

COMMUNICATION
from the European Affairs Committee of the Federal Council
of 13 February 2014

to the European Parliament and the Council
pursuant to Article 23 f (4) of the Austrian Constitution

COM (2013) 892 final

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

Under the current legislative framework, food from clones falls under the scope of the Novel Food Regulation, as cloning in food production is a new technique. Food from clones therefore is subject to pre-market approval based on a food safety risk assessment.

In 2008, the Commission presented a proposal to streamline the approval process for novel food. Within the framework of the legislative procedure, the law-makers intended to amend the proposal to introduce specific rules on cloning. However, no agreement was reached on the scope and the content of these amendments, so that the proposal was abandoned after a failed conciliation procedure 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.

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

In the opinion of the European Food Safety Authority (EFSA), cloning primarily represents an animal welfare hazard related to the low efficiency of the technique. In its updated opinion on the cloning of animals from 2012, EFSA concluded that scientific knowledge available on cloning has increased, but that nevertheless its efficiency remains low compared with other reproduction techniques.

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

The proposal envisages a provisional prohibition of cloning of animals for food production and the placing on the market of live clones and embryos of clones.

The prohibition does not apply to areas in which cloning may be justified, such as in research, for the preservation of rare breeds or endangered species, or for the production of medicinal products and medical devices.

Austria has repeatedly underlined the importance of and the need for rules on cloning at European level and advocated the elaboration of a proposal for a horizontal regulatory regime. We therefore appreciate the fact that a proposal for a horizontal legislative framework was presented by the European Commission at the end of December 2013.

Austria explicitly welcomes the Commission's proposal.

In this context, we wish to draw attention to the joint opinion of the Austrian Länder and refer, in particular, to the issue relating to the free trade agreement with the United States of America as well as the situation arising due to the absence of an internationally binding labelling regime for clone animals and food of animal origin produced from animal clones.

Joint Opinion of the Austrian Länder

Regarding the proposals COM (2013) 892 final and COM (2013) 893 final for

- a) a Directive on the cloning of animals of the bovine, porcine, ovine, caprine and equine species kept and reproduced for farming purposes, and
- b) a Directive on the placing on the market of food from animal clones

1) General comments

- a) The Austrian Länder are in favour of the proposals for the above Directives. In particular, they explicitly welcome and support the prohibition of cloning of animals kept for farming purposes and the prohibition of the placing on the market of food from animal clones.

In Austrian cattle breeding practice, in particular, the cloning of breeding animals is not considered to be a meaningful and necessary method to ensure progress in breeding. Therefore, as a matter of principle, the envisaged provisional prohibition (for five years) of the cloning of animals kept and reproduced for farming purposes as well as a general prohibition of the placing on the market of food from animal clones is welcomed.

- b) A permanent prohibition of cloning techniques might, however, impair scientific progress. According to Article 2 (a) of the proposed text, the scope of the proposed Directive on the cloning of animals of the bovine, porcine, ovine, caprine and equine species kept and reproduced for farming purposes does not include animals kept and reproduced exclusively for purposes other than farming (such as research, sporting and cultural events, the production of medicinal products and medical devices).
- c) The Austrian Länder suggest that the contents and prohibitions of the two proposed Directives on cloning and on the placing on the market of food from animal clones be taken into consideration in the negotiations on a free trade agreement with the United States of America. To this end, the duration of the prohibition, which is currently not specified (see Article 3 of the proposals) should be changed from “provisional” to “at least five years until empirical reports become available”.

2) Proposal for a Directive on the cloning of animals of the bovine, porcine, ovine, caprine and equine species kept and reproduced for farming purposes

ad Article 3 (“Provisional Prohibition”)

- a) The heading of Article 3 should read “Provisional Prohibitions”, as Article 3 refers to two cases, i.e. the cloning of animals and the placing on the market of food from animal clones. In the proposed Directive on the placing on the market of food produced from animal clones the prohibitions are stated under paragraphs 1 and 2, whereas in the proposed Directive on the cloning of animals of the bovine, porcine, ovine, caprine and equine species kept and reproduced for farming purposes they are stated under paragraphs a and b. The formal structure of the two Directives should be harmonized.

- b) Article 3 (a) of the proposed Directive on the cloning of animals of the bovine, porcine, ovine, caprine and equine species kept and reproduced for farming purposes forbids the “cloning of animals”. It appears that the intended limitation of the prohibition to the cloning of animals of the bovine, porcine, ovine, caprine and equine species kept and reproduced for farming purposes is missing. The limitation of the prohibition can only be derived from the scope (Article 1) and the title of the proposed Directive. The limitation should therefore be clarified in Article 3 (a).
- c) According to paragraph 3.3 of the Explanatory Memorandum (“Proportionality Principle”), the proposal only addresses those aspects related to animal production for farming purposes. It does not cover other areas where cloning can be justified due to a positive risk-benefit ratio (such as research or the use of reproductive material of clones). What remains unclear, however, is whether, for instance, the use of semen of a cloned bull for breeding purposes is possible or not, as it is forbidden (production of animals for farming purposes), but may still be allowed under certain circumstances (use of reproductive material of clones).

3) Proposed Directive on the placing on the market of food from animal clones

1. ad Article 2 (“Definitions”)

Following the model of Article 2 of the proposed Directive on the cloning of animals of the bovine, porcine, ovine, caprine and equine species kept and reproduced for farming purposes, it is absolutely necessary to include a definition of “placing on the market”.

2. ad Article 3 (“Provisional Prohibitions”)

- a) The heading “Provisional Prohibitions” does not apply in this instance, as the article only covers a single prohibition, i.e. the placing on the market under paragraph 1. Paragraph 2 of Article 3 is not a separate prohibition, but an instruction to the Member States.
- b) Article 3 contains a general provision stating that food from clones must not be placed on the market. As stated in the Explanatory Memorandum (Item 2.1.1., last sentence), the European Group on Ethics in Science and New Technologies did not see convincing arguments to justify the production of food from clones and their first-generation offspring. However, the proposal presented fails to clarify if and to what extent subsequent generations are to fall under the scope of the Directive.
- c) Finally, practical implementation and the supervision of compliance by the Member States as provided for in Art.3 para.2 (no import of food from animal clones from third countries into the EU) remain unclear, as an internationally binding labelling regime for animal clones and food of animal origin from animal clones is either non-existent or unknown in this country (see also Considering 7).