FRATINIVERGANO
EUROPEAN LAWYERS
TRADE PERSPECTIVES©

Issue No. 23 of 16 December 2016

Season's Greetings

2016 is drawing to a close and all of us in the International Trade and Food Law Group of *FratiniVergano* would like to wish you, your colleagues and families all the best for a peaceful holiday season and for a successful and healthy 2017. We hope that you have enjoyed *Trade Perspectives*© throughout this year and that you have always found it stimulating and timely. As usual, we have published a total of 23 issues and invested a great deal of time and energy in this undertaking. We have done it with the usual passion and drive.

You can find all previous issues of *Trade Perspectives*© on our website: http://www.fratinivergano.eu/en/trade-perspectives/.

For the year to come, we will continue with our editorial efforts, beginning with the publication of the next issue of *Trade Perspectives*© on 13 January 2017. *Trade Perspectives*© is now circulated to almost 5,000 recipients worldwide and not a single week goes by without new readers asking to be added to our circulation list. This fills us with pride, but also with a deep sense of commitment and discipline towards our readers' expectations. Thank you for your interest in our publication and for helping us to make it a better and more useful tool of discussion. We look forward to continue hearing from you regularly and to another year of exciting international trade and food law developments.

EU trade policy and trade negotiations revisited - Belgium's Walloon region proposes a new approach to the negotiation of the EU's trade agreements

On 5 December 2016, Paul Magnette, the head of Government of Belgium's Walloon region, presented the *Namur Declaration* (hereinafter, the Declaration), a collection of propositions that Magnette and some forty signatories, mainly from academia from across the EU, suggest as the guiding principles in the negotiation of any future EU trade agreements. This Declaration aims at stimulating a debate about the future approach of EU trade policy and trade negotiations.

The Declaration comes after Wallonia refused, this past October, to grant the Belgian federal executive the full powers to approve the signing by the EU of the Comprehensive Economic and Trade Agreement (hereinafter, CETA) between the EU and Canada, thus shortly putting the entire deal at risk of failure. By the end of October, having secured several concessions, the Belgian region withdrew its opposition and the signing of the CETA proceeded as

planned. This crisis, however, has led to the adoption of the three-page Declaration, which addresses the concerns of the Walloon authorities and, as the preamble of the Declaration asserts, those of a growing number of European citizens. The main idea behind the Declaration, according to its signatories, is that trade, rather than being an end in itself, must serve the goals of sustainable development, inequality reduction and climate change mitigation. The principles put forward in the Declaration are intended to implement this understanding and ensure that the negotiating process is transparent and subject to democratic control procedures, while negotiated legal texts do not result in an erosion of governments' control over domestic public policy. The first of the Declaration's three sections addresses the concerns on transparency and democratic control, the second discusses the compliance of trade agreements with socio-economic, sanitary and environmental legislation, and the third deals with public interests in the dispute resolution mechanism.

Section one, titled '*Respect for democratic procedures*', calls for a closer involvement of national parliaments and civil society throughout the process and an assessment of the treaty's social and environmental impact. These propositions largely reflect the EU's already established practice of conducting comprehensive *Sustainability Impact Assessments* and publicising *interim* results of negotiations. In particular, the impact assessments (*i.e.*, the analyses of the potential economic, social, human rights and environmental impacts that a trade agreement could have in the EU, in the partner country and in other relevant countries) provide for a consultation process involving relevant stakeholders, inside and outside the EU. The CETA specifically commits each party to review, monitor and assess the impact of its implementation on sustainable development in the respective party's territory (Article 22.3(3) of the CETA). One requirement of the Declaration, which goes beyond the procedural *status quo*, is for the transparency and consultation process, including public and parliamentary debates in EU Member States, to start even before the negotiating mandate is established.

A proposition that stands apart in this section is the suggestion '*not to favour*' the provisional application of so-called '*mixed*' agreements (*i.e.,* agreements touching upon policy areas that do not fall under the exclusive competence of the EU). Whether comprehensive trade and economic agreements like the CETA are '*mixed*' remains unclear. While the European Commission (hereinafter, Commission) had originally considered the CETA to fall under the exclusive competence of the EU, it decided to propose the CETA as a '*mixed*' agreement (see *Trade Perspectives*, Issue No. 13 of 1 July 2016). Article 218(5) of the Treaty on the Functioning of the European Union (TFEU) allows the EU to take a decision to provisionally apply an international agreement during the period of its ratification by EU Member States. Provisional application allows the parties to an agreement to give its provisions immediate effect without having to wait until all ratification instruments have been deposited, which, in the case of the EU composed of 28 Member States, may take several years to complete – a frustrating prospect after a years-long negotiation process for all those expecting to benefit from the agreement. The Declaration raises a legitimate point: if a '*mixed*' agreement envisages provisional application, a Member State may, depending on the terms of provisional application, find itself legally bound by international obligations to which it was committed by an executive that, under that Member State's domestic law, does not have the requisite powers.

The potential implications of this are well illustrated by the famous Yukos case. In this case, the arbitration tribunal *found* that it had jurisdiction over the dispute and awarded the claimants a USD 50 billion compensation. This was despite the fact that the Energy Charter Treaty (ECT), under which the claims were brought, applied to the respondent (*i.e.*, the Russian Federation) only provisionally because Russia had never ratified the ECT and, as the Hague district court later ruled in a decision setting aside the tribunal's award, Russia's agreement, in Article 27 of the ECT, to submit disputes to international arbitration could not take effect before ratification of the ECT by the Russian Parliament. This stems from the fact that public law disputes are generally not subject to arbitration under Russia's domestic law.

The abolishment of provisional application, however, would likely mean a considerably prolonged waiting period after the conclusion of any trade agreement, which is normally

already shaped in close consultation with national legislatures. The CETA arguably offers a good solution by allowing provisional application on cautious and nuanced terms. As usual and pursuant to Article 30.7.3(a) of the CETA, provisional application only starts after the parties have notified that the internal requirements and procedures necessary for provisional application have been completed. Article 30.7.3(b) of the CETA allows each Party to carve out the provisions that it does not want to provisionally apply. If either Party raises an objection against the other Party's choice, the agreement does not provisionally apply at all. Finally, Article 30.7.3(c) of the CETA allows either Party to terminate provisional application by written notice. Therefore, the CETA provides EU Member States with a reasonable opportunity to ensure that only provisions that do not require approval by national legislatures apply on a provisional basis.

Section two of the Declaration, titled '*Compliance with socio-economic, sanitary and environmental legislation*', includes seven propositions, which seek to secure governments' power to regulate in the public interest and ensure that a trade agreement contributes to sustainable development and climate objectives. Most of the demands in this section do not appear revolutionary. The suggested '*positive list*' approach (*i.e.*, the explicit listing of the activities that the parties open to competition instead of proclaiming general liberalisation of all activities and listing exceptions) had been used in previous EU trade agreements and was only recently abandoned. The key reason for the proposal to revert to the old method is that governments want to ensure that they do not commit to liberalisation today in respect of services and service sectors that will be brought to light in the future (*e.g.,* as a result of future technology advancements). As regards the suggestion for the parties to commit to not lower their social, sanitary, and environmental norms in an attempt to promote exports and attract investment, some argue that there has indeed been a '*race to the bottom*', in particular with respect to labour standards, due to competition for foreign direct investment.

Therefore, it comes as no surprise that governments maintaining high environmental, labour, and tax standards may wish to avoid downward competitive pressures. It does not appear likely, however, that a full-fledged prohibition to downgrade standards will be integrated in future agreements. While some governments may want to preserve their freedom to '*regulate up*', others may want to retain the right to '*regulate down*'. Relevant provisions in the EU's recently signed trade agreements have been formulated in a hortatory or '*best efforts*' language and, importantly, recognise each party's right to establish its own levels of protection. For instance, the parties to the EU-Viet Nam Free Trade Agreement, currently pending ratification, undertake to '*strive to ensure*' that their laws and policies reach high levels of domestic protection in the environmental and social areas. In the EU-Singapore Free Trade Agreement, also currently pending ratification, the parties '*recognise that it is inappropriate*' to encourage trade or investment by weakening or reducing the protections afforded under their domestic labour and environmental laws and '*shall strive towards*' providing and encouraging high levels of environmental and labour protection. The parties to the CETA agree to '*seek to ensure*' that their labour laws '*provide for and encourage high levels of labour protection*'.

The Declaration also proposes to include in FTAs a requirement for the EU's trade partners to ratify certain human rights, ILO, and environmental conventions. The EU has extensively used human rights conditionality in its Generalised System of Preferences (GSP), which offers developing countries preferential market access in exchange for commitments in the field of human rights (including ratification of human rights and ILO conventions). The distinctive feature of the GSP, however, is its unilateral character, meaning that the beneficiaries are unable to negotiate the terms of the deal. It has also been a general policy of the EU to provide in its FTAs that the protection of human rights constitutes an '*essential element*' of the agreement, *i.e.* an element whose violation amounts, under international law, to a material breach of the agreement and thus gives the EU the right to unilaterally terminate the entire FTA (Article 60 of the Vienna Convention on the Law of Treaties). It is questionable, however, whether this strategy may be successful with partners of economic and political standing comparable to that of the EU and across the entire spectrum of conventions mentioned in the declaration. The US, for one, generally shuns environmental

agreements. Thus, in certain cases, the obligation to '*make continued and sustained efforts towards ratifying*' certain conventions (the language used, for instance, in the EU's FTA with Viet Nam and that with Singapore) is arguably as much as can be realistically achieved.

Section three of the Declaration, titled '*Guarantee public interests in the dispute resolution mechanism*', addresses concerns that international arbitration may not pay sufficient regard to public interest and suggests favouring recourse to national and European courts instead. This preference appears difficult to implement in practice, as international arbitration of investment disputes has arguably become the standard of international investment protection. No matter how independent a national judiciary is in its decisions, it is still part of the government against which an aggrieved investor brings a claim. While investors could arguably accept, in some cases, a requirement to exhaust local judicial remedies, a complete renouncement of international arbitration seems unlikely. International arbitration, especially in commercial cases, has often been wrapped in secrecy, which fuelled the suspicions of civil society. The EU, however, appears to have achieved much progress in this area. In particular, the CETA's chapter on the settlement of investment disputes provides for the publication of an extensive list of case documents, opens all hearings to the public, and, generally, incorporates the Rules on Transparency developed by UNCITRAL (*i.e.*, the United Nations Commission on International Trade Law), which set a reasonably high standard of openness. The Appellate Tribunal to be established under the CETA is intended to be an additional safety valve designed to ensure the development of a consistent body of case law. Finally, the CETA calls for the establishment of a *'World Investment Court*' (*i.e.*, a multilateral investment tribunal and appellate mechanism for the resolution of investment disputes) in cooperation with other countries, as a response to the criticisms waged against the current investor-state dispute settlement system. The EU and Canada have embarked on engaging at least 10 to 20 partner countries to set up this institution and held the first meetings in December 2016. As regards the special needs of smaller claimants (*i.e.*, small and medium-sized enterprises and individuals), referred to in the Declaration, the CETA already provides for consultations via videoconferencing and establishes an obligation of the respondent State to give sympathetic consideration to a request that the tribunal, which will normally hear cases in divisions of three members, consist of a sole member to reduce costs. The CETA further provides for the development of supplemental rules that would aim at reducing the financial burden on those claimants that are natural persons or SMEs.

Therefore, the propositions of the *Namur Declaration* appear to be evolutionary at best and are far from revolutionising EU trade policies. However, the *Namur Declaration* is poised to only be a first contribution to a much larger debate on EU trade negotiations and future trade agreements to be expected for 2017 and beyond. The EU and its Member States will have to decide, in the years to come, how to move forward with the ongoing and future trade negotiations. Now is the time for interested stakeholders to take part in the reshaping of the approach to EU trade negotiations and the future of EU-negotiated trade agreements. The EU must overcome the tedious issues that have surrounded the conclusion of its most recent trade agreements, as recently witnessed with the CETA, which risk diminishing its credibility and its negotiating position.

The European Commission reinforces its push to grant individual EU Member States the option of restricting or prohibiting the use of genetically modified food and feed

At the beginning of December 2016, the Commission reportedly re-initiated its efforts to persuade EU Member States to adopt a regulation allowing individual EU Member States the option of restricting or prohibiting the use of genetically modified food and feed (hereinafter, GM food and feed). Such an '*opt-out*' mechanism is already in effect regarding the cultivation of genetically modified organisms (hereinafter, GMOs), which the Commission originally proposed to extend to GM food and feed in April 2015. Such an approach looks poised to have significant legal implications, something that EU Member States and Members of the

European Parliament (hereinafter, MEPs) already criticised when the Commission's proposal was first tabled in 2015.

The EU's '*GMO legal framework*' consists, in particular, of *Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms* and *Regulation (EC) No. 1829/2003 on genetically modified food and feed*. The comprehensive GMO legal framework covers the placing on the market of GMOs and GM food and feed. According to the Commission, these acts aim at ensuring the safety of GMOs and GM food and feed, and at establishing an internal market for those products. Currently, once GM food and feed is authorised in the EU. EU Member States may only prohibit, restrict or impede the free circulation of such products within their territory under very strict conditions laid down in EU law, namely the provision of evidence of a severe risk to health or to the environment. Until 2015, this had also been the case for GMO cultivation, but has changed under *Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory*. Directive (EU) 2015/412 provides EU Member States with the option to decide whether or not to permit the cultivation of EU-approved GMOs in their territories (see *Trade Perspectives*, Issue No. 17 of 24 September 2010 and Issue No. 2 of 23 January 2015).

In the *Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No. 1829/2003 as regards the possibility for the Member States to restrict or prohibit the use of genetically modified food and feed on their territory* (hereinafter, the *Proposal*) of 22 April 2015, the Commission suggested to also use this approach for the use of GM food and feed. More specifically, the *Proposal* would allow EU Member States to adopt measures restricting or prohibiting the use of GM food and feed provided that such measures are: (a) reasoned and based on compelling grounds in accordance with EU law, which shall, in no case, conflict with the risk assessment carried out pursuant to Regulation (EC) No. 1829/2003; and are (b) proportional and non-discriminatory. The *Proposal* also provides for a standstill period between the publication of any draft decision by an EU Member State for such measures and their entry into force in order to allow the Commission and other EU Member States to analyse and comment on the draft.

In 2015, the *Proposal* faced scepticism in the Council of the EU and within in the European Parliament. In July 2015, the Agriculture Ministers' Council considered the *Proposal* "*not useful*" and "*unworkable*" and, in October 2015, the European Parliament almost unanimously rejected the current *Proposal* from the Commission. Following these developments, Members of the Council of the EU requested the Commission to provide further information on the legal implications of the *Proposal*. The Commission has now reportedly submitted to the Council of the EU a confidential document providing an analysis of the legal implications of the 2015 *Proposal*. Such legal implications are manifold and may further delay any measures in this respect. A parallel request by Members of the Council of the EU, for the preparation of an impact assessment of the proposed changes, does not appear to have been fulfilled yet.

EU Member States and a number of MEPs were especially concerned with the implications for the internal market when rejecting the *Proposal* in 2015. Reportedly, MEPs stressed that the *Proposal* would risk undermining the Single Market. Indeed, a number of legal issues appear to be contentious. While the assertions by MEPs that the proposed new rules would require the implementation of border controls between EU Member States appear exaggerated, because the *Proposal* refers to the use and not the mere import, such a move is poised to cause significant disturbances on the EU market. GM feed is imported into the EU for European livestock and a ban of GM food in a number of EU Member States would obviously considerably impair intra-EU trade of such products. Articles 28-37 of the Treaty of the Functioning of the EU (hereinafter, TFEU) relate to the free movement of goods within the EU internal market. Therefore, the *Proposal* stresses that EU Member States "*will need to justify the measures taken based on grounds to be in accordance with Article 36 TFEU*

and the notion of overriding reasons of public interest as developed by the case-law of the Court of Justice [of the EU]".

Another question pertains to the enforcement of such bans, insomuch that products would need to be tested by EU Member State authorities to assure compliance with national bans. Closely connected to this issue is the question of labelling GM foodstuffs under *Regulation (EC) No. 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms*, as well as GMO-free foodstuffs. This is a sensitive issue for many consumers and is evidenced by the increased use of '*GMO-free*' labels and claims on foodstuffs that have spread across the EU, in particular in Germany and France, in recent years (see *Trade Perspectives*, Issue No. 15 of 24 July 2015). Rules on such labels vary in EU Member States and the proposed new rules would further contribute to this piecemeal approach.

The *Proposal* prominently notes that any restriction or prohibition by an EU Member State "*will need to comply with the international obligations of the Union*". This, however, may be easier said than done. Indeed, concerns over the compatibility of the new EU rules with the EU's international obligations likely have contributed to a previous delay of the EU's GMO framework. The EU was found to be in violation of its WTO obligations in the framework of the *EC – Biotech* products dispute, where a WTO panel ruled, in relevant part, that the EU engaged in a *de facto moratorium* leading to "*undue delays*" on the approval of GM products. The panel in that dispute further found that the safeguard measures maintained by certain EU Member States were inconsistent with the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (hereinafter, SPS Agreement), inasmuch as they were not based on risk assessments within the meaning of Article 5.1 of the SPS Agreement, breaching also Article 2.2 of the SPS Agreement. In this regard, it is important to note that the *Proposal* specifically underlines that, since the authorisation of the GM food or feed would be determined with respect to risks to health and the environment, EU Member States would have to refer to "*other compelling grounds*". Arguably, the overall system whereby EU Member States may '*opt-out*' of the EU-level authorisation of GM food and feed may result in barriers to trade, inasmuch as GM food and feed may be excluded from certain EU jurisdictions, possibly in contravention of the prohibition of quantitative restrictions envisaged in Article XI of the General Agreement on Tariffs and Trade (hereinafter, GATT). However, it may be argued that, within the context of a potential WTO challenge of EU Member States' GM food and feed bans, Article XX of the GATT (*i.e.*, the '*General Exceptions*' clause) might be invoked as a justification to the restrictions at hand (see *Trade Perspectives*, Issue No. 6 of 21 March 2014).

The *Proposal* is clearly motivated by fundamental disagreements *vis-à-vis* GMOs and GM food and feed within the EU membership. As the Commission pointed out in its *Proposal*, EU Member States usually do not justify their abstentions or no-votes on the decisions of authorisations of a GMO or of GM food and feed on scientific evidence, but rather on the basis of other considerations. Article 7(1) of *Regulation (EC) No. 1829/2003* requires the Commission to base its decisions on EFSA's opinions, as well as on "*any relevant provisions of Community law and other legitimate factors relevant to the matter under consideration*". This has led to the situation that EU Member States have never reached a qualified majority in favour of or against a Commission draft decision authorising GM food or feed. This then required the Commission to adopt the decision itself, which made it subject to criticism from GMO-sceptics. The Commission can, therefore, be expected to continue pushing ahead with this *Proposal*. Reports indicate that the Slovak Presidency of the Council of the EU will not take up this issue in the last few weeks of its presidency. Thus, it remains to be seen if and when the Maltese Presidency of the first half of 2017 will resume discussions on this *Proposal*. In anticipation of the upcoming debate on the issue and the potential changes to the current legal regime, operators and interested parties with an interest in this matter (both for and against GM food and feed) should carefully analyse any new proposal, develop a position and engage with the relevant stakeholders at EU and EU Member States' level.

Belgium introduces new rules on maximum levels for vitamins, minerals and trace minerals in food supplements and fortified foods

On 25 November 2016, Belgium notified the Commission under the so-called TRIS (*i.e.*, Technical Regulation Information Service) procedure, set up under *Directive (EU) 2015/1535 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services,* of a draft Royal Decree amending the Royal Decree of 3 March 1992 concerning the placing on the market of nutrients and foodstuffs to which nutrients have been added.

The draft Royal Decree (hereinafter, Draft Decree) modifies the current maximum levels for vitamins, minerals and trace minerals established in the existing Royal Decree, which dates back to 1992. The modified maximum levels proposed in the Draft Decree are based on recent scientific data, in particular, on the Opinion No. 9285 of the Superior Health Council (hereinafter, SHC) on dietary recommendations for Belgium, issued on 7 September 2016, and on the most recent data resulting from the Belgian Food Consumption Survey 2014 on the intake of vitamins, minerals and trace minerals. The Statement of Grounds of the TRIS notification provides that the maximum levels in the Draft Decree are presented in a more accessible format (*i.e.*, the maximum levels are conveniently displayed in Annex 1, whereas in the existing decree the maximum levels need to be calculated using the '*recommended daily allowance*' or '*RDA*'.

The Draft Decree establishes, in its Annex 1, maximum levels for vitamins, minerals and trace minerals in food supplements and fortified foods, which may not exceed the stated recommended daily intake/quantity of the nutrient equivalent to the average daily nutrient intake (defined in Annex 2 of the existing Royal Decree). Food supplements are regulated at EU level by *Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements* and fortified foods by *Regulation (EC) No. 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods* (hereinafter, the Fortified Foods Regulation). None of the EU measures has established maximum levels for vitamins and minerals. The maximum levels for the nutrients vitamin C (1,000 mg), vitamin D (75 µg), vitamin E (39 mg), vitamin K (210 µg), folic acid (500 µg), boron (3 mg), fluoride (1.7 mg) and iron (45 mg) have been increased. Maximum levels for manganese have been reduced from 5.25 mg to 1 mg due to its neurotoxicity, as a result of manganese accumulation (as established by the SHC). The maximum levels for the nutrients vitamin A (1,200 µg), niacin (54 mg), vitamin B6 (6 mg), calcium (1,600 mg), chromium (187.5 µg), copper (2 mg), phosphorus (1,600 mg), iodine (225 µg), potassium (6,000 mg), magnesium (450 mg), molybdenum (225 µg), selenium (105 µg), zinc (22.5 mg) remain the same. Finally, the existing maximum levels for thiamine, riboflavin, pantothenic acid, vitamin B12, biotin, chloride, silicon and sodium have been removed.

To ensure safe use by certain vulnerable target groups, in respect of three nutrients, mandatory warnings will be required in the labelling of products containing a particular level of the nutrient in question as follows: 1) foodstuffs containing a daily dose of vitamin K exceeding 25 µg must display the following warning: '*Not suitable for people taking coumarin anticoagulants*.'; 2) foodstuffs containing a daily dose of potassium of at least 1,000 mg must display the following warning: '*Not suitable for elderly people or people with a renal disorder, insulin-resistant diabetes or people with arterial hypertension*'; and 3) foodstuffs containing a daily dose of zinc exceeding 10 mg must display the following warning: '*The intake of zinc should be limited to a period of a few weeks/months*'. These warnings are based on the Opinion No. 9285 of the SHC. The Draft Decree provides for the possibility of requesting derogations from the maximum levels, which must be duly substantiated. The Draft Decree also establishes that the only vitamin formulation of niacin, that is permitted to be added to food supplements and fortified foods, is nicotinamide. Furthermore, the decree contains a proposal to simplify the existing notification requirement for fortified foods. The notification procedure no longer requires a full list of ingredients of the fortified food product, since

information on the added nutrients (*i.e.*, type and amount) per recommended daily intake or quantity of the nutrient equivalent to the average daily nutrient intake now suffices.

The Draft Decree aligns the terminology of the existing decree with *Regulation (EU) No. 1169/2011 on the provision of food information to consumers* (hereinafter, FIR), adapting the names of the nutrients and using the word '*reference intake*' or '*RI*' instead of '*recommended daily allowance*' or '*RDA*'. Lastly the Draft Decree adds an additional provision to the existing decree relating to mutual recognition: '*The provisions of this Decree do not apply to products lawfully placed on the market in other Member States of the EU or in States party to the Agreement on the European Economic Area, unless the principle of mutual recognition cannot be applied in accordance with Articles 34 to 36 of the Treaty on the Functioning of the EU'* (hereinafter, TFEU). Such products will be subject to a notification procedure and, in order to verify whether the principle of mutual recognition can be applied, proof demonstrating that the product has been lawfully placed on the market in another Member State of the EU or in a State party to the Agreement on the European Economic Area must be provided. As a transitional measure, foodstuffs that do not comply with the provisions of the draft, but which do comply with the provisions of the existing decree, can still be placed on the market up to a maximum of two years from the date of entry into force of this Draft Decree.

Excessive intakes of vitamins and minerals may result in adverse health effects and, therefore, the Fortified Foods Regulation considers it necessary to set maximum amounts for them when they are added to foods. These amounts must ensure that the normal use of the products, under the instructions for use provided by the manufacturer and in the context of a diversified diet, will be safe for consumers. Therefore, those amounts act as the total maximum safe levels for the vitamins and minerals that are naturally present in the food and/or that are added to the food for whatever purpose, including for technological uses. Article 6 of the Fortified Foods Regulation provides that, when a vitamin or a mineral is added to foods, the total amount of the vitamin or mineral present, for whatever purpose, in the food as sold must not exceed maximum amounts. Measures setting those amounts will amend the non-essential elements of the Fortified Foods Regulation by supplementing it and must be adopted by the Commission. To this end, the Commission was supposed to submit draft measures on the maximum amounts by 19 January 2009. The Food Supplements Directive also provides for the establishment of maximum and minimum amounts of vitamins and minerals. In 2006, the Commission issued a *Discussion Paper on the setting of maximum and minimum amounts for vitamins and minerals in foodstuffs* and opened a public consultation that received numerous responses. However, no legislative proposal on the setting of maximum and minimum amounts for vitamins and minerals in foodstuffs or food supplements has been submitted yet. Under Article 17(3) of the Fortified Foods Regulation (similar rules apply to food supplements), EU Member States may, in compliance with the rules of the TFEU, continue to apply and amend existing national provisions on maximum and minimum amounts of vitamins and minerals listed in Annex I to the Regulation added to foods and on the conditions applicable to this addition until the adoption of corresponding EU measures. This is what Belgium is doing with the update of the existing Royal decree.

Manufacturers and importers of food supplements and fortified foods on the Belgian market may need to adjust or reformulate their products in order to comply with the Draft Decree. The establishment of not (yet) EU-harmonised legal levels for vitamins and minerals in food supplements or in fortified food in EU Member States or its non-establishment (like in Sweden) is a contentious matter. Manufacturers and importers of food supplements and fortified foods are faced with varying legislation on an important matter related to their products. The application of the principle of mutual recognition within the internal market does not resolve all issues, in particular, when products originate in third countries, and entering into discussions with national administrations may be cumbersome. On 1 September 2016, the Administrative Court in Falun, Sweden, in proceedings between a food supplements manufacturer and the Municipality of Gävle, decided to lift the Municipality's decision of 31 October 2013, which ordered that manufacturers reduce levels of vitamin B6 in all products, so that they are under the tolerable upper limit (hereinafter, UL) value of 25

mg per day set by the European Food Safety Authority (see *Trade Perspectives*, Issue No. 18 of 7 October 2016). It must be noted that the UL is the maximum level of total chronic daily intake of a nutrient (from all sources) judged to be unlikely to pose a risk of adverse health effects to humans. '*Tolerable intake*' in this context connotes what is physiologically tolerable and is a scientific judgement as determined through risk assessment (*i.e.*, the probability of an adverse effect occurring at some specified level of exposure). It is an estimate of the highest level of intake that carries no appreciable risk of adverse health effects. It must be clarified that the UL is not a recommended level of intake of nutrients (RI) relevant for, *inter alia*, the Belgian Draft Decree. The RI is the recommended daily amount of nutrients for an average adult as listed in Annex XIII to the FIR.

The '*standstill*' period under the TRIS procedure, until which other EU Member States can give an opinion on the draft Belgian decree, ends on 27 February 2017. Food business stakeholders with an interest in the matter should work with their legal advisors and respective governments to have their views and interests duly considered. The matter of levels for vitamins and minerals should be carefully monitored by interested stakeholders as further national legislation may be adopted by other EU Member States.

Recently Adopted EU Legislation

Market Access

- *Commission Implementing Regulation (EU) 2016/2253 of 14 December 2016 opening and providing for the management of Union tariff quotas for certain agricultural and processed agricultural products originating in South Africa*

- *Commission Implementing Regulation (EU) 2016/2243 of 13 December 2016 amending Regulation (EC) No 341/2007 as regards the import tariff quota for garlic originating in China*

- *Commission Implementing Regulation (EU) 2016/2244 of 13 December 2016 amending Regulation (EC) No 1979/2006 as regards the import tariff quota for preserved mushrooms originating in China*

Trade Remedies

- *Commission Implementing Regulation (EU) 2016/2257 of 14 December 2016 re-imposing a definitive anti-dumping duty and collecting definitively the provisional duty imposed on imports of certain footwear with uppers of leather originating in the People's Republic of China and produced by Chengdu Sunshine Shoes Co. Ltd, Foshan Nanhai Shyang Yuu Footwear Ltd and Fujian Sunshine Footwear Co. Ltd and implementing the judgment of the Court of Justice in joined cases C-659/13 and C-34/14*

- *Commission Implementing Decision (EU) 2016/2229 of 9 December 2016 terminating the partial interim review pursuant to Article 11(3) of Regulation (EU) 2016/1036 of the European Parliament and of the Council of the anti-dumping measures applicable to imports of sodium gluconate originating in the People's Republic of China, limited to one Chinese exporting producer, Shandong Kaison*

Food and Agricultural Law

- *Commission Implementing Regulation (EU) 2016/2259 of 15 December 2016 amending Regulation (EC) No 1235/2008 laying down detailed rules for*

implementation of Council Regulation (EC) No 834/2007 as regards the arrangements for imports of organic products from third countries

Laura Boschi, Ignacio Carreño, Tobias Dolle, Yury Rovnov, 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

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