EUROPEAN
COMMISSION

Brussels, XXX
COM(2013) 893

2013/0434 (APP)

Proposal for a

COUNCIL DIRECTIVE

on the placing on the market of food from animal clones

{SWD(2013) 519}
{SWD(2013) 520}

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 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 not adopted by the co-legislators after the Conciliation failed 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) concluded that there is no indication of any difference for food safety for meat and milk of clones and their progeny compared with those of conventionally bred animals. However EFSA has identified animal welfare hazard related to the low efficiency of the technique. It up-dated its opinion on cloning of animals last 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 address consumer perceptions on the use of food from animal clones.

1.3. Regulatory framework

Animal cloning is a new technique in food production. Thus, currently, food derived from animal clones falls under the scope of the Novel Food Regulation. Under this Regulation food produced by new techniques can only be marketed after specific authorisation. Such pre-market approval must be based on a favourable assessment of the risk for food safety which is to be undertaken by EFSA. No application has

---

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 14.01.2008.

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

ever been submitted for an authorisation to market food produced by means of the cloning technique.

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, breeders or food business operators established in the Union and in third countries. The proposal envisages a suspension on Union territory of the marketing of food from clones.

The provisional prohibitions of the marketing of food from clones complements the suspensions of the use of the technique for farming purposes and the marketing of live clones proposed in a parallel measure. The provisional prohibition of the marketing of food from clones is also kept under review to take account of potential changes in consumer perceptions on cloning linked to animal welfare concerns and of international developments.

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 countries 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 5 technical meetings were held with organisations representing farmers, breeders and 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 with 360 replied[6].

Two Eurobarometer surveys addressed cloning: a 2008 specific survey on cloning[7] performed in 27 Member States and a 2010 survey on biotechnology[8] with specific questions on cloning performed in 27 Member States and 5 non-Union European countries.

---

6 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.

7 European attitudes towards animal cloning http://ec.europa.eu/food/resources/docs/eurobarometer cloning

8 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[9] 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 food production in the Union. The economic sectors involved (farming, breeding, food industry) indicated that they have, at this time, no interest to produce food from animal 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 the 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, hold a broadly negative perception of the use of the cloning technique for the production of animals for farming purposes. As a result consumers would not want to eat food derived from a clone.

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 Union by the Treaties.

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[10]. 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 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.

---

9 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

10 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

2.2. Impact assessment[11]

Based on the experience gained in the legislative procedure which failed in March 2011 and the positions expressed by stakeholders, four options were assessed. Option 4 included, among others, the temporary suspension of the placing on the market of food from clones.

As a result of the analysis of the four options, and considering their impacts and the objectives pursued, this element of Option 4 was retained as the basis of the present proposal. Its impact on Union food business operators (FBOs) and trade is limited because trade, if any, is likely to be insignificant as FBOs have no interest to market food from clones.

This option has a positive impact on citizens: their concerns about animal welfare will be addressed as no food from clones will be placed on the market in the Union.

3. LEGAL ELEMENTS OF THE PROPOSAL

3.1. Legal basis

The Treaty does not provide, for the adoption of this Directive, powers other than those under Article 352. This Directive addresses animal welfare concerns of consumers related to the use of a reproduction technique that has no impact on the safety or quality of the food produced but implies animal suffering. Article 169 TFEU calls the Union to promote the interest of consumers when adopting measures under Article 114 in the context of the completion of the internal market. Under Article 13 TFUE, in formulating and implementing the Union's internal market policy, the Union and the Member States must pay full regard to the welfare requirements of animals since animals are sentient beings. According to an established case-law[12], the choice of Article 114 TFUE as a legal basis is justified where there are differences between national rules which are such as to hinder the functioning of the internal market. Recourse to that provision is also possible if the aim is to prevent the emergence of such obstacles to trade resulting from the divergent development of national laws. However, the emergence of such obstacles must be likely and the measure in question must be designed to prevent them. In the present case, no current or likely divergence between national legislations was detected. Moreover, during the Conciliation referred to in paragraph 1.1. above, Member States expressed their willingness to see measures on cloning at EU level, but they did not specify which type of national measures they would put in place in the absence of EU initiative.

3.2. Subsidiarity principle

Isolated Member States measures on food from clones, if adopted, could lead to distortions of the markets concerned. Moreover, the measure concerns import controls. It is thus necessary to ensure that the same conditions apply and thus to address the matter at Union level.

---

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

12 See for example C-58/08 Vodafone [2010] ECR p. I-4999, paragraphs 32 and 33 and the case-law cited.

3.3. Proportionality principle

Animal cloning in food production has no benefit for the consumer and the food industry has no interest to market food from clones. At its present state of development it also appears that its use in food production is of limited benefit. The suspension of the marketing of food from clones complements the suspensions of the use of the technique for farm purposes and the marketing of live clones (animal clones) proposed in a parallel measure and thus strikes a reasonable fair balance between animal welfare, citizens' concerns and the interests of farmers, breeders and other stakeholders involved.

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.

2013/0434 (APP)

Proposal for a

COUNCIL DIRECTIVE

on the placing on the market of food from animal clones

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 352(1) thereof,

Having regard to the proposal from the European Commission,

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

After obtaining the consent of the European Parliament,

Acting in accordance with a special legislative procedure,

Whereas:

(1) Food from animal clones, as food derived from a new reproduction technique, falls within the scope of the Regulation (EC) No 258/97 of the European Parliament and the Council[13] and is thus subject to pre-market approval.

(2) An opinion of the European Food Safety Authority (EFSA) first adopted on 15 July 2008 and confirmed in 2009, 2010 and 2012[14] found no indication of any differences in food safety between food products from healthy animal clones and their progeny compared with those from healthy conventionally bred animals. However, EFSA also concluded that animal welfare problems related to the health of surrogate mothers, namely those carrying the clones, and the clones themselves exist[15]. EFSA concluded that surrogate dams suffer in particular from placenta dysfunctions contributing to increased levels of miscarriages. This contributes, amongst other things, to the low efficiency of the cloning technique, which is 6% to 15 % for animals of the bovine species and 6 % for animals of the 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. A high mortality rate is a characteristic of the cloning technique.

---

13 Regulation (EC) N° 258/97 of the European Parliament and the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ L 43, 14.2.1997, p. 1).

14 Scientific Opinion of the Scientific Committee 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

15 Opinion and statements on 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: 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

(3) The specific report on cloning by the European Group on Ethics in Science and New Technologies (EGE) of 2008[16] 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".

(4) The majority of Union citizens disapprove of cloning for food production due to animal welfare and general ethical concerns. They do not want to consume food from animal clones.

(5) The use of cloning technique and the placing on the market in the Union of embryo clones and animal clones for farming purposes is provisionally prohibited by the Directive [number] 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[17]. However, this prohibition does not apply to animals kept and reproduced exclusively for other purposes.

(6) In order to address consumer perceptions on cloning linked to animal welfare *concerns* it is necessary to ensure that food from animal clones 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 implies animal suffering would still be allowed.

(7) Animal cloning is allowed in certain third countries. Therefore, measures should be taken to avoid the import into the Union of food obtained from animal clones produced in those third countries.

(8) It is expected that the knowledge on the impact of cloning technique on animal welfare will increase. The cloning technique itself may improve over time and thus become more acceptable to consumers.

(9) The measures laid down in this act should be reviewed within a reasonable period of time to evaluate whether they adequately address the objectives pursued by it taking into account the experience gained by the Member States in the application of this Directive, consumer perceptions on cloning linked to animal welfare concerns and international developments.

(10) The Treaty does not provide, for the adoption of this Directive, powers other than those under Article 352. This Directive addresses animal welfare concerns of consumers related to the use of a reproduction technique that has no impact on the safety or quality of the food produced but implies animal suffering. Article 169 of the Treaty calls on the Union to promote the interests of consumers when adopting measures pursuant to Article 114 thereof in the context of the completion of the internal market. Article 13 of the Treaty, provides that in formulating and implementing the Union's internal market policy, the Union and the Member States are to pay full regard to the welfare requirements of animals since animals are sentient beings. According to the established case-law of the Court of Justice of the European Union, the choice of Article 114 of the Treaty as a legal basis is justified where there are differences between national rules which are such as to hinder the functioning of the internal market. Recourse to that provision is also possible if the aim of the act is to prevent the emergence of such obstacles to trade resulting from the divergent

---

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

17 [to be completed when text is adopted].

development of national laws[18]. However, the emergence of such obstacles must be likely and the measure in question must be designed to prevent them. In the present case, no current or likely divergence between national legislations was detected.

(11) 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. This Directive has to be implemented in accordance with these rights and principles.

HAS ADOPTED THIS DIRECTIVE:

Article 1
Subject matter

This Directive establishes rules for the placing on the market of food from animal clones.

Article 2
Definitions

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

(a) "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 clones').

(b) "Food" means food as defined in Article 2 of Regulation (EC) No 178/2002[19].

Article 3
Provisional prohibitions

1. Member States shall ensure that food from animal clones is not placed on the market.

2. Member States shall ensure that food of animal origin imported from third countries where food from clones can be legally placed on the market or exported is only placed on the market of the Union according to any specific import conditions adopted under Articles 48 and 49 of Regulation (EC) No 882/2004 of the European Parliament and of the Council, ensuring that no food from animal clones will be exported to the European Union from these third countries.

[18] See for example C-58/08 Vodafone [2010] ECR p. I-4999, paragraphs 32 and 33 and the case-law cited.

[19] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31, 1.2.2002, p. 1.

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) changes in consumer perception on cloning linked to animal welfare concerns;

   (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 months after the date of adoption 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
Entry 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*.

It shall apply from [date = 18 months after the date of adoption of this Directive].

Article 8
Addressees

This Directive is addressed to the Member States.

Done at Brussels,

For the Council
The President