Protection of Laboratory Animals Directive 86/609/EEC

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Objective

- The protection of animals used for experimental or other scientific purposes, setting rules mainly on:
 - Accommodation and care
 - The way experiments have to be performed
 - The end of the experiment reuse and freedom

Scope

- Vertebrate animals
- Used in:
 - Development, manufacture, quality, effectiveness and safety testing of drugs, foodstuffs and other substances or products
 - Protection of the environment, health and welfare of man and animal
- Outside scope:
 - Invertebrates
 - Foetal and embryonic form
 - Fundamental research, education and training

Experimental Animals

- Purpose bred: species listed in Annex I
- Animals to be obtained from breeding/supplying establishment
- No CITES Annex I animals to be used
- Individual identification mark for dogs, cats and non-human primates

Accommodation and Care

- Housing: guidelines in Annex II
- Daily checks of environmental conditions
- Competent person to observe wellbeing and state of health
- Defects of suffering to be eliminated as quickly as possible

ExperimentsThe Three Rs – reduce, replace, refinement

- Performed only if no alternative is available
- Choice of species, choice of experiments
- Designed to avoid distress, unnecessary pain and suffering
- Performed by competent authorised persons
- End of experiment:
 - Animals to be kept alive
 - Animals to be reused
 - Animals to be set free

Control Mechanisms

- Notification of experiments or of those conducting them
- Authorisation/justification of experiments involving severe pain
- Registration/approval of establishments (breeding, supply, user)
- Qualification of personnel
- Keep records/Periodic inspections

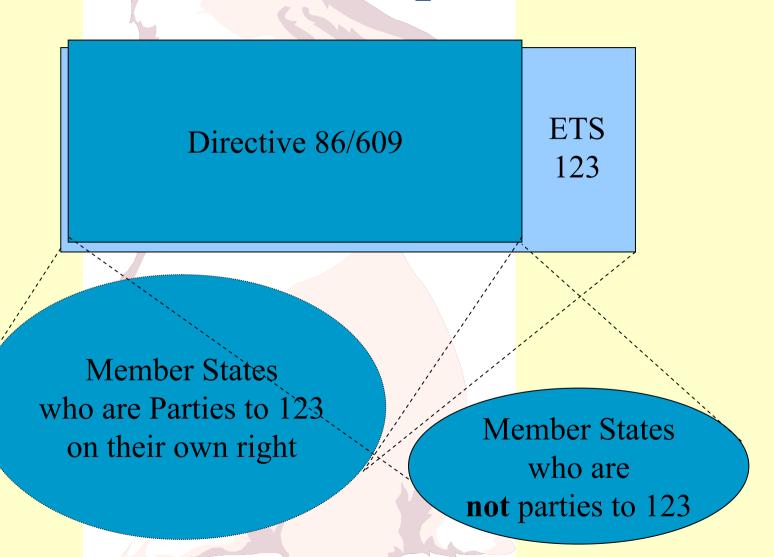
Reporting and Statistics

- MS to collect statistical information
 - Agreement on a set of 8 harmonised statistical tables
 - Key: deadlines, format, quality of data
- EU to report in intervals (not exceeding 3 years)
- The fifth EU report is under preparation (covering the year 2005)

Council of Europe Convention ETS 123 1986

- European Community is Party since 1.11.1998
- Wider scope fundamental research, education and training
- Implementing tool Directive 86/609/EEC
- Housing and Care guidelines currently under revision at the Council of Europe

Areas of competences



Watch out!

- Requirements for statistical reporting
- Revision of Guidelines on housing and care of the Council of Europe Convention
- Revision of Directive 86/609



Website:

http://europa.eu.int/comm/environment/chemicals/lab animals/home en.htm

E-mail:

env-laboratory-animals@cec.eu.int

Relationship between tables

TABLE 1 -

Number of animals used in relation to their place of origin

TABLE 2 -

Number of animals used in experiments for selected purposes

TABLE 4 -

Number of animals used in experiments for human animal diseases

- further details on columns 2.2.

2 3 and 2 7-

Further details on column 2.6

- toxicology -

TABLE 5 -

Number of animals used in production and quality control of products and devices

for human medicine and dentistry

and for veterinary medicine

- further details on columns 2.4 and 2.5 -

TABLE 3

Number of animals used in toxicological and other safety evaluations

- products vs species-

TABLE 6

Number of animals used in toxicological and other safety evaluations

- regulatory requirements vs species -

TABLE 7

Number of animals used in toxicological and other safety evaluations

- test vs species -

TABLE 8

Number of animals used in toxicological and other safety evaluations

- test vs products -