FRATINIVERGANO
EUROPEAN LAWYERS
TRADE PERSPECTIVES©

Issue No. 5 of 6 March 2015

Animal cloning and animal welfare: will EU draft rules make their way to the WTO?

On 23 February 2015, the EU Parliament's Committee on the Environment, Public Health and Food Safety (*i.e.*, the ENVI Committee) and the Committee on Agriculture and Rural Development (*i.e.*, the AGRI Committee) held a joint public hearing on the issue of cloning of animals for farming purposes. The hearing aimed at exchanging views on relevant issues related to the EU Commission's proposals on the cloning of animals for food purposes.

In December 2013, the EU Commission tabled a package of three proposals affecting the legislative framework on novel foods and animal cloning (*i.e.*, *Proposal for a Regulation of the European Parliament and of the Council on novel foods*; *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 clones*). These drafts were adopted following the failure of a 2008 proposal, which had sought to amend the novel foods regime and that, *inter alia*, envisaged specific rules on food from cloned animals (but not from their offspring). After EU Institutions failed to reach an agreement, the EU Commission put forward draft instruments addressing the issues at stake (*i.e.*, novel foods, the cloning of animals, and the placing of food from animal clones on the market) separately (see Trade Perspectives, Issue No. 4 of 21 February 2014). The three relevant proposals are currently being examined by the EU Parliament in the context of their respective legislative procedures. While the novel foods proposal was examined by the ENVI Committee in December 2014, the two other drafts (on cloning and on the placing of food from clones on the EU market) have not yet completed the committee stage.

Cloning is a relatively new technique of asexual reproduction of animals producing near exact genetic copies of the animal cloned (*i.e.*, without modification of genes). Under the current framework, food from clones is considered a novel food in the EU and is, therefore, subject to pre-market approval based on a food safety risk assessment. In relevant part, the EU Commission's proposal on animal cloning envisages a suspension (*i.e.*, a temporary prohibition) of the use of cloning for farmed animals (*i.e.*, of the bovine, porcine, ovine, caprine and equine species) and of imports into the EU of cloned animals or embryos. This is complemented by the other draft directive, which temporarily bans the marketing of food from animal clones. However, cloning will be allowed for research and other purposes, where the technique can be justified. As noted by the ENVI Committee, these proposals do not address the offspring of cloned animals and food derived therefrom. On this point, the EU Commission

indicated that, given the complexity and associated costs of implementing a labelling and traceability scheme, it is presently conducting a feasibility study that should be completed in October 2015.

According to the EU Commission, the regime envisaged in these proposals addresses consumer concerns linked to animal welfare, where cloning has no impact on the safety or quality of the food, but implies animal suffering. In addition, the EU Commission acknowledged that a majority of EU consumers disapproves cloning as a food production technique due to general ethical concerns. In 2012, the European Food Safety Authority (*i.e.*, EFSA) confirmed previous findings indicating that, while there are no differences in food safety between meat and milk from clones or their progeny and those from traditionally bred animals, there are animal health and welfare concerns associated with this technology, both affecting surrogate mothers and the clones themselves.

In formulating its approach to cloning and the status of food obtained from cloned animals, the EU must be conscious of its international obligations, including under the WTO. The draft measures envisage a temporary import ban that the EU appears to primarily justify on grounds of animal welfare, while consumers' general ethical concerns and food safety appear to be quasi irrelevant. In this sense, and in the context of a potential WTO challenge, the EU's regime could be assessed against the WTO Agreement on Technical Barriers to Trade (hereinafter, TBT Agreement). Should it be established that the EU's measures qualify as a '*technical regulation*' within the meaning of the TBT Agreement, they would be subject to the requirement that they "*not be more trade-restrictive than necessary to fulfil a legitimate objective*". Although none of the examples of '*legitimate objectives*' mentioned in the relevant provision (*i.e.*, Article 2.2 of the TBT Agreement) appear to immediately refer to animal welfare, the non-exhaustive nature of such list should not be disregarded.

In addition, any measure will need to be in accordance with the General Agreement on Tariffs and Trade (*i.e.*, GATT), including with the prohibition of quantitative restrictions envisaged in Article XI thereof. Under this framework, it appears that the EU could shield behind Article XX of the GATT, which provides for exceptions on grounds of, *inter alia*, public morals (paragraph (a) of Article XX of the GATT). In the *EC – Seal products* WTO dispute, the Appellate Body agreed with the panel that the EU's relevant measures were provisionally justified under Article XX(a) of the GATT, although it found that they were not in line with the *chapeau* (which requires that measures not be applied in a manner that would constitute "*a means of arbitrary or unjustifiable discrimination*" or "*a disguised restriction on international trade*") and, therefore, that the EU's measures were not ultimately justified (see Trade Perspectives, Issue No. 11 of 30 May 2014). Despite the absence of '*stare decisis*' in the WTO's dispute settlement system, these findings could arguably help the EU justify its measures in the context of a potential dispute, inasmuch as they appear to recognise that animal welfare concerns can be moral in nature and, therefore, that measures catering to such concerns can be justified under Article XX(a) of the GATT.

It appears that the developments linked to the ongoing legislative procedures could have some bearing on the EU's bilateral trade negotiations with the US, where meat and milk from the offspring of cloned animals are marketed and are not subject to any specific labelling requirement. Voices have called for the two trading partners to agree on a traceability and labelling scheme, which would allow for food from the offspring of clones to be marketed, while safeguarding consumer concerns. However, it is clear that any such mechanism would require detailed tracing of all generations of offspring, which, as noted by the EU Commission, would lead to substantive burdens and costs. While the EU Commission's study on this matter is being conducted, and while bilateral negotiations between the EU and the US are ongoing, companies operating in the concerned sectors are advised to remain vigilant and to maintain fluent communications with the relevant authorities, in order to ensure that their commercial interests be taken into account in all the necessary instances.

The scope of geographical indications under international law and their proper recognition under international trade agreements

On 24 February 2015, the EU Commission published its "*Report of the Eighth Round of Negotiations for the Transatlantic Trade and Investment Partnership*" (hereinafter, the Report). According to the Report, the provisions on the protection of "*geographical indications*" (hereinafter, GIs) was one issue addressed during the most recent negotiation round for the Transatlantic Trade and Investment Partnership (hereinafter, TTIP) between the EU and the US, although the US remained non-committal to their inclusion in the TTIP. Classic examples of GIs, as they are currently applied, include "*Parmigiano Reggiano*" cheese and "*Prosciutto di Parma*" ham. Under the protections afforded to GIs in most countries, the use of these terms is limited, in the examples above, to producers from specific regions of Italy that use certain processing techniques. However, many businesses in the EU are also harmed by competitors that, instead of using specific protected terms, include on their product labels or marketing material images of famous European landmarks, letters and symbols, general terms or proper names associated to European heritage and colour schemes or images of flags from certain European countries. In the context of international trade agreement negotiations, the legal history and recognition of protections against these practices supports the inclusion of provisions limiting their use in the TTIP.

The term "*geographical indications*" emerged, within the context of the WTO, in the Agreement on Trade-Related Aspects of Intellectual Property Rights of 1994 (hereinafter, TRIPs Agreement). A standard level of protection for GIs for all products is found in Article 22 thereof, where the concept is defined as "*indications which identify a good as originating in the territory of a Member, or a region or locality in that territory, where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin*". The definition of GIs used in the TRIPs Agreement merged the legal concepts of "*indications of source*" and "*appellations of origin*". The former appears in the Paris Convention for the Protection of Industrial Property of 1883, while the latter appears in the Madrid Agreement for the Repression of False or Deceptive Indications of Source on Goods of 1891 and the Lisbon Agreement for the Protection of Appellations of Origin of 1958. When the three concepts are considered together, "*indications of source*" cover the broadest area because they only require that the product on which the indication of source is used originate in a certain geographical area. For example, a reference that does not imply a particular quality, reputation or characteristic of those products would be an indication of source, but not a GI. However, GIs still cover a broader range of references than appellations of origin because appellations of origin require the specific use of a geographic name. As a result, the protections afforded to GIs under the TRIPs Agreement include indications other than specific text, such as letters, general text, symbols, images or colours that imply a particular country or place of origin. Nonetheless, in practice, it appears that such an interpretation is rarely, if ever, enforced.

In large part, it appears that the failure to properly prevent the use of such misleading letters, general text, symbols, images or colours is due to the legal approaches adopted in relation to the concept of GIs. Whereas, under the text of the TRIPs Agreement, GIs are the violations that must be prevented, the legal approaches adopted by countries have turned GIs into the protected term or product. This distinction is important because it creates a situation where, in order to protect the products, processes, or regional reputations associated to some foods, there must first be a relevant name or phrase to register with the domestic government. In the EU, the protection of GIs falls under the scope of *Regulation (EU) No. 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs*. The regulation designates two types of GIs. First, a Protected Designation of Origin (hereinafter, PDO), which applies to foodstuffs that are

produced, processed and prepared in a given geographical area using recognised '*know-how*'. Second, a protected geographical indication (hereinafter, PGI), which indicates a link with the area in at least one of the stages of production, processing or preparation. Additionally, names that have become generic (*e.g.*, Dijon mustard) and names that conflict with the name of a plant variety or an animal breed may not be registered as GIs in the EU. In the US, GIs are recognised as a sub-category of trademarks (*i.e.*, GIs may be registered as '*collective*' or '*certification*' marks). Names that have become generic or names that have already been trademarked may not receive GI-equivalent protection in the US. This general approach is also present in the recently-signed Comprehensive Economic and Trade Agreement (hereinafter, CETA) between Canada and the EU, where, in order to be afforded GI protection, a specific term must be listed in Annex I of Chapter 22 thereof.

Significant attention is given to contradicting rulings regarding whether or not certain terms and names associated to food products are '*generic*'. A well-known example is that of Fontina cheese, which in the EU has PDO status. However, in the US, the Trademark Trial and Appeal Board of the USPTO held that "*Fontina*" was a generic name, and thus did not qualify for protection as a certification mark. Another example is that of Feta cheese made in Greece, which the EU considers a PDO. The US however, considers said name to be generic. In the CETA, the EU was able to secure protection for the term "*Feta*", albeit only against new producers, but it agreed to let those producers use terms such as "*feta-like*" or "*feta-style*". The recognition of "*Feta*" under the CETA is important because new producers in Canada cannot use Greek letters or other symbols that evoke Greece on the packaging or marketing of said "*feta-like*" or "*feta-style*" cheeses. However, this approach still falls short of preventing companies that produce generic foods produced outside of Europe from using letters, general text, symbols, images or colours that associate their foods to European countries or places. For example, the terms "*ragù*" and "*Bolognese*" are not listed in Annex I of the CETA, nor are they generally considered GIs under the currently-applied legal systems throughout the world. As a result, producers of tomato sauces in Canada are not prevented from using letters, general text, symbols, images or colours the evoke Italy on their product packaging or marketing. These types of industry practices, even when also used on foods with more generic terms such as "*pasta*" and "*tomato sauce*", deceive consumers and affect the reputation of Italian food and the yearly profits of authentic food producers in Italy.

The TTIP provides an opportunity for the EU and the US to better-protect the reputations of their regional foods and the economic interests of stakeholders on both sides of the Atlantic Ocean. With particular regard to Italian products, estimates indicate that over EUR 20 billion of food products with Italian-sounding names or images that evoke Italy are sold in North America alone each year, while only approximately EUR 3 billion worth of authentic Italian food products are exported to North America yearly. A more appropriate application of the concept of GIs, as articulated in the TRIPs Agreement, would shift the focus from the registered terms themselves to the improper use of indications that reference foreign geographical areas. It may not be practical to fully restructure the legal approaches adopted in regards to the concept of GIs, but negotiators of currently pending and future preferential trade agreements should explore strategies to better-recognise the concept of a GI. Such strategies may even incorporate other legal areas, such as misleading advertising or rules of origin. Regardless of the means, a solution should prevent the use of letters, general text, symbols, images or colours that mislead consumers as to the origin of certain food products. Although the TTIP will likely remain in the negotiation stage for at least the remainder of 2015, interested parties should act quickly and reach out to relevant government officials so as to ensure that their business interests are properly considered during the negotiations.

'*Simplified'* nutrition labelling scheme proposed in France

The draft French Public Health Act, which was presented to the French Council of Ministers and is being debated in the French Parliament since the beginning of 2015, provides for the principle of '*simplified*' nutrition labelling. The use of a simplified nutrition labelling scheme will be voluntary. However, if an operator (manufacturer or distributor) wants to use a simplified nutritional labelling scheme, it appears that adherence to the model which will be proposed under the Public Health Act is required.

In particular, Article 5 of the draft Public Health Act provides that, in order to facilitate consumer information and to help make informed choices, the mandatory nutrition declaration (which applies as of 14 December 2016 under *Regulation (EU) No. 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers*, hereinafter FIR) may be accompanied by additional presentations, graphics or symbols that will be established, after consulting the national food safety agency, by Order of the French Council of State. In February 2015, together with a number of French associations (including the Society of Public Health, the Society of Paediatrics, the Association of Dieticians, the Federation of Cardiology, the Society of Nutrition, the Diabetes Association), the French Consumer Association *Que Choisir* proposed a voluntary colour-coded front-of-pack (hereinafter, FoP) nutrition labelling scheme (hereinafter, the so-called '*coloriel'* model) and has urged the Government to include it as a model in the future Public Health Act. In a recent study backing the '*coloriel'* model's efficacy, it was argued that the scheme is not only a useful tool to help consumers choose healthier options, but it also avoids stigmatising any particular food category.

The '*coloriel'* model has been referred to by *Que Choisir* as an '*effective antidote to the current nutritional marketing*' with products that over-emphasise the importance of a particular nutrient, which may lead consumers to think that a product is healthier than it actually is. The '*coloriel'* model takes into account calories, fat, saturated fat, sugar and salt (and in some cases, fibre, fruits, nuts, protein and vegetables) and combines the results on a five-point scale with dots coloured green, yellow, orange, pink or red. Red dots stand for a product that should not be consumed often or only in limited quantity, while green dots shows that the product should be consumed more often or in greater quantity.

Article 35 of the FIR, in fact, allows voluntary additional forms of expression and presentation of the nutrition information on top of the mandatory nutrition information. Voluntary nutrition labelling cannot be given in isolation; it must be provided in addition to the full mandatory ('*back-of-pack*') nutrition declaration, which comprises energy, fat, saturates, carbohydrate, sugars, protein and salt (under Article 30(1) and (3) of the FIR).

In this context, it must be noted that, on 1 October 2014, the EU Commission initiated infringement proceedings against the UK over its so-called '*traffic light*' nutrition labelling scheme. The UK scheme is a hybrid FoP food labelling scheme that includes '*percentage reference intakes'* (formerly known as guideline daily amounts or GDAs) and colour coding, which indicates whether or not the product is high (*i.e.,* red), medium (*i.e.*, amber) or low (*i.e.,* green) in fat, saturated fat, sugar and salt (depending on their content per 100g). The scheme is, in principle, voluntary, but it was recommended in June 2013 by the UK Food Standards Agency (hereinafter, FSA) and the Department of Health (see more details in Trade Perspectives, Issue No. 19 of 17 October 2014).

In relation to voluntary national nutrition labelling schemes, three legal issues are of particular relevance: 1) whether it is a '*voluntary*' scheme; 2) whether certain elements of such scheme can be classified as '*non-beneficial*' nutrition claims; and 3) whether the proliferation of such schemes are obstacles to the free movement of goods in the EU, contrary to the Treaty on the

Functioning of the EU (hereinafter, TFEU) (see TradePerspectives, Issue No. 21 of 15 November 2013).

The French '*coloriel*' nutrition labelling scheme raises concerns as to whether it is, in fact, voluntary. If an operator in France wants to use a FoP nutrition labelling scheme, it appears that adherence to the model selected under the French Public Health Act is mandatory, be it the '*coloriel*' model or any other finally supported scheme under Article 5 of the future Public Health Act. If adopted as a model, the French '*coloriel*' nutrition labelling scheme may act as a potential *de facto* barrier to trade. If evidence were to suggest that retailers, who do not use it in the future, are being pushed out of the retail market in France, this could demonstrate that the scheme is not, at least in practice, '*voluntary*'.

In relation to the question of whether certain elements of the French '*coloriel*' nutrition labelling scheme can be classified as '*non-beneficial*' nutrition claims, it must be noted that nutrition claims are, by nature, '*beneficial claims*' since the operator, who places them on its products, intends to highlight something nutritionally '*positive*'. This is the reason why '*non-beneficial*' nutrition claims (like '*rich in fat*') do not fall under the scope of *Regulation (EC) No. 1924/2006 of the European Parliament and of the Council on nutrition and health claims made on foods* (hereinafter, NHCR), which states in recital 6 that non-beneficial nutrition claims are not covered by the scope of this Regulation; EU Member States intending to introduce national schemes relating to non-beneficial nutrition claims should notify such schemes to the EU Commission and to other Member States in accordance with *Directive 98/34/EC of the European Parliament and of the Council laying down a procedure for the provision of information in the field of technical standards and regulations* (hereinafter, Directive 98/34/EC).

Recital 46 of the FIR states, in fact, that the declaration in the same field of vision of the amounts of nutritional elements and comparative indicators in an easily recognisable form to enable an assessment of the nutritional properties of a food should be considered in its entirety as part of the nutrition declaration and should not be treated as a group of individual claims. There is a societal learned association between a red light meaning '*stop'* and a green light meaning '*go*'. Arguably, a number of red or pink dots in the French '*coloriel*' scheme could indeed act as sort of '*non-beneficial*' nutrition claim, inasmuch as the whole group of red dots could be interpreted as a claim that this product is nutritionally disadvantageous. Reportedly, the scheme does not intend to stigmatise any product, but (looking at it in detail), it does not appear to be clear why. On the other hand, it appears that a number of green or yellow dots in the French '*coloriel*' scheme could act as '*beneficial*' nutrition claims. Arguably, the question to answer, in order to establish whether the NHCR applies, is whether the whole '*ensemble*' of the complex '*coloriel'* nutrition labelling given in five colour codes (in its overall context) has a positive or a negative connotation and, therefore, is a claim and not a part of the nutritional declaration.

In relation to the assertion that the French '*coloriel'* nutrition labelling scheme could constitute a barrier to trade in breach of Article 34 TFEU, and that the multiplication of similar systems would undermine the EU's harmonisation efforts and fragmentise the internal market, it could be argued that classifying foods into colour categories (although, as stated above, the scheme reportedly does not intend to stigmatise any product) is overly-simplistic and eventually does not take into account how different foods are combined in a total dietary context. Moreover, it would need to be looked at whether the French '*coloriel'* nutrition labelling scheme discriminates many quality agro-food products like cheese, meat, marmalade and sweets, which would be labelled with red or pink dots due to their content of salt, sugars or fats. The only foods that are currently not included in the '*coloriel*' scheme are, in fact, oils, cheeses and soft drinks, which are expected to be covered in a future proposal. But how will this future proposal avoid the stigmatisation of certain products? Consumers could understand the scheme as a form of discrimination towards certain foods.

Regarding the question of whether the proposed French scheme constitutes a barrier to trade in breach of the principle of free movement established in Article 34 TFEU, it must be noted that the FIR opens the possibility to voluntary schemes. Article 35(1)(g) of the FIR, in fact, provides that, in addition to the mandatory nutrition information in the EU format, additional nutritional information may be given by other forms of expression and/or presented using graphical forms or symbols in addition to words or numbers, provided that their application does not create obstacles to the free movement of goods. Obstacles to goods may, according to Article 36 TFEU, be justified on grounds of, *inter alia*, the protection of health and life of humans. The EU Commission is the guardian of the treaties and must look for the most appropriate and the less trade restrictive means to achieve this objective, while preserving the achievements of the internal market and preventing obstacles to free movement of goods. There are concerns about EU Member States taking an individual approach, such as in France or the UK, as this may generate a proliferation of different voluntary national schemes across the EU. This could fragment the EU's internal market and cause confusion for consumers.

It must be noted that, besides the UK's '*traffic-light*' and the French plans for a '*coloriel*' scheme, developments are also expected in relation to the Nordic keyhole nutrition labelling scheme, which was established in Sweden in 1989, but is currently also used on labels for food products in Denmark and Norway. Sweden's National Food Agency (NFA) is planning to undergo an image makeover to modernise the keyhole scheme. NFA was recently granted 4 million Swedish Crowns (around EUR 430,000) of Government funds to encourage healthy eating. In collaboration with the National Board of Health and the Public Health Agency, NFA will reportedly spend the majority of the funds on encouraging health professionals to educate on good eating habits and on continued dialogues with food business operators (retailers that currently use the label in Sweden include Coop and ICA; manufacturers include Arla, Findus, and Unilever) to use the keyhole labelling symbol. A question to answer is whether this publicly funded scheme, which is used across the food industry, is still voluntary.

In the next months, interested parties should continue observing whether or not a French scheme is adopted, which may hinder intra-EU trade and discriminate against certain products. The same may apply to makeover of the Swedish scheme. In principle, there are no good or bad foods, only good or bad overall diets. Nutrition claims are strictly limited to the ones defined in Annex I to the NHCR. This is why no additional '*non-beneficial*' claims (as, arguably, under the French model) or other '*beneficial claims*' in the overall context of promotion of a product are permitted.

Recently Adopted EU Legislation

Trade Remedies

- *Commission Implementing Regulation (EU) 2015/309 of 26 February 2015 imposing a definitive countervailing duty and collecting definitively the provisional duty imposed on imports of certain rainbow trout originating in Turkey*

Customs Law

- *Council Decision (EU) 2015/285 of 17 February 2015 on the position to be adopted on behalf of the European Union within the EEA Joint Committee established by the Agreement on the European Economic Area, as regards the replacement of Protocol 4 to that Agreement, on rules of origin, by a new*

Protocol which is aligned to the Regional Convention on pan-Euro-Mediterranean preferential rules of origin

Food and Agricultural Law

- *Commission Implementing Decision (EU) 2015/261 of 6 February 2015 amending Decisions 2010/470/EU and 2010/471/EU as regards the animal health certification requirements for trade in and for imports into the Union of semen, ova and embryos of animals of the equine species*

Other

- *Council Decision (EU) 2015/362 of 2 March 2015 establishing the position to be taken on behalf of the European Union within the General Council of the World Trade Organization on the United States' request for a WTO waiver to extend and expand the scope of the US Caribbean Basin Economic Recovery Act (CBERA)*

- *Commission Regulation (EU) 2015/282 of 20 February 2015 amending Annexes VIII, IX and X to Regulation (EC) No. 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards the Extended One-Generation Reproductive Toxicity Study*

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