



## WC6 Follow-up Symposium in Tokyo

Roppongi Hills Mori Tower  
February 23, 2008

**ACCREDITATION AND INSPECTION OF ANIMAL  
EXPERIMENTS ACCORDING TO CURRENT LEGAL  
REQUIREMENTS IN EU COUNTRIES**

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*European Treaty Series - No. 123*

**EUROPEAN CONVENTION FOR THE PROTECTION OF  
VERTEBRATE ANIMALS USED FOR EXPERIMENTAL  
AND OTHER SCIENTIFIC PURPOSES**

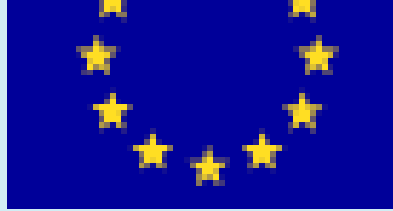
**Strasbourg, 18.III.1986**

➤ Implemented in the EU by Directive 86/609/EEC



# **Council of Europe Convention ETS 123 1986**

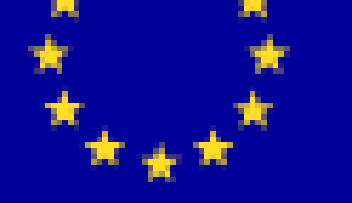
- **Community is a party since 1.11.1998**
- **Wider scope - education and training**
- **Implementing tool - Directive 86/609/EEC**



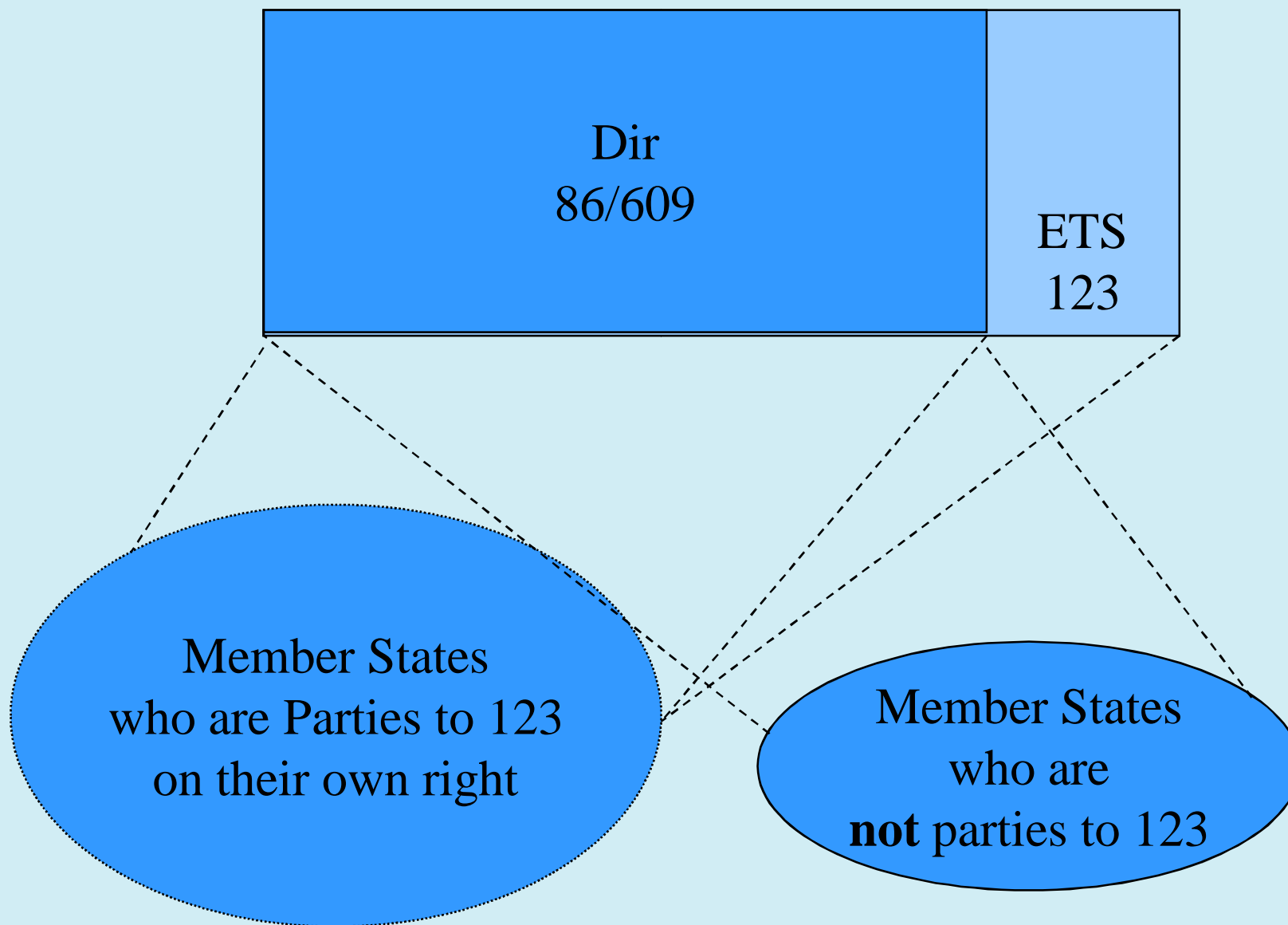
# **Directive 86/609/EEC**

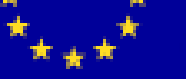
on the approximation of laws, regulations and  
administrative provision of the Member States  
regarding

**the protection of animals used for  
experimental and other scientific  
purposes**



# Areas of competences EU and Council of Europe





**RTD  
FWPs**

**Alternative  
methods**

**Food safety**

**Agriculture**

# Directive 86/609/EEC

**Pharmaceuticals**

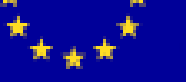
**Biocides**

**REACH  
Chemicals**

**Pesticides**

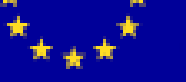
**GLP**

**Cosmetics**



## The Scope

- **development, manufacture, quality, effectiveness and safety testing of drugs, foodstuffs and other substances or products**
- **the protection of environment, health, welfare of man and animals**



# EU Directive 86/609/EEC

## The Directive sets minimum standards for

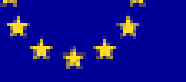
- acquisition of animals
- personnel handling animals or supervising the experiments
- authorization of establishments
- maintaining records

As well as guidance on accommodation and care of the animals



**Council of Europe Guidelines**  
**“On Accommodation and Care of Laboratory Animals”**  
**(Appendix A of Convention ETS 123)**

**adopted by the EU Commission on June 18, 2007**



# EU Directive 86/609/EEC

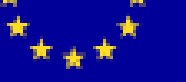
## Guidelines for accommodation and care of animals

### 1. The physical facilities and environment

- ventilation, noise, humidity, lighting

### 2. Care

- health, transport, quarantine, caging
- water, bedding, feeding, cleaning
- exercising and handling
- humane killing



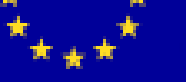
# EU Directive 86/609/EEC

## **Art 19, paragraph 4**

“In user establishments, only animals from breeding or supplying establishment shall be used unless a general or special exemption has been obtained under arrangements determined by the authority. Bred animals shall be used whenever possible. Stray animals of domestic species shall not be used in experiments...”

## **Art 14, paragraph 1**

“Persons who carry out experiments or take part in them and persons who take care of animals used for experiments, including duties of a supervisory nature, shall have appropriate education and training.”



# EU Directive 86/609/EEC

## **Art 15**

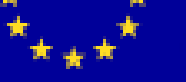
“Breeding and supplying establishments shall be approved by or registered with, the authority... “

## **Art 19, paragraph 1**

“User establishments shall be approved by or registered with, the authority... “

## **Art 13, paragraph 1**

“On the basis of requests for authorization and notifications received, and on the basis of the reports made, the authority in each Member State shall collect , and as far as possible periodically make publicly available, the statistical information on the use of animals in experiments...”



## Authorisation and ethical evaluation

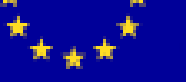
**Authorisation of projects, establishments and persons dealing with experimental animals and inspections are key elements of the legal framework for the protection of experimental animals in EU Member States**

Directive 86/609/EEC and Recommendation 2007/526/EC are defining the conditions for

- **authorisation of experimental projects** conducted on experimental animals,
- the **authorisation and inspection of establishments**, where animal experiments are being conducted,
- the **authorisation of persons carrying out procedures** using animals and being responsible for directing or designing procedures and projects.

Another important element is the **ethical evaluation** of projects comprising of an assessment of the

- **scientific aims**,
- incorporation of the “**Three Rs**”,
- assigned **severity classes** and
- **harm-benefit analysis**.

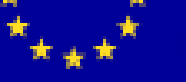


## Establishments and procedures

All establishments shall have **installations and equipment suited to the species of animals housed** and/or to the performance of the procedures conducted. Their design, construction and method of functioning shall ensure that the procedures are performed as effectively as possible in line with the principles of **refinement, reduction and replacement**.

Each establishment shall have **sufficient trained staff**, including

- a minimum of persons responsible on site for the welfare and care of the animals bred, kept or used in the establishment,
- an animal welfare officer and
- a person responsible for the functioning and maintenance of the equipment used on the animals.

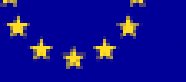


## Education and training of personnel

According to the EU legislation the position of an **animal welfare officer** (NACWO Notified Animal Care and Welfare Officer) has for the first time been introduced in most EU Members States.

**Education and training of personnel** should follow recommendations of **FELASA** (Federation of European Laboratory Animal Sciences Associations), which is focusing on the following groups with different levels of academic background and responsibilities, e.g.

- animal care staff,
- personnel responsible for performing procedures on animals,
- scientists directing the project and
- animal welfare officers (in the UK veterinary surgeons).

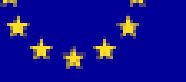


## National Competent Authorities (CA)

National Competent Authorities (CA) will provide authorisation to an establishment after evaluation of the application.

After authorisation of an establishment the CA should ensure the establishment act according to EU legislation thus keeping its authorisation rightfully.

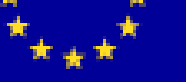
The National CA will visit to verify at least once per year that breeding, supplying and user establishments comply with the recommendations of the general provisions and the species specific provisions of the EU Directive and its annexes. Unannounced inspections are encouraged.



## Statistics on the use of laboratory animals

**An agreement between the Commission and the Member States on a set of 8 statistical tables covering:**

- origin of the animals
- purpose of the experiments
- experiments in relation to human and animal diseases
- toxicological and other safety evaluations
- regulatory requirements
- types of tests



# EU Directive 86/609/EEC

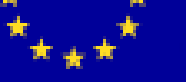
## COMMISSION STAFF WORKING DOCUMENT

*Annex to the:*

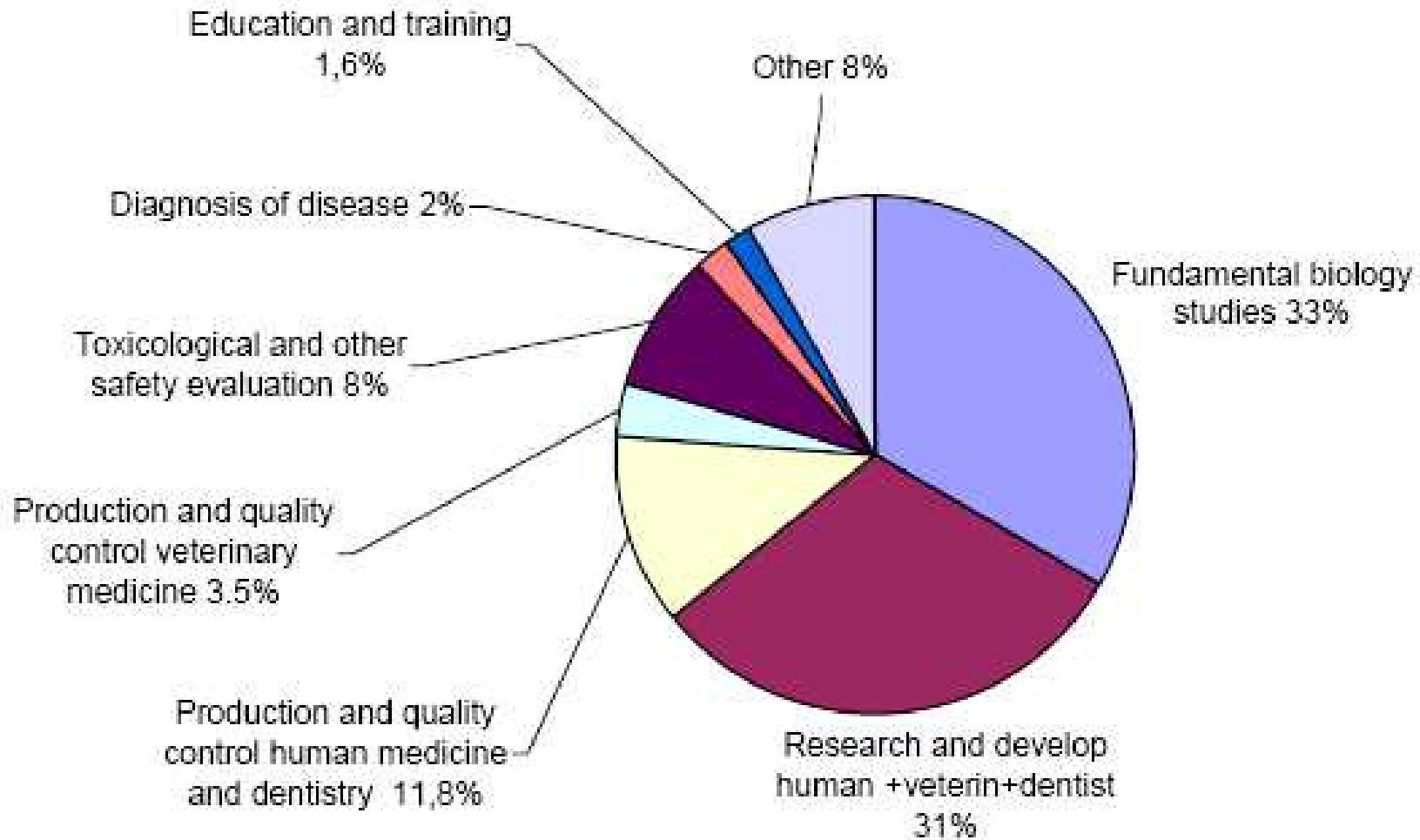
## REPORT FROM THE COMMISSION TO THE COUNCIL AND THE EUROPEAN PARLIAMENT

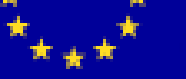
**Fifth Report on the Statistics on the Number of Animals used  
for Experimental and other Scientific Purposes  
in the Member States of the European Union**

{COM (2007) 675 final}

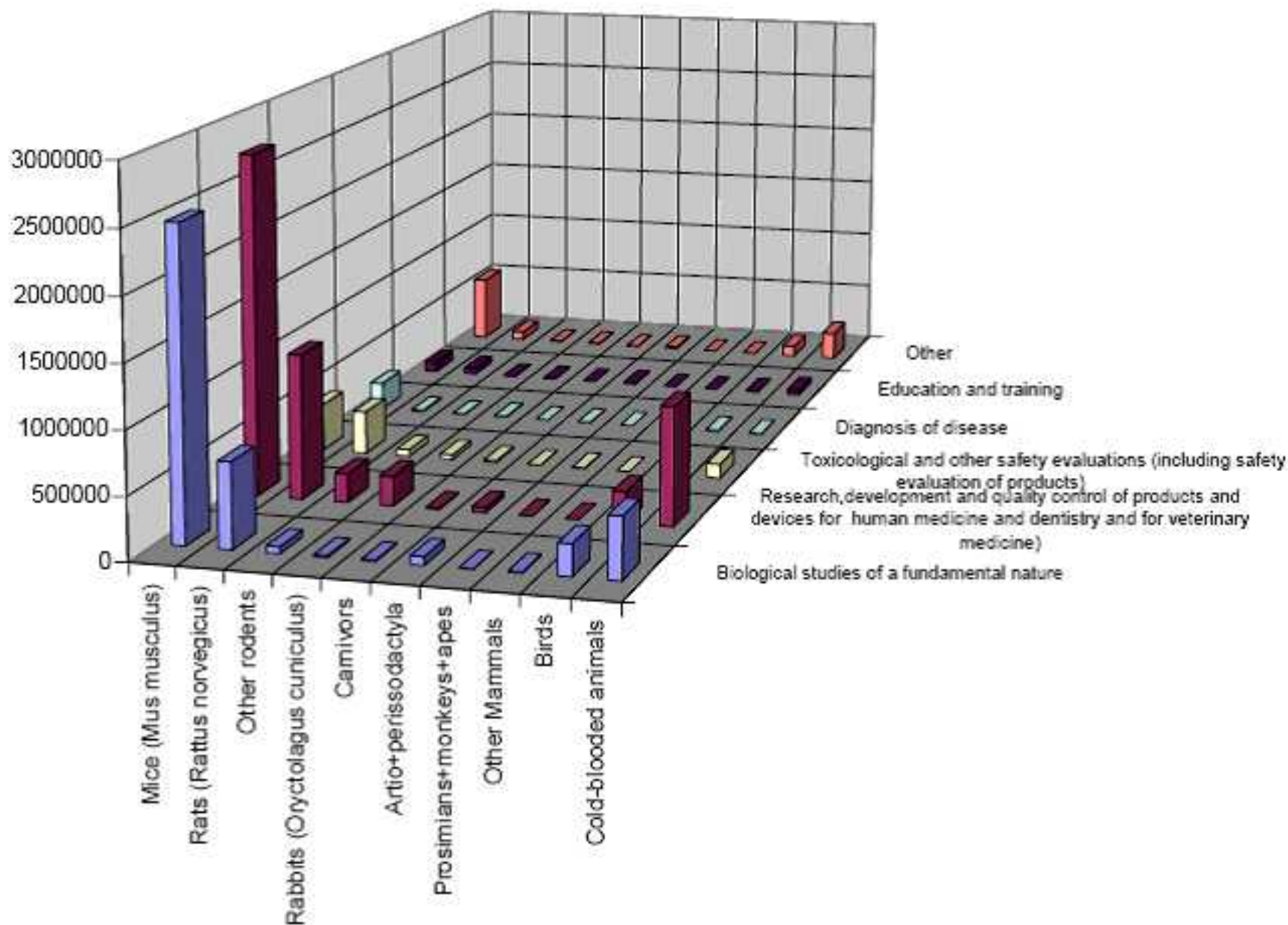


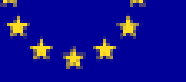
### Purposes of experiments





# Species and experimental purposes





## The Directive also

- calls for active application of the 3Rs: Reduction, Refinement and Replacement
- encourages into the development and validation of alternative methods

**To replace, reduce and refine the use of animals in experiments**

### **3 Rs CONCEPT of RUSSELL & BURCH (1959, 1992)**

#### *The Principles of Humane Experimental Technique*

#### **REFINE**

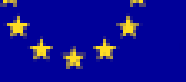
improve the quality of the experiment,  
e.g. to *use humane and more appropriate endpoints*

#### **REDUCE**

reduce suffering & animal numbers  
(*biostatistics*) but not the quality of the experiment

#### **REPLACE *ultimate goal***

complete replacement of a specific animal  
experiment



## Alternative methods to animal experiments

### Art 7, paragraph 2

“An experiment shall not be performed if another scientifically satisfactory method of obtaining the result sought, not entailing the use of an animal, is reasonably and practically available.”

### Art 23, paragraph 1

“The Commission and Member States should encourage research into the development and validation of alternative techniques which could provide the same level of information as that obtained in experiments using animals but which involve fewer animals or which entail less painful procedures, and shall take such other steps as they consider appropriate to encourage research in this field.”

# INTERNATIONAL CENTRE FOR ALTERNATIVES TO ANIMAL EXPERIMENTS

1981

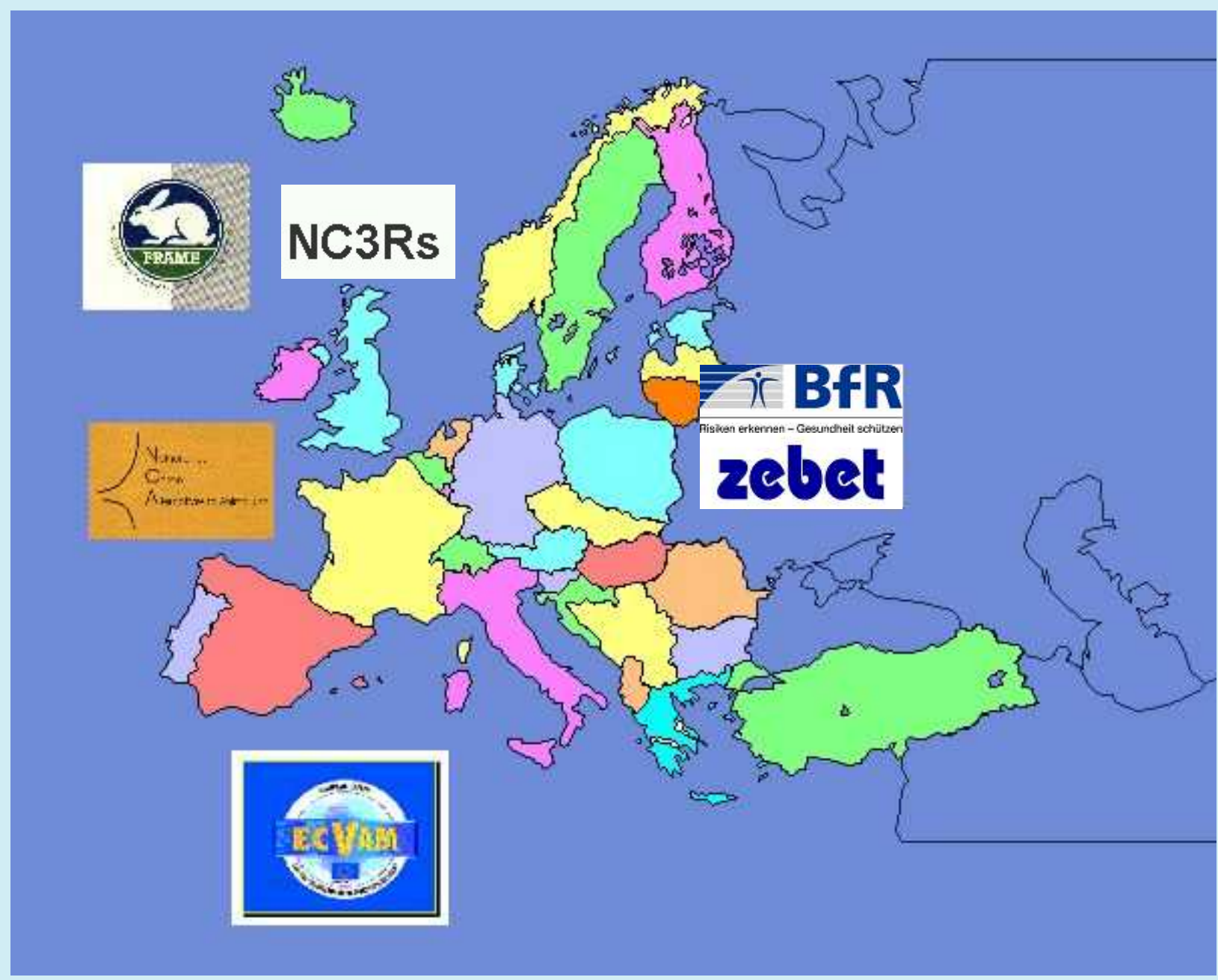
CAAT  
Hopkins



ICCVAM  
USA

2005

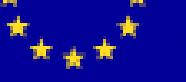
JaCVAM  
Japan



2001



POLAND

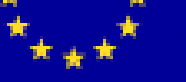


# European Centre for the Validation of Alternative Methods - ECVAM - October 1991 -

To coordinate the validation of alternative  
test methods at Community level

Art 23, paragraph 1

“The Commission and Member States should encourage research into the development and ***validation of alternative techniques*** which could provide the same level of information as that obtained in experiments using animals...”

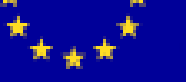


## EU Directive 86/609/EEC

# R for reduction and refinement

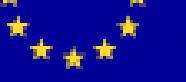
### Art 7, paragraph 3

“... In a choice between experiments, those which use the minimum number of animals, involve animals, with the lowest degree of neurophysiological sensitivity, cause the least pain, suffering, distress or lasting harm and which are most likely to provide satisfactory result shall be selected...”



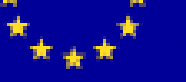
## Driving forces for the revision

- Directive dating back to 1986
- Directive's text containing inappropriate legal provisions and language (Convention formulation)
- Increasing consideration for animal welfare and ethical aspects in general
- Acceptance of the Three Rs as the basis for improved animal welfare and good science



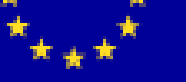
## Main elements of the revision

- The scope of the Directive
- Authorisation of establishment, personnel and projects
- Ethical evaluation of projects and permanent ethical review system at establishments
- Use of non-human primates
- Transparency and enforcement
- Further promotion of Three Rs



## The Three Rs in the heart of the revision

- *Ethical evaluation* of project proposals
- *Permanent Ethical review system* at all establishments (breeding, supplying, user)
- *Co-ordination* of ethical matters at national level



# REVISION of EU Directive 86/609/EEC

## Ethical Evaluation of Projects

- Implementation of the Three Rs
  - origin, numbers and species of animals, and their relevance
  - existence of alternative methods, avoidance of duplication
  - relevance and the statistical design of the chosen methods
  - use of anesthesia, pain relieving methods, humane end points
  - housing and care conditions ...
- Evaluation of severity of procedures (degree of suffering, number of animals)
- Harm-benefit analysis of projects



Thank you very much for your attention !

**Horst Spielmann**

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