

Issue No. 1 of 12 January 2018

- Outcome and comments on the 11th Ministerial Conference of the World Trade Organization (WTO)
- The use of energy from renewable sources: Diverging positions by the European Commission, the Council of the EU and the European Parliament ahead of the 'trilogue' negotiations
- Modernised EU novel foods regulation with a specific notification procedure for new traditional foods from third countries comes into effect
- Recently Adopted EU Legislation

In this edition of *Trade Perspectives*[©], we are hosting an article on the 11th Ministerial Conference of the World Trade Organization written by Mr. Kevin Verbelen, Policy Officer International Business & Trade at the Flanders Department of Foreign Affairs. All views expressed in the article are personal to the author and do not necessarily express or reflect the views of the Government of Flanders or of *FratiniVergano - European Lawyers*.

Going forward, we look forward to hosting other articles by fellow lawyers, academics, inhouse counsels, government officials and others readers of *Trade Perspectives*[©], so as to further enrich our debates and provide different perspectives on international trade developments.

Outcome and comments on the 11th Ministerial Conference of the World Trade Organization (WTO)

From 10 to 13 December 2017, the 11th Ministerial Conference (hereinafter, MC11) of the World Trade Organization (hereinafter, WTO) took place in the Argentine capital Buenos Aires. What had been predicted by many observers has become reality. The objective to keep the multilateral trading system alive has been achieved. Unfortunately and regrettably, this is almost the only positive outcome of the conference.

Some viewed the presence of United States Trade Representative (hereinafter, USTR) Robert Lighthizer as a positive signal from the United States of America (hereinafter, US). However, the message he brought with him from Washington left little doubt about what was achievable in Buenos Aires. "As President Trump has said when he spoke at the United Nations: we are all here to defend the interests of our own citizens". The question of whether Lighthizer returned to Washington with a different opinion about the inefficiency of the WTO must be answered in the negative. Although the US has a particularly large share of responsibility in the absence of any significant progress in Buenos Aires, it should be noted that in each of the dossiers discussed in Buenos Aires, different coalitions of WTO Members have blocked progress. USTR Lighthizer concluded that since multilateral agreements were not in reach, the way forward was one of more plurilateral negotiations with likeminded WTO Members. The intervention of the European Trade Commissioner Cecilia Malmstöm did not leave any doubt about the disappointment in Europe: "all WTO Members have to face a simple fact: we failed to achieve all our objectives, and did not achieve any multilateral

outcome". The intensity of the crisis that the WTO and the multilateral trading system are currently facing is unseen before and leads to worried discussions on how to proceed with and within the WTO.

Prior to MC11, many had hoped that a tangible agreement would be reached regarding fisheries subsidies. After all, WTO Members had already concluded discussions on a work programme for future negotiations in Geneva. In addition, only five alternative text proposals were still on the table, which could have led to a ministerial declaration. The African group, however, continued to request Special and Differentiated Treatment (hereinafter, SDT), even though all Members of the United Nations had agreed with the Sustainable Development Goal (hereinafter, SDG) 14.6, which calls for "the prohibition of certain forms of fisheries subsidies which contribute to overcapacity and overfishing, and eliminate subsidies that contribute to illegal, unreported and unregulated (hereinafter, IUU) fishing, and refrain from introducing new such subsidies, recognizing that appropriate and effective special and differential treatment for developing and least developed countries should be an integral part of the WTO fisheries subsidies negotiation, by 2020". The US, supported by many other Members of the WTO, could therefore not accept the position of the African Group, nor the ACP-position, which also wished to eliminate subsidies that contribute to IUU fishing, but limited to those implemented in its national laws, regulations and administrative procedures and only in waters beyond its economic zones. Requesting SDT for IUU fishing was, in the opinion of many WTO Members, unacceptable if Members truly mean to implement SDG 14.6 by 2020. In their opinion, SDT for fishing was still an option, but not to sustain IUU fishing within or outside the economic zone. It is mainly for this reason that WTO Members did not manage to go beyond establishing a work programme. In this work programme, WTO Members commit themselves to find an agreement to implement SDG 14.6 by the end of 2019, in time for the next WTO Ministerial Conference. What was also agreed is that Members will improve reporting on existing fisheries subsidy programs and thus improve transparency.

Discussions regarding agriculture focussed on four topics: export restrictions, special safeguard mechanisms, public stockholding and domestic support. Regarding export restrictions, negotiations focussed on a proposal from Singapore, which provided for a notification duty of 30 days before an export restrictive measure is implemented, except for unforeseeable circumstances or urgencies. However, certain WTO Members did not agree with the idea of a notification obligation and others did not want to support an exception for actions taken by the World Food Programme. The Philippines actively sought a solution regarding the discussion on the special safeguard mechanism since its rice waiver had expired in July 2017. Under this waiver, the Philippines had to provide only minimal market access for rice imports, and established country-specific quotas. Since the expiration of the waiver on 30 June 2017, the importation of rice into the Philippines is subject to ordinary customs duties again. Except the Philippines, however, no other WTO Member engaged actively on this subject. Concerning the other two major topics on the table, public stockholding and domestic support, the US did not agree to any reference to these topics within the Doha Development Agenda (hereinafter, DDA), nor did it want to give in on anything related to SDT. Furthermore, the US also blocked any negotiation on cotton. In the absence of any outcome regarding public stockholding and domestic support, India did not agree on any of the new topics, nor did it agree to a work programme on agriculture. The stalemate on these issues, which had emerged in Geneva, could therefore not be overcome in Buenos Aires.

Due to the tough discussions on agriculture, even the extension of the *moratorium* on duties on electronic transmissions (which allows tariff-free cross-border trade in goods that cross the border electronically) was uncertain until the very last hour of the conference. The *moratorium* on non-violation and situation complaints under the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) was eventually also extended. This *moratorium* provides that WTO Members agree not to file TRIPS non-violation cases. Non-violation complaints are allowed if one government can show that it has

been deprived of an expected benefit because of another government's action, or because of any other situation resulting in nullification or impairment.

Even though some discussions on services took place in Geneva in 2017, little was expected to be concluded in Buenos Aires. Ministers committed to continue the debate on services. These talks are likely to focus on trade facilitation and domestic regulation in services. Prior to the MC11, work had progressed well regarding a work programme on e-commerce, but lacked consensus for it to be adopted in Buenos Aires. Even though the work programme was not realised, a group of 71 likeminded WTO Members, including Australia; Brazil; Canada; the EU; Hong Kong; Japan; South-Korea; Mexico; Norway; Singapore; Switzerland; Turkey; Ukraine; and the US, have committed themselves to a meeting in early 2018 to nonetheless start talks on e-commerce. The group remains open to other WTO Members wishing to participate. As such, the road is open for a plurilateral agreement on e-commerce. What the impact will be on the stalled negotiations on the Trade in Services Agreement (TiSA) is unclear. Also on services, 60 WTO Members, counting each EU Member State as one, agreed on a Ministerial Statement in which they commit to continue working on the basis of the recent proposals regarding domestic regulation. They would also welcome new proposals, allowing other WTO Members to still join the plurilateral group of likeminded 'pioneers'.

The absence of agreement on agriculture caused the absence of a multilateral outcome on the so called "new topics" (i.e., topics that are not part of the DDA). These included micro, small and medium-sized enterprises (MSMEs), investment facilitation, sustainable development and gender. Regarding MSMEs, some 87 WTO Members, counting each EU Member State as one, agreed on a Ministerial Statement in which they commit to consider several issues relevant to MSMEs that could facilitate international trade for them. An informal work programme will be drafted, since a formal work programme would need the support of all WTO Members. However, plurilateral negotiations are not being pursued at this stage. On investment facilitation, some 70 countries, counting each EU Member State as one, agreed to continue discussions on investment facilitation with specific attention to development. WTO Members will aim at improving transparency and predictability and they will work out ways to streamline and speed up administrative procedures. Another new topic concerns gender and trade. 119 WTO Members agreed on a declaration on trade and women's economic empowerment. Even though several countries and regions, such as the Government of Flanders, have developed cooperation programmes that aim at empowering women to participate actively in the economy, there is no doubt that women are not sufficiently involved in international trade. The declaration provides a framework in which WTO Members can implement trade policies with a goal to improve women's economic performance and to promote the economic activities developed by women.

Susana Malcorra, Foreign Minister of Argentina and Chairwoman of the MC11, whose relentless efforts in finding agreement on a Ministerial Declaration were highly appreciated by many, could not avoid the 11th Ministerial Conference of the WTO resulting in a disappointing outcome. WTO Members left Buenos Aires without an agreed Ministerial Declaration and with only a very limited work programme for fisheries. Work programmes on agriculture, ecommerce and services were not even reached. The only positive multilateral outcome is the extension of the abovementioned moratoria. Initiatives on e-commerce, services, MSMEs, investment facilitation and gender are all plurilateral in nature, thereby only affecting the WTO Members wishing to take part. Also worrying is that there was no commitment or even a perspective for a solution regarding the appointment of judges to the Appellate Body of the WTO. Taking into account the amount of cases between the US and China alone, and noting that the Appellate Body can now only count on one US, one Chinese, an Indian and a Mauritian judge, the Appellate Body is de facto severely impaired in the ability to perform its tasks, since it needs three judges that are not citizens of the disputing parties. The failure of the MC11, combined with an increasingly 'crippled' Appellate Body, raises serious questions about the effectiveness and even the future of the WTO and of the multilateral trading system as a whole.

Even though the EU showed a lot of engagement to keep up some level of ambition, it too, failed to deliver. Legal hurdles prevented the EU to sign the Buenos Aires Declaration presented by a group of Latin-American countries, as the EU is not allowed to support a document that refers to deeper economic integration in regions outside of the EU, in which around 50 WTO Members expressed their support for the WTO and for the safekeeping of the multilateral trading system. However, the EU did draft a declaration with Japan and the US, which focuses on trade defence and combatting overcapacity. Not singing the Buenos Aires Declaration and rather co-writing a declaration aimed at only negative aspects of trade could be perceived as the EU having arguably other priorities than what it normally advocates: an unconditional support for the multilateral trading system.

Agreeing that a plurilateral negotiation on e-commerce is the likely way forward, developing countries should start to reconsider their positions. No link to the Doha Development Agenda was made in Buenos Aires. The inflexible position of the African Group and the ACP could very likely backfire when more plurilateral negotiations are pursued, because it is harder for the Governments of developing countries to keep up with plurilateral negotiations. In addition, the objectives in the DDA could perhaps never be obtained, if the multilateral trading system kept on failing to deliver results. Therefore, the challenge for all WTO Members will be to prepare themselves for more plurilateral negotiations, to be open for new topics, while building a multilateral consensus around the essential elements of the DDA, which could be obtained in what will hopefully be a more optimistic outcome of the 12th Ministerial Conference of the World Trade Organisation, likely to take place at the end of 2019.

The use of energy from renewable sources: Diverging positions by the European Commission, the Council of the EU and the European Parliament ahead of the 'trilogue' negotiations

On 15 January 2018, the European Parliament will debate the *Report on the proposal for a directive of the European Parliament and of the Council on the promotion of the use of energy from renewable resources (recast)* (hereinafter, the Final Report). The vote on the Final Report is scheduled for 17 January. On 6 December 2017, the European Parliament's Committee on Industry, Research and Energy (hereinafter, ITRE) had submitted this report, which forms the basis of the debate and vote in the plenary. The outcome of the vote in the plenary session will become the European Parliament's negotiating mandate and is the last step before the 'trilogue', the negotiations on legislative proposals between the European Parliament, the Council of the EU (hereinafter, Council) and the European Commission (hereinafter, Commission) can take place. A comparative analysis between the proposal of the Commission and the positions of the Council and the European Parliament shows clearly diverging approaches. For example, depending on the outcome of the 'trilogue', the effects on certain biofuels, in particular palm oil biodiesel, can be significantly different.

Currently, the EU's renewable energy framework is governed by *Directive 2009/28/EC of the European Parliament and of the Council of 23 April 2009 on the promotion of the use of energy from renewable sources and amending and subsequently repealing Directive 2001/77/EC and 2003/30/EC (Renewable Energy Directive and, hereinafter, RED). The RED serves as the EU's legislative approach to ensure that it meets its 2020 targets for reducing energy consumption (<i>i.e.*, to reduce greenhouse gas emissions by 20%, to increase the share of renewable energy to 20% of consumption, and to achieve energy savings of 20%). On 30 November 2016, in order to expand the timeframe of its renewable energy framework until 2030, the Commission published a *'Proposal for a recast of the directive on the promotion of the use of energy from renewable sources'* (hereinafter, RES). The proposed RES Directive was presented as part of the *'Clean Energy for all'* package of proposals, which includes eight different legislative proposals (*i.e.*, on energy efficiency, energy performance in buildings, renewable energy, governance, electricity market design, and rules

for the regulator ACER). The main purpose of the RES Directive is to increase the share of renewable energy sources in the EU energy mix to at least 27% by 2030 (a goal set by the Council in October 2014). The Commission proposal was submitted to the Council and the European Parliament in February 2017.

The proposed RES Directive sets a new binding target for the share of renewable energy consumed in the EU in 2030, which will no longer be translated into national targets. Currently, the EU-level renewable energy consumption target for 2020 relies heavily on EU Member States' national targets for implementation. The proposed RES Directive requires that, by 2030, 27% of energy consumption in the EU be derived from renewable sources, but removes the requirement that 10% of transport fuel consumption be derived from such sources after 2020. The current 10% target was established in the RED. Regarding biofuels, the two most relevant articles are Articles 7 and 25 of the proposed RES Directive. Under Article 7, the Commission proposes how to calculate the share of energy from renewable sources, and includes a decreasing maximum share of first generation biofuels (i.e., biofuels and biouliquids made from food and feed crops), starting from 2021 as a way of addressing emission from Indirect Land Use Change (hereinafter, ILUC). ILUC refers to emissions created as a result of increased land demand for the production of biofuels, where such land could have been used for food, feed or fibre production. The proposed RES Directive divides the calculation of the gross final consumption (i.e., the energy delivered to industry, transport, households, and services) of energy from renewable resources in each Member State into three final types of consumption: 1) Electricity; 2) Energy for heating and cooling; and 3) Energy in transport. Regarding the final consumption of energy in road and rail transport, the proposed RES Directive requires that biofuels and bioliquids, as well as biomass fuels, from food or feed crop, be reduced from 7% to 3.8% in 2030. As another way to address ILUC, EU Member States may set lower limits and distinguish between different types of biofuels and bioliquids produced from food and feed crops. In its proposal, the Commission expressly includes an example explaining that EU Member States may set a lower limit for the contribution from biofuels produced from oil crops, taking into account ILUC. Article 25 establishes an EU-level obligation for fuel suppliers to provide 6.8% of low-emission and renewable fuels by 2030, including renewable electricity and advanced biofuels (i.e. biofuels and bioliquids made from non-food crops and residues). This is intended to stimulate decarbonisation (i.e., the reduction or removal of carbon dioxide from energy sources) and energy diversification, and to ensure a cost-efficient contribution of the sector to the overall target achievement. Regarding biomass, the proposed RES Directive extends the greenhouse gas emission saving criteria to biomass fuels. Under the RES, biomass fuels produced from agricultural biomass should fall under the same criteria as biofuels and bioliquids. This means that bioenergy should not be produced from raw materials obtained from lands with high biodiversity value, and with high carbon stock. Furthermore, a new riskbased sustainability criterion for forest biomass, as well as land use and land use change and forestry requirements, are introduced in order to ensure proper carbon accounting of carbon impacts of forest biomass used in energy generation.

In the European Parliament, the ITRE Committee is the responsible Committee for the proposed RES Directive. The *Rapporteur* of the ITRE Committee presented a draft report on the RES on 18 May 2017, which was considered in the ITRE Committee on 22 June 2017 and tabled for amendments at the end of June 2017. Other relevant European Parliament Committees, such as the Committee on Transport and Tourism, the Committee on Agriculture and Rural Development, the Committee on Petitions, the Committee on Development and the Committee on Environment, Public Health and Food Safety (hereinafter, ENVI) also adopted their opinions on the proposed RES Directive. The Committee on International Trade is notably absent from the list of involved Committees. Each of the Committees submitted its opinion to the ITRE Committee, which considered them ahead of the adoption of its report. Particularly noteworthy is the opinion submitted by the ENVI Committee, which actually holds lead competence on the articles relating to biofuels and sustainability criteria contained in the proposed RES Directive. The ENVI Committee adopted its opinion on the proposed RES Directive on 23 October 2017 and

submitted it to the ITRE Committee in November. The key points of the ENVI Committee's opinion are the reintroduction of national targets and the phase-out of food-based, first generation biofuels by 2030, with those derived from palm oil to be phased-out already from 2021. Other key points are the setting of biomass sustainability standards, which aim at minimising the risk allowing sustainable forest biomass to benefit from support schemes, and the proposal to increase the share of advanced biofuels to 9% of fuels supplied by 2030. On 28 November 2017, the ITRE Committee adopted its Final Report, which is currently tabled for debate in the plenary on 15 January 2018.

The Final Report of the European Parliament's ITRE Committee, tabled on 6 December 2017, is the text with more diverging positions. The Final Report sets an EU-level binding target of at least 35% share of renewable energy sources and re-introduces the national targets, which were removed by the proposal of the Commission. The Final Report also adds that "[e]ach Member State shall ensure that the share of energy from renewable sources in all forms of transport in 2030 is at least 12 % of the final consumption of energy in transport in that Member State". It also raises the EU level obligation for fuel suppliers to provide 10% of low-emission and renewable fuels by 2030 (as compared to 6.8% in the Commission's proposal), including renewable electricity and advanced biofuels. Most relevant, is the inclusion of a new recital (Recital 25a) and a new wording within Article 7 of the proposed RES Directive. The new recital refers to the European Parliament Resolution of 4 April 2017 on 'palm oil and deforestation of rainforest'. According to Recital 25a, the European Parliament calls on the Commission to take measures to phase-out the use of vegetable oils that drive deforestation, including palm oil, as a component of biofuels, preferably by 2020. The resolution also calls for a single certification scheme for sustainable palm oil. The proposed changes to Article 7 are arguably the most controversial aspects vis-à-vis the Commission's proposal and the Council's position. The three EU Institutions concur on a 7% limit of the contribution from biofuels and bioliquids, as well as biomass, from food and feed crop for the calculation of final consumption of energy in road and rail transport in each EU Member State. However, while the Council maintains the cap at 7% and the Commission reduces it to 3.8% by 2030, the European Parliament goes further and states that the limit must be reduced to 0% in 2030. Furthermore, it explicitly mentions that "[t]he contribution from biofuels and bioliquids produced from palm oil shall be 0% from 2021". The Final Report tabled by the ITRE Committee also states, in Article 7 of the proposed RES Directive, that the Commission should develop a methodology to certify 'low ILUC-risk biofuels and bioliquids' by 31 December 2019.

Within the Council, EU Energy Ministers discussed the proposed RES Directive on 27 February and 26 June 2017. The Council agreed on its general approach on the proposed RES Directive on 18 December 2017 and now stands ready to start negotiations with the Commission and the European Parliament, as soon as the latter has agreed on its negotiating mandate. The Council, in its position agreed on 18 December 2017, supports the 27% EU target for 2030 as proposed by the Commission. However, it introduces a 14% renewable target for each EU Member State in the transport sector for 2030 and a sub-target of 3% for advanced biofuels (for which double counting will be allowed, which means that the use of advanced biofuels counts double for the final target calculation). Regarding biomass, the Council does not make any amendment to the Article 7 proposed by the Commission. However, it adds a sub-paragraph to Article 25. Although this is an additional paragraph, the wording does not differ from the proposed wording on Article 7 on the Commission's proposal. The only difference is that the Council maintains the 7% cap, while the Commission proposed a reduction to 3.8% in 2030 of final consumption of energy in road and rail transport. The Council expressed in its position that the existing cap of 7% on first generation biofuels is maintained to provide certainty to investors and proposed that the EU Member States that set lower cap should be rewarded with the option of lowering its overall target for renewables in transport.

While the Council and the Commission appear to be more or less on the same page, substantial differences exist between the Commission proposal, the Council position and the

Final Report of the ITRE Committee. The main differences concern the renewable energy target in the transport sector and the target for the calculation of each EU Member State's gross final consumption of energy from renewable sources, including biofuels and bioliquids. as well as from biomass fuels consumed in transport if produced from first generation biofuels. Of particular concern is the difference in wording regarding biofuels and bioliquids derived from palm oil. While the Commission proposal and the Council only mention the possibility of EU Member States distinguishing different types of biofuels and bioliquids from food and feed crops, providing as examples biofuels from oil crops, the Final Report of the ITRE Committee introduces a phase-out of biofuels and bioliquids from palm oil. Of note is the fact that neither the RES Directive proposal by the Commission, nor the Council's position single out biofuels from palm oil, but rather mention biofuels from oil crops in more general terms. Some EU policymakers, environmental associations, and ethanol producers, have welcomed the Final Report of the ITRE Committee and are expecting a positive outcome from the vote in plenary on 17 January 2018. However, palm oil producers and producing countries have already expressed their willingness to challenge any EU decision, should palm oil indeed be discriminatorily singled out and phased-out before all others. Further criticism concerns the biomass criteria. Although the proposed RES Directive includes sustainability criteria for biomass in general, there are still concerns that the criterion for forest biomass is not strong enough and that it could lead to deforestation, especially when it comes to 'solid biomass', which is burned to generate electricity (i.e., burning whole trees for biomass instead of only wood waste and residues).

On 17 January 2018, the European Parliament will vote in plenary on the ITRE Final Report. The outcome will become the European Parliament's negotiating mandate. This is the last step before the 'trilogue' between the institutions can begin. While the adoption of the Report in the European Parliament's plenary regarding the phase-out of biofuels from palm oil does not yet mean that such phase-out at the EU level will actually take place, it already sets the stage for the negotiations. The 'trilogue' will be the last step in the process and the final opportunity to influence the legislative process before an agreement by the EU institutions will be reached. All interested stakeholders, including governments, businesses, in particular the transport industry and palm oil producers, trade associations and NGOs, in the EU and beyond should monitor any further developments and remain or become actively involved in the final steps of this important piece of EU legislation. The worrying profiles of evident discrimination against a single commodity, which incidentally is not produced in the EU, should encourage a sound review of the proposed measure under the applicable rules of the WTO, which may avoid the future trade distortions and dispute settlement procedures that will inevitably ensue.

Modernised EU novel foods regulation with a specific notification procedure for new traditional foods from third countries comes into effect

Since 1 January 2018, Regulation (EU) 2015/2283 of 25 November 2015 on novel foods (hereinafter, the NFR) is applicable. It repeals and replaces Regulation (EC) No 258/97 and Regulation (EC) No 1852/2001, which were in force until 31 December 2017. The aim of the NFR is to improve conditions so that food businesses can easily bring new and innovative foods to the EU market, while a high level of food safety for consumers is maintained. Most relevant for international trade, the NFR includes a specific notification procedure for new traditional foods from third countries.

Novel foods are foods that were not used for human consumption to a significant degree within the EU before 15 May 1997, irrespective of the dates of accession of EU Member States. This includes newly developed, innovative food, or food produced using new technologies and production processes, as well as food traditionally consumed outside of the EU. The first EU rules on novel foods were established by Regulation (EC) No 258/97 of the European Parliament and of the Council on novel foods. Those rules needed to be updated to simplify the current authorisation procedures and to take account of recent developments

in EU law and technological progress (for the history of the adoption of the NFR, see *Trade Perspectives*, Issue No. 11 of 29 May 2015 and Issue No 18 of 9 November 2015).

The main features and improvements of the NFR are the following: 1) Expanded categories of novel foods; 2) Generic authorisations of novel foods; 3) A simplified, centralised authorisation procedure; 4) Promotion of innovation by granting an individual authorisation for five years; 5) Establishment of an EU list of authorised novel foods; and 6) A faster and structured notification system for traditional foods from third countries.

The NFR defines in Article 3(2)a) the expanded categories of novel foods, including: 1) Foods originating from plants, animals, microorganisms, cell cultures, minerals, etc.; 2) Specific categories of foods (e.g., insects, vitamins, minerals, food supplements, etc.); 3) Foods resulting from production processes and practices; and 4) State of the art technologies (e.g., foods with intentionally modified or new molecular structure, nanomaterials), which were not produced or used in the EU before 1997 and thus may be considered to be novel foods.

Under the NFR, all authorisations (new and existing) are generic, as opposed to the applicant-specific, restricted novel food authorisations under the previous novel foods regime. As a consequence, any food business operator can place an authorised novel food on the EU market, provided the authorised conditions of use, specifications and labelling requirements are respected. Food industry sources have described the generic nature of authorisations as not being an incentive for companies to invest in a lot of safety investigations for the novel product and have stated that it would really depend on what companies can do to protect their intellectual property. The NFR foresees, however, the possibility to promote innovation by granting an individual authorisation for five years based on protected data. This means that, according to Article 26 of the NFR, on request, an applicant may be granted an individual authorisation for the placing on the market of a novel food if it is based on newly developed scientific evidence and proprietary data. Such data shall not be used for the benefit of a subsequent application during a period of five years from the date of the authorisation of the novel food without the agreement of the initial applicant.

The NFR provides for a simplified, centralised authorisation procedure managed by the European Commission (hereinafter, Commission) using an online application submission system. Centralised, safety evaluations of the novel foods will be carried out by the European Food Safety Authority (hereinafter, EFSA). The Commission consults the EFSA on the applications and bases its authorisation decisions on the outcome of the EFSA's evaluation. Industry sources state that the major problem of the previous system was time, with on average three and a half years to achieve a novel food approval and in some cases, even five or six years. The new procedure aims at improving efficiency and transparency by establishing deadlines for the safety evaluation and authorisation procedure, thus reducing the overall time spent on approvals. Commission Implementing Regulation (EU) 2017/2469 of 20 December 2017 laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods sets out the administrative, technical and scientific requirements that must be included in a novel food application and dossier. In addition, specifically on the scientific requirements, the EFSA has issued, already on 21 September 2016, detailed guidance. Both the legal text of the implementing act and the EFSA guidance are expected to assist food business operators and facilitate the preparation and submission of a novel food application.

The EU list of authorised novel foods foreseen by the NFR is a positive list containing all authorised novel foods. Novel foods that are authorised in the future will be added to the EU list by means of Commission Implementing Regulations. Once a novel food is added to the EU list, it is automatically considered as being authorised and it can be placed on the EU market. Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 on

establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on Novel Foods entered into force on 9 January 2018. This is the initial EU list, already containing 125 entries of novel foods authorised under the previous system. Under the previous Regulation (EC) No 258/97 on novel foods, 228 applications for novel foods have been submitted to individual EU Member States and more than 400 notifications were made for foods that were substantially equivalent to existing foods or food ingredients as regards their composition, nutritional value, metabolism, intended use and the level of undesirable substances contained therein.

In order to facilitate their marketing, Articles 14 to 20 of the NFR provide for a faster and structured notification system for traditional foods from third countries, which are considered novel foods in the EU, on the basis of a history of safe food use. If the safety of the traditional food in question can be established on the basis of evidence of a history of consumption in the third country, and if there are no safety concerns raised by EU Member States or EFSA, the traditional food will be allowed to be placed on the EU market within four months. Including an EFSA assessment, the procedure should take less than 18 months, providing more certainty for producers. According to Article 3(2)b), "History of safe food use in a third country" means that "the safety of the food in question has been confirmed with compositional data and from experience of continued use for at least 25 years in the customary diet of a significant number of people in at least one third country prior to a notification referred to in Article 14". On 20 December 2017, the administrative, technical and scientific requirements, which should be included in a notification of a traditional food from a third country and which is considered novel in the EU, have been adopted in Commission Implementing Regulation (EU) 2017/2468 laying down administrative and scientific requirements concerning traditional foods from third countries in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods. Prior to this Implementing Act, on 22 September 2016, EFSA had issued detailed guidance on the information, which should be included in the notification, in particular in relation to establishing the safe history of consumption of the traditional novel food in third countries.

The previous EU regulation on novel foods had been significantly criticised in the past by a diverse set of stakeholders for applying market safety standards and evaluations to so-called 'biodiversity-based' products and traditional foods that are not commensurate to the level of risk posed by these products and for impeding their access to the EU market. This has occurred even if the product in question had a long historical record of traditional safe use in third countries. These concerns even reached the level of the World Trade Organization's (WTO) Sanitary and Phytosanitary (SPS) Committee in a submission by Peru in June 2011. While, in its submission, Peru acknowledged the importance of consumer protection and health, it indicated that, because there was no significant marketing of many biodiversity-based products in the EU before 1997, and despite a long history of safe human consumption in the countries of origin, these products were treated as novel foods and subject to stringent safety and risk assessment requirements. These requirements might infringe obligations under the WTO SPS Agreement, which require WTO Members to ensure that SPS measures are not more trade-restrictive than required to achieve an appropriate level of protection.

In response to such concerns, foods historically consumed outside the EU will from now on be fast-tracked for approval if no EU Member State or EFSA objects. It must be said that new or novel foods have been coming to Europe throughout history. It is interesting to see that there was a time when potatoes, tomatoes, bananas and other tropical fruits, plus a number of spices and maize were considered something 'novel' in Europe. In recent times, after the previous novel foods regulation entered into force in 1997, other products arrived in Europe like chia oil and seeds, baobab fruits and noni fruits. However, these products had to go through the novel foods approval procedure. This trade restriction for 'biodiversity-based' products and traditional foods does no longer apply. Under the NFR, the simplified notification procedure may be applied for the placing on the EU market of, for example, exotic berries like the *Peruvian camu*, the *lucuma* fruit or the *yacon* herb. Nevertheless,

applications for third countries' new traditional foods under the NFR must be carefully assessed and practice will show if the new procedure works well.

The first authorisation procedures for novel foods are reportedly already under way. It remains to be seen when the first notifications of new traditional foods from third countries reach the Commission. Interested stakeholders are encouraged to be prepared to navigate the new procedures and to work with their legal advisors prior to submitting new novel food dossiers to the Commission.

Recently Adopted EU Legislation

Customs Law

- Commission Implementing Regulation (EU) 2018/49 of 11 January 2018 amending Council Implementing Regulation (EU) No 501/2013 following a 'new exporter' review pursuant to Articles 11(4) and 13(4) of Regulation (EU) 2016/1036 of the European Parliament and of the Council
- Commission Implementing Decision (EU) 2018/52 of 11 January 2018 terminating the partial interim review concerning imports of certain threaded tube or pipe cast fittings of malleable cast iron originating in the People's Republic of China and Thailand

Trade Remedies

 Notice concerning the anti-dumping measures in force in respect of imports to the Union of steel ropes and cables originating, inter alia, in the People's Republic of China, as extended to imports of steel ropes and cables consigned from, inter alia, the Republic of Korea, whether declared as originating in the Republic of Korea or not

Food and Agriculture Law

- Amendments adopted by the European Parliament on 19 January 2016 on the proposal for a regulation of the European Parliament and of the Council on a multiannual recovery plan for Bluefin tuna in the eastern Atlantic and the Mediterranean repealing Regulation (EC) No 302/2009 (COM(2015)0180 — C8-0118/2015 — 2015/0096(COD))
- European Parliament resolution of 20 January 2016 on Commission Delegated Regulation (EU) No .../... of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for processed cerealbased food and baby food (C(2015)06507 — 2015/2863(DEA))

Other

 Decision No 1/2017 of the EU-Georgia Association Committee in Trade configuration of 6 December 2017 establishing the list of arbitrators referred to in Article 268(1) of the Association Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and Georgia, of the other part [2018/2] European Parliament resolution of 21 January 2016 on Association Agreements / Deep and Comprehensive Free Trade Areas with Georgia, Moldova and Ukraine (2015/3032(RSP))

Ignacio Carreño, Tobias Dolle, Lourdes Medina Perez, Kevin Verbelen 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

Rue de Haerne 42, B-1040 Brussels, Belgium Tel.: +32 2 648 21 61 - Fax: +32 2 646 02 70

www.FratiniVergano.eu

Trade Perspectives® is issued with the purpose of informing on new developments in international trade and stimulating reflections on the legal and commercial issued involved. Trade Perspectives® does not constitute legal advice and is not, therefore, intended to be relied on or create any client/lawyer relationship.

To stop receiving Trade Perspectives® or for new recipients to be added to our circulation list, please contact us at:

TradePerspectives@FratiniVergano.eu