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EU Publishes Proposals on Animal Cloning

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Report Highlights:

On December 18, 2013, the European Commission published two proposals on animal cloning, together with a new proposal for a novel foods regulation. One of the proposed animal cloning directives would ban animal cloning and marketing of cloned animals for food purposes in the EU; the second proposal would prohibit the marketing of food from cloned animals but not from its offspring. The Commission drafted these new and separate proposals on animal cloning and novel foods as result of the failed conciliation procedure in 2011 between the European Parliament and Council on the previous novel foods proposal.

EU Publishes Proposals on Animal Cloning

Executive Summary

On December 18, 2013, the European Commission published two long-awaited proposals on animal cloning, in conjunction with a new proposal for a novel foods regulation. The first proposed directive under the co-decision procedure would ban animal cloning for food purposes in the European Union (EU) and the import of cloned animals or embryos. The second proposal would ban the marketing of food, both meat and dairy, from cloned animals, but not from their offspring. Although there is currently no animal cloning for food production occurring in the EU, these proposals are consistent with risk assessments done by competent authorities in the EU and other countries' that show no differences in food safety between food products from cloned animals or their offspring and conventionally-bred animals. The Commission promised to draft these new and separate proposals on animal cloning and novel foods after a conciliation procedure between the European Parliament and Council on a novel foods proposal failed in 2011.

BACKGROUND

Currently, the EU Novel Foods Regulation from 1997 is the only EU legislation covering animal cloning. Under the Novel Foods Regulation, food “produced from non-traditional breeding techniques” (implicitly including cloning) – but not from their offspring – requires a pre-market authorization in order to be imported or sold in the EU. In January 2008, the European Commission proposed a revision of the EU’s Novel Foods Regulation to simplify the authorization procedure. Under the co-decision procedure, the Parliament and the Council proposed to add more measures for food derived from clones and offspring of clones. In March 2011, the European Parliament and Council of the European Union failed to bridge differences over the introduction of mandatory labeling requirements for all food produced from the offspring of clones. For more information on the failure of the Conciliation procedure see [GAIN report “EU Novel Foods Proposal failed to win Approval”](#). As a result, the proposed Novel Foods revision could not become law and the current Novel Foods Regulation still applies (more information on the FAS Mission to the EU’s [Novel Foods Webpage](#)).

NEW LEGISLATIVE PROPOSALS ON ANIMAL CLONING PUBLISHED

On December 18, 2013, the Commission [announced](#) three legislative proposals: 1) a [proposal on the cloning of animals of the bovine, porcine, ovine, caprine and equine species kept and reproduced for farming purpose](#); 2) a [proposal on the placing on the market of food from animal clones](#); and 3) a new proposed regulation for [novel foods](#).

The [first](#) proposal on animal cloning would ban animal cloning for food purposes in the EU for bovine, porcine, ovine, caprine and equine species, as well as imports of cloned animals and embryos. The ban on cloning would be in place for five years, after which the scientific progress on the efficacy of the cloning technique would be reassessed. This proposal for a European Parliament and Council Directive has to be adopted under the ordinary legislative procedure (co-decision). Under this procedure, both the European Parliament (EP) and Council have to reach agreement on the Commission proposal. The legal

basis for this proposal is Art. 43 of the Lisbon Treaty and refers to the Common Agricultural Policy which is normally covered by the Agriculture (AGRI) Committee in the EP.

The [second proposal](#) (banning the marketing of food, i.e. meat and dairy products from cloned animals in the EU) is a Council directive under the consent procedure (legal basis: Article 352(1) of the Lisbon Treaty), which allows the EP the right to oppose the proposal, but not to amend it. However, without the EP's consent, the Council cannot adopt it and the Council must also act unanimously on this proposal. This is a proposal for a Council Directive to be adopted under the consent procedure.

The proposed legal instrument for both proposals is a directive. Unlike a regulation, which is binding in its entirety and automatically enters into force on a set date throughout the EU, Member States have to transpose the rules set out in a directive into national legislation. The objective of the proposed rules is the same for all Member States (MS) but how and when the MS will implement the directives can vary. According to the explanatory memorandum that accompanies both proposals, a directive “allows Member States to employ existing control tools as appropriate for the implementation of Union rules and thus to limit the administrative burden”.

Neither of the proposed cloning directives would cover offspring from cloned animals, nor products derived from their offspring. In a [press release](#), Health Commissioner Borg explained that labeling for fresh meat from offspring of cloned animals could be required at a later date, pending a feasibility study report from DG AGRI on the consequences of labeling for both the EU domestic meat market and meat imports. Because of the expected length of time necessary for the legislative approval procedure, it is unlikely that this draft legislation will be implemented before 2016 at the earliest. DG SANCO has a [webpage on animal cloning and novel foods, as well as](#) the [Impact Assessment](#), and a [FAQ document](#), among other related documents.

For more information on the EU decision-making procedures, see GAIN report [“Adopting EU Framework Legislation on Cloning – How does it work?”](#) This report explains the different stages and key actors in the development of new framework legislation on animal cloning for food production, from the Impact Assessment to the final phase of the ordinary legislative procedure.

Timeline

December 18, 2013: Commission proposals on animal cloning for food production:

- The [first proposal](#) would ban animal cloning for food purposes in the EU, as well as imports of cloned animals and embryos.
- The [second proposal](#) would ban the marketing of food, i.e. meat and dairy products from cloned animals in the EU.

The [Impact Assessment](#), on which these proposals are based, was published simultaneously. [Public consultation](#) closed on September 3, 2012

July 2012: [Update of the European Food Safety Authority's \(EFSA\) scientific opinion “Roadmap”](#) published in February 2012

ANIMAL CLONING RISK ASSESSMENTS

In January 2008, the U.S. Food and Drug Administration (FDA) released a final risk assessment in which it concludes that meat and milk from cow, pig, and goat clones and the offspring of any animal clones are as safe as food from conventionally bred animals. FDA's risk assessment and other information on animal cloning can be downloaded from their website at www.fda.gov/cvm/cloning.htm.

In July 2008, the European Food Safety Authority (EFSA) published its [final scientific opinion](#) on the implications of animal cloning. EFSA states that there is no indication that differences exist in terms of food safety between food products from healthy cattle and pig clones and their progeny, compared with those from healthy conventionally-bred animals. In September 2010, EFSA published a [further statement](#) on animal cloning following the endorsement of its Scientific Committee. The Scientific Committee concurred that no new scientific information had become available that required EFSA to reconsider its previous conclusions and recommendations.

In December 2011, the Commission requested a [further update from EFSA](#) regarding the status of cloning of farmed animals for food production purposes. On July 5, 2012, EFSA published an [update of its scientific statement](#) reiterating its earlier findings: with respect to food safety, there are no indications that food products derived from healthy clones or their offspring are different from those of healthy conventionally bred animals. There are also no scientific indications that animal cloning presents a greater risk to genetic diversity, biodiversity, or the environment than conventionally bred animals.