden. Ist das Vorhaben genehmigt, übermittelt die zuständige Behörde die anonymisierte Projektzusammenfassung an das BfR zur Veröffentlichung in der Datenbank. Das BfR übernimmt keine Verantwortung für die Richtigkeit der Inhalte der Projektzusammenfassung. Diese liegt beim Antragsteller.

Die übermittelten Projektzusammenfassungen werden vom BfR innerhalb von 12 Monaten in der Datenbank veröffentlicht. Dies dient dazu, die Öffentlichkeit über Tierversuchsvorhaben zu informieren.

Zum Schutz des geistigen Eigentums und personenbezogener Angaben werden die Daten anonymisiert der Öffentlichkeit zur Verfügung gestellt. Die Projektzusammenfassungen erlauben daher per Gesetz keine Angaben zum Verfasser. Rückschlüsse auf die Einrichtungen, in welchen das Projekt stattfindet, sind technisch nicht möglich.

DIRECTIVE 2010/63/EU

Article 44 Amendment, renewal and withdrawal of a project authorisation

Article 45 Documentation

Article 46 Avoidance of duplication of procedures

Article 47 Alternative approaches

Article 48 Union Reference Laboratory

Article 49 National committees for the protection of animals used for scientific purposes

Article 50 Adaptation of Annexes to technical progress

Article 51Exercise of the delegation

Article 52 Revocation of the delegation

Article 53 Objections to delegated acts

Article 54 Reporting

Article 55 Safeguard clauses

Article 56 Committee

1. The Commission shall be assisted by a Committee.
2. Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.
3. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at 3 months.

Article 57 Commission report

DIRECTIVE 2010/63/EU

Article 58 Review

Article 59 Competent authorities

Article 60 Penalties

Article 61Transposition

Article 62 Repeal

Article 63 Amendment of Regulation (EC) No 1069/2009

Article 64 Transitional provisions

Article 65 Entry into force

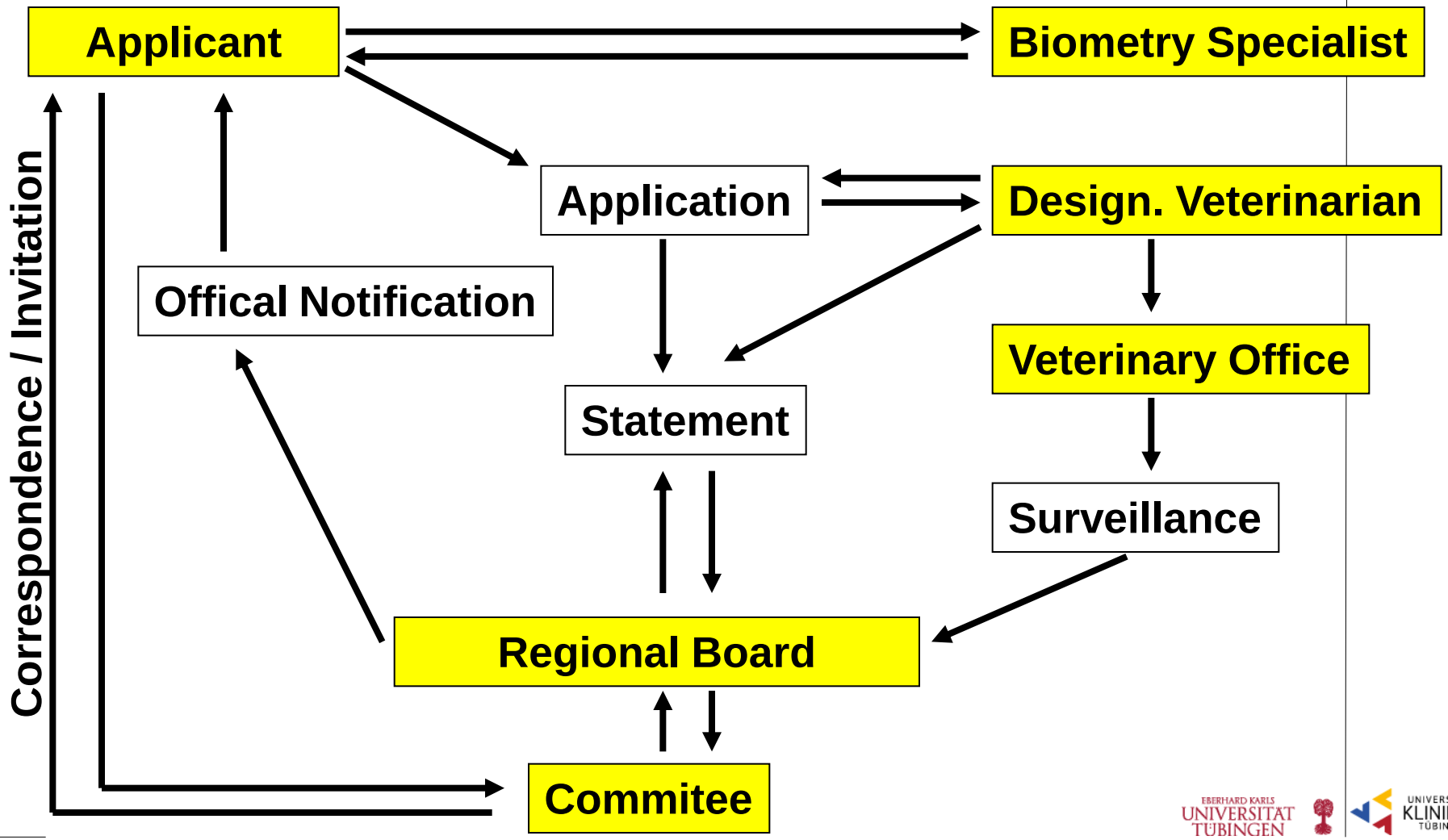
Article 66 Addressees

Paperwork needed

Checkliste

1x	**kompletter Tierversuchsantrag** mit Original-Unterschrift
2x	**Kopie des kompletten Antrags**
6x	**Antragskopie ab Punkt 2**
1x	**Bestätigung sachlicher Mittel** (im Original)
3x	**Personalbogen** (davon 1x im Original für jeden Mitarbeiter)
3x	**nichttechnische Projektzusammenfassung** (3x als Papierform und 1x als CD)
9x	**Schlüsselpublikationen** (max. 5 und 5 MB Volumen) auf eine CD
9x	**Biometrisches Gutachten** (wird nicht bei jedem Antrag benötigt)
3x	**Abschlussbeurteilung genetisch veränderter Zuchtlinien** (wird nicht bei jedem Antrag benötigt) (3x als Papierform oder 1x als CD)

Official Channels



Thank you very much for your attention.