



## EUROPEAN COMMISSION

*Brussels, 25.7.2014*

*C(2014) 5425 final*

*Dear President,*

*The Commission would like to thank the Tweede Kamer for its opinion on the following Commission proposals: 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) 892 final} (hereafter Cloning Technique Proposal), a proposal on the Council Directive on the placing on the market of food from animal clones {COM(2013) 893 final} (hereafter Cloning Food Proposal) and the proposal for a Regulation of the European Parliament and of the Council on novel foods {COM(2013) 894 final} (hereafter Novel Food Proposal).*

*The Commission takes note of the variety of views expressed by different political parties of Tweede Kamer. The Commission would like to underline that in the legislative process the Cloning Technique Proposal and Cloning Food Proposal are treated separately from the Novel Food Proposal. Therefore the Commission would like to address Tweede Kamer's observations concerning these different proposals separately below.*

### *Cloning Technique Proposal and Cloning Food Proposal*

*In response to Tweede Kamer's comments on consultation processes and methods, the Commission would like to underline, that it addressed the matter with the general public, Member States, stakeholders and third countries using in particular questionnaires, computer assisted surveys and dedicated meetings. For details the Commission would like to refer the Tweede Kamer to the Impact Assessment accompanying the two proposals.*

*The measures are proposed in the form of Directives as this type of act would allow Member States to incorporate the proposed rules in existing national laws on animal welfare and authorisation of research with animals, i.e. in particular the rules transposing Directive 98/58/EC on the protection of animals kept for farming purposes and Directive 2010/63/EU of the European Parliament and of the Council on the protection of animals used for scientific purposes. This would limit the administrative burden in Member States and facilitate access to and visibility of the rules for business operators and citizens if embedded in national rules.*

*Concerning third countries, the Commission would like to observe that the measures have been notified to them in respect of the Union's obligations under the Agreement on Technical Barriers to Trade of the World Trade Organisation.*

*Ms Anouchka VAN MILTENBURG  
President of the Tweede Kamer  
Postbus 20018  
2500 EA Den Haag*

*The Commission also would like to address the questions on the scope of the Cloning Technique Proposal. As indicated in the Explanatory Memorandum to the proposal, the Commission has taken account of the results of the consultations, and the proposal addresses justified concerns in a proportionate manner, having regard to the limits of the powers conferred to the Commission by the Treaties. The measures have therefore been limited to the animals actually concerned (i.e. the surrogate mothers and the clones) and the species likely to be cloned (bovine, porcine, caprine, ovine and equine) for farming purposes. Article 1 would limit the scope to (a) the cloning of animals in the Union and (b) the placing on the market of embryo clones and animal clones. Offspring of animal clones conventionally conceived would not be covered (unless re-cloned). This is because these animals would be covered by Council Directive (EC) No 98/58 on the protection of animals kept for farming purposes.*

*The scope of the measure on the cloning technique may not be extended to pets or other animals solely used for leisure purposes as the legal basis, Article 43 of the Treaty on the Functioning of the European Union, does not confer the necessary powers to Union institutions.*

*Concerning enforcement, the Commission points out that the Cloning Food Proposal refers in its Article 3 to Articles 48 and 49 of Regulation (EC) No 882/2004 of the European Parliament and of the Council under which specific import conditions can be adopted.*

*The Commission notes that the principle of proportionality is enshrined in Article 5(4) of the Treaty on European Union and Protocol No 2. It requires that action at EU level must be necessary and appropriate to the objective pursued and does not unnecessarily overburden one party to satisfy another. Labelling food from clone offspring would require that all operators involved in the food chain would have to distinguish food stemming from offspring of clones. It would thus be necessary to maintain a documented link between food and animal. This would require parentage information for each individual animal to be conveyed throughout the food production chain. The Commission considered in particular the option of labelling fresh bovine meat from offspring of cloned animals. The Commission however found that the very complex option of labelling fresh bovine meat from offspring of cloned animals required more time so that a comprehensive impact analysis and feasibility study could be carried out, without prejudging the outcome of this analysis or the final decision to be adopted.*

#### *Novel Food Proposal*

*With reference to the Tweede Kamer's question on the consequences of the proposal for a Regulation of the European Parliament and of the Council on novel foods for new techniques such as cisgenesis, the Commission would like to inform the Tweede Kamer of the actions it has launched with the objective to clarify the legal status of New Plant Breeding Techniques, including cisgenesis.*

*The first action was the setting up of a Working Group on the establishment of a list of techniques which might fall under the scope of Directive 2001/18/EC and Directive 90/219/EEC, with the objective of evaluating these techniques in the light of the existing legislation and of the most recent available scientific data.*

*The second action was the study on "New Plant Breeding Techniques: state-of-the-art and prospects for commercial development" carried out by the Institute for Prospective Technological Studies of the European Commission Joint Research Centre in cooperation with the Institute for Health and Consumer Protection.*

*The third action was the request to the European Food Safety Authority (EFSA) Panel on genetically modified organisms (GMOs) to deliver a scientific opinion on three techniques, namely cisgenesis, intragenesis and site directed nuclease technique, in terms of the risks they might pose and the applicability of the existing EFSA guidance documents on GM plants for their risk assessment.*

*Furthermore, a legal analysis of these techniques is currently ongoing within the Commission. The decision to include or exclude a technique from the scope of the Directives depends on the interpretation of the definition of GMOs set out in Directives 2001/18/EC and 2009/41/EC and of the techniques listed in the Annexes of these Directives. This evaluation is complex and requires a thorough legal analysis by the Commission, which is currently ongoing. The conclusions of this analysis cannot be anticipated yet but will be shared with the Member States.*

*Regarding the Tweede Kamer's question on the guarantees on protecting human health and nanomaterials, the Commission notes that the general condition for authorising a novel food is that it would not, on the basis of the scientific evidence, pose a safety risk to human health. This condition is included in Article 6(a) of the proposal. Engineered nanomaterials, as defined in letter t of Article 2(2) of Regulation (EC) No 1169/2011 on the provision of food information for consumers, are novel foods if not consumed to a significant degree by humans in the European Union prior to 15 May 1997. In accordance with the provisions of Regulation (EC) No 1169/2011, as from 13 December 2014, all ingredients present in the form of "engineered nanomaterials" must be clearly indicated in the list of ingredients followed by the word "nano" in brackets.*

*The points above are based on the initial proposals presented by the Commission which are currently in the legislative process involving both the European Parliament and the Council at which your government is represented.*

*The Commission hopes that these clarifications address the issues raised by the Tweede Kamer and looks forward to continuing our political dialogue in the future.*

*Yours faithfully,*

*Maroš Šefčovič  
Vice-President*