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COMPROMISE AMENDMENTS

1 - 7

Draft report

Renate Sommer, Giulia Moi
(PE5511.999v01-00)

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

Proposal for a directive
(COM(2013)0892 – C8-0002/2014 – 2013/0433(COD))

(Joint committee meetings: Rule 55 of the Rules of Procedure)

Compromise Amendment 1 (legal instrument and scope)
EPP, EFDD, ECR, ALDE, GUE/NGL, GREENS/EFA

If the Compromise Amendment is adopted, Amendments 1, 6, 16, 17, 38, 39, 73-77, 94, 111-112, 120-124, 126-129, 138, INTA 1 fall

Proposal for a directive
Title

Text proposed by the Commission

Amendment

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

Proposal for a **regulation** of the European Parliament and of 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. Adopting it will necessitate corresponding changes throughout.)

Or. en

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

Or. en

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**

It shall apply to **all species of** animals kept and reproduced for farming purposes.

(‘the animals’) kept and reproduced for farming purposes.

Or. en

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” (*“the 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*;

Or. en

Compromise Amendment 2 (descendants and germinal products)
EPP, EFDD, S&D, GUE/NGL, GREENS/EFA

If the Compromise Amendment is adopted, Amendments 15, 18, 19, 24, 67, 76 (last part), 88-89, 113-119, 134, 139-150, INTA 7, INTA 10 fall

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.

Or. en

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

Text proposed by the Commission

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

Amendment

(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.**

Or. en

**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;

Or. en

Proposal for a directive
Article 1 – 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;

Or. en

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

Text proposed by the Commission

Amendment

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

Or. en

Compromise Amendment 3 (definition of cloning)
EPP, EFDD, S&D, ALDE, GUE/NGL, GREENS/EFA
If the Compromise Amendment is adopted, Amendments 130-133 fall

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**”);

**Compromise Amendment 4 (imports of products from clones and descendants)
EPP, EFDD, S&D, GUE/NGL, GREENS/EFA**

If the Compromise Amendment is adopted, Amendments 9, 25, 57, 68, 78 C, 84, 90-92, 152-158, INTA 5, INTA 6, INTA 11, INTA 12 fall

**Proposal for a directive
Recital 4 c (new)**

Text proposed by the Commission

Amendment

(4c) 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^{1a}, 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.

^{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).***

**Proposal for a directive
Recital 4 d (new)**

Text proposed by the Commission

Amendment

(4d) 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 within the meaning of Article III.4 of the General Agreement on Tariffs and Trade (GATT) to animals, embryos, germinal products, food and feed that do not derive from the use of the cloning technique. 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.

Or. en

**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 [date: 6 months after the entry into force of this Regulation] and shall, if necessary, present a proposal to amend other legislation in the field of animal health or zootechnical and genealogical conditions for imports.

Or. en

Compromise Amendment 5 (Recital on animal welfare basis)

EPP, EFDD, S&D, ALDE, GUE/NGL, GREENS/EFA

If the Compromise Amendment is adopted, Amendments 41-43, 56 fall

Proposal for a directive

Recital 1

Text proposed by the Commission

Amendment

(1) Council Directive 98/58/EC¹⁴ 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/EC¹⁴, ***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 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 to 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).

Or. en

Compromise Amendment 6 (Recital on EFSA conclusions)
EPP, EFDD, S&D, ALDE, GUE/NGL, GREENS/EFA

If the Compromise Amendment is adopted, Amendments 44-48, 51 fall

Proposal for a directive
Recital 2

Text proposed by the Commission

(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 miscarriages¹⁵ 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.

Amendment

(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 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 miscarriages¹⁵, **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}.**

^{14a} <http://www.efsa.europa.eu/en/efsajournal/doc/767.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>

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>

Or. en

**Compromise Amendment 7 (Recitals on citizens' concerns and general reasons)
EPP, EFDD, S&D, GUE/NGL, GREENS/EFA**

If the Compromise Amendment is adopted, Amendments 5, 7, 54, 58-66, 78 A, 79-83, 106, INTA 2 fall

**Proposal for a directive
Recital 2 e (new)**

Text proposed by the Commission

Amendment

(2e) The majority of Union citizens disapprove of cloning for farming purposes due to, inter alia, animal welfare and general ethical concerns, as clearly and consistently shown by consumer research^{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. the 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

Or. en

Proposal for a directive
Recital 3

Text proposed by the Commission

(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**.

Amendment

(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**.

Or. en