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signed by Mr Jordi AYET PUIGARNAU, Director

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Subject: COMMISSION STAFF WORKING DOCUMENT EXECUTIVE
SUMMARY OF THE IMPACT ASSESSMENT Accompanying the
document 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, and Proposal for a COUNCIL DIRECTIVE on the
placing on the market of food from animal clones

Delegations will find attached document SWD(2013) 520 final.

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COMMISSION STAFF WORKING DOCUMENT
EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT

Accompanying the document

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, and**

Proposal for a

COUNCIL DIRECTIVE

on the placing on the market of food from animal clones

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Executive Summary

1. PROBLEM DEFINITION

Cloning is a relatively new technique which allows the asexual reproduction of an individual animal. Cloning does not involve any genetic modification and the clone is not a GMO. In fact, the clone is a near exact genetic copy of the original animal (the donor). Although the cloning technique itself does not *improve* the animal's performance, breeders may consider cloning beneficial because it allows *increasing* the quantity of reproductive material (semen, ova or embryos) of a particularly valuable animal.

Cloning is used in research and the production of medicinal products and medical devices. It is also a method to increase the population of rare breeds or endangered species.

In farming, cloning is used to multiply the reproductive material of high performance "elite" animals¹. Predominantly the semen of male animal clones is used for artificial insemination, i.e. with a traditional breeding technique.

Offspring is the first generation where one parent is a clone, while descendants are all further generations where none of the parents is a clone.

Clones are usually not bred and raised to produce food (hereafter "food from clones"). While food could be obtained from clones produced for other purposes as a side-effect, this would be economically unattractive and thus rather unlikely.

According to the information available to the Commission, there is currently no cloning activity in the EU for food purposes.

The European Food Safety Authority (EFSA)² concluded that there is no indication of any difference for food safety for meat and milk of clones and their progeny compared with those of conventionally bred animals.

However, cloning of farm animals for food production is under discussion for three reasons:

(a) *Welfare and health of animals linked to the use of the cloning technique*

EFSA highlighted that surrogate dams (carrying the clones) and the clones themselves suffer in the application of the technique.

(b) *The negative perception that EU citizens have of the cloning technique if used for food production*

In surveys the vast majority (above 80 %) of *EU citizens* expressed *broadly negative perception* of the use of cloning technique for food production. This perception appears to be at least partly the result of:

- the unfounded assumption that cloning of food producing animals poses a risk to food safety and human health;
- the false idea that cloning involves genetic modification;
- general scepticism towards new technologies in biosciences;
- fear that negative effects of cloning manifest themselves only later.

¹ Particular in USA and Canada.

² Opinion of 2008 up-dated in 2009, 2010 and 2012.

(c) *The request of the co-legislator to address the issue*

Inter-institutional discussions on cloning started in 2009 in the context of the negotiations on a proposal streamlining the approval process of the 1997 Novel Food Regulation. No agreement could be reached between Member States and the European Parliament on any of the issues linked to cloning. The conciliation failed. Following this failure, the European Parliament called upon the Commission to present a proposal on cloning based on an impact assessment.

The following actors could be affected by potential measures:

- EU farmers which raise animals for food production;
- EU breeders which produce or import reproductive materials (semen, embryo and ova);
- EU food industry (including distribution, retail and importers) which places food on the EU market;
- EU consumers as beneficiaries of availability of food products;
- Third country³ breeding/cloning companies and food operators who export reproductive material, live animals and food of animal origin to the EU if cloning takes place in their country.

2. ANALYSIS OF SUBSIDIARITY

Council Directive 98/58/EC 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.

Yet different national approaches to animal cloning could lead to market distortion. Measures regulating the use of the cloning technique would address the associated animal health and welfare concerns. They would prevent the development of diverging national legislation and the consequent disruptions of the concerned agricultural markets. They would thus also ensure level playing field for breeders and farmers and uniform conditions of production for farmers.

As breeding/cloning companies and food operators in third countries are also concerned it is necessary to ensure that the same conditions apply to them. The matter should thus be addressed at Union level.

3. OBJECTIVES OF EU INITIATIVE

General objectives

To address concerns on cloning for farming purposes, to ensure uniform conditions for farmers in the EU and to protect consumer interests as regard food from cloned animals.

Specific objectives

- *Objective 1:* To ensure uniform conditions of production of farmers in the EU while protecting health and welfare of farmed animals;

³ Mainly for bovine (food production) and to a lesser extent for porcine and even less for caprine and ovine; primarily in the US, Canada, Argentina, Brazil and Australia but possibly also in other third countries. The number of clones is not known but should be relatively low in view of the high costs and low success rate of the technology (source: consultant's study and Commission questionnaire- details in Annex III).

- *Objective 2:* To protect consumer interests as regards food from cloned animals;
- *Objective 3:* To safeguard the competitiveness of farmers, breeders and food businesses in the EU.

4. POLICY OPTIONS

In light of the issues and objectives outlined above, 4 options were analysed:

Option 1: no policy change.

Summary of the option

- *Food: pre-market approval (PMA) for food from clones under existing Novel Food Regulation - Cloning technique: Member States address concerns by implementing Directive 98/58/EC.*

This option appears to have the lowest economic impact of all options but does only partially address consumer concerns and animal welfare. It incurs costs for food business operators (FBOs)⁴ if they were to apply for a marketing authorisation. No request for authorisation has ever been filed and therefore no food from clones has been marketed so far in the EU.

If such authorisation would be granted mandatory labelling of food from clones and prerequisite tracing could be required for the product authorised. However, in view of the aforementioned EFSA opinions, it is doubtful whether an authorisation could be refused. Moreover, this option carries the risk that Member States address animal welfare concerns with potentially diverging national legislation supplementing Directive 98/58/EC. Finally, as this option covers only the cloning technique, farmers and breeders could still import cloned animals.

Option 2: Pre-market approval (PMA) of food from clones, food from offspring and descendants⁵.

Summary of the option

- *Food: PMA for food from clones, their offspring and descendants*
- *Cloning technique: Member States address concerns by implementing Directive 98/58/EC.*
- *Traceability : systems needed for the live animals, reproductive material and the derived food.*

The costs for FBOs to obtain PMA would be considerably higher, as more food would be covered by this option. Moreover, FBOs would have to be able to distinguish food from clones, offspring or descendants, by linking it to an individual animal, and to a valid

⁴ Estimated up to 400.000 € and where the application is referred to EFSA for an opinion, additional 83 000 € per application for Novel Food to be borne by the EU budget.

⁵ This option was supported - for food from clones and offspring (1st generation) - by unanimity by the Council in first reading during the inter-institutional discussions on the Novel Food. As the offspring and the following generations present exactly the same characteristics (produced with traditional breeding techniques), it is appropriate for sake of coherence and completeness that this option also includes food of the following descendants of clones.

authorisation⁶. Regarding the impacts of identification and traceability, reference is made to option 3. This would hardly be possible for importers and their third country suppliers. Food prices are likely to increase due to additional compliance costs.

Option 3: labelling of food (from clones, offspring and descendants)

Summary description of the option

- food obtained from (i) clones, or from (ii) offspring or (iii) from descendants;
- labelling could be (iii) voluntary or (iv) mandatory.

This option requires, as pre-requisite, identification and traceability of cloned animals, their reproductive material and of food obtained thereof. To ensure the labelling is correct, it is necessary to create a documented link between a food and the animal (animal clone, the offspring, the descendant).

Regarding identification of animals, Union operators are already obliged under Union legislation⁷ to identify individual animals of most species. The costs and feasibility of traceability of animals, their reproductive material and of the food depend largely on the scope of the measure.

Tracing food from *cloned animals* would concern only a very low number of animals in the EU.

Conversely, tracing food to offspring and descendants would affect much more food and a much higher number of animals in the EU. Moreover, it would imply identifying and tracing the individual animals descending from clones as well as their reproductive material. This is more costly with every generation between the clone, the animal (be it offspring or descendant), the reproductive material and the food.

The traceability requirements for food to an individual animal and for animals across generations would have significant impacts on the EU food supply chain. Operators would need - throughout their operations - to be able to recognise whether every food is derived or not from progeny of clones. This would incur considerable costs.

Segregation of the food chain between “clone/progeny” and “non-clone/progeny” may limit implementation costs in terms of traceability. Yet such segregation would cause considerable market disruption, since all food business operators would have to obtain food from specific predetermined sources.

Third countries generally do not dispose of individual animal identification systems and of national databases like the Union. In view of the costs, it is unlikely that third country operators would establish systems for the EU market only. No third country has expressed any readiness to put in place EU like identification and traceability systems. This option may therefore create major trade disruptions with the EU.

For the aforementioned reasons, farmer and industry representatives expressed themselves against labelling of food from offspring and descendants. They also underlined the risk of trade disruption.

⁶ See impacts of traceability of food from offspring and descendants in option 3 below, paragraph b) and c).

⁷ Mainly on animal health and zootechnics.

Under this option animal welfare problems are not directly addressed.

Option 4: Temporary suspension of the technique and of imports of live clones, their reproductive material and their food.

Summary description of the option

- *Food: Suspension of import of food from clones.*
- *Cloning technique: Suspension of the cloning technique in the Union and of imports of live clones and of their reproductive material.*

The impact on Union FBOs and trade is limited because trade in live clones, if any, is very limited and – as mentioned under Option 1- no food from clone has been marketed in the EU up to now. The cloning technique seems to be currently not used in the EU for food purposes. However, traditional breeding techniques use reproductive material from clones to produce offspring. Therefore, suspending the use of reproductive material of clones could jeopardize the competitiveness of the Union's farming sector as it would deprive it of competitive genetic material.

This option has a positive impact on consumers: their concerns about animal welfare will be addressed as no cloning would take place in the Union and no food from clones marketed in the Union.

This option has a positive impact on animal welfare and creates a level playing field for all farmers and breeders in the Union.

5. COMPARISON OF OPTIONS

In comparing the aforementioned policy options, and considering their impacts, it appears that option 4 (excluding the suspension of import of reproductive material) is best suited to address the objectives set out in section 3. It addresses better animal welfare concerns and consumer concerns than options 1 and 2, while avoiding the economic repercussions of options 2 and 3.

6. MONITORING AND EVALUATION

The monitoring and evaluation can be carried out through various means, namely on the basis of:

- scientific progress monitored by EFSA for option 1 and 4 (to assess whether cloning is still a breeding that causes unnecessary pain),
- the number of applications made and pre-market approvals (option 1 and option 2) to assess which food has been authorised,
- surveys at national or EU level to assess which food is labelled (option 3) on the EU market, and possible changes in consumers' attitude towards cloning (option 4),
- statistics⁸ on the number of clones/offspring/descendants raised in the EU or imported (option 3).

⁸ Eurostat, TRACES (Commission management tool for tracking the movement of animals and of products of animal origin from both outside of the EU and within EU territory).