Cloning of animals kept and reproduced for farming purposes


(Ordinary legislative procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to Parliament and the Council (COM(2013)0892),

– having regard to Article 294(2) and Article 43(2) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0002/2014),

– having regard to Article 294(3) of the Treaty on the Functioning of the European Union,


– having regard to the opinion of the European Economic and Social Committee of 30 April 2014,  

– having regard to Rule 59 of its Rules of Procedure,

– having regard to the joint deliberations of the Committee on the Environment, Public Health and Food Safety and the Committee on Agriculture and Rural Development under Rule 55 of the Rules of Procedure,

– having regard to the report of the Committee on the Environment, Public Health and Food Safety and the Committee on Agriculture and Rural Development and the opinion of the Committee on International Trade (A8-0216/2015),

1 Texts adopted of that date, P7_TA(2010)0266.

2 OJ C 311, 12.9.2014, p. 73.
1. Adopts its position at first reading hereinafter set out;

2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;

3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 43(2),

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee¹,

Acting in accordance with the ordinary legislative procedure²,

Whereas:

¹ OJ C 311, 12.9.2014, p. 73.
In the implementation of Union policy, and having regard to the Treaty on the Functioning of the European Union, a high level of protection of human health and consumer protection, as well as a high level of animal welfare and environmental protection, should be guaranteed. At all times, the precautionary principle, as laid down in Regulation (EC) No 178/2002 of the European Parliament and of the Council¹, should be applied. [Am. 2]

The cloning of animals is not in line with Council Directive 98/58/EC, which lays down general minimum welfare standards for animals bred or kept for farming purposes.Directive 98/58/EC calls on Member States to avoid unnecessary pain, suffering or injury of farm animals, and, more specifically, states in point 20 of its Annex that “natural or artificial breeding or breeding procedures which cause, or are likely to cause, suffering or injury to any of the animals concerned must not be practised”. If cloning causes unnecessary pain, suffering or injury, Member States have to act at national level to avoid it. Different national approaches to animal cloning or the use of products derived from animal cloning could lead to market distortion. It is thus necessary to ensure that the same conditions apply to all involved in the production and distribution of live animals and of products derived from animals throughout the Union. [Am. 3]
The European Food Safety Authority (EFSA) concluded, in its 2008 opinion on animal cloning\(^1\), that “the health and welfare of a significant proportion of clones have been found to be adversely affected, often severely and with a fatal outcome”. More specifically, EFSA has confirmed that surrogate dams used in cloning suffer in particular from placenta dysfunctions contributing to increased levels of miscarriages\(^2\), with possible adverse effects on their health. This contributes, amongst other things, to the low efficiency of the technique, 6 to 15 % for bovine and 6 % for porcine species, and the need to implant embryo clones into several dams to obtain one clone. In addition, clone abnormalities and unusually large offspring result in difficult births and neonatal deaths. High mortality rates at all development stages are characteristic of the cloning technique\(^3\).  

\(^1\) [Am. 4]

\(^2\) Scientific Opinion of the Scientific Committee on Food Safety, Animal Health and Welfare and Environmental Impact of Animals derived from Cloning by Somatic Cell Nucleus Transfer (SCNT) and their Offspring and Products Obtained from those Animals


As regards food safety, EFSA has stressed the importance of acknowledging that the database is limited, and in its 2008 opinion on animal cloning concluded: “Uncertainties in the risk assessment arise due to the limited number of studies available, the small sample sizes investigated and, in general, the absence of a uniform approach that would allow all the issues relevant to this opinion to be more satisfactorily addressed.” For example, EFSA has stated that information is limited on the immunological competence of clones and recommended in that opinion that, if evidence of reduced immunocompetence of clones becomes available, the question should be investigated as to “whether, and if so, to what extent, consumption of meat and milk derived from clones or their offspring may lead to an increased human exposure to transmissible agents”. [Am. 5]
(2b)  As regards potential impacts on the environment, EFSA has stated that limited data is available and, with regard to potential impacts on genetic diversity, EFSA has drawn attention to the fact that there could be an indirect effect due to overuse of a limited number of animals in breeding programmes, and that increased homogeneity of a genotype within an animal population may increase the susceptibility of that population to infection and other risks. [Am. 6]

(2c)  The European Group on Ethics in Science and New Technologies in its specific report on cloning in 2008\(^1\) expressed doubts that animal cloning for food production purposes can be justified “considering the current level of suffering and health problems of surrogate dams and animal clones”. [Am. 7]

One of the objectives of the Union’s common agriculture policy enshrined in Article 39 of the Treaty on the Functioning of the European Union (TFEU) is to “increase agricultural productivity by promoting technical progress and by ensuring the rational development of agricultural production”. That objective aims, inter alia, at improving production and, with regard to the rational development of agricultural production, it entails the optimum utilisation of the factors of production, namely appropriate production for marketing purposes that takes into account the interests of consumers. [Am. 8]
In accordance with the case-law\(^1\) of the Court of Justice of the European Union, Article 43 TFEU is the appropriate legal basis for any legislation concerning the production and marketing of agricultural products listed in Annex I TFEU which contributes to the achievement of one or more of the objectives of the common agricultural policy set out in Article 39 TFEU. Even where such legislation could be directed to objectives other than those of the common agricultural policy, which, in the absence of specific provisions, would be pursued on the basis of Article 114 TFEU, it may involve the harmonisation of provisions of national law in that area without recourse to Article 114 being necessary. Furthermore, measures taken in the context of the common agricultural policy may also affect importation of the products concerned. [Am. 9]

(2f) As 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. Cloning for farming purposes could lead to animal clones or the descendants of animal clones entering the food chain. Consumers are strongly opposed to the consumption of food from animal clones or from their descendants. [Am. 10]

(2g) 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. [Am. 11]

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Taking into account the objectives of the Union's common agricultural policy, the results of the recent scientific assessments of EFSA and based on the available studies, the animal welfare requirement provided in Article 13 of the Treaty TFEU and the citizens' concerns, it is prudent appropriate to provisionally prohibit the use of cloning in animal production for farm farming purposes of certain species and the placing on the market of animals and products derived from the use of the cloning technique. [Am. 12]
Animal clones are not produced in order to serve for meat or milk production, but rather to use their germinal products for breeding purposes. It is the sexually reproduced descendants of animal clones which become the food-producing animals. Although animal welfare concerns might not be apparent in the case of descendants of cloned animals, as they are born by means of conventional sexual reproduction, in order for there even to be a descendant, a cloned animal progenitor is required, which entails significant animal welfare and ethical concerns. Measures aimed at addressing animal welfare concerns and consumers’ perceptions relating to the cloning technique should therefore include within their scope germinal products of animal clones, descendants of animal clones and products derived from descendants of animal clones. [Am. 13]
(4) Currently animals of bovine, porcine, ovine, caprine and equine species are likely to be cloned for farming purposes. The scope of this Directive should therefore be limited to the use of cloning for farming purposes of those five species. [Am. 14]

(4a) With regard to the marketing of agricultural products, in connection with the ban on the use of cloning and in order to address consumer perceptions on cloning linked to, inter alia, animal welfare, the lack of adequate research and general ethical concerns, it is necessary to ensure that food from animal clones and their descendants does not enter the food chain. Less restrictive measures, such as food labelling, would not entirely address citizens’ concerns since the marketing of food produced with a technique that involves animal suffering would still be allowed. [Am. 15]
The use of cloning in animal production for farming purposes is already taking place in certain third countries. Pursuant to Regulation (EC) No 178/2002, food imported from third countries for placing on the market within the Union is to comply with Union relevant requirements of food law or with conditions recognised by the Union to be at least equivalent to those requirements. Therefore, measures should be taken to avoid the import from third countries into the Union of animal clones and their descendants and of products obtained from animal clones and their descendants. The Commission should supplement or propose to amend the relevant zootechnical and animal health legislation 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. [Am. 16]
(4c) Animal clones, embryo clones, descendants of animal clones, germinal products of animal clones and of their descendants, and food and feed from animal clones and their descendants cannot be considered like products to animals, embryos, germinal products, food and feed that do not derive from the use of the cloning technique within the meaning of Article III.4 of the General Agreement on Tariffs and Trade (GATT). Furthermore, the prohibition of the cloning of animals and of 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, and food and feed from animal clones and their descendants is a measure that is necessary to protect public morals and to protect animal health within the meaning of Article XX of the GATT. [Am. 17]

(4d) Steps should be taken to ensure that trade agreements which are currently being negotiated do not encourage the authorisation of practices which may have an adverse effect on the health of consumers and farmers, on the environment or on animal welfare. [Am. 18]
The application of this Regulation can be jeopardised if it is impossible to trace food obtained from animal clones and their descendants. Therefore, pursuant to the precautionary principle and in order to enforce the prohibitions set out in this Regulation, it is necessary to establish, in consultation with the relevant stakeholders, traceability systems at Union level. Such systems would enable competent authorities and economic operators to collect data on animal clones, descendants of animal clones and germinal products of animal clones and of their descendants, and food from animal clones and their descendants. The Commission should 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. [Am. 19]
In its 2010 report to the European Parliament and the Council, the Commission stated that measures to establish the traceability of imports of semen and embryos in order to set up data banks of offspring in the Union were appropriate. The Commission should therefore act accordingly. [Am. 20]

Consistent with the implementation of the ban on cloning which is laid down in this Regulation, targeted trade promotion measures adopted by the Commission should be applied in order to support high-quality meat production and animal husbandry in the Union. [Am. 21]
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, the evolution of consumer perceptions, and international developments, in particular trade flows and the Union's trade relations. [Am. 22]

According to the latest Eurobarometer survey, the majority of Europeans do not consider animal cloning in food production to be safe for their health or for that of their family. Furthermore, when it comes to animal cloning, there are more countries in Europe expressing a clear preference for decisions to be taken primarily from the standpoint of moral and ethical issues, rather than on the basis of scientific evidence. Therefore, before this legislation is reviewed, the Commission should carry out an official EU-Survey to reassess consumers' perceptions. [Am. 23]
(5b) The power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the establishment of rules for traceability systems for animal clones, descendants of animal clones and for germinal products of animal clones and of their descendants. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council. [Am. 24]

(6) This Directive Regulation respects the fundamental rights and observes the principles recognised by the Charter of Fundamental Rights of the European Union, and notably in particular the freedom to conduct a business and the freedom of the sciences. This Directive Regulation has to be implemented applied in accordance with these rights and principles. [Am. 25]
Since the objective of this Regulation cannot be sufficiently achieved by the Member States but can rather, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective,

HAVING ADOPTED THIS DIRECTIVE AND REGULATION:
Article 1

Subject matter and scope

This Directive Regulation lays down rules on:

(a) the cloning of animals in the Union;
(b) the placing on the market and import of embryo clones and animal clones, embryo clones, descendants of animal clones, germinal products of animal clones and of their descendants, and food and feed from animal clones and their descendants.

It shall apply to all species of animals of the bovine, porcine, ovine, caprine and equine species ("the animals") kept and reproduced for farming purposes.
Article 1a
Objective

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. [Am. 29]

Article 2
Definitions

For the purposes of this Directive Regulation, the following definitions shall apply:

(a) "animals "kept and reproduced for farming purposes" ("animals") means animals kept and reproduced for the production of food, feed, wool, skin or fur or for other farming purposes. It shall not include animals kept and reproduced exclusively for other purposes such as research, the production of medicinal products and medical devices, and the preservation of rare breeds or endangered species, sporting and cultural events and of rare breeds identified as such by the competent authorities of the Member States, where no alternative methods are available; [Am. 30]
"cloning" means asexual reproduction of animals with to create, by, inter alia, using a technique whereby the nucleus of a cell of an individual animal is transferred into an oocyte from which the nucleus has been removed to create, genetically identical individual embryos ("embryo clones"), that can subsequently be implanted into surrogate mothers in order to produce populations of genetically identical animals ("animal clone clones"); [Am. 31]

“descendants of animal clones” means animals, other than animal clones, where at least one of the progenitors is an animal clone; [Am. 32]

“germinal products” means semen, oocytes and embryos collected or produced from animals for the purpose of reproduction; [Am. 33]

“traceability” means the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution; [Am. 34]
"placing on the market" means the first making available of an animal or a product on the internal market;

“food” means food as defined in Article 2 of Regulation (EC) No 178/2002.

Article 3
Provisional Prohibition [Am. 36]

Member States The following shall provisionally prohibit be prohibited: [Am. 37]

(a) the cloning of animals;

(b) the placing on the market of animal clones and embryo clones and import of animal clones, embryo clones, descendants of animal clones, germinal products of animal clones and of their descendants, and food and feed from animal clones and their descendants. [Am. 38]
Article 3a
Import conditions

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.

Germinal products and food and feed of animal origin shall not be imported from third countries unless the accompanying import certificates show that they are not derived from 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 Article 48 or Article 49 of Regulation (EC) No 882/2004 of the European Parliament and of the Council 1 by ...* and shall, if necessary, present a proposal to amend other legislation in the field of animal health or zootechnical and genealogical conditions for imports. [Am. 39]

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* 6 months from the entry into force of this Regulation.
Article 3b

Traceability

To provide competent authorities and economic operators with the information they need for the application of point (b) of Article 3, traceability systems shall be established for:

(a) animal clones;
(b) descendants of animal clones;
(c) germinal products of animal clones and of their descendants.

The Commission shall be empowered to adopt delegated acts, in accordance with Article 4a, to establish detailed rules for the inclusion of the information referred to in points (a) to (c) of the first subparagraph in the certificates provided for in animal health and zootechnical legislation or in the certificates drawn up by the Commission for those purposes. Those delegated acts shall be adopted by ...*. [Am. 40]

* 6 months from the entry into force of this Regulation.
Article 4

Penalties

Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive Regulation and shall take all measures necessary to ensure that they are implemented and applied. The penalties provided for must shall be effective, proportionate and dissuasive and shall ensure a level playing field. Member States shall notify those provisions to the Commission by [date for transposition of the Directive ] at the latest ...* and shall notify it without delay of any subsequent amendment affecting them. thereto. [Am. 41]

* 1 year from the entry into force of this Regulation.
Article 4a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 3a shall be conferred on the Commission for a period of five years from ...*. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five year period. The delegation of power shall be tacitly extended for periods of an identical duration unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

* Date of entry into force of this Regulation.
3. The delegation of power referred to in Article 3a may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5. A delegated act adopted pursuant to Article 3a shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council. [Am. 42]
Article 5
Reporting and Review

1. By [date = 5 years after the date of transposition of this Directive ...]*, the Member States shall report to the Commission on the experience gained by them on the application of this Directive Regulation. [Am. 43]

2. The Commission shall present a report to the European Parliament and the Council on the application of this Directive Regulation taking into account:

(a) the reports submitted by Member States in accordance with paragraph 1;

(b) all available scientific and technical evidence of progress, in particular relating to the animal welfare aspects of cloning and food safety issues, and the progress made in establishing reliable traceability systems for clones and the descendants of clones; [Am. 44]

(ba) the evolution of consumer perceptions on cloning; [Am. 45]

* 6 years from the entry into force of this Regulation.
(c) international developments;

(ca) consumers' concerns in relation to public health and animal welfare;  
[Am. 46]

(cb) ethical issues relating to animal cloning. [Am. 47]

2a. The Commission shall make the report referred to in paragraph 2 publicly available. [Am. 48]

2b. 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. [Am. 49]
Article 6

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. [Am. 50]
Article 7

Entering Entry into force [Am. not concerning all languages]

This Directive Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

It shall apply from ...* [Am. 52]

Article 8

Addressees

This Directive is addressed to the Member States. [Am. 53]

This Regulation shall be binding in its entirety and directly applicable in all Member States. [Am. 54]

Done at

For the European Parliament For the Council

The President The President

* 1 year from the entry into force of this Regulation.