EUROPEAN COMMISSION

MEMO

Brussels, 18 December 2013

FAQ: Commission tables proposals on animal cloning and novel food

ANIMAL CLONING

1) What is cloning?

Cloning animals means creating animals by using the genetic material from a cell from another animal. It is a form of asexual reproduction performed in a laboratory. The closest natural analogy to a clone is identical twins. As identical twins, clones and cell donor animals share exactly the same genetic inforamtion (DNA).

Yet cloning is not like photocopying. In practice the nucleus of normal body cell, e.g. from the ear, is transferred into an egg (oocyte) from another animal from which the nucleus has been removed. The manipulated oocyte is implanted into a surrogate mother who will - if everything goes well - give birth to the clone. The clone will eventually develop into an adult animal.

2) Why is cloning important?

Currently, cloning is used for research purposes in the EU. Cloning may be used to multiply animals which have shown important traits, like higher milk yields or better adaptation to demanding environmental conditions. Even if cloning were to be more widely used, this would rather be to reproduce high-value, elite animals such as top-performing breeding animals and/or endangered species.

In the farming sector elite animals are cloned because their reproductive material (semen, ova, and embryos) bears a high commercial value. Cloning allows the production of higher quantities of reproductive material with the genes of the elite animals. Hence clones are used as breeding animals whose offspring is conceived naturally or via artificial insemination.

It is important to underline that, for the moment, cloning is so expensive that its use for food production is not lucrative.

3) What is the difference between cloning and genetic modification?

Cloning does not involve any genetic modification. In fact, the clone is a near exact genetic copy of the donor animal.

4) Where is cloning carried out?

Australia, Argentina, Brazil, Canada, Japan and United States, confirmed that animals are cloned on their territory but could not indicate to what extent. In the United States, Canada and Brazil clones are registered by private companies. In Canada, the legal situation on cloning is similar to that in the EU, i.e. food produced from cloned animals is considered novel and requires pre-market approval.

5) Does cloning impact on animal welfare?

The European Food Safety Authority (EFSA) has confirmed that surrogate dams used in cloning suffer in particular from placenta dysfunctions contributing to increased levels of miscarriages. This contributes, amongst other things, to the low efficiency of the technique, 6 to 15 % for bovine and 6 % for porcine species, and the need to implant embryo clones into several dams to obtain one clone. In addition, clone abnormalities and unusually large offspring result in difficult births and neonatal deaths.

6) Is food from clones or food derived from their off-spring safe to eat?

According to EFSA's opinion there is no indication that differences exist in terms of food safety between food products from healthy cattle and pig clones and their off-spring, compared with those from healthy conventionally-bred animals. No relevant data was available for other species, i.e. horses, sheep and goats. Yet EFSA presumed that the results for these species would be similar.

7) Is cloning ethical?

The European Group on Ethics in Science and New Technologies (EGE) in 2008[1] expressed doubts that animal cloning for food production purposes can be justified: "considering the current level of suffering and health problems of surrogate dams and animal clones". The EGE also concluded that it did "not see convincing arguments to justify the production of food from clones and their offspring". –THIS TEXT IS ALSO IN OUR LEGISLATIVE PROPOSAL.

According to Eurobarometer studies, the majority of EU citizens disapprove the use of cloning for food production on animal welfare and general ethical grounds. They do not want to eat food from animal clones.

8) Why is the Commission adopting new rules now?

In 2008, the Commission presented a proposal to amend the Novel Food Regulation. The co-legislative procedure discussions provoked a debate on the introduction of specific rules on cloning which went beyond the scope of the Novel Food Regulation. No agreement was reached between the European Parliament and the Council. As a result, the Commission was asked to prepare a separate legislative proposal on cloning in food production based on an impact assessment. This issue has been in the work programme of the Commission in 2012 and 2013.

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[1] Ethical aspects of animal cloning for food supply 16 January 2008: http://ec.europa.eu/bepa/european-group-ethics/docs/publications/opinion23_en.pdf

9) What is "preliminary" prohibition?

The prohibitions should only apply on a provisional basis since the technique is likely to develop and would therefore need to be reviewed. Such review should take into account the experience gained by Member States in implementing the measures, scientific and technical progress and international developments.

10) What will be the impact on the farming, food and research sectors?

The proposals will not restrict cloning for uses other than farming such as research, conservation of rare breeds and endangered species or use of animals for the production of pharmaceuticals and medical devices.

11) Will negotiations with trading partners be affected?

The proposals intend to prohibit the marketing of clones or food for human consumption. It is not likely that such measures will have a high trade impact however the issue at stake relates more to the animal welfare concerns which need to be addressed at the EU level.

12) How is cloning linked to the Novel Food Regulation?

Since animal cloning is a new technique in food production, food derived from animal clones falls currently under the scope of the Novel Food Regulation.

13) Why did the Commission propose Directives and not Regulations?

Directives are binding, as to the result to be achieved, upon all of the Member States to whom they are addressed, but leave to the national authorities the choice of form and methods. Directives give Member States certain flexibility by allowing them to integrate measures on cloning into existing national implementing instruments e.g. Directives concerned with animal testing, zootechnics and clinical trials. Member States can therefore employ existing control tools as appropriate for the implementation of EU rules. This approach limits the administrative burden.

14) Why will the food from offspring not be labelled?

The Commission considered labelling of food from clones, their offspring and descendants. Labelling requires confidence that its content is correct. To ensure this, it is necessary to create a documented link between a food and the animal/animal clone. This requires that parentage information for every food producing animal is conveyed through the food production chain. This becomes more complicated and therefore costly with every generation between the clone and the animal, reproductive material and the food. Breeders, farmers and importers and ultimately consumers would have to bear these additional costs. For official controls, checking the accuracy of statements on labels would require in particular for food from offspring and descendant meticulous investigation into the accompanying documentation and thus bind considerable resources. The impact of labelling would therefore be disproportionate to the objective and cannot be justified.

NOVEL FOOD

15) What is a novel food?

Novel Food is defined as food not consumed to any significant degree in the EU prior to May 1997 (when the first Novel Food legislation entered into force). This can be newly developed, innovative food or food produced using new technologies and production processes as well as food traditionally eaten outside of the EU.

16) Has novel food been authorised in the EU?

Up until the beginning of December 2013, there have been around 150 applications (7-10 applications/year). So far around 70 novel foods have been authorised for use in the EU. Authorised novel food include products traditionally eaten in non-EU countries such as "noni juice" (made from a Tahitian plant), and food produced using the latest technological innovations such as oils and dairy products enriched with phytosterols/phytostanols to reduce cholesterol. Other examples include "salatrim" a reduced-energy fat, DHA-rich oil, a high-pressure fruit juice (which is an example of a food derived from new production processes).

For a full list of authorised novel food:
http://ec.europa.eu/food/food/biotechnology/novelfood/authorisations_en.htm

17) Why is the Commission revising the legislation on novel food?

Following a 2008 impact assessment, it appeared that the current provisions for novel food needed to be updated, in line with new technological developments and scientific advice and with the objective to reduce the considerable length (3 ½ years in average) for the authorisation procedure. A previous revision was proposed by the Commission back in 2008, but its final adoption by the Council and the European Parliament failed because of the cloning issue.

The aim of today's proposal is to increase the efficiency of the authorisation procedure, enable a quicker delivery of safe, innovative food on the market and remove unnecessary barriers to trade, whilst ensuring a high level of food safety.

18) What are the main changes being introduced?

The proposed Regulation creates a centralised authorisation system, which will allow greater certainty for applicants seeking authorisation for a novel food and will simplify and speed up the authorisation process.

EFSA will perform the risk assessment for the novel food application, while the Commission will manage the files of each applicant, putting forward a proposal for the authorisation of novel food which is found to be safe.

To remove any barriers to trade caused by the long authorisation process for traditional food from non-EU countries, the proposal also introduces a more appropriate assessment procedure for food new to the EU. If the history of safe use of the food in a non-EU country can be demonstrated, and there are no safety objections from Member States or EFSA, the

food will be allowed to be placed on the market on the basis of a notification from the food business operator in the non-EU country.

Data protection provisions are also included in the proposal. Newly developed scientific evidence and proprietary data will not be allowed to be used for the benefit of another application for 5 years after the novel food has been authorised.

19) What are the requirements for a novel food to be authorised for use in the EU?

Novel food will only be approved for use in the EU if they do not present a risk to public health, are not nutritionally disadvantageous when replacing a similar food and are not misleading to the consumer. They must undergo a scientific assessment prior to authorisation to ensure their safety. The authorisation sets out, as appropriate, the conditions for their use, their designation as a food/food ingredient and labelling requirements.

20) What are the labelling requirements for novel food?

Novel food is subject to the general labelling requirements (Directive 2000/13/EC). Specific additional requirements for the labelling of novel food may also apply, if necessary to properly inform the consumer. The label must mention the name of the food, and, where appropriate, specify the conditions of use. Any nutrition and health claim should only be made in accordance with the Health and Nutrition Claims Regulation 1924/2006 (see MEMO/06/200).

21) What are the requirements for nanomaterial?

Nanomaterial is materials engineered at the scale of atoms and molecules. The proposal specifies that engineered nanomaterials, as defined in the Regulation on Food Information to Consumers, require a Novel Food authorisation before being used in foodstuffs. This confirms that nanomaterial's are covered by the Novel Food Regulation.

22) Will the proposal affect innovation in the food sector?

The aim of the proposal is to make the authorisation procedure for novel food simpler, faster and more efficient, so that innovate food which is safe to consume can be put on the market within short delays. Moreover, the data protection provisions will help to protect the interests of companies which produce new, innovative products, and should help to encourage innovation in the food sector.

23) Are there any novel food applications in the pipeline?

Over recent years, there have been around 7-10 applications per year for novel food authorisations across the EU. Examples of recent authorisations include rooster comb extract (which has a high hyaluronic acid content) or chia seeds (commonly used in the South America).

24) Can Member States ban/approve a novel food independently of the EU?

No. The Novel Food Regulation lays down harmonised measures for the authorisation of novel food, which means that once a foodstuff is approved for marketing in the EU, it can be sold in any Member State. However, a Member State can suspend or provisionally restrict the marketing and use of any novel food if they believe it to constitute a health hazard according to the safeguard provisions of the General Food Law (Regulation (EC) No 178/2002). The Member State authorities must inform the Commission, which then carries out an investigation into the protective measure of the Member State. If a food is found to pose any risk to consumers, the Commission can immediately suspend its authorisation for marketing in the EU.