

Procedure file

Basic information	
COD - Ordinary legislative procedure (ex-codecision procedure) Directive	2013/0433(COD) Awaiting Council's 1st reading position
Cloning of animals of the bovine, porcine, ovine, caprine and equine species kept and reproduced for farming purposes	
Subject	
3.10.03 Marketing and trade of agricultural products and livestock	
3.10.04 Livestock farming	
3.10.04.02 Animal protection	
4.20.02.04 Genetics and bioethics	

Key players			
European Parliament	Committee responsible	Rapporteur	Appointed
	ENVI Environment, Public Health and Food Safety		14/07/2014
		PPE SOMMER Renate	14/07/2014
		EFDD MOI Giulia	
		Shadow rapporteur	
		PPE AYUSO Pilar	
		S&D AGUILERA Clara	
		S&D SÂRBU Daciana Octavia	
		ECR NICHOLSON James	
		ECR WOJCIECHOWSKI Janusz	
		ALDE FEDERLEY Fredrick	
		ALDE MÜLLER Ulrike	
		GUE/NGL ECK Stefan	
		GUE/NGL HAZEKAMP Anja	
		Verts/ALE BOVÉ José	
		Verts/ALE STAES Bart	
	AGRI Agriculture and Rural Development		14/07/2014
		PPE SOMMER Renate	14/07/2014
		EFDD MOI Giulia	
		Shadow rapporteur	
		PPE AYUSO Pilar	
		S&D AGUILERA Clara	
		S&D SÂRBU Daciana Octavia	
		ECR NICHOLSON James	
		ECR WOJCIECHOWSKI Janusz	
		ALDE FEDERLEY Fredrick	

ALDE [MÜLLER Ulrike](#)

GUE/NGL [ECK Stefan](#)

GUE/NGL [HAZEKAMP Anja](#)

Verts/ALE [BOVÉ José](#)

Verts/ALE [STAES Bart](#)

Former committee responsible

AGRI Agriculture and Rural Development

Committee for opinion

Rapporteur for opinion

Appointed

INTA International Trade

03/09/2014

S&D [KIRTON-DARLING Jude](#)

ITRE Industry, Research and Energy

The committee decided not to give an opinion.

IMCO Internal Market and Consumer Protection

The committee decided not to give an opinion.

Former committee for opinion

INTA International Trade

20/01/2014

S&D [PIRILLO Mario](#)

ENVI Environment, Public Health and Food Safety

20/03/2014

PPE [MAZEJ KUKOVIČ Zofija](#)

ITRE Industry, Research and Energy

IMCO Internal Market and Consumer Protection

Committee for opinion on the legal basis

Rapporteur for opinion

Appointed

JURI Legal Affairs

Commission DG

Commissioner

[Agriculture and Rural Development](#)

HOGAN Phil

Council of the European Union
European Commission

European Economic and
Social Committee

Key events

18/12/2013	Legislative proposal published	COM(2013)0892	Summary
16/01/2014	Committee referral announced in Parliament, 1st reading/single reading		
20/10/2014	Committee referral announced in Parliament, 1st reading/single reading		
17/12/2014	Referral to joint committee announced in Parliament		
17/06/2015	Vote in committee, 1st reading/single reading		
25/06/2015	Committee report tabled for plenary, 1st reading/single reading	A8-0216/2015	Summary
08/09/2015	Results of vote in Parliament		
08/09/2015	Debate in Parliament		
08/09/2015	Decision by Parliament, 1st reading/single reading	T8-0285/2015	Summary

Technical information	
Procedure reference	2013/0433(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Directive
Legal basis	Rules of Procedure EP 58; Treaty on the Functioning of the EU TFEU 043-p2
Mandatory consultation of other institutions	European Economic and Social Committee
Stage reached in procedure	Awaiting Council's 1st reading position
Committee dossier	CJ14/8/02399

Documentation gateway					
Legislative proposal		COM(2013)0892	18/12/2013	EC	Summary
Document attached to the procedure		SWD(2013)0519	18/12/2013	EC	
Document attached to the procedure		SWD(2013)0520	18/12/2013	EC	
Committee draft report		PE551.999	23/03/2015	EP	
Amendments tabled in committee		PE554.978	28/04/2015	EP	
Committee opinion	INTA	PE551.983	28/05/2015	EP	
Amendments tabled in committee		PE560.690	09/06/2015	EP	
Committee report tabled for plenary, 1st reading/single reading		A8-0216/2015	25/06/2015	EP	Summary
Text adopted by Parliament, 1st reading/single reading		T8-0285/2015	08/09/2015	EP	Summary
Commission response to text adopted in plenary		SP(2015)649	22/10/2015	EC	

Additional information	
European Commission	EUR-Lex

2013/0433(COD) - 18/12/2013 Legislative proposal

PURPOSE: to suspend the use of the technique and the marketing of animal clones for farming purposes ensures that all Union farmers and breeders are subject to the same conditions while adequately protecting animal welfare.

PROPOSED ACT: Directive of the European Parliament and of the Council.

ROLE OF THE EUROPEAN PARLIAMENT: the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

BACKGROUND: Directive 98/58/EC on the protection of animals kept for farming purposes sets very general minimum animal welfare standards for animals used in agriculture. It does not refer explicitly to cloning, but calls on Member States to avoid unnecessary pain, suffering or injury in farm animals. If cloning causes unnecessary pain, suffering or injury Member States have to act at national level to avoid it.

In 2008, the Commission presented a [proposal](#) to streamline the approval process in Regulation (EC) N° 258/97 on novel foods. In the legislative procedure, lawmakers aimed to amend the proposal to introduce specific rules on cloning. Yet no agreement was reached on the scope and features of these insertions so that the proposal was abandoned after a failed Conciliation in March 2011.

As a result, the Commission was asked to prepare a legislative proposal on cloning in food production based on an impact assessment outside the Novel Food Regulation.

The European Parliament [resolution of 6 July 2011](#) on the Commission Work Programme 2012 requested a legislative proposal to prohibit

food from clones, offspring and descendants.

The European Food Safety Authority (EFSA) views cloning primarily as an animal welfare hazard related to the low efficiency of the technique. It up-dated its opinion on cloning of animals in 2012 concluding that scientific knowledge available on cloning has increased but that nevertheless its efficiency remains low compared to other reproduction techniques.

Union citizens, on the other hand, held a broadly negative perception of the use of the cloning technique for the production of animals for farming purposes.

IMPACT ASSESSMENT: the option calling for a temporary suspension of the technique and of imports of live clones was retained as the basis of the present proposal.

CONTENT: the proposal envisages a suspension on Union territory of:

- the use of the technique for food production purposes;
- the marketing of live clones (animal clones).

These provisional prohibitions will confine a production technique causing distress to animals to areas where it appears to have particular benefit.

The provisional prohibitions are kept under review given the development of knowledge on the technique and progress in the application of the technique in areas outside farming.

This proposal excludes cloning carried out in research, for the preservation of rare breeds or endangered species and for the production of medicinal products and medical devices.

2013/0433(COD) - 25/06/2015 Committee report tabled for plenary, 1st reading/single reading

The Committee on the Environment, Public Health and Food Safety and the Committee on Agriculture and Rural Development jointly adopted the report by Renate SOMMER (EPP, DE) 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.

The committee recommended that the European Parliaments position adopted at first reading following the ordinary legislative procedure should amend the commission proposal as follows:

Choice of legal instrument: while the Commission considers that a Directive is the most appropriate instrument for this legislation, Members proposed using a Regulation as the legal instrument as this would enhance legal certainty and ensure the rationality and consistency of the enforcement, while respecting the subsidiarity and proportionality principles.

Purpose and scope: Members considered that the Regulation should establish rules concerning the placing on the market and import of:

- animal clones,
- embryo clones,
- descendants of animal clones,
- germinal products of animal clones and of their descendants (meaning semen, oocytes and embryos collected or produced from animals for the purpose of reproduction),
- food and feed from animal clones and their descendants.

It shall apply to all species of animals kept and reproduced for farming purposes and not only animals of the bovine, porcine, ovine, caprine and equine species as was proposed by the Commission.

Moreover, the objective of this Regulation is to address concerns relating to animal health and welfare and to consumers' perceptions and ethical considerations with regard to the cloning technique. It has been clearly and consistently shown by consumer research, the majority of Union citizens disapprove of cloning for farming purposes due to, inter alia, animal welfare and general ethical concerns.

Provisional or permanent prohibitions: although the proposal qualifies the prohibitions on the use of cloning as provisional, referring to a suspension of the use of the technique, Members suggested a pure and simple prohibition.

Import conditions: Members stated that animals shall not be imported from third countries unless the accompanying import certificates show that they are not animal clones or descendants of animal clones.

In order to ensure that import certificates accompanying animals and germinal products and food and feed of animal origin indicate whether they are, or are derived from, animal clones or descendants of animal clones, the Commission shall adopt specific import conditions under [Regulation \(EC\) No 882/2004](#) of the European Parliament and of the Council by 6 months from the entry into force of this Regulation and shall, if necessary, present a proposal to amend other legislation in the field of animal health or zootechnical and genealogical conditions for imports.

Traceability: the report noted that traceability systems shall be established for animal clones; descendants of animal clones; germinal products of animal clones and of their descendants. The Commission shall be empowered to adopt delegated acts to establish detailed rules for such systems.

Reports and reviews: this Regulation shall be reviewed within a reasonable time, taking into account the experience gained by the Member States in its application, scientific and technical progress, the evolution of consumer perceptions, and international developments, in particular trade flows and the Union's trade relations.

By means of an official EU-Survey, the Commission shall launch a public consultation aimed at assessing any new trends regarding consumers' perceptions of food products from cloned animals.

2013/0433(COD) - 08/09/2015 Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 529 votes to 120, with 157 abstentions, a legislative resolution 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.

Parliaments position adopted at first reading following the ordinary legislative procedure amended the Commission proposal as follows:

Choice of legal instrument: Parliament voted to use a Regulation as the appropriate legal instrument (as opposed to a Directive as proposed by the Commission).

Objective and scope: Parliament recalled that animal cloning for food production purposes jeopardises the defining characteristics of the European farming model, which is based on product quality, food safety, consumer health, strict animal welfare rules and the use of environmentally sound methods.

In this regard, the objective of this Regulation is to address concerns relating to animal health and welfare and to consumers' perceptions and ethical considerations with regard to the cloning technique.

Members recalled that the majority of Union citizens disapprove of cloning for farming purposes due to, inter alia, animal welfare and general ethical concerns.

Provisional or permanent prohibitions: although the proposal qualifies the prohibitions on the use of cloning as provisional, Parliament favoured a pure and simple prohibition.

Thus, the Regulation shall prohibit the placing on the market of:

- animal clones,
- embryo clones,

and the import of:

- animal clones,
- embryo clones
- descendants of animal clones,
- germinal products of animal clones and of their descendants (meaning semen, oocytes and embryos collected or produced from animals for the purpose of reproduction),
- food and feed from animal clones and their descendants.

The Regulation shall apply to all species of animals kept and reproduced for farming purposes and not only animals of the bovine, porcine, ovine, caprine and equine species as was proposed by the Commission.

Import conditions: Members stated that animals shall not be imported from third countries unless the accompanying import certificates show that they are not animal clones or descendants of animal clones.

In order to ensure that import certificates accompanying animals and germinal products and food and feed of animal origin indicate whether they are, or are derived from, animal clones or descendants of animal clones, the Commission shall adopt specific import conditions under [Regulation \(EC\) No 882/2004 of the European Parliament and of the Council](#) by 6 months from the entry into force of this Regulation and shall, if necessary, present a proposal to amend other legislation in the field of animal health or zootechnical and genealogical conditions for imports.

Traceability: Parliament noted that traceability systems shall be established for animal clones; descendants of animal clones; germinal products of animal clones and of their descendants. The Commission shall be empowered to adopt delegated acts to establish detailed rules for such systems. The power to adopt delegated acts shall be conferred on the Commission for a period of five years (tacitly extended for periods of an identical duration) from the entry into force of the Regulation.

Penalties: the penalties provided for shall be effective, proportionate, dissuasive and shall ensure a level playing field.

Reports and reviews: by 6 years from the entry into force of this Regulation, the Member States shall report to the Commission on the experience gained by them on the application of this Regulation, scientific and technical progress, the evolution of consumer perceptions, and international developments, in particular trade flows and the Union's trade relations as well as ethical issues relating to animal cloning.

By means of an official EU-Survey, the Commission shall launch a public consultation aimed at assessing any new trends regarding consumers' perceptions of food products from cloned animals.

The Regulation shall apply from 1 year from the entry into force of this Regulation.