REPUBLIC OF AUSTRIA Bundesrat The President

Vienna, 13 February 2014 Ref. 27000.0040/3-L2.1/2014

Dear Mr Barroso,

The EU Committee of the Bundesrat adopted the following communication pursuant to Article 23f(4) of the Federal Constitutional Act (B-VG) in its sitting of 13 February 2014 in the context of its deliberations on:

COM (2013) 892 final

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.

Yours sincerely,

(Michael Lampel)

Annex

To: Mr Barroso

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COMMUNICATION to the European Parliament and the Council

pursuant to Article 23f(4) of the Federal Constitutional Act (B-VG) from the EU Committee of the Bundesrat 13 February 2014

COM (2013) 892 final

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.

Currently, foodstuffs obtained from cloned animals fall within the scope of the Novel Foods Regulation, as cloning in food production is considered to be an innovative technology. These foodstuffs, before being placed on the market, therefore require authorisation issued on the basis of a food safety risk assessment.

In 2008, the Commission published a proposal to tighten up the authorisation procedure in the Novel Foods Regulation. In the course of the legislative procedure, the legislator suggested that the proposal be amended to include specific rules on cloning. As no agreement could be reached on the scope and content of these amendments, the proposal was dropped following a failed conciliation procedure in March 2011. The Commission was asked, on the basis of a follow-up assessment, to draw up a legislative proposal on cloning in food production, independent of the Novel Foods Regulation.

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

In the view of the European Food Safety Authority (EFSA), cloning first of all raises certain animal welfare issues, to do with the inefficiency of the technology. In its 2012 updated report on animal cloning, the EFSA came to the conclusion that, although the available know-how on cloning has increased, its efficiency, compared to other reproductive techniques, was still poor.

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

The proposal provides for a temporary ban on the use of cloning for farm animals and a ban on the marketing of live clones and cloned embryos.

The ban does not apply to other areas where cloning can be justified, such as research, for the preservation of rare breeds or endangered species or for the production of medicinal products and medical devices.

Austria has repeatedly stressed at European level the importance and necessity of rules on cloning, calling for the drafting of a separate proposal providing for horizontal regulation. It is therefore pleased that the European Commission presented this proposal for a horizontal regulation framework at the end of December 2013.

We expressly welcome the Commission's proposal.

We would also refer to the joint position of the Austrian provinces enclosed with this communication, in particular the section concerning the free trade agreement with the United States and the issue of the lack of internationally binding rules on labelling for cloned animals and food of cloned animal origin.

Joint position of the Austrian provinces

on proposals COM(2013) 892 and 893 final, concerning a:

- 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;
- b) Directive on the placing on the market of food from animal clones.

1) General

- a) The above-mentioned proposals for directives are welcomed. In particular, we expressly welcome and support the ban on the cloning of farm animals and the ban on the placing on the market of food from animal clones.
 In the Austrian cattle breeding industry in particular, the cloning of breeding animals is not considered to be a sensible and necessary way of securing progress in breeding. We are therefore fully in favour of the planned temporary (five-year) ban on cloning animals kept and bred for farming and a general ban on the placing on the market of food from animal clones.
- b) A permanent ban on cloning could form an obstacle to scientific progress. However, pursuant to Article 2(a) of the proposal for a Directive on the cloning of animals of the bovine, porcine, ovine, caprine and equine species kept and reproduced for farming purposes, the scope of the Directive does not include animals kept and reproduced exclusively for other purposes such as research, sporting and cultural events and the production of medicinal products and medical devices.
- c) We would urge that the content and prohibitions contained in both proposals for directives on cloning and the placing on the market of food from animal clones also be taken into account in the negotiations on a free trade agreement with the United States. Moreover, the currently vague duration of the prohibition in Article 3 should be changed from 'provisional' to 'at least five years pending relevant reports on experience'.
- 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

Article 3 ('Provisional prohibition')

a) The title of Article 3 should be 'Provisional prohibitions' in the plural, as Article 3 covers two different issues (cloning and placing on the market). The proposal for a Directive on the placing on the market of food from animal clones provides for these prohibitions in points 1 and 2, whilst the proposal for a Directive on the cloning of animals of the bovine, porcine, ovine, caprine and equine species kept and reproduced for farming purposes provides for them in points (a) and (b). The formal structure of these two directives should be harmonised.

- b) Article 3(a) of 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 bans 'the cloning of animals'. The Article does not state that the scope is intended to be limited to animals of the bovine, porcine, ovine, caprine and equine species kept and reproduced *for farming purposes*. The restriction is referred to merely in the 'Subject matter and scope' (Article 1) and the title of the proposal. Clarification should be added in Article 3(a).
- c) According to point 3.3 of the Explanatory Memorandum ('Proportionality principle'), 'the 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 of clones).' However, it is unclear whether, for example, it would be possible to use semen from a cloned bull for breeding purposes, as this is apparently banned ('animal production for farming purposes'), but possibly also allowed ('use of reproductive material of clones').

3) Proposal for a Directive on the placing on the market of food from animal clones

1. <u>Article 2 ('Definitions')</u>

As in Article 2 of the Proposal for a Directive on the cloning of animals of the bovine, porcine, ovine, caprine and equine species kept and reproduced for farming purposes, the concept of 'placing on the market' must be defined.

2. Article 3 ('Provisional prohibitions')

- a) The title 'Provisional prohibitions' in the plural is not appropriate here because just one prohibition is laid down, i.e. the prohibition on placing on the market in Article 3(1). Article 3(2) does not contain a prohibition but rather instructions to the Member States.
- b) Article 3 provides in general terms that food from cloned animals should not be placed on the market. It can be seen from the Explanatory Memorandum (last sentence of point 2.1.1) that the European Group of Ethics in Science and New Technologies concluded that it did 'not see convincing arguments to justify the production of food from clones and their offspring'. However, it is unclear in the proposal whether and to what extent offspring are intended to be included in the scope of the Directive.
- c) It is unclear how the Member States are supposed to implement and enforce in practice the provisions of Article 3(2) (no import into the EU from third countries of food from cloned animals), as there are no binding international labelling rules for animal clones and foods produced from such animals (as far as we know) (see also recital 7).