



EUROPEAN PARLIAMENT

2014 - 2019

Committee on International Trade

2013/0433(COD)

28.5.2015

OPINION

of the Committee on International Trade

for the Committee on the Environment, Public Health and Food Safety and the
Committee on Agriculture and Rural Development

on the proposal for a directive of the European Parliament and of the Council
on the cloning of animals of the bovine, porcine, ovine, caprine and equine
species kept and reproduced for farming purposes
(COM(2013)0892 – C7-0002/2014 – 2013/0433(COD))

Rapporteur: Jude Kirton-Darling

PA_Legam

SHORT JUSTIFICATION

Background

Animal cloning ("genetic copying") for farming purposes raises animal health and welfare, consumer choice and ethical issues and poses a long-term regulatory challenge. At present cloning is mostly used to produce breeding animals and the food potentially marketed in the EU would be derived from offspring of clones.

Currently in the EU the marketing of food from clones requires a pre-market approval based on a scientific food safety assessment by the European Food Safety Authority (EFSA), as governed under the "Novel Food Regulation" (EC) No 258/1997. Its current review excludes regulation of cloning from its scope and is dealt with in two separate Commission proposals of 18 December 2013. Until this legislation on food derived from cloned animals and their descendants enters into force, cloning remains under the existing "Novel Food Regulation" (EC) No 258/1997. So far, no business operator has applied for an authorisation to market food produced using the cloning technique in the EU.

Although animals are not cloned for food production in the EU, commercial agricultural cloning takes place in several countries, including Argentina, Australia, Brazil, Canada, and the US and may also be undertaken in Chile, China, New Zealand and Uruguay, where cloning companies operate.

As meat and milk from clone descendants and clones themselves start entering the food supply chain, it is imperative to ensure forward-looking regulation and a level-playing field in this domain. It is important to note that none of the third countries have established viable traceability and labelling systems or systems of identification and registration for imports of the offspring of clones or food derived from them.

Conclusions and recommendations of the European Food Safety Authority contained in its 2008 opinion and reconfirmed in its statements in 2009 and 2010 recognised animal health and welfare concerns due to mortality rates associated with the cloning technology. The proposed package on animal cloning takes into account animal welfare and ethical concerns, aiming to bring more legal certainty in the field by around 2016.

WTO compatibility

Your rapporteur deems it essential to ensure regulatory consistency with the WTO framework – the General Agreement on Tariffs and Trade (GATT), the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) and the Agreement on Technical Barriers to Trade (TBT) – and a level-playing field within the rules-based system.

Cloning technique currently does not stand up to the animal welfare standards, and concerns of EU citizens regarding cloning and animal welfare must be taken into account. There are no international SPS standards on cloning and no science-based evidence proving risks on food safety. As there are no direct food safety concerns related to the cloning technology, but rather

animal health and welfare ones, current proposals must pass the test of the GATT and TBT Agreements.

Articles I and III of the GATT prohibit measures resulting in discrimination between the “like products”. If food derived from the clones and their offspring would be “likened” to conventional food, the consistency of the proposed measures with the WTO rules would be justifiable under Article XX GATT exceptions.

The proposals were notified by the EU under the Technical Barriers to Trade Agreement only as a precautionary measure, as prohibitions on placing on the market would not constitute “a technical regulation”, in contrast to introduction of any labelling requirements.

As demonstrated by the Seals products dispute (DS400 and DS401), Article XX of GATT covers animal welfare protection and is justified for moral concerns, if it does not constitute “arbitrary and unjustifiable discrimination”.

Your rapporteur is convinced that provisional prohibition of marketing of animal clones, embryo clones and food for human consumption derived from animal clones and their offspring is a proportionate measure addressing justified concerns. Alternative measures such as prior authorisation and labelling would not entirely resolve ethical and animal welfare concerns in this case.

AMENDMENTS

The Committee on International Trade calls on the Committee on the Environment, Public Health and Food Safety and the Committee on Agriculture and Rural Development, as the committees responsible, to take into account the following amendments:

Amendment 1

Proposal for a directive Title

Text proposed by the Commission

Proposal for a
DIRECTIVE OF THE EUROPEAN
PARLIAMENT AND OF THE COUNCIL
on the cloning of animals of the bovine,
porcine, ovine, caprine and equine species
kept and reproduced for farming purposes

Amendment

Proposal for a
REGULATION OF THE EUROPEAN
PARLIAMENT AND OF THE COUNCIL
on the cloning of animals of the bovine,
porcine, ovine, caprine and equine species
kept and reproduced for farming purposes
(This amendment applies throughout the

text. Adopting it will necessitate corresponding changes throughout.)

Justification

Using a Regulation as the legal instrument enhances legal certainty and ensures consistency of enforcement, while respecting the subsidiarity and proportionality principles.

Amendment 2

Proposal for a directive Recital 3

Text proposed by the Commission

(3) Taking into account the objectives of the Union's agricultural policy, the results of the recent scientific assessments of EFSA and the animal welfare requirement provided in Article 13 of the Treaty, it is prudent to ***provisionally*** prohibit the use of cloning in animal production for farm purposes of certain species.

Amendment

(3) Taking into account the objectives of the Union's agricultural policy, the results of the recent scientific assessments of EFSA and the animal welfare requirement provided in Article 13 of the Treaty, it is prudent to prohibit the use of cloning in animal production for farm purposes of certain species.

Amendment 3

Proposal for a directive Recital 3 a (new)

Text proposed by the Commission

Amendment

(3a) Traceability systems established for food from animal clones and germinal products could support the enforcement of the measures contained in this Regulation, in particular by providing competent authorities and economic operators with useful information. The Commission should therefore endeavour to obtain commitments in this regard from trading partners of the Union in which cloning of animals is carried out for

farming purposes, within the framework of ongoing and future trade negotiations, at both bilateral and multilateral levels;

Amendment 4

Proposal for a directive Recital 5

Text proposed by the Commission

(5) It is expected that **the** knowledge **on** the impact of the cloning technique on the welfare of the animals used will increase. The cloning technique is likely to improve over time. Consequently prohibitions **should only apply provisionally**. This **Directive** should therefore be reviewed within a reasonable time taking into account the experience gained by the Member States in its **implementation**, scientific and technical progress and international developments.

Amendment

(5) It is expected that knowledge **of** the impact of the cloning technique on the welfare of the animals used will increase. The cloning technique is likely to improve over time. Consequently, prohibitions **could be reviewed and/or updated in the event of evident improvements in the said cloning technique**. This **Regulation** should therefore be reviewed within a reasonable time, taking into account the experience gained by the Member States in its **application**, scientific and technical progress, **changes in consumer perceptions**, and international developments, **in particular trade flows and the Union's trade relations**.

Amendment 5

Proposal for a directive Recital 5 a (new)

Text proposed by the Commission

Amendment

(5a) (5a) Embryo clones, animal clones, food from animal clones, germinal products of animal clones and food derived therefrom cannot be considered like products, within the meaning of Article III.4 of the GATT, to embryos, animals, food from animals, germinal products and food derived therefrom respectively.

Amendment 6

Proposal for a directive Recital 5 b (new)

Text proposed by the Commission

Amendment

(5b) The prohibition of the cloning of animals, of the placing on the market of animal clones and embryo clones, and of the placing on the market of food from animal clones germinal products and food derived therefrom is a measure that is necessary in order to protect public morals and animal health, within the meaning of Article XX of the GATT.

Amendment 7

Proposal for a directive Article 1 – paragraph 1 – point b

Text proposed by the Commission

Amendment

(b) the placing on the market of embryo clones ***and*** animal clones.

(b) the placing on the market of embryo clones, animal clones ***and germinal products of animal clones.***

Amendment 8

Proposal for a directive Article 3 – title

Text proposed by the Commission

Amendment

Provisional prohibition

Prohibition

Amendment 9

Proposal for a directive Article 3 – introductory part

Text proposed by the Commission

Member States shall provisionally prohibit:

Amendment

1. The following shall be prohibited:

Amendment 10

**Proposal for a directive
Article 3 – point b a (new)**

Text proposed by the Commission

Amendment

(ba) food derived from animal clones.

Amendment 11

**Proposal for a directive
Article 3 – paragraph 1 a (new)**

Text proposed by the Commission

Amendment

1a. In the case of food of animal origin imported from third countries where food from clones and germinal products and food derived therefrom can be legally placed on the market or exported, Member States shall ensure that such food is only placed on the market of the Union in accordance with any specific import conditions adopted under Articles 48 and 49 of Regulation (EC) No 882/2004 of the European Parliament and of the Council*. Member States shall further ensure that no food from animal clones or germinal products and food derived therefrom is exported to the Union from those third countries.

*** Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law,**

*animal health and animal welfare rules
(OJ L 165, 30.4.2004, p. 1).*

Amendment 12

Proposal for a directive Article 3 – paragraph 1 b (new)

Text proposed by the Commission

Amendment

1b. Likewise, Member States shall ensure that neither animal clones or embryo clones, nor germinal products of animal clones are imported into the Union and that food imported from third countries where animal cloning is allowed for farming purposes complies with relevant requirements of Union food law or with conditions recognised by the Union to be at least equivalent to those requirements.

Amendment 13

Proposal for a directive Article 5 – paragraph 2 – point b

Text proposed by the Commission

Amendment

(b) scientific and technical progress, in particular relating to the animal welfare aspects of cloning;

(b) scientific and technical progress, in particular relating to the animal welfare aspects of cloning ***and consumer perceptions***;

Amendment 14

Proposal for a directive Article 5 – paragraph 2 – point c

Text proposed by the Commission

Amendment

(c) international developments.

(c) international developments, ***and in particular the impact of this Regulation on trade flows and on the Union's trade relations.***

Amendment 15

Proposal for a directive

Article 6

Text proposed by the Commission

Amendment

Article 6

deleted

Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by [date = 12 month after the date of transposition of this Directive]. They shall forthwith communicate to the Commission the text of those provisions.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Amendment 16

Proposal for a directive

Article 8

Text proposed by the Commission

Amendment

Article 8

deleted

Addressees

This Directive is addressed to the Member States.

Amendment 17

**Proposal for a directive
Article 8 a (new)**

Text proposed by the Commission

Amendment

Article 8a

This Regulation shall be binding in its entirety and directly applicable in all Member States.

PROCEDURE

Title	Cloning of animals of the bovine, porcine, ovine, caprine and equine species kept and reproduced for farming purposes	
References	COM(2013)0892 – C7-0002/2014 – 2013/0433(COD)	
Committees responsible Date announced in plenary	ENVI 16.1.2014	AGRI 16.1.2014
Opinion by Date announced in plenary	INTA 16.1.2014	
Rapporteur Date appointed	Jude Kirton-Darling 3.9.2014	
Rule 55 – joint committee meetings Date announced in plenary	17.12.2014	
Discussed in committee	14.4.2015	6.5.2015
Date adopted	28.5.2015	
Result of final vote	+: –: 0:	34 6 1
Members present for the final vote	William (The Earl of) Dartmouth, Maria Arena, Tiziana Beghin, David Borrelli, Daniel Caspary, Marielle de Sarnez, Santiago Fisas Aixelà, Christofer Fjellner, Eleonora Forenza, Yannick Jadot, Ska Keller, Jude Kirton-Darling, Bernd Lange, Jörg Leichtfried, David Martin, Emmanuel Maurel, Emma McClarkin, Anne-Marie Mineur, Alessia Maria Mosca, Franz Obermayr, Artis Pabriks, Franck Proust, Godelieve Quisthoudt-Rowohl, Inmaculada Rodríguez-Piñero Fernández, Tokia Saïfi, Matteo Salvini, Marietje Schaake, Helmut Scholz, Joachim Schuster, Joachim Starbatty, Adam Szejnfeld, Iuliu Winkler, Jan Zahradil	
Substitutes present for the final vote	Goffredo Maria Bettini, Dita Charanzová, Georgios Epiteidos, Seán Kelly, Sander Loones, Frédérique Ries, Adina-Ioana Vălean, Jarosław Wałęsa	