Placing on the market of food from animal clones

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PURPOSE: to establish rules on the placing on the market of food from animal clones.

PROPOSED ACT: Directive of the European Parliament and of the Council.

ROLE OF THE EUROPEAN PARLIAMENT: Council may adopt the act only if Parliament has given its consent to the act.

BACKGROUND: food from animal clones, as food derived from a new reproduction technique, falls within the scope of the Regulation (EC) No 258/97 of the European Parliament and the

Council and is thus subject to pre-market approval.

In 2008, the Commission presented a proposal to streamline the approval process in the Novel Food Regulation. In the legislative procedure lawmakers aimed to amend the proposal to introduce specific rules on cloning. Yet no agreement was reached on the scope and features of these insertions so that the proposal was not adopted by the co-legislators after the Conciliation failed 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.

In 2008, the **European Food Safety Authority (EFSA)** delivered an opinion on cloning. It focused on animal clones, their progeny and of the products obtained from those animals. This opinion was up-dated by three statements in 2009, 2010 and 2012. Based on the available data EFSA saw animal welfare problems related to the health of surrogate mothers (carrying the clones) and the clones themselves.

The majority of Union **citizens** disapprove of cloning for food production due to animal welfare and general ethical concerns. They do not want to consume food from animal clones.

In order to address consumer perceptions on cloning linked to animal welfare concerns, the Commission considers it necessary to ensure that food from animal clones does not enter the food chain.

IMPACT ASSESSMENT: the option calling for a temporary suspension of the placing on the market of food from clones was retained as the basis of the present proposal.

CONTENT: the proposed Directive provides that the Member States should ensure that **food from animal clones does not enter the food chain**.

Animal cloning is allowed in certain third countries. For example, Argentina, Australia, Brazil, Canada, and the United States confirmed that animals are cloned on their territory but could not indicate to what extent. Therefore, **measures should be taken to avoid the import into the Union of food obtained from animal clones produced in those third countries**.

Member States shall lay down the rules on **penalties** applicable to infringements of the national provisions adopted pursuant to this Directive.

The measures laid down in this act should be **reviewed** within a reasonable period of time (by 5 years after the date of transposition of this Directive) to evaluate whether they adequately address the objectives

pursued by it taking into account the experience gained by the Member States in the application of this Directive, consumer perceptions on cloning linked to animal welfare concerns and international developments.