



OPINION OF THE GROUP OF ADVISERS  
ON THE ETHICAL IMPLICATIONS OF BIOTECHNOLOGY  
TO THE EUROPEAN COMMISSION

N°7

21.05.96

\*\*\*\*\*

**ETHICAL ASPECTS OF GENETIC MODIFICATION OF ANIMALS**

Reference : Opinion requested by the European Commission on 29 September 1992

Rapporteur : Prof. Egbert Schrotten

\*\*\*\*\*

The Group of Advisers to the European Commission on the Ethical Implications of Biotechnology (GAEIB),

Having regard to the Commission's request of 29 September 1992 for an Opinion on Ethics and Biotechnology for vertebrate animals, including fish,

Having regard to the Commission's White Paper on Growth, Competitiveness, Employment (December 1993), in particular chapter 5B,

Having regard to the Treaty on European Union, namely the annexed Declaration n° 24 on the protection of animals,

Having regard to Council Directive 86/609/EEC regarding the protection of animals used for experimental and other scientific purposes,

Having regard to Council Directive 90/220 EEC, regarding the deliberate release into the environment of Genetically Modified Organisms,

Having regard to the European Conventions of the Council of Europe for the protection of animals kept for farming purposes (1976-EST 87) and in particular the Protocol of Amendment thereto, and for the protection of vertebrate animals used for experimental or other scientific purposes (1986-EST 123),

Having regard to the United Nations Convention on Biodiversity of 6 June 1992, ratified by the European Union on 25 October 1993,

Having regard to the hearings, organized by the GAEIB, with experts, representatives of consumers, patients' groups and pharmaceutical Industries, representatives of animal and environment protection associations, researchers and members of the European Parliament and of the Council of Europe (21 June 1995 and 20 February 1996),

Having regard to the report of Prof. Egbert Schrotten on the ethical aspects of genetic modification of animals.

## 1. WHEREAS :

1.1 The Opinion addresses the genetic modification of animals brought about by DNA technology, including transfer of genes (transgenesis) and the deletion of genes (“knock-out”).

1.2 Genetic modification of animals is a developing technology which will add to rather than replace existing techniques. It can be used :

- In fundamental bio-medical research to improve our genetic and physiological knowledge;
- To make models of human diseases;
- For the production of proteins or other substances for therapeutic aims;
- As an alternative source of tissues and organs for “xenotransplantation”;
- To obtain or to improve desired features of farmed animals including fish, such as disease resistance and food production.

1.3 In this context, international competition is strong because practical applications are to be anticipated, both :

- Medical (e.g. models of cystic fibrosis, production of alpha-1-antitrypsin for the treatment of acute respiratory distress syndrome);
- And agricultural (e.g. improved meat quality in pigs, better wool production in sheep, fish with increased growth rate).

1.4 Man has always been trying to modify nature, for instance by animal breeding. However, modern animal biotechnology differs from traditional breeding, more specifically by :

- The methods used : direct intervention on a micro level (cells, DNA, genes) by highly sophisticated technologies;
- The range of the new methods : breaking through species and even kingdom barriers;
- The speed and precision of such modern technology;
- The introduction of new objectives : for instance xenotransplantation.

1.5 In our societies, besides the potential benefit we can expect from these techniques, there are concerns, for example :

- Harm to animal health and welfare;
- Impact on human health;
- Animals are being used as mere instruments for human benefit and interests;
- It is seen as an infringement of animal “integrity” or of the “intrinsic” or “inherent” value of animals;

- It is seen as “unnatural for example because it transgresses species boundaries;
  - It is seen as taking environmental risks the consequences of which are difficult to calculate;
  - It is seen as a slippery slope towards eugenic applications on human beings.
- 1.6 Some of these public concerns about genetic modification of animals may be based on lack of information. They also reflect fundamental philosophical questions about our society and the place of science and technology therein, the place of humans in nature, the relation between humans and animals and in particular the extent to which animals may be subordinated to human needs.
- 1.7 The religious and philosophical approach of western countries traditionally gives a specific place to humans in their relationship with nature and animals, as humans are taken to have a “superior” position. This approach is shared by most people in Europe even though society has experienced, in recent decades, movements which advocate a more bio- oriented way of thinking.
- 1.8 In the pluralistic societies of the European Union, a complete consensus on moral and philosophical issues is not likely. However, we all may agree that vertebrate animals, as sentient beings, deserve special ethical awareness, and that genetic modification of animals means an increase of scientific power and thus of responsibility. On the map of these new technologies, the ethical pathways are not yet clearly marked, which implies the adoption of a policy of prudence.
- 1.9 The use of genetically modified animals or products issuing from them, may have potential implications for humans, which should be taken into account, namely concerning :
- Our security as a consumer
  - Our right to be informed
  - The protection of our environment (including biodiversity).
- 1.10 Since it involves additional ethical issues, the controversial question of legal protection of genetically modified animals requires a separate opinion.

## **2. SUBMITS THE FOLLOWING OPINION TO THE EUROPEAN COMMISSION :**

2.1 Genetic modification of animals may contribute to human wellbeing and welfare, but is acceptable only when the aims are ethically justified and when it is carried out under ethical conditions.

2.2 These conditions would include the following :

- The public's right to protection against risks as well as their right to adequate information;
- Human responsibility for animals, nature and the environment, including biodiversity;
- The duty to avoid or minimize animal suffering since unjustified or disproportionate suffering is unacceptable;
- The duty of reducing, replacing and when possible refining the experimentation adopted for the use of animals in research.

2.3 In view of the consequences this technology may have for the health of humans and animals, for the environment and society, a policy of great prudence is required.

2.4 The scope of this policy should apply to :

- The making of genetically modified animals;
- The use and care of these animals;
- The release of these animals;
- Putting genetically modified animals and their products onto the market (including import/export).

2.5 Concerning these points, licensing bodies in all Member States should have the task of assessing research projects and applications in the light of the above mentioned principles.

2.6 The task of these licensing bodies would include at least the assessment of :

- The objectives : transparency and ethical acceptability;
- The risks : human health, environmental impact;
- Animal health, welfare and care;
- The proportionality of means and ends concerning genetic modifications of animals;
- The quality of these procedures;
- The possibility of alternatives.

- 2.7 Great care should be taken to prevent the release into the environment of genetically modified animals capable of surviving and breeding in the wild.
- 2.8 Research into the ethical, philosophical and social aspects of animal biotechnology should be stimulated. Research into and monitoring of the possible consequences of animal biotechnology for the public and the environment should be supported at the European level.
- 2.9 There should be appropriate and understandable information for the public about genetic modification of animals and their products. The European Institutions should strive to :
- Systematically bridge the information gap;
  - Stimulate the dialogue between research, industry and the public;
  - Create platforms for participation of the public in decision making.

\*\*\*\*\*

In accordance with its terms of reference, the Group of Advisers on the Ethical Implications of Biotechnology hereby presents this Opinion to the European Commission.

The Members:

Anne McLaren

Margareta Mikkelsen

Luis Archer

Octavi Quintana-Trias

Stefano Rodota

Egbert Schrotten

Dietmar Mieth

Gilbert Hottois

The Chairman,

Noëlle Lenoir