

Review of Directive 86/609 on the protection of animals used for scientific purposes

Summary of position

EuropaBio welcomes the review of Directive 86/609. Its members fully support the highest standards for animal care and animal welfare as well as the principles of replacement, reduction, and refinement in animal research. Animal research has played an instrumental role in virtually every major medical advance in the last century and today, no full replacement for animal research yet exist in finding ways to treat some debilitating and life-threatening diseases.

By potentially placing further red tapes on research and additional administrative burden for innovative biotechnology small and medium size enterprises (SMEs), the proposal, in its current form, could jeopardize Europe's capacity to research and innovate. Europabio is particularly concerned with:

- 1. Restrictions on the use on non-human primates (NHPs) for research in life-threatening or debilitating diseases (Article 8)**
- 2. Restrictions of re-use of animals (Art 16)**
- 3. Restrictions on the use of second generation NHPs (Art. 10)**
- 4. Lack of definition of severity classes and de-facto ban of severe studies (Art. 15)**
- 5. Inclusion of embryonic and transgenic forms in scope (Art. 2)**
- 6. Potential increase of administrative burden placed on SMEs**

These points are developed further below.

About EuropaBio

EuropaBio is the European Association for Bioindustries, solely and uniquely bringing together bioscience companies from all fields of research and development, testing, manufacturing and distribution of biotechnology products. It has 79 corporate members operating worldwide, 5 associate members, 6 BioRegions and 25 national biotechnology associations representing some 1800 small and medium sized enterprises involved in research. Its mission is to promote an innovative and dynamic biotechnology-based industry in Europe. www.europabio.org

EuropaBio is a founding trade association of the European Partnership for Alternative Approaches to animal testing (EPAA), a joint initiative between industry and the European Commission. www.epaa.eu.com

Primary Areas of Concern

1. Restrictions on the use on non-human primates (NHPs) for research in life-threatening or debilitating diseases (Article 8)

- This restriction in the draft Directive has the potential to limit advances in fundamental and applied research in the EU. Whilst industry does seek to limit the use of NHPs as much as possible, in some instances it remains inescapable to meet scientific and legal requirements on product safety and efficacy. In many cases the only model which is able to mimic human diseases and corresponding drug reactions is based on the use of NHPs.
- Examples include:
 - **Diseases affecting the immune system:** cancer and HIV/AIDS research, which are highly species specific and where research on monoclonal antibodies safety and transplantation are vital
 - **Central Nervous System (CNS) diseases:** Parkinson's Disease, stroke or Alzheimer's Disease
 - **Infectious diseases:** most parasites, viruses and bacteria are highly species specific and the development of vaccines, anti-viral and anti-parasites medicines still relies on the use of NHPs
 - **Endocrine diseases:** diabetes, growth disorders or infertility involves the hormone system and are species specific

2. Restrictions of re-use of animals (Art 16)

- As the draft text of the Directive stands today, it would only allow the re-use of an animal if the previous procedure was classified as 'up to mild'. This provision, by establishing the use of different animals after each procedure, would have an effect contrary to the principle of reduction of animal research and would significantly increase the numbers of animals used for mild and moderate procedures.
- The biggest impact would be on long-living species such as dogs and non-human-primates. For instance, EuropaBio estimates a 20-fold increase in dogs used for pharmacokinetic studies if the current proposal is adopted.

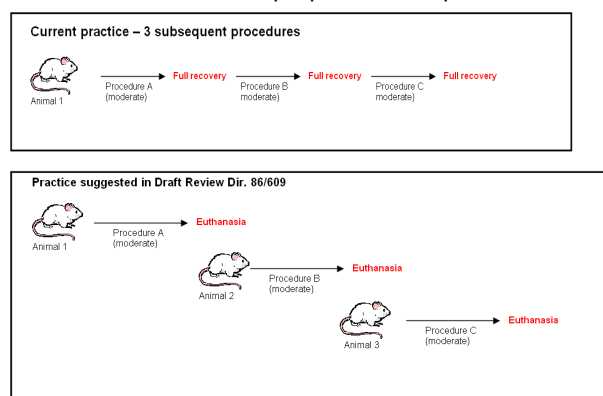


Illustration 1: Current practice and practice suggested in Draft Directive 86/609.

3. Restrictions on the use of second generation NHPs (Art. 10)

- The draft text proposes that only animals that are at least grandchildren of animals caught in the wild (F2) – or higher generations – can be used for research. In the case of macaques where scientists have not yet succeeded in creating self-sustaining colonies, this will be very difficult within the seven year timescale required.

- Even if successful, it would take at least 10 years to establish a sufficient number of F2 NHPs for research which would have a dramatic delaying impact on European research over the next decade. In addition, the risk of delocalisation of research outside of the EU would also increase.
- Since F2 NHPs would be specifically bred for European research, it would also have a cost impact, affecting in particular the ability of academic institute and SMEs to conduct research.

4. Lack of definition of severity classes and *de facto* ban of severe studies (Art. 15)

- The draft proposal defers the establishment of criteria for classification until after the Directive is adopted and includes a *de facto* ban of studies classified as severe. Clearer evidence-based definitions of the severity classes should however be developed prior to the implementation of the revised Directive.
- Robust scientific justification and ethical review should guide the development of the severity classification as projects looking at unmet medical needs in the field of chronic pain related to cancer and neurological diseases or transplantation may stop if a ban on some type of studies is implemented.

5. Inclusion of embryonic and transgenic forms in scope (Art. 2)

- The proposed text foresees the inclusion of embryonic or foetal forms as from the last third of their normal development. This will hugely increase statistics required on animal numbers, the administrative burden for registration and the reporting procedures with no tangible benefit.
- As an example, during the flu vaccine manufacturing season, millions of eggs are used per day, all of which may have to be included under this provision. This would lead to an increased bureaucratic burden for companies, ethics committees and other authorities, and would jeopardize Europe's seasonal flu vaccine production and, ultimately, Europe's ability to prepare to a viral pandemic event.

6. Potential increase of administrative burden placed on SMEs

- The EC has stated its intention to reduce the burden and costs of legislation for SMEs and larger companies in order to improve competitiveness, and to continue to strive for the goals laid out in the Lisbon and Gothenburg agendas.
- Therefore, the EC should assess the impact of knock-on effects, particularly on smaller companies and academic institutions, and identify ways to minimise the extra administrative burden that would result from the Directive if implemented in its current draft form.

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