EUROPEAN
COMMISSION

Brussels, XXX
COM(2013) 892

2013/0433 (COD)

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

{SWD(2013) 519}
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EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

1.1. Background of the proposal

Cloning is a relatively new technique of asexual reproduction of animals producing near exact genetic copies of the animal cloned, i.e. without modification of genes.

In food production cloning is a new technique. Hence, under the current legislative framework, food from clones falls under the scope of the Novel Food Regulation[1] and is thus subject to pre-market approval based on a food safety risk assessment.

In 2008 the Commission presented a proposal[2] to streamline the approval process in the Novel Food Regulation. In the legislative procedure lawmakers aimed to amend the proposal to introduce specific rules on cloning[3]. 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[4].

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[5] concluding that scientific knowledge available on cloning has increased but that nevertheless its efficiency remains low compared to other reproduction techniques.

1.2. Objectives of the proposal

The objective of this proposal is to ensure uniform conditions of production for farmers while protecting the health and welfare of animals.

1.3. Regulatory framework

Directive 98/58/EC[6] 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.

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1 Regulation (EC) N° 258/97 of the European Parliament and the Council of 27 January 1997 concerning novel foods and novel food ingredients.

2 Proposal for a Regulation of the European Parliament and of the Council on novel foods COM(2007) 872 final of 14.1.2008.

3 Report from the Commission to the European Parliament and the Council on animal cloning for food production COM (2010) 585 of 19.10.2010 suggested to (i) to suspend temporarily the use of the cloning technique, clones and of food from clones for five years; (ii) to trace imported reproductive materials of clones. http://ec.europa.eu/dgs/health_consumer/docs/20101019_report_ec_cloning_en.pdf

4 For example, 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: http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P7-TA-2011-0327+0+DOC+XML+V0//EN (Procedure 2011/2627(RSP), point 31)

5 EFSA Statement of 2012 overall conclusion p.18. EFSA statements 2012 and 2010: http://www.efsa.europa.eu/en/efsajournal/pub/2794.htm and http://www.efsa.europa.eu/en/efsajournal/pub/1784.htm

6 Council Directive 98/58/EC of 20 July 1998 concerning the protection of animals kept for farming purposes OJ L 221, 8.8.1998, p. 23.

1.4. Consistency with other policies and objectives of the Union

This initiative responds to the above-mentioned concerns while avoiding unnecessary burdens for farmers and breeders established in the Union and in third countries.

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 initiative 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.

2. RESULTS OF CONSULTATIONS WITH THE INTERESTED PARTIES AND IMPACT ASSESSMENT

2.1. Consultation process

2.1.1. Consultation methods and main sectors targeted

Member States, stakeholders and third country trade partners were consulted.

The Standing Committee for the Food Chain and Animal Health was the main forum for discussions with Member States. In addition all Member States completed a specific questionnaire on cloning on their territory.

Stakeholders were consulted in the Advisory Group of the Food Chain. Twenty-two organisations representing all sectors concerned (farmers, breeders, food industry, retailers, consumers and animal rights activists) participated. In addition five technical meetings were held with organisations representing farmers, breeders and the food industry.

A specific questionnaire was sent to the 15 major third country trade partners of which 13 replied.

The general public was consulted via the Interactive Policy Making Initiative in March 2012. This tool reaches approximately 6000 subscribers of which 360 replied[7].

Two Eurobarometer surveys addressed cloning: a 2008 specific survey on cloning[8] performed in 27 Member States and a 2010 survey on biotechnology[9] with specific questions on cloning performed in 27 Member States and 5 non-Union European countries.

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7 Of which: 34 came from professional organisations, 34 from non-governmental organisations,16 from national administrative bodies, 1 from a third country, 9 from enterprises, 26 from the academia, 10 from Member States and 230 from individuals.

8 European attitudes towards animal cloning http://ec.europa.eu/public_opinion/flash/fl_238_en.pdf and http://ec.europa.eu/food/food/resources/docs/eurobarometer_cloning_sum_en.pdf

9 Special Eurobarometer, Biotechnology report, October 2010 http://ec.europa.eu/public_opinion/archives/ebs/ebs_341_en.pdf

The specific report on cloning by the European Group on Ethics in Science and New Technologies (EGE) of 2008[10] expressed doubts that animal cloning for farming purposes can be justified "*considering the current level of suffering and health problems of surrogate dams and animal clones*". The EGE also concluded that it did "*not see convincing arguments to justify the production of food from clones and their offspring*".

2.1.2. Summary of responses and how they have been taken into account

Member States confirmed that animals are presently not cloned for faming purposes in the Union. The economic sectors involved (farming and breeding) indicated that they have, at this time, no interest to produce animals for farm purposes though cloning. Farmers and breeders however stressed that to remain competitive they need to have access to high performance genes including the reproductive material of clones.

Argentina, Australia, Brazil, Canada, and the United States confirmed that animals are cloned on their territory but could not indicate to what extent. In Brazil, Canada and United States clones are registered by private companies. In Canada the legal situation on cloning is similar to that in the Union, i.e. food produced from animal clones is considered novel and requires pre-market approval. Argentina, Australia, Brazil, Canada, New Zealand, Paraguay and the United States pointed out that measures should be science-based. They moreover stressed that measures should be no more trade-restrictive than necessary to fulfil legitimate objectives.

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.

This initiative takes account of the results of the consultations. It addresses justified concerns in a proportionate manner and considers the limits of the powers conferred to the Commission by the Treaties. This implies limiting the measures to the animals concerned (i.e. the surrogate mothers and the clones) and the species likely to be cloned (bovine, porcine, caprine, ovine and equine) for farming purposes.

2.1.3. External expertise

In 2008 the European Food Safety Authority (EFSA) delivered an opinion on cloning. It focused on animal clones, their progeny and of the products obtained from those animals. This opinion was up-dated by three statements in 2009, 2010 and 2012[11]. Based on the available data EFSA saw animal welfare problems related to the health of surrogate mothers (carrying the clones) and the clones themselves. Surrogate dams suffer in particular from placenta dysfunctions contributing to increased levels of miscarriages. This contributes, amongst others, to the low efficiency of the technique (6-15 % 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

[10] Ethical aspects of animal cloning for food supply 16 January 2008:
http://ec.europa.eu/bepa/european-group-ethics/docs/publications/opinion23_en.pdf
http://ec.europa.eu/bepa/european-group-ethics/docs/publications/opinion23_en.pdf

[11] Food safety, animal health and welfare and environmental impact of animals derived from cloning by SCNT and their offspring and products obtained from those animals (opinion and statements):
http://www.efsa.europa.eu/en/efsajournal/doc/767.pdf;
http://www.efsa.europa.eu/en/efsajournal/doc/319r.pdf;
http://www.efsa.europa.eu/en/efsajournal/doc/1784.pdf;
http://www.efsa.europa.eu/en/efsajournal/doc/2794.pdf

neonatal death. A high mortality rate is a characteristic of the cloning technique. On the other hand EFSA repeatedly stated that cloning has no impact on the safety of meat and milk obtained from the clones.

2.2. Impact assessment[12]

Based on the experience gained in the legislative procedure which failed in March 2011 and the positions expresses by stakeholders, four options were assessed[13]. As a result of the analysis of the four options, and considering their impacts and the objectives pursued, elements of Option 4 (i.e. temporary suspension of the technique and of imports of live clones) were retained as the basis of the present proposal. Suspending 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. To preserve the competitiveness of Union farmers, the proposal does not regulate reproductive material of clones.

3. LEGAL ELEMENTS OF THE PROPOSAL

3.1. Legal basis

The proposal is based on Article 43 TFEU (agriculture). The objectives of the Union's agricultural policy enumerated in Article 39 TFEU require ensuring, amongst others, the rational development of agricultural production. This implies ensuring uniform conditions of production for farmers. In choosing the means to achieve these objectives, account must also be taken of Article 13 TFEU. Article 13 TFEU requires that in formulating and implementing of, amongst others, the Union's agriculture policy that the Union and the Member States pay full regard to the welfare requirements of animals since they are sentient beings.

3.2. Subsidiarity principle

Isolated approaches to animal cloning could lead to distortions of the agricultural markets concerned. It is thus necessary to ensure that the same conditions apply and thus to address the matter at Union level.

3.3. Proportionality principle

The suspension of the cloning technique and the suspension of imports of live clones are suitable and necessary measures to achieve the objectives. They also present the best cost-benefit ratio to resolve the issues at stake.

At its present state of development it appears that the use of the cloning technique for farming purposes is of limited benefit. For this reason, this proposal addresses only those aspects related to animal production for farming purposes. It does not cover other areas where cloning can be justified due to a positive risk-benefit ratio (such as research or the use of reproductive material of clones).

The suspension of the cloning technique and of imports of animal clones for farming purposes thus strikes a reasonable fair balance between animal welfare, citizens' concerns and the interests of farmers, breeders and other stakeholders involved.

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[12] See for further details the accompanying Impact assessment Commission Staff working document SEC (2013) XXX.

[13] (1) no policy change, (2) pre-market approval of food from clones, offspring and descendants, (3) labelling of food from clones, offspring and descendants, (4) suspension of the cloning techniques and of imports of live clones, of food from clones and of reproductive material of clones.

3.4. Choice of instruments

The proposed instrument is a Directive. Other types of measures would not be appropriate for the following reasons:

(i) a directive allows Member States employ existing control tools as appropriate for the implementation of Union rules and thus to limit the administrative burden;

(ii) soft law instruments are considered insufficient to prevent the use of a technique throughout the Union.

In accordance with the Joint Political Declaration of Member States and the Commission on explanatory documents, Member States have undertaken to accompany, only in justified cases, the notification of their transposition measures with one or more explanatory documents explaining the relationship between the components of a directive and the corresponding parts of national transposition instruments. Considering the limited legal obligations set by this Directive, explanatory documents from the Member States in the context of transposition of this Directive are not needed.

4. BUDGETARY IMPLICATION

This initiative has no budgetary implications for the EU and requires no additional human resources in the Commission.

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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,

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

After transmission of the proposal to the national Parliaments,

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) Council Directive 98/58/EC[14] lays down general minimum welfare standards for animals bred or kept for farming purposes. It calls on Member States to avoid unnecessary pain, suffering or injury of farm animals. 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 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 throughout the Union.

(2) The European Food Safety Authority (EFSA) has confirmed that surrogate dams used in cloning suffer in particular from placenta dysfunctions contributing to increased levels of miscarriages[15]. 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.

(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.

(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.

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[14] Council Directive 98/58/EC of 20 July 1998 concerning the protection of animals kept for farming purposes (OJ L 221, 8.8.1998, p. 23).

[15] 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 http://www.efsa.europa.eu/en/topics/topic/cloning.htm?wtrl=01

(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.

(6) This Directive respects the fundamental rights and observes the principles recognised by the Charter of Fundamental Rights of the European Union, and notably the freedom to conduct a business and the freedom of the sciences. This Directive has to be implemented in accordance with these rights and principles.

HAVE ADOPTED THIS DIRECTIVE:

Article 1
Subject matter and scope

This Directive lays down rules on:

(a) the cloning of animals in the Union;

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

It shall apply to animals of the bovine, porcine, ovine, caprine and equine species ('the animals') kept and reproduced for farming purposes.

Article 2
Definitions

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

(a) animals "kept and reproduced for farming purposes" means animals kept and reproduced for the production of food, 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, the preservation of rare breeds or endangered species, sporting and cultural events;

(b) "cloning" means asexual reproduction of animals with 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");

(c) "placing on the market" means the first making available of an animal or a product on the internal market.

Article 3
Provisional prohibition

Member States shall provisionally prohibit:

(a) the cloning of animals;

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

Article 4
Penalties

Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. 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.'

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.

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

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

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

   (c) international developments.

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.

Article 7
Entering into force

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

Article 8
Addressees

This Directive is addressed to the Member States.

Done at Brussels, [Date].

For the European Parliament	*For the Council*
The President	*The President*