

CORTES GENERALES

REPORT 6/2014 BY THE JOINT COMMITTEE ON THE EUROPEAN UNION OF 11 FEBRUARY 2014, ON THE APPLICATION OF THE PRINCIPLE OF SUBSIDIARITY BY THE FOLLOWING PROPOSALS:

– 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) 892 FINAL] [2013/0433 (COD)] {SWD (2013) 519 FINAL} {SWD (2013) 520 FINAL}.

– FOR A COUNCIL DIRECTIVE ON THE PLACING ON THE MARKET OF FOOD FROM ANIMAL CLONES [COM (2013) 893 FINAL] [2013/0434 (APP)] {SWD (2013) 519 FINAL} {SWD (2013) 520 FINAL}.

BACKGROUND

A. The Protocol on the Application of the Principles of Subsidiarity and Proportionality annexed to the Treaty of Lisbon of 2007, which has been in force since 1 December 2009, has established a control procedure for national parliaments to check whether draft European legislative acts comply with the principle of subsidiarity. This Protocol was transposed in Spain by Law 24/2009 of 22 December 2009 amending Law 8/1994 of 19 May. In particular, the new Articles 3(j), 5 and 6 of Law 8/1994 constitute the legal basis for this report.

B. 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, and the proposal for a Council Directive on the placing on the market of food from animal clones were approved by the European Commission and submitted to the national parliaments, which have eight weeks within which to check the control on the subsidiarity of the initiatives, ending on 17 February 2014.

C. On 3 February 2014, the Bureau and Spokespersons of the Joint Committee on the European Union adopted the agreement to examine the European legislative initiatives in question, appointing Rubén Moreno Palanques (MP) as rapporteur, and requesting from the Government the report referred to in Article 3 j) of Law 8/1994.

D. The Government provided a report relating to the two proposals. In both cases, it was concluded that the initiatives were in line with the principle of subsidiarity.

E. At its meeting on 11 February 2014, the Joint Committee on the European Union approved this.

REPORT

1.- Article 5(1) of the Treaty on European Union indicates that *"The use of Union competences is governed by the principles of subsidiarity and proportionality". In accordance with Article 5(3) of this Treaty, "Under the principle of subsidiarity, in areas which do not fall within its exclusive competence, the Union shall act only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States, either at central level or at regional and local level, but can rather, by reason of the scale or effects of the proposed action, be better achieved at Union level".*

2.- The first legislative proposal subjected to this analysis is based on Article 43(2) of the Treaty on the Functioning of the European Union (TFEU), which establishes the following:

Article 43.2

2. The European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee, shall establish the common organisation of agricultural markets provided for in Article 40(1) and the other provisions necessary for the pursuit of the objectives of the common agricultural policy and the common fisheries policy.

The agricultural policy objectives of the Union are specified in Article 39 TFEU, which requires, among other things, that the rational development of agricultural production be ensured. This involves guaranteeing uniform production conditions for farmers.

When choosing how to achieve these objectives, account must be taken of Article 13 TFEU. This Article requires that, in formulating and implementing the Union's agriculture policy among other things, the Union and the Member States must, since animals are sentient beings, pay full regard to the welfare requirements of animals.

The second legislative proposal subjected to this analysis is based on Article 352 of the Treaty on the Functioning of the European Union (TFEU). Article 352(1), known as the "flexibility clause", is a special legal basis intended to adjust the Union competences to the objectives assigned by the Treaties where these have not provided for the powers needed to achieve the objectives. Article 352 establishes the following:

1. If action by the Union should prove necessary, within the framework of the policies defined in the Treaties, to attain one of the objectives set out in the Treaties, and the Treaties have not provided the necessary powers, the Council, acting unanimously on a proposal from the Commission and after obtaining the consent of the European Parliament, shall adopt the appropriate measures. Where the measures in question are adopted by the Council in accordance with a special legislative procedure, it shall also act unanimously on a proposal from the Commission and after obtaining the consent of the European Parliament.

2. Using the procedure for monitoring the subsidiarity principle referred to in Article 5(3) of the Treaty on European Union, the Commission shall draw national Parliaments' attention to proposals based on this Article.

3. Measures based on this Article shall not entail harmonisation of Member States' laws or regulations in cases where the Treaties exclude such harmonisation.

4. This Article cannot serve as a basis for obtaining objectives pertaining to the common foreign and security policy and any acts adopted pursuant to this Article shall respect the limits set out in Article 40, second paragraph, of the Treaty on European Union.

The first recital of the proposal states: "Food from animal clones, as food derived from a new reproduction technique, falls within the scope of Regulation (EC) No 258/1997 of the European Parliament and of the Council and is thus subject to pre-market approval".

Recital 10 reads as follows: "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 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."

Article 2(1) (Definitions) of the proposal defines "food" for the purposes of the proposal as "food as defined in Article 2 of Regulation (EC) No 178/2002" (General Food Safety Regulation). Even though the proposal does not infringe the principle of subsidiarity, the legal base and the justification used must be subject to a more detailed legal and technical analysis.

3.- Cloning is an asexual breeding technique, used to obtain practically identical copies of the cloned animal from the genetic point of view, i.e. without modifying the genes of the nuclear chromosomal DNA, which are only different due to the few mitochondrial DNA genes which come from the ovum of the donor used for cloning.

In food production, cloning is a new technique. According to the current legislative framework, food derived from clones falls within the scope of the Regulation on novel food¹ and, consequently, is subject to authorisation prior to being placed on the market on the basis of a risk assessment for food safety, even though this reproduction technique has no impact on the safety or quality of the foods produced.

In 2008, the Commission adopted a proposal for a Regulation of the European Parliament and of the Council on novel foods.

The discussions in the context of the ordinary legislative procedure focus mainly on the provisions applicable to:

- nanomaterials;
- the cloning of animals for food production;
- traditional foods from third countries;
- the criteria which must be examined for risk assessment and management, and
- the authorisation procedure for novel foods in accordance with the Treaty on the Functioning of the European Union (Treaty of Lisbon).

The discussions stagnated in relation to issues surrounding animal cloning. The Conciliation Committee did not reach a final agreement at its last meeting, held in 2011, and the proposal was not adopted by the EU legislator.

¹ Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients.

The Commission considered that issues related to the cloning of farm animals ought to be dealt with in a separate proposal, on the basis of an impact assessment.

4.- The European Food Health Authority (EFSA) sees cloning above all as "*an animal welfare hazard related to the low efficiency of the technique. In an opinion on animal cloning updated in 2012, it concluded that scientific knowledge available on cloning had increased but that nevertheless its efficiency remained low compared to other reproduction techniques*". It also "*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 is one of the reasons for 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*". It uses the argument that "*clone abnormalities and unusually large offspring result in difficult births and neonatal deaths. A high mortality rate is a characteristic of the cloning technique*".

In reality, some arguments are inaccurate:

- the size of offspring depends on the number of cloned embryos planted in the surrogate mother, and could in any case succeed only in the porcine species;
- the claimed suffering of surrogate mothers is no greater than the suffering of substitute mothers in which embryos for animal production are planted, for example cattle for milk production. In the case of dairy cattle for example, practically 100% of animal production is not by natural or artificial insemination but by direct implantation of the embryo;
- the success of the technique may be low, but not very low compared with routine implantation of embryos obtained by *in vitro* fertilisation for animal production. For example, in the latter case embryo implantation has a success rate of 50% in cattle, but the success rate of vitrified and frozen embryos, which are customary, drops to 30%, even though these embryos were created by *in vitro* fertilisation, with no other type of manipulation, unlike the cloned embryo whose creation involves greater technical complexity. In the case of porcine livestock, cloning success is higher than indicated by the EFSA.

In the first cloning of a fighting bull at world level, which I had the opportunity to direct, 21 cloned embryos were obtained, some of which were vitrified and frozen for an extended period of time. Since it was the first experiment, the development of the technique required considerable preliminary work in order to create suitable conditions. This called for the use of 300 ova obtained from 1 500 ovaries from cows slaughtered for meat production, used as donors. Of the 21 cloned embryos, 14 were implanted in as many substitute mothers of the *Holstein* breed or Friesian dairy cows, and seven in Predajas fighting-bull brood cows.

Three of the clones survived until term. One of them suffered from "Large Offspring Syndrome" – described in the animal cloning processes – and the other two were born normal, with a success rate of 7.14% and 14.28% in the two respective animal groups, and an average of 9.52%, despite being the first experiment conducted at global level in the cloning of fighting bulls. Presumably, the success rate should be higher in later procedures, and with technical modifications which can improve it.

Under no circumstances was animal suffering noted, at least no more than can be experienced by cattle in which embryos obtained by *in vitro* fertilisation are implanted, which is routine procedure. For example, the clone with "Large Offspring Syndrome"

had a somewhat more laborious birth, but this was also the case for 30% of heifers with offspring obtained from *in vitro* fertilisation embryos.

On the other hand, the myostatin gene is defective in cattle specimens of the Belgian Blue breed, obtained by selective breeding (growth factor which limits the growth of the muscle tissue). This is the reason for its enormous muscle mass (an average of 1 200 kg in adult development), and they are born by Caesarean in 85 to 90% of cases. They are authorised for breeding (50% of the total population of bovine livestock in Belgium) despite the fact that the same argument of suffering for surrogate mothers could be used much more justifiably for the purpose of banning them.

It must be noted that the success rate argument does not take account of a fundamentally important element: the main practical interest of animal cloning is not to create an animal for farming purposes of importance in itself. If this was the case, the success rate criterion would be relevant. The real interest of animal cloning lies in preserving indefinitely the genetic wealth of animals for breeding, to be passed on to following generations, since the animal cannot transmit it beyond its own fertile life.

It is the F1 (the first filial) generation of the cloned animal which is ultimately of interest, and which receives the nuclear chromosomal genetic make-up, without the mitochondrial load of the donor ovule in the case of males, and which equates to indefinitely extending the capacity to transfer the desirable genetic characteristics of the cloned animal for farming purposes.

Furthermore, this is a good reason for preserving cellular samples of animals of exceptional genetic interest for livestock production and others, similar to the Svalbard Global Seed Vault, the biggest seed bank in the world, created to safeguard the biodiversity of crop species used for food in the event of a world catastrophe.

5.- The aim of the first proposal is to guarantee the existence of uniform production conditions for livestock producers, at the same time protecting the health and welfare of animals.

Directive 98/58/EC concerning the protection of animals kept for farming purposes establishes very general minimum standards for the welfare of animals used in agriculture. It makes no explicit reference to cloning but urges the Member States to avoid unnecessary pain and suffering or harm to farm animals. If cloning were to cause pain, suffering or unnecessary harm, the Member States should take action at national level to avoid it.

In the proposal, provision is made for the suspension on EU territory:

- of the use of the cloning technique for food-production purposes;
- of the placing on the market of live clones (clones of animals).

These provisional bans are intended to confine a production technique said to cause suffering in animals to fields in which it offers specific advantages.

The provisional bans will be reviewed, taking account of advances in technical knowledge and changes to its application in fields outside agriculture.

This initiative therefore excludes cloning performed for investigative purposes, cloning to preserve rare or threatened species, and the production of medicinal and health products.

6.- The interested parties were consulted in the framework of the Advisory Group on the Food Chain. Farmers, breeders, the food industry, retailers, consumers and animal rights activists participated. A specific questionnaire was sent to the 15 main trading partners from third countries, 13 of whom replied. And the public was consulted in March 2012 via the Interactive Policy-Making Initiative, with a limited response (360 of the 6 000 consulted).

In its specific report on cloning of 2008, the European Group on Ethics in Science and New Technology (EGE) 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".

7.- The Member States have confirmed that, at present, animals are not being cloned for farming purposes in the EU. The economic sectors in question (livestock and breeding) indicated that, at the moment, they had no interest in cloning animals for farming purposes. However, farmers and breeders underlined that in order to remain competitive, they had to have access to high-yield genes, including reproductive material from clones. This reinforces my point in the report on the real interest of cloning animals for farming purposes.

Argentina, Australia, Brazil, Canada and the United States confirmed that animals were being cloned on their territories. Argentina, Australia, Brazil, Canada, the United States, New Zealand and Paraguay pointed out that the measures should be based on scientific data. They also highlighted that the measures should not restrict trade more than was necessary to achieve legitimate objectives.

EU citizens, on the other hand, expressed an overall negative opinion on the use of cloning techniques to reproduce animals for farming purposes, although it should be pointed out that the sample was very small (360 of 6 000 consulted).

8.- Based on the experience acquired in the legislative procedure which failed in March 2011 and the positions expressed by the interested parties, a decision was reached to base this proposal on the temporary suspension of the technique and of live clone imports. "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". But in order to maintain the competitiveness of EU farmers, the proposal does not regulate reproductive material from clones.

9.- With regard to compliance of the first proposal with the principle of subsidiarity established in the current Treaty on European Union, isolated plans on animal cloning could give rise to distortions of the corresponding agricultural markets. As a result, uniform conditions need to be guaranteed and, consequently, the issue must be dealt with at EU level.

10.- Bearing in mind the state of current development of the cloning technique, it is argued that "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 from clones).”

It is argued that suspending the cloning technique and imports of animals clones for farming purposes thus constitutes a reasonably happy medium between animal welfare, citizens' concerns and the interests of farmers, breeders and other interested parties, as regards compliance with the principle of proportionality.

11.- However, significantly, EFSA has stated repeatedly that cloning does not influence the safety of meat and milk from clones. There are no indications of any difference in terms of food safety between meat and milk from clones and their offspring, and that from animals obtained by conventional breeding.

In this sense, the second proposal for a Council Directive on the placing on the market of food from animal clones is intended as a means to deal with consumers' perception of the use of food from animal clones. This is a perception which, it should be repeated, was obtained by means of a consultation in March 2012 through the Interactive Policymaking Initiative, a tool which involved 6 000 subscribers, of which only 360 responded.

12.- The second proposal provides for the suspension on EU territory of the placing on the market of food from clones. It aims to establish a ban on the sale of food from animal clones on the EU market, including those which could originate in third countries.

The provisional ban on the placing on the market of food obtained from clones supplements the suspension of the use of this technique for farming purposes and the placing on the market of live clones covered in the first proposal in question. The provisional ban on the placing on the market of food obtained from clones will also be revised to take account of possible changes in consumers' perception of cloning in relation to concerns relating to animal welfare and international development.

13.- It is argued that its impact on food business operators (FBOs) and on trade will be limited because trade will probably be insignificant, or even non-existent, since FBOs are not interested in the sale of food from clones.

And at the same time, it aims to have a positive impact for citizens, bearing in mind their concerns relating to animal welfare, because no food obtained from clones would be introduced to the EU market.

14.- Regarding compliance with the principle of subsidiarity of the second proposal, the adoption of isolated measures by the Member States on food obtained from clones could distort the corresponding markets. Furthermore, the measure affects import controls. Consequently, we need to guarantee the application of these conditions and thus broach the issue at EU level.

It argues that "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 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".

15.- Cloning in Spain is not currently used as a selection method in livestock improvement and reproduction. It is used mainly in research projects, outside the scope of this proposal. Therefore, Spain does not produce food from animal clones to be placed on the market. According to the available information, it is the same elsewhere in the EU. In any case, we need to consider whether the ban makes sense, bearing in mind the use of the system in third countries already, the possible repercussions for the WTO, and the compliance controls to be established.

CONCLUSION

For the above reasons, the Joint Committee on the European Union considers that 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, and the proposal for a Council Directive on the placing on the market of food from animal clones comply with the principle of subsidiary established in the Treaty on European Union.