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## **EGE Opinion**

# **Ethics of animal cloning for food supply**

**The view I express are my own and do not necessarily reflect those of the European Commission**

**BEPA**

**European Commission**





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## topics covered

**EC Activities in bioethics**

**EGE Remit**

**Position of the EGE**

**Requests to the EC**





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# embedding of ethics in EC activities: how, when, where?



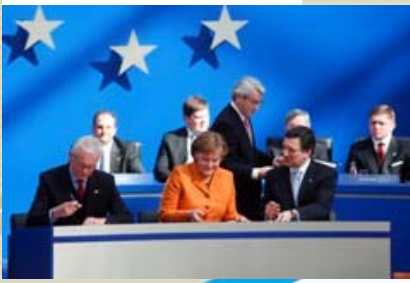


# EC Activities

- BEPA is the service with horizontal responsibility for ethics within the Commission and 4 main activities characterise the Commission work in the fields of bioethics and ethics of science:

1. **Policy Design/Legislative Proposals**
2. **Structuring the pan-European debate on bioethics**
3. **Research Funding**
4. **Networking.**





## Policy Design Legislative Proposals

- The relevance of bioethics with regard to the **Community policies** is particularly marked; some examples of relevant policies include the **Science and Society Action Plan** (COM(2001)714), the **Action plan Life Sciences and Technology** (COM(2007) 175), the **Nanotechnology Action Plan** (COM(2007) 505 final), etc. .





## Policy Design

### Legislative Proposals

- Issues of bioethics in the legislative sphere cover very many disparate areas of policy; from **clinical trials** (Directive 2001/20/EC) to **patents** (Directive 94/48); from **data protection** (Directive 95/46) to **research** (FP) or production of **medicinal products** (Directive 2001/83/EC and others, e.g. 2003/63/EC); from **animals used for experimental** and other scientific purposes (Directive 86/609/EC) to **animal welfare** (Protocol to the Amsterdam Treaty) etc. The list of Community regulations also includes applications of **biotechnology, information technologies** and several areas of **biomedical sciences**.





## Structuring EC work on bioethics

- An **inter-services platform on ethics and EU policies**. The platform, serves to rationalise and coordinate Commission activities in the fields of bioethics and ethics of science and new technologies. In 2006, the platform has discussed a number of Commission initiatives, such as: *Animal cloning for food market; Radio Frequency Identification Devices; Scientific Integrity; Ethics of Nanomedicine; Privacy Enhancing Technologies; Data Profiling and Personal Data Matching; Towards a EU- AU Strategic Partnership; Ethics, Research and Globalisation;*





## Structuring the pan-European debate on bioethics

- The Commission finances **pan-European debates on bioethics and networking between relevant bioethics bodies**. Some examples of networking activities promoted and supported by the Commission include:
  - a) The **Forum of National Ethics Councils (NEC Forum)** established in 2003 by DG Research and clustering the National Ethics Committees of the 27 Member States. It now involves all 27 Member States.





## Structuring the pan-European debate on bioethics



- the Commission participates in a number of **international fora dealing with bioethical issues** on behalf of the European Community and particularly, but not only, in the Council of Europe.
- Financial support to bioethics initiatives carried out by International Organisations (for example Unesco and Council of Europe in 2008) is also provided to the EC.





# Research

- Since the 4th EU Framework Programme for research a research programme on bioethics the Commission has financed pan-European interdisciplinary **research into the ethics of science and bioethics**. Under FP7 this research effort has been reinforced by the financial support of **ethics, governance, human rights and democracy** research projects under the Science, Economy and Society research programme.





## Ethics review

- DG Research, with the help of external independent experts, also conducts an **ethical review** to monitor that Commission-funded research proposals involving issues of major significance on bioethics are ethically sound (e.g. **use of human biological material, involvement of vulnerable people in research activities –children, aged peoples etc., use of non-human primates** etc.).





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# Remit of the EGE



# Structuring the pan-European debate on bioethics



- In order to equip itself with expertise on bioethics, the Commission in 1991 set up the **European Group on Ethics in Science and New Technologies** (EGE), an independent group, with the mandate to advise the Commission on ethical questions relating to sciences and new technologies.
- Following President Barroso's requests, in 2006-2007 the EGE has issued Opinions on (1) *ethics and nanomedicine*, (2) *Ethics review of FP7 human embryonic stem cells projects* (3) *animal cloning for food supply*





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## From GAEIB to EGE

- > 1991 - 1997      The Group of Advisers on the Ethical Implications of Biotechnology
  
- > 1998 - 2000      EGE's first mandate
  
- > 2001 - 2004      EGE's 2nd mandate
  
- > 2005 – 2009      EGE's 3rd mandate





## European Group on Ethics in Science and New Technologies (EGE)

- The **EGE** is an **independent, pluralist and multidisciplinary** body which **advises** the European Commission on **ethical aspects of science and new technologies** in connection with the preparation and implementation of Community legislation or policies

[http://europa.eu.int/comm/european\\_group\\_ethics/index\\_en.htm](http://europa.eu.int/comm/european_group_ethics/index_en.htm)





## European Group on Ethics in Science and New Technologies (EGE)

- The **EGE** is composed by 15 members that participate in their personal capacities, the experts belong to a set of disciplines, such as ethics, law, science, philosophy, theology, political science, medicine etc.
- The EGE issues Opinions after hearings, round table and discussions with the main experts of the fields.







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## European Group on Ethics in Science and New Technologies (EGE)



Göran Hermerén, Linda Nielsen, Rafael Capurro, Inez de Beaufort, Pere Puigdomenèch Rosell and Günter Virt, (from the former EGE)  
new members: Emmanuel Agius, Diana Bánáti, Anne Cambon-Thomsen Jozef Glaza, Hille Haker, Julian Kinderlerer, Krzysztof Marczewski Paula Martinho da Silva, Francesco Busnelli





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## OPINIONS EGE 1998-2005



- n° 11 Ethical aspects of **human tissue banking** (21/07/1998)
- n° 12 Ethical aspects of research involving **the use of human embryo in the context of the 5th framework program** (23/11/1998)
- n° 13 Ethical issues of **healthcare in the information society** (30/07/1999)
- n° 14 Ethical aspects arising from **doping in sport** (14/11/1999)
- n° 15 Ethical aspects of **human stem cell research and use** (14/11/2000)
- n° 16 Ethical aspects of **patenting inventions involving human stem cells** (07/05/2002)
- n° 17 Ethical aspects of **clinical research in developing countries** (04/02/2003)
- n° 18 Ethical aspects of **genetic testing in the workplace** (28/07/2003)
- n° 19 Ethical aspects of **umbilical cord blood banking** (16/03/2004)
- n° 20 Ethical aspects of **ICT implants in the human body** (16/3/ 2005)
- n° 21 Ethical aspects of **Nanomedicine** (January 2007)
- N° 22 Ethical review of **FP7 hESC** (July 2007)
- N.23 Ethics of **Animal Cloning for food supply** (January 2008)





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# **EGE Opinion on Ethical Implications of Animal Cloning for food supply**





# Preparatory works

- 10 months of internal working meetings, expert hearings, a public consultation launched in the Europa web site (800 contributions received) and a round table with representatives from academia, industry, NGOs, civil society, International organisations and industry on **January 16, 2007**, the EGE has adopted the Opinion on *ethical aspects of animal cloning for food supply*.





## Remit

- The EGE has already issued an Opinion on ethics of animal cloning in 1997, but due to the state of the art of the technology at that moment, it did not address the ethics of animal cloning specifically for food supply. The EGE Opinion complements and updates the previous one and **is intended to be complementary to EFSA's.**





# Remit

- The EGE Opinion did **NOT** address:
- **genetically modified animals** (genetic modifications to produce nutraceuticals, bio-pharming or prevent animal diseases in farm breeding or increasing the added value of food products from cloned animals and their offspring)
- **cloning techniques as such .**





# Opinion

- The major arguments advocated *in favour* of cloning for food comprise economic reasons e.g.
  1. **European competition** on the free market;
  2. **industrial development**;
  3. **improve food production and quality**;
  4. **Minimise costs** -cheaper food production.





# Opinion

## *Arguments against:*

- **concerns based on human health and safety, animal health and welfare, animal integrity, biodiversity, risk of epidemics, social and economic consequences on rural areas, agricultural trade; negative effects on the attitude towards animals; slippery slope (cloning of human beings).**







# Opinion

- **The Group was aware that different positions exist on the moral acceptability of using animals in modern farming and is aware that some positions against the instrumental use of animals for human purposes are **categorical**. The Group therefore recognises that **for some people animal cloning for food production is *per se* an ethically unacceptable practice even if strict conditions are respected.****





# Opinion

- **The EGE is of the opinion that at this moment there are no categorical arguments against animal cloning for breeding with the purpose of food production. The EGE is not convinced so far that there are (enough) good reasons to 'alleviate' the ethical concerns.**
- **The EGE emphasized that embarking in cloning for food supply is opening a new dimension in the general context of breeding that is not only technical and will create a moral unease that can not be simply discarded.**





# Opinion

- The Group, in line with EFSA findings, is of the opinion that to date animal welfare and health are affected by animal cloning, in particular for surrogate dams and the first generation of clones. **The Group therefore expresses its doubts on the fact that the existing arguments in support of cloning for food would ethically justify the current animal clones' welfare and health situation.** At present, this consideration **cannot** be extended to clones' offspring in absence of proper data.





# Ethics principles

- Main ethics principles advocated:
  - **protection of human health**
  - **protection of animal health and welfare**
  - **protection of Citizens' rights**
  - **need of public discussion**





# Ethics concerns to be addressed

- *Food safety*
- To guarantee safety of **food products for human consumption as a pre-condition** for their marketing.
- *Animal welfare and health*
- 1) To **respect** as much as possible **animal welfare**; 2) to carry out **studies on long term animal welfare and health implications, including comparative analyses** with other animal farming assisted and traditional reproductive technologies; 3) **the Commission to prepare a Code of Conduct for responsible farm animal breeding, including animal cloning.**





# Ethics concerns to be addressed

- *Biodiversity*
  - 1) **To protect**, as much as possible, **biodiversity** in farm animals stocks also to avoid risks of global epidemics; 2) **the Commission to take proper measures to preserve the genetic heritage of animals' species.**
- *Public perception*
- **To launch a thematic EUROBAROMETER survey** on animal cloning for food supply.
- *Public participation*
- **To promote public discussion** on animal cloning for food supply.





# Ethics concerns to be addressed

- *Traceability and Labelling*
- 1) **To apply the current EU legislation to food regarding traceability of food products; 2) the Commission to work out target procedures for the labelling of food products from offspring prior their introduction in the market.**





# Ethics concerns to be addressed

- *Global Trade*
- 1) To launch an **international discussion** on considerations of free trade and ethical concerns regarding the cloning of animals; 2) to make the **import of materials from cloned animals and their offspring (e.g. semen and food products) conditional to the requests indicated in this EGE Opinion (e.g. traceability provisions).**







# Ethics concerns to be addressed

- *Additional research*

- To concentrate research efforts to **solve the lack of knowledge** on (1) **scientific aspects** indicated in the EFSA report; (2) **animal welfare and health for other farmed species** than the ones covered by EFSA and FDA; (3) **ethical, legal and Social Implications of animal cloning for food**; (4) **qualitative studies on public perception**; (5) **exclusion clauses stated in EC/98/44 (Art. 6) and EPO 23d with regard to animal cloning for food**; (7) **research on food philosophy**





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**And now?**





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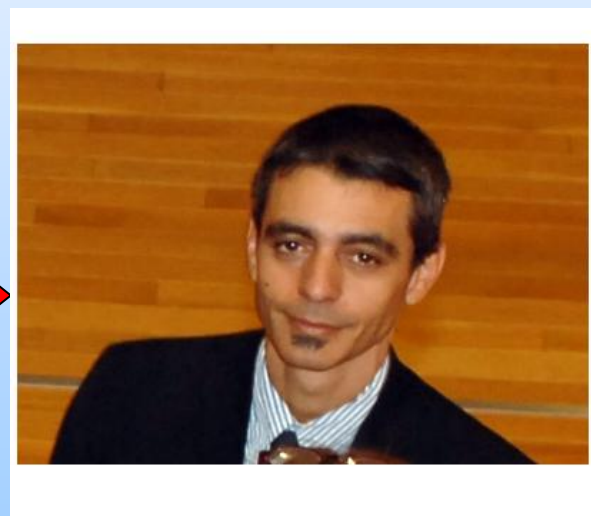


**The view I express are my own and do not necessarily reflect those of the European Commission.**

**NO** →



→ **Yes**





- The Commission will **examine** in detail the Opinions of these two independent bodies. Upon completion of this examination, the Commission will launch a wide **consultation** to obtain stakeholders' feedback. It must be made clear that **the two opinions relate to the risk assessment** of the relevant aspects deriving from the cloning of animals for food production. **The Commission has not made any risk management decision** on this matter.





- The Commission has also begun work on a **Eurobarometer study** to learn about consumers' attitudes and demand for information on cloning. The results of this survey should be available in the **second half of 2008**.
- A **comprehensive discussion** on animal cloning is indispensable with regard to deciding on the EU's future approach to the production and use of cloned animals in the food chain. **The Commission intends to lead this discussion** and obtain the widest feedback possible before deciding on the necessity to propose any actions..





# Personal Contact:

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## Information available:

BEPA homepage: [http://ec.europa.eu/dgs/policy\\_advisers/index\\_en.htm](http://ec.europa.eu/dgs/policy_advisers/index_en.htm)

EGE homepage: [http://europa.eu.int/comm/european\\_group\\_ethics/index\\_en.htm](http://europa.eu.int/comm/european_group_ethics/index_en.htm)





# EU Policy

## • STEP 2

- The notion of **Europe as a community of values** and the **role of the EU as a main actor in International affairs** explain the Commission intention to concentrate effort, in full respect of its Powers and the Institutional role of different International organisations, in **global discussions on research and innovation, science and technology, a debate where bioethics play a central role.**

