

Animal Cloning and Nanotechnology



food-related regulatory aspects from an
EU perspective

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http://ec.europa.eu/comm/food/animal/index_en.htm

This presentation does not necessarily represent the views of the European Commission

What does a clone look like, when seen by the eyes of a regulative mind?

Is [animal] cloning anything **special**?



A frequent statement:

Animal cloning is
- unlike plant cloning -
something **special** because
it is “unnatural”.



What is natural?



Selective mating

Artificial insemination

In-vitro-fertilisation

Embryo transfer

Embryo splitting

Embryonic cloning

Somatic cell nuclear transfer

GM - animals

Assisted Reproductive Techniques (ARTs)

natural?
traditional?

unnatural?
innovative?

Current Legislation

- Current zootechnical legislation does not prohibit cloning.
- Import of semen or embryos is legal without labeling.
- Animal welfare Directive 98/58/EC: ... *breeding procedures likely to cause suffering or injury to any of the animals concerned must not be practised ...*
(EU Parliament is debating a motion on this basis).

Current Legislation (2): Novel Foods Regulation 97/258

- **Article 1:** *The Regulation applies to food from animals, except for foods obtained by traditional breeding practices.*
So, food from clones is not exempt and is Novel Food.
- **Article 3:** *Novel Foods must not be dangerous, misleading or nutritionally disadvantageous.*
- **Article 7:** *Specific labelling requirements shall apply to ensure that the final consumer is informed of the presence of material which gives rise to ethical concerns.*

**DRAFT Opinion of the
European Food Safety Authority (EFSA)
on food safety, animal health and environmental aspects
19 December 2007:**

‘The currently available data indicate that food products from clones of cattle and pigs and their progeny are as safe as food products of livestock derived by conventional breeding.

....

...there is no expectation that clones or their progeny would pose any new or additional environmental risks...’

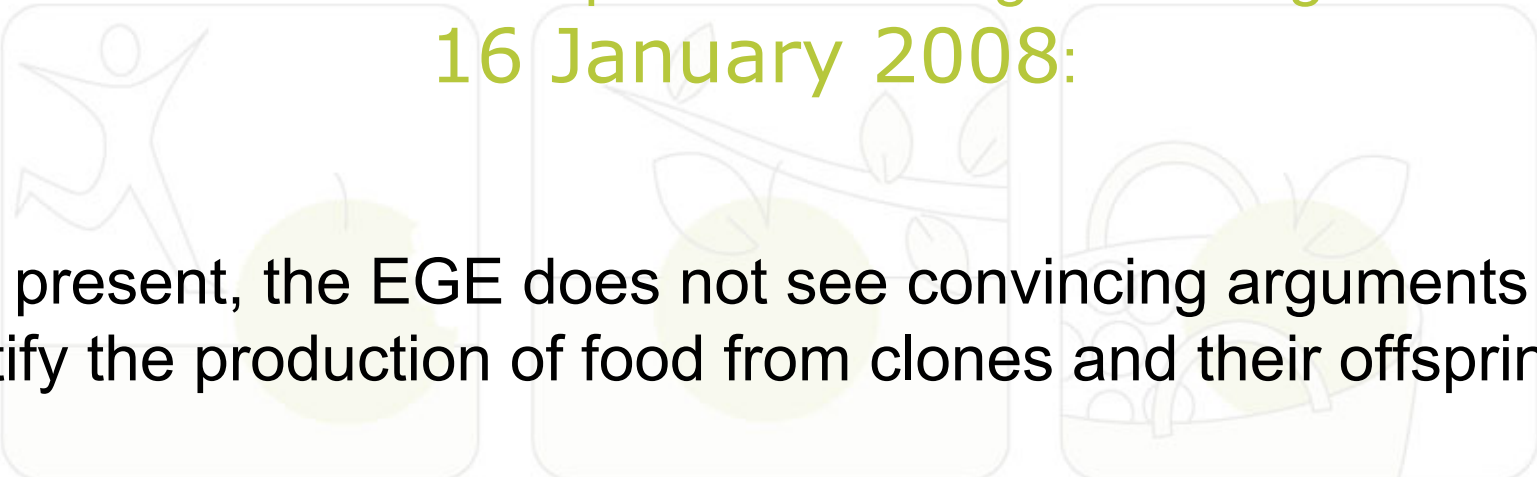
http://www.efsa.europa.eu/EFSA/DocumentSet/sc_opinion_clon_public_consultation.pdf

(public comment window closed 25 February, final opinion expected April/May 2008)

Opinion of the European Group on Ethics in Science and new Technologies (EGE)

on the ethical aspects of cloning technologies

16 January 2008:



‘At present, the EGE does not see convincing arguments to justify the production of food from clones and their offspring.’

Minority opinion:

‘the need to protect the right of free choice of consumers’

Next Steps:

- EU wide representative poll on consumer opinions (Summer 2008).
- Final EFSA Opinion (April/May 2009).
- Commission debate, possibly further stakeholder consultations.
- Formal legislative proposal and/or communication of proposed regulatory practice.

Nanotechnology in food

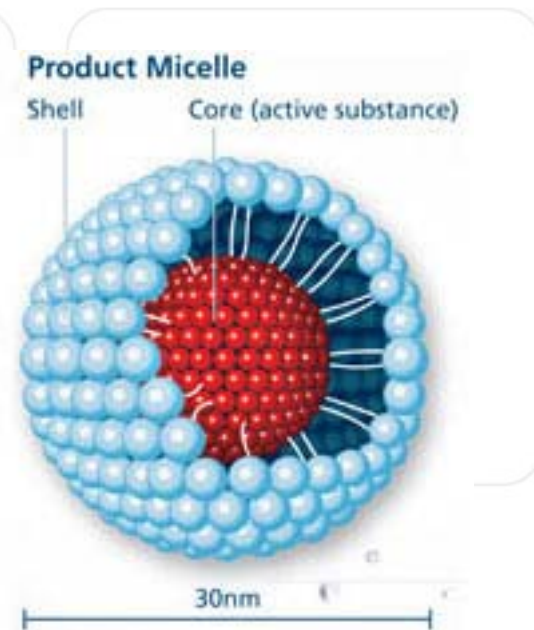
- General Food Law: Regulation 178/2002
- Novel Food: Regulation 258/97/EC
- Food contact materials: Reg. 1935/2004/EC
- Food additives: Directive 89/107/EEC
- Feed legislation
- ➔ **Legal philosophy**
 - Driven by safety
 - Based on risk assessment (cf., EFSA)
 - Neutral to technology



Two products in the EU (≠ authorized!)



(Synthetic) Lycopene®
(BASF, Germany)



Novasol®
(Aquanova®, Germany)

And while we are talking:

Businesses create facts.

- Semen and embryos can be traded (*are they?*).
- Meat and animal products from clone offspring are marketed in US (*and to EU?*) without restrictions.
- Nano-Vitamin C is available over the Internet¹ (*also to European consumers*).

¹<http://www.livonlabs.com/Lypo-Spheric-Vitamin-C.html>