



Animal cloning for food supply – EU regulation in the shadow of the WTO

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EU Proposes Ban on Cloning Farm Animals, Sale of Clone Meat

By Rudy Ruitenberg | Dec 18, 2013 2:13 PM GMT+0100 | [1 Comment](#) [Email](#) [Print](#)

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The proposal seeks to address worries about animal welfare and other ethical concerns related to use of cloning, the nation EU's executive I today. Cloning for that its use for food e, according to the



Majority of EU countries in favour of GMO compromise

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04/03/2014 - 15:09



A majority of EU member countries backed a compromise agreement on GMO authorisation which maintains an EU-wide approval scheme but allows national cultivation bans.

Under the proposals, drafted by Greece, which holds the rotating EU Council presidency, the European Commission and the European Food Safety Authority (EFSA) would

EU seal product ban upheld in WTO appeal

CBC News | Posted: May 22, 2014 12:48 PM NT | Last Updated: May 22, 2014 2:41 PM NT

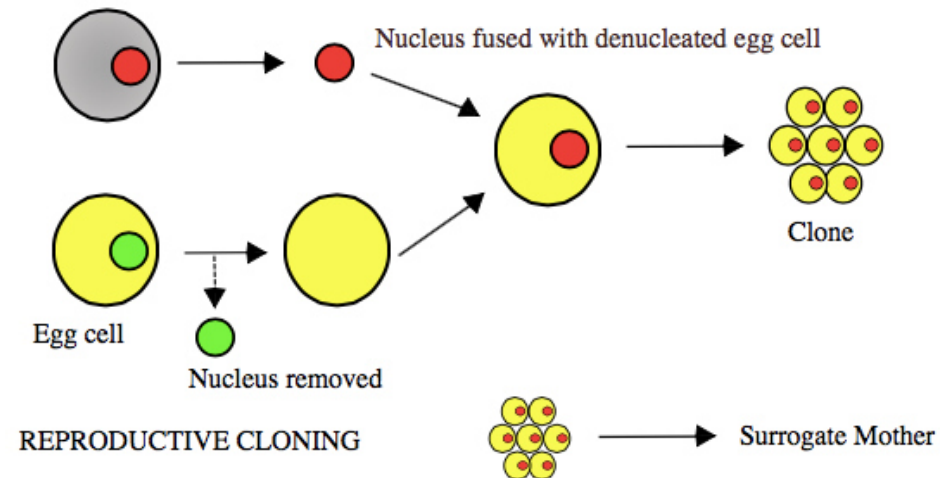


Definitions

Animal Cloning:

the reproduction of genetically identical 'copies' of an animal through **Somatic Cell Nuclear Transfer (SCNT)**. Creates genetic replicas (clones) from adult animals that share the same nuclear gene set as another organism

Somatic body cell with desired genes



Offspring / Progeny:

offspring born from an animal clone by sexual reproduction, where at least one of the parents was a clon

“Commercial cloning is a form of assisted reproductive technology and may be used to replicate ‘high quality’, high value breeding animals.”

Global trade context

- “There is **no evidence** that commercial cloning of animals for food production is taking place **in the EU** and consultations suggest it is unlikely to be established before 2020.”
- “Commercial cloning is concentrated in the **US, Canada and Argentina**, although there is some activity in **New Zealand, Australia, Chile, China and South Korea.**”
- “The most likely route for clones, clone offspring and descendants or their reproductive materials to come into the EU is **as reproductive materials** from bovine animals, and possibly porcine animals from North America, and beef products from Argentina. **Offspring** of bovine dairy clones have been produced in the EU from imported reproductive materials from North America (two such animals entered the UK food chain in 2010).”
- “**No third country identifies or tracks the offspring or descendants of clones.**”

(Source: ICF GHK report to DG Sanco, Dec 2012)

EU regulatory approach

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Farm-animal cloning should be banned in the European Union, along with imports of cloned livestock and the sale of food from such animals, the European Commission proposed in a draft law.

The proposal seeks to address worries about animal welfare and other ethical concerns related to use of cloning, the commission, the 28-nation EU's executive arm in Brussels, said today. Cloning for now is so expensive that its use for food production isn't viable, according to the agency.



2006



- Evidence gathering and consultation
- Assessment of existent legal rules



European Food Safety Authority

- **Four** opinions/updates, last in 2012
- Animal cloning (SCNT) raises **animal health and welfare concerns** due to the malfunctioning of the technique
 - E.g. high mortality and morbidity rates for clones
 - The overall success rate of the cloning procedure is less than 10 per cent in bovine animals and between 5 and 17 per cent in pigs
- **No evidence** of risks with regard to human health / food safety, or the environment
- Limited to **pigs and cattle**
- **Scientific uncertainty** due to limited number of studies, small sample sizes, absence of uniform approach to risk assessment



European Group on Ethics in Science and New Technologies, EGE

January 2008

- Doubts that animal cloning for farming purposes can be justified “considering the current level of suffering and health problems of surrogate dams and animals clones”
- “No convincing arguments to justify the production of food from clones.”
- “Whether this applies also to progeny is open to further scientific research.”



EUROBAROMETER

2008:

84 % : long-term effects of animal cloning on nature unknown

77 % : animal cloning might lead to human cloning

61 % : animal cloning is morally wrong

58 % : cloning for food production should never be justified

63 % : unlikely to buy meat or milk from cloned animals even if they are considered safe

83 % : favour special labeling for food from the offspring of clones

The Commission consulted:

- **Member States** via the Standing Committee for the Food Chain and Animal Health
- **Stakeholders** via the Advisory Group of the Food Chain
 - **22 organisations** representing all sectors concerned (farmers, breeders, food industry, retailers, consumers and animal rights activists)
- **15 major third country** trade partners via special questionnaire
- **General public** via Interactive Policy Making Initiative

2008 NFR proposal

2010 Council 1st reading

2010 Comm report

2011 Conciliatory committee fails

2009 EP 1st reading

2010 EP 2nd reading

2010 Council 2nd reading

2013 new NFR proposal

Novel Foods Reg amendment

2006 FDA draft r.a.

2008 1st EFSA opinion

2008 EP resolution

2010 EFSA update

2013 AC proposals

2008 EGE opinion

2008 Eurobarometer

2009 EFSA update

2012 EFSA update

EU policy debate on AC

The Commission shall

“submit proposals prohibiting for food supply purposes (i) the cloning of animals, (ii) the farming of cloned animals and their offspring, (iii) the placing on the market of meat or dairy products derived from cloned animals or their offspring and (iv) the importing of cloned animals, their offspring, semen and embryos from cloned animals or their offspring, and meat or dairy products derived from cloned animals or their offspring, taking into account the recommendations of EFSA and the EGE.”

European Parliament Resolution on Animal Cloning,
September 2008

New Commission Proposals on Animal Cloning for Food

| | Objective | Substance | Legal Basis | Consultation | Progeny & reproductive material |
|------------------------|--|--|--|--|---------------------------------|
| Council Directive | Addresses consumer perceptions on AC for food / animal welfare concerns | Suspends placing on the market of food from clones & imports thereof | Art 352 TFEU (flexibility clause) Subsidiarity? | Broad: MS Stakeholders (22 org) 15 TCs General public | excluded |
| Council & EP Directive | Ensures uniform farming conditions / Protects animal health and welfare | Suspends use of AC for food & the marketing of live clones | Art 43 TFEU (Common agricultural policy) | See above | excluded |

WTO aspects



- EU regulation (suspension) of animal cloning:
non-tariff barrier to trade
- SPS, GATT, TBT Agreements
- **GATT 1994**
 - Justification **on public morals grounds** (Article XX(a))
 - But, EU measure must be **necessary** and not be applied in a manner that would constitute a means **of arbitrary or unjustifiable discrimination**, or a disguised protection on trade
- Appellate Body report on **EC-Seals** (May 2014)
 - The EU Seal Regime is “**necessary to protect public morals**” within the meaning of Article XX (a) GATT 1994
 - **Not** required to “identify **the existence of a risk to EU public moral concerns** regarding seal welfare” **nor** “to identify **the exact** content of the public morals standard at issue.”
 - “Members may **set different levels of protection even when responding to similar interests of moral concern.**”

Conclusions

- A recent EU trend to be **responsive to OLF**, especially animal welfare & ethical concerns
 - But, for EU measures with a **low trade impact**
- **Previous trade disputes** (*EC-Hormones; EC-Biotech*), current **strict interpretation of the WTO rules** (SPS, precautionary principle) & recent success in *EC-Seals* likely to foster that trend
- New Commission proposals on AC raise **legal (EU competence)** and **political issues (EP and progeny!)**
- Outcome of the legislative process open, but political disagreement is likely

Art 352 TFEU (flexibility clause)

Conditions of application:

- “Policies defined in the Treaties”
- Special legislative procedure: Council decides unanimously with consent of EP
- Subsidiarity check by national parliaments
- Cannot harmonize national laws and regulations where harmonization is precluded in the Treaties
- Cannot be used to (*de-facto*) amend the Treaties (“beyond the general framework created by the provisions of the Treaties”)
- Lisbon judgment of the German Constitutional Court: German parliament must authorize the government by law to vote in the Council in a Article 352 procedure

Article 114 (Internal market harmonization clause)

- Measure must remove obstacles to the functioning of the internal market
- Or aim to prevent the emergence of such obstacles in the future, if likely
- Comm: no current or likely divergence between national legislations was detected
- Moreover, measures do not harmonize rules, but ban AC