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From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
Subject:	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 - Outcome of the European Parliament's first reading (7 to 10 September 2015)

I. INTRODUCTION

The Committee on Agriculture and Rural Development and the Committee on the Environment, Public Health and Food Safety jointly submitted a report to the plenary session containing 54 amendments (amendments 1-54). In addition, the ENF political group submitted a further two amendments (amendments 55-56).

II. DEBATE

The Co-Rapporteur from the Committee on the Environment, Public Health and Food Safety, Mrs Renate SOMMER (EPP - DE), opened the debate which took place on 8 September 2015 and:

- welcomed the fact that she and her fellow co-rapporteur from the Committee on Agriculture and Rural Development - Mrs Giulia MOI (EFDD - IT) - had succeeded in reaching agreement on a common approach for this file;
- called for the two proposals for directives to be combined as one regulation that would apply equally to all Member States. Equal application is an internal market imperative;
- called for a ban on clones and highlighted low success rates, a lack of scientific progress in recent years, high mortality rates and animal suffering;
- argued that it is not enough to prohibit cloning in the EU whilst allowing imports from non-EU states where it is not prohibited;
- noted public concern that cloning techniques might one day be applied to humans;
- stated that European citizens do not want to eat meat from cloned animals;
- called for the ban to include not only the use of cloning technology in the EU, but also the import of reproduction material, of cloned animals and of the descendants of cloned animals; and
- called for a labelling requirement for any food from cloned animals and their descendants. The GMOs experience has demonstrated that traceability is feasible - including back to non-EU states. She disagreed with the Commission's opinion that this is not possible. Pedigree books make it possible.

The Co-Rapporteur from the Committee on Agriculture and Rural Development, Mrs Giulia MOI (EFDD - IT):

- called on the Parliament to send a signal to foreign countries that the EU is not prepared to compromise on the food security of the present and future generations. EU agriculture is founded on quality and safety rather than on quantity;
- highlighted the animal welfare dimension; and
- argued that the EU's children should not be used as guinea pigs. Products from cloning have not been scientifically proven.

Commissioner ANDRIUKAITIS:

- noted that the joint committee's report had greatly extended the scope of the Commission's original proposal, but reiterated his continuing support for the Commission's position in this regard;
- recalled his earlier discussions on cloning with the Parliament and his previous explanation to the Parliament that the Commission's proposal was founded on a comprehensive analysis of the legal powers available, a rigorous impact assessment and the proportionality principle. By contrast, many of the joint committee's amendments were legally impossible or disproportionate;
- noted that descendants of cloned animals are conceived through conventional methods. They therefore do not give rise to food-safety or animal-welfare concerns. Any measures regarding descendants of cloned animals and regarding food or feed obtained from such descendants would therefore have to be justified on ethical grounds;
- recalled that it could be inferred from the 2008 Eurobarometer study that a majority of EU citizens disapprove of cloning, but noted that half of those interviewed mistakenly believed that animal cloning involves genetic modification. Since half the sample formed their opinion on incorrect presumptions, the outcome of the study has to be treated with considerable caution. The results are not sufficiently credible to justify far-reaching measures that would have a significant impact on the EU's agriculture; and
- stated that the Treaty does not provide specific powers to address the ethical concerns relating to cloning. Measures motivated essentially by ethical concerns can only be proposed under Article 352 of the Treaty, the flexibility cause. Any proposal based on Article 352 must be adopted separately under non-codecision legislative procedures.

Speaking on behalf of the Committee on International Trade, Mrs Jude KIRTON-DARLING (S&D - UK) stated that her Committee had found that the Commission's proposal was absolutely compatible with WTO rules and that it would also be possible to go further and ban not only cloned animals but also their offspring.

Speaking on behalf of the EPP political group, Mrs Pilar AYUSO (EPP - ES):

- stated her personal opinion that cloning technology is only needed for the preservation of endangered species. With this exception, it should be banned on the grounds of animal welfare and public concern;
- noted that EFSA had concluded that products from cloned animals do not pose any health risk and that it is not possible to distinguish between cloned and non-cloned animals since cloning does not involve genetic modification;
- argued that EU legislation should treat EU and non-EU farmers the same;
- stated that imports of genetic reproduction material derived from cloned animals and their descendants should be permitted under an administrative authorisation procedure. Similarly, the import of cloned animals, their offspring and their descendants - as well as products derived from these three categories - should also be authorisable if appropriately labelled and certified; and
- stressed the importance of the proposed legislative being consistent, practicable and checkable.

Speaking on behalf of the S&D political group, Mrs Daciana SÂRBU (S&D - RO):

- recalled the failure of the novel foods conciliation;
- referred to the Eurobarometer survey; and
- argued that it is not possible to foresee the long-term consequences of introducing cloned material into the food sector.

Speaking on behalf of the ECR political group, Mr James NICHOLSON (ECR - UK):

- stressed the importance of taking a science-based approach;
- recalled that EFSA had found no indication of any differences in food safety between food products from healthy cloned animals as compared to those from conventionally bred animals;
- warned that an import ban would be challenged according to the existing WTO rules; and
- argued that the joint committee's amendments would be legally unenforceable as well as unnecessary.

Speaking on behalf of the ALDE political group, Mrs Ulrike MÜLLER (ALDE - DE):

- stated her opposition to animal cloning and called for a ban on importing cloned animals, cloned embryos and any foodstuff derived from cloned animals;
- called for the two proposed directives to be converted into one regulation;
- opposed the calls for labelling and traceability across all generations. Pedigree books will have to suffice, because the imposition of an obligation of proof is not practicable. She noted the impossibility of distinguishing between a cloned animal and the original. She opposed setting up a system that would impose significant costs whilst misleading consumers; and
- interpreted the joint committee's amendments as implying an import ban on all products from countries in which cloning technology is applied.

Speaking on behalf of the EUL/NGL political group, Mrs Anja HAZEKAMP (EUL/NGL - NL):

- stated that cloning is morally repugnant and should therefore be prohibited. Farmers do not need it. Consumers do not want it. Animals suffer from it;
- warned that cloning poses a threat to small livestock producers; and
- called for an end to EU agricultural subsidies.

Speaking on behalf of the Greens/EFA political group, Mr Bart STAES (Greens/EFA - BE):

- stated that the novel foods conciliation had failed because of the Commission's obstinacy. The Commission had delayed submitting this latest proposal for too long. He referred to concerns within the Commission regarding the WTO dimension;
- supported the merger of the two proposals into one;
- supported the extension of the scope to cover descendants; and
- argued that cloning poses a threat to biodiversity.

Speaking on behalf of the EFDD political group, Mr John AGNEW (EFDD - UK):

- argued that it is up to consumers to make any concerns regarding cloning known to retailers, just as they did with battery chickens in the past. Retailers could then incorporate non-cloning into their assurance schemes;
- argued that cloning is unlikely to catch on to any significant extent; and
- stated that cloning might prove useful in the event of a livestock epidemic. The cloning of animals that had survived would preserve the species affected.

Speaking on behalf of the ENF political group, Mrs Sylvie GODDYN (ENF - FR) argued that, since it is not currently possible to check whether a product has or has not come from a cloned animal, the only way to assure citizens of the absence of clone-derived products is to suspend imports from countries which permit their trading.

Mr Peter LIESE (EPP - DE):

- warned that cloning might one day be extended from animals to humans; and
- argued that diagnostic technology could quickly be developed to ensure the practicability of the measures proposed by the joint committee. The non-verifiability argument is therefore absurd.

Mrs Clara Eugenia AGUILERA GARCÍA (S&D - ES) called for a ban on cloning for all species, provided that scientific research is not impaired.

Mr Fredrick FEDERLEY (ALDE - SE) called for a temporary - rather than a permanent - ban. A permanent ban on descendants might be problematic.

Mrs Julie GIRLING (ECR - UK):

- argued that cloning might have positive as well as negative consequences. It might open the way to improvements in animal welfare; and
- called for a temporary rather than a permanent ban.

Mr Jan HUITEMA (ALDE - NL):

- supported the Commission's approach, stating that the Commission had based itself on facts whilst the joint committee had based itself on scare-mongering;

Mrs Frédérique RIES (ALDE - BE):

- noted that the present debate was simply the latest chapter in a long-running clash between the Parliament and the Commission;
- stated that she would vote for the joint committee's report, even though she disagreed with certain elements;
- argued that the joint committee's amendments did not make sufficient allowance for research possibilities. She agreed with Mrs Girling in this respect;
- stated that the real question at that point was how to find a way out of the current impasse during the trilogue stage; and
- argued that the Commission was largely responsible for the current situation. Next to nothing had been done since the failure of the novel foods conciliation. She recalled that the Commission had in 2010 judged it appropriate to establish traceability measures - which had been demanded not only by the Parliament and by the citizens, but also by the Council. What had the Commission been doing for the last five years and what did it plan to do now?

Commissioner ANDRIUKAITIS once more took the floor and:

- reiterated his earlier point that descendants of cloned animals are conceived using conventional methods and therefore do not create any food-safety or animal-welfare concerns;
- distinguished between cloning and genetic modification;
- stated that the TTIP negotiations had had no influence on the formulation of the Commission's cloning proposal; and
- argued that traceability would require documentation through the food and animal production chain. This would create a bureaucracy that would be bound to collapse under its own weight and that would not provide any real benefit to consumers. It would, however, lead to higher food prices for the average consumer.

Mrs MOI once more took the floor and stated that EFSA reports between 2008 and 2012 had stated that there is not sufficient evidence to provide 100% assurance regarding food from cloned animals and their descendants, even if the latter are conventionally conceived. EFSA had also stated that cloning leads to epigenetic modification during the external and delicate reprogrammation stage. In the current absence of certainty, it would be wrong to subordinate our children's safety to economic interests and profit. Whose side is the Commission on - the citizens' or economic interests' ?

Mrs SOMMER once more took the floor and:

- called on the plenary to send a strong signal to the Council and the Commission;
- stated that each Member State should be clear whether or not it is on the side of the citizens when it comes to cloning. The Commission is clearly not;
- stated that the joint committee's amendments were perfectly practicable;
- stated that the Parliament does not share the Commission's fear of a WTO proceeding; and
- argued that the ECJ is on the Parliament's side regarding the legal basis, namely that Article 43 is the correct legal basis.

III. VOTE

When it voted in plenary on 8 September 2015, the Parliament adopted all 54 of the joint committee's amendments (amendments 1-54). No other amendments were adopted.

The text of the amendments adopted and the European Parliament's legislative resolution are annexed to this note.

P8_TA-PROV(2015)0285
Cloning of animals kept and reproduced for farming purposes ***I

European Parliament legislative resolution of 8 September 2015 on the proposal for a directive of the European Parliament and of the Council on the cloning of animals of the bovine, porcine, ovine, caprine and equine species kept and reproduced for farming purposes (COM(2013)0892 – C7-0002/2014 – 2013/0433(COD))

(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 its legislative resolution of 7 July 2010 on the Council position at first reading with a view to the adoption of a regulation of the European Parliament and of the Council on novel foods, amending Regulation (EC) No 1331/2008 and repealing Regulation (EC) No 258/97 and Commission Regulation (EC) No 1852/2001[1],

– having regard to the opinion of the European Economic and Social Committee of 30 April 2014[2],

– 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. 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.

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[1] Texts adopted of that date, P7_TA(2010)0266.
[2] OJ C 311, 12.9.2014, p. 73.

Amendment 1

Proposal for a directive
Title

Text proposed by the Commission	*Amendment*
Proposal for a ***Directive*** of the European Parliament and the Council on the cloning of animals ***of the bovine, porcine, ovine, caprine and equine species*** kept and reproduced for farming purposes	Proposal for a ***Regulation*** of the European Parliament and the Council on the cloning of animals kept and reproduced for farming purposes *(The first part of this amendment, namely the change from Directive to Regulation, applies throughout the text.)*

Amendment 2

Proposal for a directive
Recital -1 (new)

Text proposed by the Commission	*Amendment*
	(-1) 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 Council[1a] should be applied.

[1a] 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).

Amendment 3

Proposal for a directive
Recital 1

Text proposed by the Commission	*Amendment*
(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.	(1) ***The cloning of animals is not in line with*** Council Directive 98/58/EC[14]***, 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"***. 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 animals ***and of products derived from animals*** throughout the Union.
[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).	[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).

Amendment 4

Proposal for a directive
Recital 2

Text proposed by the Commission	*Amendment*
(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	(2) The European Food Safety Authority (EFSA) ***concluded, in its 2008 opinion on animal cloning[14a], that "the health and welfare of a significant proportion of clones [...] have been found to be adversely affected, often severely and with***

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.

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[15], ***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[15a].***

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[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

[14a] http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/sc_op_ej767_animal_cloning_en.pdf

[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

[15a] http://www.efsa.europa.eu/en/efsajournal/doc/2794.pdf

Amendment 5

Proposal for a directive
Recital 2 a (new)

Text proposed by the Commission	*Amendment*
	(2a) As regards food safety, EFSA has stressed the importance of acknowledging that the data base 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".

Amendment 6

Proposal for a directive
Recital 2 b (new)

Text proposed by the Commission	*Amendment*
	(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.

Amendment 7

Proposal for a directive
Recital 2 c (new)

Text proposed by the Commission	*Amendment*
	(2c) The European Group on Ethics in Science and New Technologies (EGE) in its specific report on cloning in 2008[1a] 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".

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[1a] Ethical aspects of animal cloning for food supply 16 January 2008: http://ec.europa.eu/bepa/european-group-ethics/docs/publications/opinion23_en.pdf

Amendment 8

Proposal for a directive
Recital 2 d (new)

Text proposed by the Commission	*Amendment*
	(2d) 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.

Amendment 9

Proposal for a directive
Recital 2 e (new)

Text proposed by the Commission	*Amendment*
	(2e) In accordance with the case-law[1a] 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.

[1a] United Kingdom of Great Britain and Northern Ireland v Council of the European Communities, C-68/86, EU:C:1988:85; Commission of the European Communities v Council of the European Communities, C-11/88, EU:C:1989:310; Commission of the European Communities v Council of the European Communities, C-131/87, EU:C:1989:581.

Amendment 10

Proposal for a directive
Recital 2 f (new)

Text proposed by the Commission	*Amendment*
	(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 [1a]. 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.

[1a] See e.g. Eurobarometer reports of 2008 and 2010:

http://ec.europa.eu/public_opinion/flash/fl_238_en.pdf and http://ec.europa.eu/public_opinion/archives/ebs/ebs_341_en.pdf

Amendment 11

Proposal for a directive
Recital 2 g (new)

Text proposed by the Commission	*Amendment*
	(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.

Amendment 12

Proposal for a directive
Recital 3

Text proposed by the Commission	*Amendment*
(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***.	(3) Taking into account the objectives of the Union's ***common*** agricultural policy, the results of the scientific assessments of EFSA ***based on the available studies,*** the animal welfare requirement provided in Article 13 ***TFEU and the citizens' concerns***, it is ***appropriate*** to prohibit the use of cloning in animal production for ***farming*** purposes ***and the placing on the market of animals and products derived from the use of the cloning technique***.

Amendment 13

Proposal for a directive
Recital 3 a (new)

Text proposed by the Commission	*Amendment*
	(3a) 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.

Amendment 14

Proposal for a directive
Recital 4

Text proposed by the Commission	*Amendment*
(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.	***deleted***

Amendment 15

Proposal for a directive
Recital 4 a (new)

Text proposed by the Commission	*Amendment*
	(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.

Amendment 16

Proposal for a directive
Recital 4 b (new)

Text proposed by the Commission	*Amendment*
	(4b) 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 of the European Parliament and of the Council, 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.

Amendment 17

Proposal for a directive
Recital 4 c (new)

Text proposed by the Commission	*Amendment*
	(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.

Amendment 18

Proposal for a directive
Recital 4 d (new)

Text proposed by the Commission	*Amendment*
	(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.

Amendment 19

Proposal for a directive
Recital 4 e (new)

Text proposed by the Commission	*Amendment*
	(4e) 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.

Amendment 20

Proposal for a directive
Recital 4 f (new)

Text proposed by the Commission	*Amendment*
	(4f) 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.

Amendment 21

Proposal for a directive
Recital 4 g (new)

Text proposed by the Commission	*Amendment*
	(4g) 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.

Amendment 22

Proposal for a directive
Recital 5

Text proposed by the Commission	*Amendment*
(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.	(5) This ***Regulation*** should be reviewed within a reasonable time, taking into account the experience gained by the Member States in its ***application***, scientific and technical progress***, the evolution of consumer perceptions,*** and international developments***, in particular trade flows and the Union's trade relations***.

Amendment 23

Proposal for a directive
Recital 5 a (new)

Text proposed by the Commission	*Amendment*
	(5a) 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 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.

Amendment 24

Proposal for a directive
Recital 5 b (new)

Text proposed by the Commission	*Amendment*
	(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.

Amendment 25

Proposal for a directive
Recital 6

Text proposed by the Commission	*Amendment*
(6) This ***Directive*** respects the fundamental rights and observes the principles	(6) This ***Regulation*** respects the fundamental rights and observes the

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.	principles recognised by the Charter of Fundamental Rights of the European Union, and ***in particular*** the freedom to conduct a business and the freedom of the sciences. This ***Regulation*** has to be ***applied*** in accordance with these rights and principles.

Amendment 26

Proposal for a directive
Recital 6 a (new)

Text proposed by the Commission	*Amendment*
	(6a) 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.

Amendment 27

Proposal for a directive
Article 1 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) the placing on the market of ***embryo clones and*** animal clones.	(b) 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***.

Amendment 28

Proposal for a directive
Article 1 – paragraph 2

Text proposed by the Commission	*Amendment*
It shall apply to animals ***of the bovine, porcine, ovine, caprine and equine species ('the animals')*** kept and reproduced for farming purposes.	It shall apply to ***all species of*** animals kept and reproduced for farming purposes.

Amendment 29

Proposal for a directive
Article 1 a (new)

Text proposed by the Commission	*Amendment*
	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.

Amendment 30

Proposal for a directive
Article 2 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(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***;	(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 endangered species ***and of rare breeds identified as such by the competent authorities of the Member***

States, where no alternative methods are available;

Amendment 31

Proposal for a directive
Article 2 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(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***”);	(b) “cloning” means asexual reproduction of animals ***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**,** 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***”);

Amendment 32

Proposal for a directive
Article 2 – paragraph 1 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) “descendants of animal clones” means animals, other than animal clones, where at least one of the progenitors is an animal clone;

Amendment 33

Proposal for a directive
Article 2 – paragraph 1 – point b b (new)

Text proposed by the Commission	*Amendment*
	(bb) “germinal products” means semen, oocytes and embryos collected or produced from animals for the purpose of reproduction;

Amendment 34

Proposal for a directive
Article 2 – paragraph 1 – point b c (new)

Text proposed by the Commission	*Amendment*
	(bc) "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;

Amendment 35

Proposal for a directive
Article 2 – paragraph 1 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) "food" means food as defined in Article 2 of Regulation (EC) No 178/2002.

Amendment 36

Proposal for a directive
Article 3 – title

Text proposed by the Commission	*Amendment*
Provisional prohibition	Prohibition

Amendment 37

Proposal for a directive
Article 3 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
Member States shall ***provisionally prohibit:***	***The following*** shall ***be prohibited:***

Amendment 38

Proposal for a directive
Article 3 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) the placing on the market ***of embryo clones and animal clones.***	(b) 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.***

Amendment 39

Proposal for a directive
Article 3 a (new)

Text proposed by the Commission	*Amendment*
	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 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.

****OJ please insert the date: 6 months from the entry into force of this Regulation.***

Amendment 40

Proposal for a directive
Article 3 b (new)

Text proposed by the Commission	*Amendment*
	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 ...*.

	****OJ please insert the date: 6 months from the entry into force of this Regulation.***

Amendment 41

Proposal for a directive
Article 4 – paragraph 1

Text proposed by the Commission	*Amendment*
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.'***	Member States shall lay down the rules on penalties applicable to infringements of this ***Regulation*** and shall take all measures necessary to ensure that they are ***applied***. The penalties provided for ***shall*** be effective, proportionate***,*** dissuasive ***and shall ensure a level playing field***. Member States shall notify those provisions to the Commission by ***...**** and shall notify it without delay of any subsequent amendment ***thereto***.
	****OJ please insert the date: 1 year from the entry into force of this Regulation.***

Amendment 42

Proposal for a directive
Article 4 a (new)

Text proposed by the Commission	*Amendment*
	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.

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.

**** OJ please insert the date of entry into force of this Regulation.***

Amendment 43

Proposal for a directive
Article 5 – paragraph 1

Text proposed by the Commission	*Amendment*
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	1. By ***...****, the Member States shall report to the Commission on the experience gained by them on the application of this

them on the application of this ***Directive***.	***Regulation***.
	****OJ please insert the date: 6 years from the entry into force of this Regulation.***

Amendment 44

Proposal for a directive
Article 5 – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) scientific and technical progress, in particular relating to the animal welfare aspects of cloning;	(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***.

Amendment 45

Proposal for a directive
Article 5 – paragraph 2 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) the evolution of consumer perceptions on cloning;

Amendment 46

Proposal for a directive
Article 5 – paragraph 2 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) consumers' concerns in relation to public health and animal welfare;

Amendment 47

Proposal for a directive
Article 5 – paragraph 2 – point c b (new)

Text proposed by the Commission	*Amendment*
	(cb) ethical issues relating to animal cloning.

Amendment 48

Proposal for a directive
Article 5 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. The Commission shall make the report referred to in paragraph 2 publicly available.

Amendment 49

Proposal for a directive
Article 5 – paragraph 2 b (new)

Text proposed by the Commission	*Amendment*
	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.

Amendment 50

Proposal for a directive
Article 6

Text proposed by the Commission	*Amendment*
Article 6	***deleted***
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.

Amendment 52

Proposal for a directive
Article 7 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	It shall apply from ...*.
	****OJ please insert the date: 1 year from the entry into force of this Regulation.***

Amendment 53

Proposal for a directive
Article 8

Text proposed by the Commission	*Amendment*
Article 8	***deleted***
Addressees	
This Directive is addressed to the Member States.	

Amendment 54

Proposal for a directive
Ending part (new)

Text proposed by the Commission	*Amendment*
	This Regulation shall be binding in its entirety and directly applicable in Member States.