

**Issue No. 21 of 20 November 2015**

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**The WTO Appellate Body circulates its compliance Report in *US – Tuna II (Mexico)***

On 20 November 2015, the WTO Appellate Body circulated its Report in *United States – Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products – Recourse to Article 21.5 of the DSU by Mexico* (hereinafter, *US – Tuna II*).

The dispute has been formally ongoing for over 7 years. In fact, it was on 24 October 2008 that Mexico requested WTO consultations with the US with respect to: 1) provisions in the US Dolphin Protection Consumer Information Act; 2) US labelling standards for ‘dolphin-safe’ tuna, in particular that which is harvested in the Eastern Tropical Pacific (hereinafter, ETP) Ocean; and 3) a relevant US Circuit Court of Appeals ruling. Unable to find a mutually agreed solution with the US, Mexico requested the establishment of a WTO panel on 9 March 2009, which was eventually established by the WTO Dispute Settlement Body (hereinafter, DSB) on 20 March 2009 (see [Trade Perspectives, Issue No. 5 of 13 March 2009](#)). However, the origins of the dispute actually date back to 1991, prior to the creation of the WTO, when Mexico requested a panel decision under the original General Agreement on Tariffs and Trade (hereinafter, GATT) to address its claims regarding an embargo implemented by the US on Mexican tuna imports. The panel had concluded that the US embargo violated that GATT because it was based on the domestic production process of tuna in Mexico, rather than on the quality of the content of the product (*i.e.*, the ‘*process versus product*’ distinction). The panel had also concluded that the US labelling rules regarding the use of the ‘dolphin-safe’ label were consistent with GATT because they were designed to prevent deceptive advertising practices on all tuna products. Regardless, the panel report was never adopted by the GATT parties, and thus the US did not lift the embargo until 1997.

In *US – Tuna II*, Mexico’s claims centred on Articles I:1 and III:4 of the General Agreement on Tariffs and Trade 1994 (hereinafter, GATT 1994) and Articles 2.1, 2.2 and 2.4 of the Agreement on Technical Barriers to Trade (hereinafter, TBT Agreement). Article I:1 of the GATT 1994 requires WTO Members to accord any advantage, favour, privilege or immunity, granted to any product originating in or destined to any other country, to the ‘*like*’ products originating in or destined to other WTO Members (*i.e.*, to provide Most-Favoured Nation, or MFN, Treatment). Article III:4 of the GATT 1994 requires WTO Members to accord treatment no less favourable than that accorded to ‘*like*’ domestic products to products imported from other WTO Members (*i.e.*, to provide National Treatment). Under the TBT Agreement, and with respect to technical regulations, Article 2.1 also requires WTO Members to provide National Treatment to products imported from other WTO Members. Article 2.2 of the TBT Agreement requires WTO Members to ensure that technical regulations are not prepared,

adopted or applied with a view to, or with the effect of, creating unnecessary obstacles to international trade, and, in particular, that they are not more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks that non-fulfilment would create. Article 2.2 of the TBT Agreement provides a non-exhaustive list of '*legitimate objectives*' (e.g., animal life or health), as well as relevant considerations for assessing risks (e.g., related processing technology or intended end-uses of products). Lastly, Article 2.4 of the TBT Agreement requires Members to base technical regulations on relevant international standards, unless said standards are "*ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems*". In its request for the establishment of a WTO panel, Mexico took issue with aspects of the measures and US Circuit Court of Appeals ruling establishing that '*dolphin-safe*' labels could not be used on tuna products if, *inter alia*, the tuna was harvested in the ETP Ocean by a vessel using purse-seine nets and no certification was provided proving that dolphins were not killed or seriously injured during the catching of tuna.

The long-winded dispute has seen the release of numerous reports. On 15 September 2011, the WTO DSB circulated the panel report, concluding in large part that the US measures were inconsistent with GATT 1994 and the TBT Agreement (see [Trade Perspectives, Issue No. 17 of 23 September 2011](#)). The threshold issue was whether the labelling measure fell within the scope of the TBT Agreement as a "*technical regulation*", which is defined in Annex 1 of the TBT as a "*document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory*". The key issue in this regard was whether the US labelling requirements were '*mandatory*', given that non-'*dolphin-safe*' tuna was still allowed to enter the US market. The panel concluded that the measure was '*mandatory*' in that no tuna product "*may be labelled dolphin-safe or otherwise refer to dolphins*" if such product does not meet the conditions of the measure at issue. The panel went on to find that the US had not violated its obligations under Article 2.1 of the TBT Agreement because tuna products were not distinguished by the nationality of the product, but rather by the fishing and purchasing practices, geographical location and economic and marketing choices. The panel also found that the US violated its obligation under Article 2.2 of the TBT Agreement because the US '*dolphin-safe*' labelling requirements were more trade restrictive than necessary to fulfil the legitimate objectives of the US, in part because the panel accepted a less trade restrictive alternative provided by Mexico. However, the panel found that the US measure was consistent with its obligation under Article 2.4 of the TBT Agreement because, although the international standards cited by Mexico in the Agreement on the International Dolphin Conservation Program (hereinafter, AIDCP) were relevant, the AIDCP standards were not an appropriate or effective means of achieving the US objectives. Mexico and the US appealed the decisions of the panel and, on 16 May 2012, the Appellate Body circulated its Report (see [Trade Perspectives, Issue No. 10 of 18 May 2012](#)). The Appellate Body agreed with the panel that the measure was a '*technical regulation*' under the TBT Agreement, but reversed the panel's conclusion under Article 2.1 of the TBT Agreement because a majority of the tuna from Mexico was ineligible for the label, while that from the US was, which created a modification of the conditions of competition that was specifically detrimental to Mexican products. The Appellate Body also reversed the panel's conclusions in regards to Article 2.2 of the TBT Agreement, stating that the AIDCP standard was unfit for the measure's objectives. Lastly, the Appellate Body upheld the panel's conclusion under Article 2.4 of the TBT Agreement, but for different reasons, namely that accession to the AIDCP is not freely open to all WTO Members and thus did not qualify as a relevant international standard.

In response to the Appellate Body Report, the US amended its measures. However, on 14 November 2013, Mexico requested compliance proceedings under Article 21.5 of the WTO DSB's Understanding on Rules and Procedures Governing the Settlement of Disputes, claiming that the US amendments did not comply with the recommendations and rulings of the Appellate Body because the measure continued to require documentation and tracking and

verification information depending on where the tuna was caught. Mexico also complained that the measure continued to bar tuna caught by '*setting on dolphins*' (i.e., chasing and encircling dolphins with a net in order to catch the tuna associating with them) from being labelled as '*dolphin-safe*'. On 14 April 2015, the WTO DSB circulated the panel's compliance report, which concluded that the US '*eligibility criteria*' excluding from importation tuna caught by '*setting on dolphins*' were consistent with the US WTO obligations because adequate, and less harmful, fishing methods were available that align with the US objectives. However, the panel concluded that the certification and tracking and verification requirements under the US measure, which are based on geographical location of where the tuna was caught, *de facto* discriminated against Mexico in violation of Article 2.1 of the TBT Agreement.

The panel also concluded that the US amendments violated Articles I:1 and III:4 of GATT 1994 and that exceptions under Articles XX(b) and XX(g) of GATT 1994 were not applicable because the US measures were applied in an arbitrarily or unjustifiably discriminatory manner, as described in the *chapeau* of Article XX of GATT. Mexico and the US again appealed that decision of the panel and, on 20 November 2015, the Appellate Body circulated its Report. The Appellate Body reversed the findings of the panel under Article 2.1 of the TBT Agreement because it did not agree with the segmented analysis that the panel applied when assessing the '*eligibility criteria*' (relating to fishing methods), '*certification requirements*' and '*tracking and verification requirements*'. The Appellate Body then completed the legal analysis on its own, finding that the "*determination provisions*" of the US measure do not provide for observer certification in all circumstances of comparably high risks and are, therefore, not reconcilable with the measure's objectives and, as such, are inconsistent with Article 2.1 of the TBT Agreement. The Appellate Body similarly found that the amended measure modifies the competitive conditions to the detriment of Mexican tuna products, inconsistently with Articles I:1 and III:4 of GATT 1994. Lastly, the Appellate Body agreed with the panel that the amended measure is not applied consistently with the *chapeau* of Article XX of GATT 1994.

The Appellate Body Report on the compliance proceedings serve as an additional victory for Mexico, as it will now have the option to suspend concessions in retaliation to the US failure to comply. Nonetheless, from a legal perspective, the most significant effects of the dispute arguably still arise from the original GATT panel decision, which introduced the '*product versus process*' distinction, and the original Appellate Body Report in *US – Tuna II*, which confirmed that a label can still be '*mandatory*', and therefore classified as a '*technical regulation*' under the TBT Agreement, even if said label is not required for the importation of a good. Stakeholders should continue to monitor developments, as it will be interesting to observe how or if the US chooses to comply with the Appellate Body Report or be subject to '*retaliation*'.

## Are additional nutrition labelling schemes voluntary food information?

The objective of the nutrition labelling provisions in *Regulation (EU) No. 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers* (hereinafter, FIR) is to harmonise nutritional information on energy and on certain nutrients on food. Nutrition labelling was optional under the FIR's predecessor, *Council Directive 90/496/EEC of 24 September 1990 on nutrition labelling for foodstuffs* and was only compulsory in two cases: 1) where a nutrition claim appeared on labelling, in presentation or in advertising or 2) on fortified foods to which vitamins and minerals have been added. In principle, nutrition labelling is becoming mandatory for all foodstuffs as of 14 December 2016. Food business operators (hereinafter, FBOs) can introduce nutrition labels on their products earlier than 14 December 2016, but must then comply with all requirements of the FIR. In addition to the mandatory nutrition declaration, the FIR permits other forms of expression and presentation, and in some EU Member States, in particular, France, a myriad of additional nutrition labelling schemes are proposed or implemented. For a long while, the

UK was the champion in terms of the proliferation of different FoP (front-of-pack) nutrition labelling schemes. In order to streamline the schemes and reduce consumer confusion, a hybrid scheme with colour coded guideline daily amounts (GDAs) / reference intakes (RIs) was introduced in 2013 (in relation to that scheme, see [TradePerspectives Issue No. 21 of 15 November 2013](#)).

On 27 October 2015, French retailers and distributors that are members of the French Trade and Retailing Federation (*i.e.*, *Fédération du Commerce et de la Distribution*, or FCD in its French acronym), such as *Auchan*, *Carrefour*, *Casino*, *Monoprix* and *Système U*, presented a so-called simplified nutrition labelling system, named ‘SENS’ (according to the French acronym for ‘*système d’étiquetage nutritionnel simplifié*’) to various ministries and consumer associations at a meeting held at France’s Ministry of Health. The retailer *Carrefour* names the nutrition labelling system ‘*Aquellefréquence*’ (‘*how frequently*’, in English). ‘SENS’ or ‘*Aquellefréquence*’ are based on the ‘SAIN, LIM’ system, which was developed starting in 2008 as part of the French Food Safety Agency’s (AFSSA in its French acronym) working group on nutrient profiles, and which has been the subject of numerous scientific publications. The ‘SAIN, LIM’ system (SAIN stands for Individual Adequacy Score for Nutritional recommendations and LIM for Score of compounds to LIMit from a nutritional point) ranks foods according to their nutritional quality (score SAIN) and their shortcomings (score LIM). An algorithm is used to calculate the nutritional value of the product, which then results in the colour of a symbol. The symbol’s design comes in the shape of an inverted pyramid that is full to a greater or lesser degree, depending on the colour assigned to the product (green, blue, amber, and purple). These colours, in turn, represent different indicators of how frequently the food in question may be consumed. Green-labelled foods can be eaten ‘often’; blue ‘from time to time’; amber ‘in moderation’; and purple ‘occasionally, or in small quantities’. It is important to note that there is no red symbol.

The FIR establishes, in Article 32(2) and (4) and in Article 33, the forms of expression and, in Article 34(2), how nutrition labelling must be presented. However, Article 35(1) of the FIR permits additional forms of expression and/or presentation of the energy value and the amount of nutrients (*i.e.*, fat, saturates, carbohydrate, sugars, protein and salt) by other forms using graphical forms or symbols in addition to words or numbers. Such additional forms of expression and/or presentation are only possible where the following requirements are met: “(a) they are based on sound and scientifically valid consumer research and do not mislead the consumer; (b) their development is the result of consultation with a wide range of stakeholder groups; (c) they aim to facilitate consumer understanding of the contribution or importance of the food to the energy and nutrient content of a diet; (d) they are supported by scientifically valid evidence of understanding of such forms of expression or presentation by the average consumer; (e) in the case of other forms of expression, they are based either on the harmonised reference intakes set out in Annex XIII, or in their absence, on generally accepted scientific advice on intakes for energy or nutrients; (f) they are objective and non-discriminatory; and (g) their application does not create obstacles to the free movement of goods”. These requirements for additional forms of expression and/or presentation pose quite a challenge. According to Article 35(2) of the FIR, EU Member States may recommend to FBOs the use of one or more additional forms of expression or presentation of the nutrition declaration that they consider as best fulfilling the requirements set out above.

In a report, where different nutrition labelling systems were assessed under Article 35 of the FIR (*i.e.*, *AVIS relatif à l’information sur la qualité nutritionnelle des produits alimentaires* of 25 June 2015, published on 28 August 2015), the French Government’s advisory health body, *Haut Conseil de la Santé Publique* (HCSP in its French acronym) concluded that only the five-colour system 5C (in relation to that scheme, see [TradePerspectives Issue No. 5 of 6 March 2015](#)) met the requirements of Article 35 of the FIR and could be recommended (and not, *inter alia*, ‘SENS’ or ‘*Aquellefréquence*’).

In addition, an analysis by the French Fund for Food and Health (*Fonds Français pour l'Alimentation et la Santé*, FFAS in its French acronym) concluded that the requirements of Article 35 of the FIR are not met by the '*Aquellerequance*' nutrition labelling system because, *inter alia*, "*proteins are not systematically addressed. This system can take into account foods (fruits, vegetables, nuts), which is not provided for in Article 35(1)*". However, FFAS's analysis raises another matter. It states that "*Article 36 of the FIR relates to requirements for voluntary information on foods where food business operators may take the initiative*" and that "*it follows from this provision that each food business operator is free to take the initiative of a voluntary information, including a graphic representation system of nutrition information, provided that the three requirements laid down in Article 36 of the FIR are met*".

Article 36 and 37 of the FIR constitute the chapter on voluntary food information of the FIR. In the legislative procedure, the Council had insisted that even information that was provided on a voluntary basis should respect the legal requirements of mandatory food information set out in Sections 2 and 3 of Chapter IV of the FIR. Article 36 of the FIR deals with substantial questions and Article 37 concerns the presentation of voluntary food information. Article 36(1) of the FIR provides requirements where *mandatory* food information referred to in Articles 9 and 10 FIR is provided on a *voluntary* basis. Article 9 lists the mandatory labelling particulars, including the name of the food; the list of ingredients; and a nutrition declaration (as of 14 December 2016); Article 10 establishes additional mandatory particulars for specific types or categories of foods. For example, when a voluntary nutrition declaration is made on foods that are normally exempt from compulsory nutrition labelling pursuant to Article 16(3), in conjunction with Annex V of the FIR (including single ingredient foods; waters; herbs, spices or mixtures thereof; salt and salt substitutes; table top sweeteners; certain coffee products; teas; vinegar; chewing-gums; food in packaging or containers the largest surface of which has an area of less than 25 cm<sup>2</sup>) or on alcoholic beverages that are exempt according to Article 16(4) of the FIR. If such food information is provided *voluntarily*, it has to meet the criteria of the provisions of Article 29-35 of the FIR in every respect, as they are applicable to the corresponding *mandatory* information. Therefore, if FBOs want to voluntarily put a nutrition declaration on (e.g.,) their vinegar, at least the following must be indicated (in the prescribed format): energy value; and the amounts of fat, saturates, carbohydrate, sugars, protein and salt.

Paragraph 2 of Article 36 of the FIR sets out that all food information provided on a voluntary basis must not mislead the consumer; must not be ambiguous or confusing for the consumer; and must, where appropriate, be based on the relevant scientific data. Other categories of voluntary food information are subdivided in the voluntary food information, which falls under the categories of paragraph 3 of Article 36 (*i.e.*, information on the possible and unintentional presence in food of substances or products causing allergies or intolerances; information related to suitability of a food for vegetarians or vegans; the indication of reference intakes for specific population groups in addition to the reference intakes set out in Annex XIII; and information on the absence or reduced presence of gluten in food) and further voluntary information under Article 36(4) of the FIR (*i.e.*, where voluntary food information is provided by FBOs on a divergent basis, which might mislead or confuse the consumer). Under Article 36(4) of the FIR, additional cases of provision of voluntary food information to the ones referred to in paragraph 3 may be established by delegated acts. This may include green claims, animal welfare claims, halal and kosher labels.

In view of the above, FFAS's analysis that Article 36 of the FIR relates to requirements for voluntary information on foods where FBOs may take the initiative and that it follows from this provision that each FBO is free to take the initiative of a voluntary information, including a graphic representation system of nutrition information, provided that the three requirements laid down in Article 36(2) of the FIR are met, is arguably not correct. Article 35 of the FIR addresses additional forms of nutritional information. Article 36(1) of the FIR concerns only cases where nutrition information is provided on a voluntary basis because the respective

food is actually exempted from nutrition labelling, such as, for example, vinegar. Article 36(2) of the FIR addresses all voluntary food information (*i.e.*, all *voluntarily* given *mandatory* information and all further *voluntary* information). Article 36(2) of the FIR arguably does not apply to *mandatory* information, such as the nutrition declaration. In conclusion, Article 36 of the FIR does not appear to provide operators with a “*green light*” for whatever voluntary nutrition labelling scheme.

Moreover, even if additional voluntary nutrition information schemes, such as ‘*SENS*’ or ‘*Aquellefréquence*’, fell under the scope of Article 36(2) of the FIR, the three requirements (*i.e.*, 1) not misleading the consumer; 2) not be ambiguous or confusing for the consumer; and, 3) where appropriate, be based on the relevant scientific data) are not easy to meet. For example, nutritional values and nutrients appear to be taken into consideration by ‘*SENS*’ and ‘*Aquellefréquence*’, but are not ‘*legible*’ because the colour of the inverted pyramid is calculated by an ‘*invisible*’ algorithm. Foods with a purple symbol may be stigmatised because they are only to be consumed occasionally. In addition, the indication of consumption frequencies without indication of portion sizes may mislead consumers.

A health bill is currently being examined by the French Parliament and includes an article calling for symbolic or graphic information to represent nutritional values. Such an EU Member State initiative is foreseen only by Article 35(2) of the FIR and not by Article 36. The bill was to be voted by deputies in the Parliament on 16 November 2015. However, the vote has been postponed. The proliferation of nutrition labelling schemes creates obstacles to the free movement of goods. In addition to the harmonised EU scheme, the FIR permits additional forms of expression, which are bound to strict requirements. Nutrition labelling is, with certain exceptions, mandatory. The FIR’s provisions on voluntary food information do not establish that FBOs are free to take the initiative of providing any type of voluntary information, including a graphic representation system of (*mandatory*) nutrition information.

## The text of the Trans-Pacific Partnership Agreement is released

On 5 November 2015, New Zealand and the US published the text of the Trans-Pacific Partnership Agreement (hereinafter, TPP), which is still subject to legal review and authentication. The agreement covers a wide range of areas, such as, *inter alia*, market access and non-tariff measures, services trade and investment, government procurement, competition, intellectual property rights, as well as standards on labour and environment. As such, the agreement may have an impact on the negotiation of future trade and investment agreements.

The TPP technically serves as an expansion and amendment of the Trans-Pacific Strategic Economic Partnership Agreement (hereinafter, P4) signed by Brunei Darussalam, Chile, New Zealand and Singapore in 2005. In addition to the original P4 members, the 8 other TPP parties now include Australia, Canada, Japan, Malaysia, Mexico, Peru, the US and Vietnam (for more information, see [Trade Perspectives, Issue No. 22 of 29 November 2013](#)). As a result, the TPP membership represents 40% of the global economy. The first round of negotiations took place in Melbourne, Australia, on 15 March 2010 and the negotiations concluded on 5 October 2015. Throughout the negotiation process, reports have indicated that key issues included, *inter alia*, the use of investor-to-state dispute settlement (see [Trade Perspectives, Issue No. 19 of 17 October 2014](#)), various intellectual property rights issues, the flow of electronic commerce, the environment, labour standards, currency manipulation, and sector specific concessions in, *inter alia*, dairy, automobiles, textiles and agriculture. The final text of the agreement, including all annexes, appendixes, schedules and side letters, includes more than 6,000 pages organised along 30 chapters. Interested parties should take time to review the agreement in full, but a few areas addressed by the TPP are particularly interesting.

One innovative aspect of the TPP is its treatment of non-tariff measures, especially as they pertain to sanitary and phytosanitary (hereinafter, SPS) measures, market access, technical barriers to trade (hereinafter, TBT), state-owned enterprises (hereinafter, SOEs) and the technology sector. Chapter 7 of the TPP addresses SPS measures, reaffirming existing rights and obligations under the WTO Agreement on the Application of SPS Measures (hereinafter, WTO SPS Agreement), including recognising the obligations of TPP parties regarding assessment of risk under Article 5 of the WTO SPS Agreement. Chapter 7 of the TPP also provides detailed considerations for parties to implement during SPS-related risk analysis procedures. On a related note, the TPP also specifically addresses the importation of genetically-modified organisms, but within Chapter 2 on “*National Treatment and Market Access*”, Section C (regarding Agriculture). In particular, Article 2.29 of the TPP, titled “*Trade of Products of Modern Biotechnology*”, includes transparency requirements relating modern biotechnology products and specific procedures for cooperation following the inadvertent low level presence (LLP) in a “*shipment of plants or plant products [...] of rDNA plant material that is authorized for use in at least one country, but not in the importing country*”. Chapter 2 of the TPP also includes a section dedicated to the administration of tariff rate quotas (hereinafter, TRQs), as well as appendixes for TRQs in each TPP signatory party.

With respect to TBTs, Chapter 8 of the TPP incorporates by reference specific articles of the WTO TBT Agreement, and adds provisions to further address international standards, guidelines and recommendations, conformity assessment and transparency. Arguably the most novel aspect of the TPP in the area of TBTs is its extensive incorporation of issue- and sector-specific annexes, concerning: a) wine and distilled spirits; b) information and communications technology products; c) pharmaceuticals; d) cosmetics; e) medical devices; f) proprietary formulas for prepackaged foods and food additives; and g) organic products. Such annexes are intended to add further clarity to the obligations of TPP parties and promote greater regulatory coherence. For example, Annex 8-F of the TPP on proprietary formulas and prepackaged foods and food additives requires that TPP parties ensure that information requirements regarding proprietary formulas be limited to what is necessary to achieve the legitimate objective sought, as well as the confidentiality of proprietary formulas. Annex 8-F of the TPP also clarifies that parties are allowed to require that ingredients be listed on labels consistently with *Codex Alimentarius*’ General Standard for the Labelling of Prepackaged Foods (*i.e.*, Codex Standard 1-1985) and General Standard for the Labelling of Food Additives when sold as such (*i.e.*, Codex Standard 107-1981), as amended, except when those standards would be an ineffective or inappropriate means for the fulfilment of a legitimate objective.

Provisions regulating the use of SOEs are contained in Chapter 17 of the TPP. The chapter aims to ensure that SOEs do not unjustifiably discriminate against suppliers of goods and services from other TPP parties, or make sales and purchasing decisions that are not based on standard commercial considerations such as price, quality and availability of inputs and outputs. Australia’s Department of Foreign Affairs and Trade states that some of the rules regulating SOEs in the TPP are “*ground-breaking*”, and, according to a chapter summary published by the US Trade Representative, the TPP is the “*first Free Trade Agreement (FTA) to seek to address comprehensively the commercial activities of SOEs that compete with private companies in international trade and investment*”. However, Chapter 17 does contain exceptions to its obligations, including measures implemented on a temporary basis in response to a national or global economic emergency, the use of import-export banks and smaller SOEs that do not reach a threshold annual revenue, calculated in accordance with Annex 17-A of the TPP.

With respect to the technology sector, the TPP is important, in part, because it includes chapters that address, *inter alia*, electronic commerce and intellectual property. Chapter 14 on Electronic Commerce ensures the free flow of data across borders in Article 14.11, and

prohibits TPP parties from requiring that companies maintain domestic computer servers and storage devices for processing or storing information for commercial use in Article 14.13 (for more information on local data storage requirements, see [Trade Perspectives, Issue No. 19 of 23 October 2015](#)). However, cross-border data rules do not apply to financial services, nor to Australian credit-reporting agencies, and the local data storage requirements include an exception for measures to achieve a legitimate public policy objective. Chapter 18 on Intellectual Property provides for 70 years of copyright protection, and includes detailed provisions in Article 18.82.1 regarding internet services providers (hereinafter, ISPs), including that TPP parties implement legal incentives for ISPs to cooperate with copyright owners to deter the unauthorised storage and transmission of copyrighted materials or, in the alternative, to take other action to deter the unauthorised storage and transmission of copyrighted materials. However, Article 18.82.1 also precludes monetary relief against ISPs for copyright infringements that they do not control, initiate or direct. Lastly, with respect to the technology sector, Article 2.20 requires TPP parties to implement the WTO Information Technology Agreement, while Annex 8-B of Chapter 8 on TBTs provides specific provisions addressing “*Information and Communication Technology (ICT) Products that Use Cryptography*”.

The TPP also explicitly regulates market protection of new biologics. In this regard, Article 18.52 of the TPP, in conjunction with Article 18.50 on the “*Protection of Undisclosed Test or Other Data*”, requires TPP parties to provide market protection to new biologic medicines through either eight years of data exclusivity or, alternatively, five years of data exclusivity, along with “*other measures*”, to deliver a comparable outcome in the market, and recognising that market circumstances contribute to effective market protection. In recognition, *inter alia*, of the early stage of the international and domestic regulation of biologics, signatory parties have also agreed to consult after ten years, or as otherwise decided, to review the TPP biologics provisions, with a view to providing effective incentives for the development of new biologic medicines, as well as to facilitating timely access to medicines, including follow-on biosimilars. Said provisions were the outcome of a compromise reached by the signatory parties on one of the reportedly thorniest issues of the TPP negotiations.

Nonetheless, it is not yet clear whether the text of the TPP will be approved by all of its parties. Most notably, the US Congress will soon vote under the Trade Promotion Authority process. In that regard, the House and Senate are allowed only ‘yes’ or ‘no’ votes on the agreement, which means that individual issues could delay its approval. In addition, Canada’s leadership recently changed, and it appears that the Liberal Party led by Prime Minister Justin Trudeau may not agree with some provisions of the TPP, as approved to by the previous administration under ex-Prime Minister Stephen Harper. Interested parties should monitor developments in relation to the ratification process of the TPP.

## Recently Adopted EU Legislation

### Market Access

- *Commission Implementing Regulation (EU) 2015/2067 of 17 November 2015 establishing, pursuant to Regulation (EU) No. 517/2014 of the European Parliament and of the Council, minimum requirements and the conditions for mutual recognition for the certification of natural persons as regards stationary refrigeration, air conditioning and heat pump equipment, and refrigeration units of refrigerated trucks and trailers, containing fluorinated greenhouse gases and for the certification of companies as regards stationary refrigeration, air conditioning and heat pump equipment, containing fluorinated greenhouse gases*



- *Council Decision (EU) 2015/2021 of 10 November 2015 establishing the position to be taken on behalf of the European Union within the Ministerial Conference of the World Trade Organization on the accession of the Republic of Liberia to the World Trade Organization*

## Trade Remedies

- *Commission Implementing Regulation (EU) 2015/2018 of 11 November 2015 withdrawing the acceptance of the undertaking for two exporting producers under Implementing Decision 2013/707/EU confirming the acceptance of an undertaking offered in connection with the anti-dumping and anti-subsidy proceedings concerning imports of crystalline silicon photovoltaic modules and key components (i.e. cells) originating in or consigned from the People's Republic of China for the period of application of definitive measures*

## Food and Agricultural Law

- *Commission Implementing Decision (EU) 2015/2022 of 10 November 2015 amending Decision 2008/866/EC, on emergency measures suspending imports from Peru of certain bivalve molluscs intended for human consumption, as regards its period of application*

## Other

- *Commission Implementing Regulation (EU) 2015/2068 of 17 November 2015 establishing, pursuant to Regulation (EU) No. 517/2014 of the European Parliament and of the Council, the format of labels for products and equipment containing fluorinated greenhouse gases*
- *Commission Decision (EU) 2015/2056 of 13 November 2015 amending Decisions 2009/300/EC, 2009/563/EC, 2009/894/EC, 2011/330/EU and 2011/337/EU in order to prolong the validity of the ecological criteria for the award of the EU Ecolabel to certain products*

*Ignacio Carreño, Eugenia Laurenza, Anna Martelloni, Bruno G. Simões and Paolo R. Vergano contributed to this issue.*

FratiniVergano specializes in European and international law, notably WTO and EU trade law, EU agricultural and food law, EU competition and internal market law, EU regulation and public affairs. For more information, please contact us at:

**FRATINIVERGANO**  
EUROPEAN LAWYERS

Rue de Haerne 42, B-1040 Brussels, Belgium Tel.: +32 2 648 21 61 - Fax: +32 2 646 02 70  
[www.FratiniVergano.eu](http://www.FratiniVergano.eu)

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