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 well-being and state of health
- Defects of suffering to be eliminated as quickly as possible
Experiments
The 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

Member States who are Parties to 123 on their own right

Member States who are not parties to 123

Directive 86/609

ETS 123
Watch out!

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

Website:
http://europa.eu.int/comm/environment/chemicals/lab_animals/home_en.htm

E-mail:
env-laboratory-animals@cec.eu.int
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 -

Relationship between tables