Food

This section aims at updating readers on the latest developments of risk-related aspects of food law at the EU level, giving information on legislation and case law on various matters, such as food safety, new diseases, animal health and welfare and food labelling.

European Commission Proposes to Revise the EU's Legislative Framework on Novel Foods and Animal Cloning

*Ignacio Carreño**

I. Introduction

On 18 December 2013, the European Commission adopted a package of three proposals to revise the EU's legislative framework on novel foods. The package consists of a proposal for a *Regulation of the European Parliament and of the Council on novel foods*,[1] a 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*[2] and a proposal for a *Council Directive on the placing on the market of food from clones*.[3]

II. Background

Novel food is food which was not consumed in the EU to a significant degree before May 1997 when *Regulation No. (EC) 258/97 on novel foods and novel food ingredients* entered into force. This can be newly developed, innovative food or food produced using new technologies and production processes, as well as food traditionally consumed outside of the EU. So far, only around 70 novel foods have been authorised for use in the EU in 17 years, including '*noni juice*' (made from a Tahitian plant),[4] food produced using the latest technological innovations such as oils[5] and dairy products[6] enriched with phytosterols/phytostanols to reduce cholesterol, '*salatrim*' (a reduced-energy fat),[7] DHA-rich oil,[8] a high-pressure fruit juice,[9] baobab dried fruit pulp,[10] and chia seeds (commonly used in the South America).[11]

In 2008, the European Commission presented a proposal to amend Regulation No. (EC) 258/97, which was to be adopted in the co-legislative procedure by the European Parliament and the Council. The legislative discussions focused mainly on the provisions

* Senior Associate, FratiniVergano, Brussels. An earlier version of this article has been previously published in TradePerspectives, Issue number 4, 21 February 2014, Available on the Internet at: http://www.fratinivergano.eu/TradePerspectives.html, (last accessed on 7 October 2014).

1 COM(2013) 894 final.

2 COM(2013) 892 final

3 COM(2013) 893 final.

4 Commission Decision 2003/426/EC authorising the placing on the market of '*noni juice*', OJ 2003 L144/12.

5 Commission Decision 2007/343/EC of 15 May 2007 authorising the placing on the market of oil enriched with phytosterols/phytostanols as a novel food ingredient under Regulation (EC) No. 258/97 of the European Parliament and of the Council, OJ 2007 L 129/63.

6 Commission Decision 2004/845/EC of 12 November 2004 on authorising the placing on the market of milk based beverages with added phytosterols/phytostanols as novel foods or novel food ingredients, OJ 2004 L 366/14.

7 Commission Decision 2003/867/EC authorising the placing on the market of salatrim as a novel food ingredient, OJ 2003 L326/32.

8 Commission Decision 2003/427/EC authorising the placing on the market of oil rich in DHA, OJ 2003 L144/13.

9 Commission Decision 2001/424/EC of 23 May 2001 authorising the placing on the market of pasteurised fruitbased preparations using high pressure pasteurisation under Regulation (EC) No. 258/97 of the European Parliament and of the Council, OJ 2001 L151/42.

10 Commission Decision 2008/575/EC authorising the placing on the market of Baobab dried fruit pulp as a novel food ingredient, OJ 2008 L183/38.

11 Commission Implementing Decision 2013/50/EU authorising an extension of use of Chia (*Salvia hispanica*) seed as a novel food ingredient under Regulation (EC) No. 258/97 of the European Parliament and of the Council, OJ 2013 L21/34.

applicable to nanomaterials, the cloning of animals for food production, traditional foods from third countries, the criteria to be examined for risk assessment and risk management, and to the procedure for the authorisation of novel foods. The discussions reached a stalemate on a limited number of issues (in particular those linked to the cloning of animals). No agreement could be reached between the European Parliament and the EU Member States represented in the Council on any of the issues linked to cloning. A conciliation procedure failed on 28 March 2011.[12] Following this failure, the European Commission was asked to prepare new proposals.

III. Comment

Authorisation and use of novel foods and food ingredients have been harmonised in the EU since 1997 when Regulation (EC) No. 258/97 was adopted. Currently, an application for the pre-market authorisation of a novel food is first considered by a food assessment body in an EU Member State. The initial assessment report is circulated for comments and objections to all EU Member States by the European Commission. If no reasoned safety objections are presented, the novel food may be placed on the market. If reasoned safety objections are presented, an authorisation decision is required by the European Commission. In most cases, this includes an additional assessment, which is carried out by the European Food Safety Authority (hereinafter, the EFSA). The authorisation under current rules is granted to the applicant (individual authorisation). In addition, another applicant may notify to EU Commission of the placing on the market of a food that is substantially equivalent to the authorised food. This notification has to be substantiated by scientific evidence showing the substantial equivalence of the notified food to the authorised food.

The principle aim of the proposal on novel foods is to increase the efficiency of the authorisation procedure. The proposed Regulation establishes a centralised authorisation procedure, which will allow greater certainty to applicants seeking authorisation for a novel food and will simplify and reduce the considerable length (three and a half years on average) for the authorisation procedure. The EFSA will perform the risk assessment for the novel food application. According to the proposal on novel foods, engineered nanomaterials (*i.e.*, materials engineered at the scale of atoms and molecules) require a novel food authorisation before being used in foodstuffs. To remove any barriers to trade caused by the lengthy authorisation process for traditional food from non-EU countries, the proposal introduces a new assessment procedure for food that is new to the EU. If the history of safe use of the food in a non-EU country is demonstrated, and there are no safety objections from EU Member States or the 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 five years after the novel food has been authorised.

Cloning is a relatively new technique of asexual reproduction of animals producing near exact genetic copies of the animal cloned, but without the modification of genes. Currently, food from clones falls under the scope of Regulation (EC) No. 258/97 (although no application has so far been received) and would thus be subject to a pre-market approval based on a safety risk assessment. In the legislative package on novel foods, the EU Commission adopted two draft Directives addressing animal welfare and ethical concerns related to the use of the technique. One of the proposed Directives bans the use of the cloning technique in the EU for farmed animals (*i.e.*, bovine, porcine, ovine, caprine and equine) and bans imports into the EU of these cloned animals. The other proposed Directive bans the marketing of food, such as meat or milk from animal clones from being placed on the EU market. However, cloning will be allowed for purposes such as research, conservation of rare breeds and endangered species or for use in the production of pharmaceuticals and medical devices, where the technique can be justified. The 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*

12 For more background see Trade Perspectives, Issue No. 5 of 10 March 2011 and Issue No. 10 of 20 May 2011, available on the Internet at http://www.fratinivergano.eu/TradePerspectives.html,(last accessed on 7 October 2014).

species, and the need to implant embryo clones into several dams to obtain one clone".[13] In addition, "*clone abnormalities and unusually large offspring result in difficult births and neonatal deaths*".[14] In other words, EFSA views cloning primarily as an '*animal welfare hazard*' related to the low efficiency of the technique. Taking into account the objectives of the EU's agricultural policy, the results of the recent scientific assessments by the EFSA and the animal welfare requirement provided in Article 13 of the EU Treaty, the European Commission considers that it is, therefore, prudent to provisionally prohibit the use of cloning in animal production for farm purposes of certain species. Thus, under the proposed new legislative framework, no cloning for farming purposes will be carried out in the EU and no such clone will be imported as long as animal welfare concerns persist.

The European Commission's proposals to ban the farming of cloned animals and the sale of their meat were already criticised by Members of the European Parliament, which argue that the EU should take tougher action to prevent cloning.[15] On the other hand, although the European Commission argues that the proposals intending to prohibit the marketing of clones or derived food for human consumption are not likely to have a high impact on trade, as the issue at stake relates more to the animal welfare concerns, which need to be addressed at EU level, the proposed measures could cause significant trade distortions of agricultural exports (*i.e.*, beef) from countries such as Argentina, Australia, Brazil, Canada, and the US. In consultations carried-out with interested parties, some countries confirmed to the European Commission that animals are cloned in their territories. Furthermore, the draft Directive on the placing on the market of products from clones does not appear to address the issue of products from the offspring of clones and possible labelling requirements.

A ban on imports of any food of animal origin (*i.e.*, meat, milk and processed products) from third countries where cloning technology exists, or which may have imported reproductive material from clones, may conflict with a number of WTO obligations, such as the prohibition on quantitative restrictions established in Article XI of the GATT and the obligations in Article 2 of the SPS Agreement to apply a sanitary measure only to the extent necessary to protect human or animal health, only if based on sufficient scientific evidence, and not in a manner which would constitute a disguised restriction on international trade. In the above-mentioned consultations with the EU, trade officials from Argentina, Australia, Brazil, Canada, New Zealand, Paraguay and the US pointed out that SPS measures should be science-based.

The EU measures may contravene Article 5.1 of the SPS Agreement, which requires that an SPS measure be based on an appropriate assessment of the risks to human or animal life or health. On the other hand, the EU appears to argue that its restrictive measures are necessary on the basis of the precautionary principle in Article 5.7 of the SPS Agreement, and under some of the general exceptions found in Article XX of the GATT, such as the public morals exception of Article XX(a) and the exception for human and animal health of Article XX(b).

IV. Conclusion

The proposals on novel foods and animal cloning are still at an early stage of the legislative procedure. The European Parliament and the Council will consider the Commission's draft legislation under the ordinary legislative procedure (*i.e.*, the former co-decision procedure). At this stage, the Commission estimates that the draft legislation will enter into force in 2016 at the earliest. The European Parliament's Environment, Public Health and Food Safety Committee has yet to give its opinions. The extent to which WTO law may allow future EU measures on animal cloning to be justified on such grounds will depend on the actual context, design and effect of the EU measures, and may ultimately need to be assessed under the WTO dispute settlement mechanism. While the proposed regulation on novel foods does not appear to be conflictive, the proposed measures on cloning may

13 Food safety, animal health and welfare and environmental impact of animals derived from cloning by SCNT and their offspring and products obtained from those animals. Opinion and statements are available on the Internet at http://www.efsa.europa.eu/en/efsajournal/doc/767.pdf; http://www.efsa.europa.eu/en/efsajournal/doc/319r.pdf; http://www.efsa.europa.eu/en/efsajournal/doc/1784.pdf; and http://www.efsa.europa.eu/en/efsajournal/doc/2794.pdf (last accessed on 7 October 2014).

14 *Supra*.

15 David Haworth, MEPS attack Commission's animal cloning proposals as too weak, Global meat news of 24 February 2014. Available on the Internet at http://www.globalmeatnews.com/Industry-Markets/MEPS-attack-Commission-s-animal-cloning-proposals-as-too-weak (last accessed on 7 October 2014).

be. Interested parties should closely monitor the next steps taken by the EU Institutions and be prepared to participate in shaping the upcoming EU legislation by interacting with EU Institutions, their own Governments, relevant trade associations and affected stakeholders.