FRATINIVERGANO
EUROPEAN LAWYERS
TRADE PERSPECTIVES©

Issue No. 4 of 21 February 2014

New rules on animal health are being discussed at the EU Parliament: A new opportunity for EU animal welfare rules?

On 11 February 2014, the EU Parliament's Committee on Agriculture and Rural Development (hereinafter, the AGRI Committee) adopted a report on the EU Commission's *Proposal for a Regulation of the European Parliament and of the Council on Animal Health* (hereinafter, the EU Commission's proposal). The report, which was drafted by the *rapporteur* (*i.e.*, MEP Marit Paulsen), taking into account the opinions of the EU Parliament's Committee on the Environment, Public Health and Food Safety, the Committee on Fisheries and the Committee on Legal Affairs, proposes that a number of amendments be brought to the EU Commission's proposal. It is expected that the AGRI Committee's report be voted by the EU Parliament's plenary in March or April 2014.

The EU Commission's proposal, which was tabled on 6 May 2013, aims at laying down a single and comprehensive EU legal framework on animal health, thus bringing an end to the current situation where relevant provisions are scattered over more than 40 basic directives and regulations. In relevant part, the EU Commission's proposal lays down: (i) obligations for concerned actors (including operators, pet keepers and veterinarians) and EU Member States with respect to disease detection, notification and information; (ii) preventive measures related to notification and surveillance, such as animal vaccination and health checks; (iii) requirements for EU Member States to draw up and implement contingency plans to deal with certain diseases; (iv) rules to ensure animal identification and traceability, as well as conditions for the registration and approval of establishments and the obtainment of health certificates; and (v) requirements relevant for the purposes of import and export, as well as *intra*-EU trade of animals and animal products.

One of the most interesting features of the EU Commission's proposal possibly relates to its all-encompassing purpose, whereby it seeks to incorporate a number of animal health-related concerns such as public health, environment protection, food security and animal welfare into the core of the proposal (*i.e.*, the prevention and control of animal diseases which are transmissible to animals or humans). While most of these related concerns are extensively addressed both at EU and WTO levels, important imbalances appear to exist concerning animal welfare which, within the WTO context, is only covered by means of international standards. Although the World Organisation for Animal Health (hereinafter, OIE), which constitutes the standard-setting organisation recognised by the WTO in animal

health-related matters, has developed and incorporated animal welfare standards into its relevant Codes, the status of animal welfare within the WTO framework remains rather unclear. The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (hereinafter, the SPS Agreement) encourages WTO Members to base their SPS measures on relevant international standards, but does not envisage any specific reference to animal welfare, as neither does the Agreement on Technical Barriers to Trade (hereinafter, TBT Agreement). In addition, animal welfare arguably does not provide for a valid ground to overcome the WTO basic '*national treatment*' and '*most-favoured nation*' obligations (which require that imported products not be discriminated against *vis-à-vis* '*like*' domestic or imported goods), to the extent that the manner in which animals have been treated appears not to affect '*likeness*' of final products. Furthermore, measures adopted to enforce animal welfare principles on imported products could amount to import restrictions inconsistent with Article XI of the General Agreement on Tariffs and Trade (hereinafter, GATT). Of relevance in these cases might be Article XX of the GATT, which provides for a '*General Exceptions*' clause, although it does not explicitly mention animal welfare.

Despite the lack of direct references to animal welfare in the WTO '*covered Agreements*', a WTO panel recently ruled, in the context of the dispute *European Communities – Measures Prohibiting the Importation and Marketing of Seal Products*, that the EU's regime, adopted to address public moral concerns connected to the welfare of seals, constituted a '*legitimate objective*' within the meaning of Article 2.2 of the TBT Agreement, despite not being expressly listed in that provision. The panel also found that such concern was provisionally justified under paragraph (*a*) of Article XX of the GATT, concerning measures "*necessary to protect public morals*". The panel did not discuss whether paragraph (*b*) of Article XX of the GATT (which provides for an exception on grounds of "*...animal...life or health*") provided for a valid justification, inasmuch as it found that the EU failed to make a *prima facie* case under such provision. Although the panel eventually found that the EU's measures did not meet the requirements of the *chapeau* of Article XX, and therefore were not justified under the '*General Exceptions*' clause (see Trade Perspectives, Issue No. 22 of 29 November 2013), its findings on the scope of Article XX paragraph (*a*) of the GATT and Article 2.2 of the TBT, as well as those concerning '*likeness*' between products conforming and non-conforming to the EU's requirements on animal welfare (which were never disputed by the parties), provide for a useful benchmark for the assessment of future measures adopted for the protection of animal welfare. It remains to be seen whether, and to what extent, the panel's relevant findings will be upheld or modified by the Appellate Body.

In any event, there are a number of additional issues concerning the status of animal welfare under the WTO that could benefit from further clarification, including notably whether animal welfare falls within the scope of the SPS Agreement or whether it constitutes an issue relevant under the TBT Agreement. In relation to this, it is noted that the EU has discussed issues related to animal welfare before the TBT Committee and maintained before the SPS Committee that "*the SPS Agreement does not cover animal welfare*", despite having a number of free trade agreements (hereinafter, FTAs) in place (such as those concluded with Chile and Korea) that deal with animal welfare under their SPS Chapter.

Regardless of the EU's apparently inconsistent approach to the issue of animal welfare before the WTO and in FTA contexts, the EU Commission's proposal, which explicitly states that the relationship between animal health and animal welfare be taken into account, looks poised to shed some light over the current status of animal welfare. In addition, it may be reasonably assumed that it will, together with the delegated and implementing acts that it foresees be adopted, contribute to the normalisation of the presence of animal welfare provisions in relevant trade instruments. In this context, operators involved in animal welfare matters are advised to maintain fluent communications with their authorities, in order to ensure that their concerns are duly and timely taken into account within the relevant *fora*, both within regulatory processes and trade negotiations.

The US requests WTO consultations with India concerning measures relating to solar cells and solar modules

On 10 February 2014, the US requested WTO consultations with India concerning certain measures relating to domestic content requirements (hereinafter, DCRs) under "*Phase II*" of the Jawaharlal Nehru National Solar Mission (hereinafter, NSM) for solar cells and solar modules. The request marks a revival of previous consultations held between India and the US regarding "*Phase I*" of the same programme and a continuation of the debate surrounding strategies to promote the development of renewable energy sources.

The NSM is a three-phase initiative by India to promote ecologically sustainable growth through the increased use of solar power electricity generation, while also addressing recent energy security issues present in India. Reports indicate that the energy security issues relate to energy shortages due, in large part, to India's reliance on coal-powered electricity. The first phase of the NSM lasted from 2012 to 2013 and focused on capturing the easiest-to-achieve solar-powered energy options, promoting off-grid rural populations and producing modest capacity additions in India's energy grid. "*Phase II*", which is to last from 2013 to 2017, intends to aggressively scale-up solar energy production throughout India. The specific approach to "*Phase III*" will not be known until closer to 2017, given that the programme envisions periodic review of its effectiveness. However, the target of the entire mission is adding 20 gigawatts of grid-connected capacity and 2 gigawatts of off-grid capacity by 2022. The controversial characteristics of the NSM relate to its payment structure and the use of DCRs. The long-term power purchase contracts between developers and the relevant government entities bundle the relatively expensive solar-powered electricity with cheaper unallocated energy quotas through the Government, which lowers the average cost of power. Additionally, the programme includes DCRs. Out of the total capacity of 750 megawatts under "*Batch I*" of "*Phase II*", a capacity of 375 megawatts will only be allocated to developers that purchase and use solar cells and solar modules made in India. At the time developers bid for the contracts, they must select whether they want to bid in the "*DCR*" group or the "*Open*" group. The developers may submit separate bids under each group as well.

The initial request for WTO consultations by the US occurred on 6 February 2013 (see Trade Perspectives, Issue No. 4 of 22 February 2013). That request concerned "*Phase I*" of the NSM and asserted that India's measures appeared to be inconsistent with Article III:4 of the GATT, Article 2.1 of the Agreement on Trade-Related Investment Measures (hereinafter, TRIMs Agreement) and numerous articles in the Agreement on Subsidies and Countervailing Measures (hereinafter, SCM Agreement) relating to prohibited subsidies and the causation of serious prejudice. The recent request for consultations by the US clarifies that it is a supplement, rather than a replacement, of last year's request. Indeed, though the previous consultations between India and the US did not result in a mutually agreed solution, the US never took steps to progress or withdraw the dispute until now. The supplemental request uses language almost identical to its predecessor, except in its updated list of disputed measures and in its indication of WTO obligations with which the measures appear to be inconsistent. In the newest request, the US again cites Article III:4 of the GATT, alleging that the disputed measures provide less favourable treatment to imported solar cells and solar modules than the treatment accorded to '*like*' products originating in India. Additionally, the US claims India has violated Article 2.1 of the TRIMs Agreement because the disputed measures are TRIMs that violate Article III of the GATT. Interestingly, in the newest request, the US chose not to cite any articles in the SCM Agreement. Even so, if the dispute progresses to the panel stage, the US will not be precluded from raising issues under the SCM Agreement.

Should the dispute progress through the WTO dispute settlement mechanism, the recent *Canada – Renewable Energy* dispute is likely to have a significant influence on the outcome. That dispute, whose panel and Appellate Body reports were adopted on 24 May 2013, dealt with a similar scheme to promote the development of renewable energy generation by promoting, *inter alia*, wind- and solar-photovoltaic generated electricity. The EU and Japan successfully challenged a feed-in tariff (hereinafter, FIT) programme by the Government of Ontario, Canada, which provided certain generators of renewable energy long-term contracts if they satisfied contractual obligations including DCRs pertaining to the construction and use of generation facilities. Reports suggest that government officials from India hold the position that the measures amount to government procurement. If so, India may be planning to counter the US allegations relating to Article III of the GATT by demonstrating that Article III:8(a) of the GATT is applicable. Article III:8(a) of the GATT pertains, in part, to laws, regulations, or requirements governing the procurement by governmental agencies of products (in this case electricity), and provides for derogation from the obligations contained in Article III of the GATT. However, in *Canada – Renewable Energy*, the Appellate Body found that the derogation from Article III allowed under Article III:8(a) must be understood in relation to the obligations stipulated in Article III. In particular, the product of foreign origin must be in a competitive relationship with the product purchased for the derogation to apply. When applied to the situation of DCRs on equipment that generates electricity that the government purchases, the Appellate Body in *Canada – Renewable Energy* stated that there was not a competitive relationship between the two products (*i.e.*, electricity and renewable energy equipment), and thus Article III:8(a) did not apply.

As is shown by *Canada – Renewable Energy*, the general topic of this dispute is not new. Indeed, in recent years there has been a growing debate regarding to what extent a country may adopt public policy legislation relating to energy. A study in 2013 indicated that 71 countries and 28 states or provinces had enacted FIT programmes since 1978, and that at least 13 of those currently in force contained DCRs. The EU Commission recently issued a recommendation that EU Member States abandon their FIT programmes. Following the request for consultations by the US on the NSM, India responded by questioning numerous government programmes in the US relating to renewable energy that include DCRs, which may indicate the filing of a countersuit in the near future. Here, reports suggest that the US is particularly concerned with thin film technology, which is used in the manufacture of solar energy generation components and comprises a significant portion of the solar products exported from the US to India. India is the second largest foreign market for the US solar energy industry, but exports have fallen since 2011, when they totalled USD 119 million. Interested parties in the energy sector should remain vigilant as the dispute develops, as it may have a sizable impact on future disputes.

Proposals to revise the EU's legislative framework on novel foods and animal cloning

On 18 December 2013, the EU 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*, 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* and a proposal for a *Council Directive on the placing on the market of food from clones*.

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), food produced using the latest technological innovations such as oils and dairy products enriched with phytosterols/phytostanols to reduce cholesterol, '*salatrim*' (a reduced-energy fat), DHA-rich oil, a high-pressure fruit juice, baobab dried fruit pulp, rooster comb extract (which has a high hyaluronic acid content), chia seeds (commonly used in the South America) and the synthetic vitamin K2. In 2008, the EU Commission presented a proposal to amend Regulation No. (EC) 258/97, which was to be adopted in the co-legislative procedure by the EU Parliament and the Council. The legislative discussions focused mainly on the provisions 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 cloning of animals). No agreement could be reached between the EU 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 (for more background see: Trade Perspectives, Issue No. 5 of 10 March 2011 and Issue No. 10 of 20 May 2011). Following this failure, the EU Commission was asked to prepare new proposals.

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 EU 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 EU 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. 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 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*". 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 EU 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.

Although the EU 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 which, in consultations carried-out with interested parties, confirmed to the EU Commission that animals are cloned in their territories. Furthermore, the draft Directive on 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, Argentina, Australia, Brazil, Canada, New Zealand, Paraguay and the US pointed out that 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). The extent to which WTO law may allow future EU measures 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 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.

Recently Adopted EU Legislation

Trade Remedies

- *Council Implementing Regulation (EU) No. 135/2014 of 11 February 2014 repealing the anti-dumping duty on imports of dicyandiamide originating in the People's Republic of China following an expiry review pursuant to Article 11(2) of Regulation (EC) No. 1225/2009*

Food and Agricultural Law

- *Commission Regulation (EU) No. 155/2014 of 19 February 2014 refusing to authorise certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health*
- *Commission Implementing Decision of 18 February 2014 concerning certain interim protective measures relating to African swine fever in Poland (notified under document C(2014) 1179)*
- *Commission Implementing Decision of 14 February 2014 amending Annex II to Decision 97/794/EC laying down certain detailed rules for the application of Council Directive 91/496/EEC as regards veterinary checks on live animals to be imported from third countries (notified under document C(2014) 750)*
- *Commission Implementing Decision of 14 February 2014 concerning certain protective measures relating to African swine fever in Lithuania (notified under document C(2014) 1006)*
- *Commission Implementing Decision of 13 February 2014 suspending temporarily imports from Bangladesh of foodstuffs containing or consisting of betel leaves ('Piper betle')(notified under document C(2014) 794)*
- *Commission Implementing Decision of 12 February 2014 amending Implementing Decision 2013/426/EU on measures to prevent the introduction into the Union of the African swine fever virus from certain third countries or parts of the territory of third countries in which the presence of that disease is confirmed and repealing Decision 2011/78/EU (notified under document C(2014) 715)*

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