

Industry objectives for review of Directive 86/609

Background

Directive 86/609 is the common term that refers to a piece of European Legislation that provides for the protection of laboratory animals in research across all industrial sectors.

The Directive seeks to improve the controls on the use of laboratory animals, sets minimum standards for housing and care as well as for the training of personnel handling animals and supervising the experiments. It also aims at reducing the numbers of animals used for experiments by requiring that an animal experiment should not be performed when an alternative method exists, and by encouraging the development and validation of alternative methods to replace animal testing.

The Directive was first adopted in 1986. In 2001, the Commission announced that the Directive will be reviewed in order to better reflect advancements in science and technology. This was followed by a number of expert and public consultations. It is expected that the legislative process will start in Autumn 2007.

Objectives for review of Directive 86/609

The pharmaceutical industry supports the review of the 1986 Directive and in particular:

- all provisions that implement high standards of animal welfare in the interest of high quality biomedical research and public health in Europe. All provisions should be based on sound scientific supportive evidence;
- all efforts toward the replacement of animal testing where scientifically feasible, and reduction as well as refinement where replacement cannot yet be achieved (the 3Rs);
- striking the balance between animal welfare, human health and research needs through national integrated ethical evaluation and authorization processes;
- the reduction of unnecessary bureaucracy and time lost during the administrative processes without compromising on animal welfare. Every day of delayed authorisation of new medicines delays patient access to these medicines.

Detailed considerations for review of Directive 86/609

In order to strike the balance between animal welfare, human health and research, EFPIA considers that:

- **All sentient animals used in basic and applied research and testing deserve high standards of protection as well as of housing and care. This includes animals bred for the supply of cells and tissues for alternative methods.**
- EFPIA member companies acknowledge the high sensitivity of research with **Non Human Primates (NHP)** and support continued justification of research to ensure use for essential biomedical purposes and species preservation. Industry also supports current restrictions for use of great apes. The development of self-sustaining colonies would allow sufficient breeding of species essential in biomedical research. National and European initiatives aiming at eliminating the need for NHP should be encouraged.

- Application of **administrative procedures** relating to potentially sensitive invertebrate species, such as cephalopods and decapods, should be **based on scientific evidence**.
- All Member States should have in place a **defined and effective system of authorization and inspections** covering all establishments. Unannounced regular inspections of facilities and sanctions whenever rules are breached should be seen as effective mean of enforcement. Programmes aimed at sharing best practice between Member States should be encouraged as it will help develop working methods and tools for use by local inspectors.
- **A mandatory ethical evaluation process** with **clearly defined outputs** and an adequate cost/ benefit assessment, as already applied in most Member States, is a necessary measure for approval of projects. National/local ethics committees should incorporate experts in all necessary fields, including lay members.
- As in the current Directive, **avoidable severe suffering** should not be permitted and appropriate analgesia and anesthesia should be used. Clear and simple severity classification should be included in the legislation. EFPIA member companies support **continuous review and refinement of projects**.
- Except for severe protocols, **the re-use and continued use of animals** is consistent with 3Rs and should be regarded as an ethical preference to termination. Modern technologies and devices allow animal procedures to be conducted with minimal interference, therefore minimizing the stress of handling, optimizing the quality of scientific data and dramatically reducing the number of animals used.
- Only **humane methods of euthanasia** that apply the minimum of physical and mental suffering should be used. This will be determined by the species and current veterinary knowledge and good practice.
- Where possible **animal housing and care standards set by Appendix A of the Council of Europe Convention** should be applied immediately. If new buildings are necessary, appropriate transitional periods should be set. Financial support should be made available to public research institutes and universities.
- **The 3Rs principle** should be explicitly reflected in all EU and national legislation and guidance. Further development and use of reduction, refinement and replacement techniques should be encouraged.
- Provision of **factual information on use and care, with guarantees for European competitiveness, industry and academic confidentiality and personnel safety**, will contribute to better understanding biomedical research. Annual statistical reporting at national and EU levels should include simple and clear reporting on severity classes and be accompanied by explanatory statements for increased transparency.
- **Continuous training and education** is a guarantee for best handling and care of animals and good quality research. Each establishment should ensure that personnel have an appropriate high level of competence that is maintained, enabling them to continuously improve animal welfare standards.