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Advancing commercial interests and fostering innovation – The EU is making progress with its negotiations for preferential trade agreements

In April 2018, the EU is reportedly on the verge of signing two important preferential trade agreements (with Japan and Singapore, respectively), of concluding negotiations with two important trading partners (*i.e.*, Mexico and Mercosur), and of initiating new free trade negotiations (with Australia and with New Zealand). In the meantime, negotiations are ongoing with other trading partners, such as Chile and a number of ASEAN Member States, in particular Indonesia. While free trade negotiations and agreements have often stirred controversy within the EU and beyond, preferential trade agreements undoubtedly provide countries and regions with one of the most important policy tools to advance international trade and to advance the often innovative commercial interests of their businesses and constituencies.

In recent years, the global focus of trade negotiations has shifted from the multilateral level within the WTO to regional, bilateral and region-to-region trade agreements. Perhaps somewhat reluctant at first, given its traditional preference for the multilateral approach at the WTO, the EU has now fully embraced this trend in trade policy. In its 2016 '*Trade for all*' strategy, the European Commission (hereinafter, Commission) had laid out its detailed trade policy objectives with respect to its key trading partners. With respect to the Asia-Pacific region, the Commission noted that the "*region is crucial to European economic interests*". With regards to India, the Commission underlined that an "*ambitious outcome of the FTA with India would create new trade opportunities in a combined market of more than 1.7 billion people*" and that the Commission remained ready to resume the negotiations for a comprehensive and ambitious free trade agreement. Strengthening ties with Australia and New Zealand was also determined as a priority, "*taking into account EU agricultural sensitivities*". Indeed, mainly those very agricultural sensitivities appear to be to '*blame*' for the current difficulties to reach agreement on the last outstanding issues in the negotiations with Mexico, as well as with Mercosur, which includes Argentina, Brazil, Uruguay and Paraguay. Latin American and Asia-Pacific countries clearly remain the key focus of the EU's negotiating efforts.

On 8 December 2017, the European Commissioner for Trade Cecilia Malmström and the Japanese Foreign Minister Taro Kono had announced the successful conclusion of the final discussions on the EU-Japan Economic Partnership Agreement (hereinafter, EPA). On 18 April 2018, the Commission presented the final outcome of the negotiations for the EU-Japan

EPA to the Council of the EU. At the same time, the Commission also presented the revised outcome of the negotiations with Singapore, the first ASEAN Member State with which the EU has concluded an ambitious trade agreement. The trade agreement originally negotiated with Singapore, for which negotiations were concluded back in 2014, was split into two separate agreements, one on trade and the other on investment. This split of the original agreement came after last year's opinion by the Court of Justice of the EU (CJEU) on the division of competences between EU and EU Member States with regards to the content of the EU-Singapore FTA (see *Trade Perspectives*, Issue No. 1 of 13 January 2017 and Issue No. 10 of 19 May 2017). This is the first step towards the signature and conclusion of these agreements. After approval by the Council, the agreements with Japan and with Singapore will now be submitted to the European Parliament, aiming for their entry into force before the end of the current mandate of the Commission in 2019. The EU-Japan EPA is scheduled to be signed in July of this year. In light of the EU Member States' competences, the separate investment protection agreement with Singapore will have to be ratified also by all EU Member States.

Another two agreements appear to be on the final stretch of the negotiations, although this has been the case for several months now. Originally, the EU had intended to politically conclude negotiations with Mexico, as well as with Mercosur, on the side-lines of the WTO Ministerial Conference held in Buenos Aires in December 2017. However, due to a number of unresolved issues in both negotiations, final discussions on specific aspects still continue. With regards to Mexico, the looming presidential election in Mexico in June of this year makes a timely conclusion essential. Geographical indications for EU products, including wine and cheese, and improved market access for Mexican meat exporters figure among the last remaining issues to be resolved. Reportedly, Mexico still aims at concluding the negotiations by the end of April, with negotiations in Brussels ongoing this week. Reaching agreement with Mercosur might be more challenging. At the end of March, EU officials stated that significant obstacles remained, in particular with respect to meat, geographical indications and motor vehicles. Another round of negotiations with Mercosur is scheduled for the last week of April.

A further important set of negotiations will come up soon, with the EU poised to begin negotiations with Australia, as well as with New Zealand, shortly. On 13 September 2017, the Commission had submitted the recommendations for the Council Decisions authorising the opening of negotiations for a Free Trade Agreement with Australia and with New Zealand, respectively. On 26 October 2017, the European Parliament's plenary adopted the *European Parliament resolution containing the Parliament's recommendation to the Council on the proposed negotiating mandate for trade negotiations with Australia* and the *European Parliament resolution containing Parliament's recommendation to the Council on the proposed negotiating mandate for trade negotiations with New Zealand* (see *Trade Perspectives*, Issue No. 20 of 3 November 2017). During April 2018, both Australia's Prime Minister Malcolm Turnbull and New Zealand's Prime Minister Jacinda Ardern travelled to the EU and underlined their willingness to begin negotiations as soon as possible. However, on the EU side, the Council still needs to agree on the negotiating mandate. Reports indicate that this may happen as early as at the next relevant Council meeting, currently scheduled for 22 May 2018. Concerning Australia, services would appear to become one of the key areas of negotiation. Trade in services makes up to 38% of trade from the EU to Australia, while accounting for almost 50% of trade from Australia to the EU. This is significantly higher than the share of services in the overall global trade flows of around 20%. Concerning New Zealand, agricultural products are the main export from New Zealand to the EU and will probably lead to difficult negotiations in this sensitive area.

An interesting area with respect to the EU-New Zealand negotiations could be trade in kiwifruit (for a detailed analysis, see *Trade Perspectives*, Issue No. 11 of 3 June 2016). Recent comprehensive trade and investment agreements negotiated by the EU include chapters addressing anti-competitive practices, as well as State-owned enterprises, monopolies and enterprises granted special rights. In New Zealand, Zespri Group Limited (hereinafter, Zespri) maintains a monopoly on the marketing of kiwifruit. The 1999 *Kiwifruit*

Industry Restructuring Act granted Zespri special and exclusive export authority to export kiwifruit to all foreign markets other than Australia. In particular, New Zealand expressly prohibits any operator other than Zespri from exporting kiwifruit to markets other than Australia, except where authorised by Kiwifruit New Zealand, a dedicated and Government-controlled regulatory board. New Zealand notified the WTO of Zespri's export authority as a State Trading Enterprise, stating that its objective was to "*obtain the best commercial return from world markets for producers in New Zealand*". Exports of kiwifruit outside of Zespri's export authority, where destined to markets other than Australia, are only allowed through collaborative marketing arrangements with Zespri. However, according to Kiwifruit New Zealand's 2016/17 annual report, only 1.95% of the kiwifruit exported from New Zealand was done via such collaborate marketing arrangements. The operation of Zespri, and the export licensing system applied to kiwifruit in New Zealand, might violate New Zealand's WTO obligations, although it has never been legally challenged. Although kiwifruit production is most associated with New Zealand, it is only the world's third largest producer of kiwifruit, behind China and Italy. In the EU, in addition to Italy, France and Greece are also major producers of kiwifruit. In view of addressing the anti-competitive market behaviour that is often attributed to Zespri and for purposes of improving trading conditions for EU businesses, trade in kiwifruit could, therefore, become a controversial issue in the negotiations.

Finally, the EU and India appear to be contemplating the reopening of negotiations for a comprehensive trade agreement. On 12 April 2018, senior trade officials of India and the EU held meetings in Brussels in order to discuss the long-paused negotiations for a proposed free trade agreement and to update each other on their respective positions. From 2007 to 2013, the EU and India held 16 negotiation rounds, but important differences on key issues, such as intellectual property rights, motor vehicles, alcoholic beverages, and the visa regime, impeded negotiations to reach a final stage. Data protection and services will also be sensitive issues, considering the importance of the services sector in India. It remains to be seen whether both sides are now willing to make the necessary compromises to advance the negotiations.

The EU is continuing its efforts in view of negotiating and concluding comprehensive trade agreements with a number of its key trading partners. The negotiations provide unique opportunities to facilitate trade and improve trade conditions for businesses around the world. In such bilateral negotiating settings, it is much easier than at the multilateral level to address specific issues affecting trade between the parties, such as services trade or geographical indications, anti-competitive practices and/or specific market access issues for trade in goods. Businesses within the EU and around the world stand to benefit from these agreements, in particular small- and medium-sized enterprises that cannot afford the high costs associated with overcoming non-tariff measures (NTMs) or non-tariff barriers (NTBs). However, this requires negotiators that are aware of such issues and traders able to timely and accurately convey their grievances or commercial objectives in certain markets. Businesses with commercial interests in the EU or its trading partners should carefully analyse the relevant rules and issues being negotiated and how they could be addressed in ongoing and future trade talks.

UK supermarket chain *Iceland* eliminates palm oil from its own-brand products – Does removing palm oil from food products really help the environment?

On 9 April 2018, *Iceland Foods Ltd* (hereinafter, *Iceland*), a British supermarket chain with an emphasis on the sale of frozen foods, including prepared meals and vegetables, announced its drastic decision to eliminate palm oil from all of its own-brand products. More specifically, on its website, *Iceland* states that, by the end of 2018, 100% of its own-brand food products would no longer contain palm oil. In recent years, palm oil has been at the centre of controversies for allegedly driving deforestation, putting wildlife in danger and having negative effects on human health. *Iceland* claims that its decision to remove palm oil from its products was based on environmental protection reasons alone, in an effort to stop

deforestation. This simplistic and deceptive view falls short of addressing the many environmental questions that undoubtedly must be addressed on a global level. Singling out and discriminating against palm oil alone appears to be a marketing stunt, diverting attention from the real issues and based on a number of misleading assumptions.

Palm oil is an edible vegetable oil, which is extracted from the fruit of oil palm trees. The oil palm tree produces high quality oil used not only for cooking, but also as an ingredient in food products, detergents, cosmetics and biofuels. Palm oil is a very productive crop that produces a high quantity and quality of oil at a relatively low cost and that requires a smaller area of cultivation compared to other vegetable oil crops, such as rapeseed, soybean and sunflower (in terms of the same yield). Indonesia and Malaysia are the world's most important palm oil producing countries. The use of palm oil in the food industry has increased rapidly over the last few years and increased demand of palm oil led to a growing number of oil palm plantations. However, environmental allegations with respect to oil palm cultivation, deforestation, and effects on wildlife often appear to be unsubstantiated misleading generalisations.

Anti-palm oil campaigns are not new. Marketing and labelling issues play an important commercial role in the EU and are starting to play an important role around the world. Recently, at the end of 2017, French supermarket chain *Système U* intensified its aggressive marketing campaign with respect to its decision to substitute so-called '*controversial substances*', including palm oil. Similarly, already in 2012, the French supermarket chain *Casino* introduced a '*palm oil-free*' label on its own-brand products, claiming better nutritional quality. For several years, EU food business operators and retailers, particularly in Belgium, France, Italy and Spain, have increasingly been labelling a number of foodstuffs as '*palm oil-free*' and continue waging related marketing campaigns with a denigrating agenda. This trend continues despite the arguable illegality of such labels within the EU (see *Trade Perspectives*, Issue No. 4 of 20 February 2015).

This trend now appears to have reached the UK. On 9 April 2018, the British supermarket chain *Iceland* announced its decision to eliminate palm oil from all its own-brand products by the end of 2018 (currently half of its products do not contain palm oil). *Iceland* stated that its decision was part of its environmental commitments. More specifically, *Iceland* intends to stop deforestation in Indonesia and Malaysia and to protect wildlife. On its website, *Iceland* alleges that palm oil was one of the world's "*biggest causes of deforestation*" and posed "*a significant threat to a number of species already facing extinction*". According to *Iceland*, its decision to remove palm oil from its products, would lower the demand for palm oil by more than 500 metric tonnes per year. A small amount, considering that, currently, businesses in the UK import around 400,000 metric tonnes per year. *Iceland*'s Managing Director stated that until *Iceland* could "*guarantee palm oil is not causing rainforest destruction, we are simply saying* 'no to palm oil*', we don't believe there is such a thing as 'sustainable' palm oil available to retailers*". *Iceland*'s managing director underlined that the decision to eliminate palm oil was intended to provide consumers with a choice about what they buy. *Iceland* plans to replace palm oil with "*oils and fats that do not destroy the rainforest*". Moreover and perhaps more disturbingly, in light of the legal arguments often provided in *Trade Perspectives*, *Iceland* also intends to attach a '*no palm oil*' sticker on products' packaging (see *Trade Perspectives*, Issue No. 23 of 12 December 2014 and Issue No. 4 of 20 February 2015).

Palm oil-producers and academics have expressed their disagreement with *Iceland*'s move. Palm oil-producing countries pointed out that the ban on palm oil was discriminatory and could further fuel the global campaigns of denigration against palm oil. Furthermore, palm oil-producing countries stated that replacing palm oil with other vegetable oils would actually increase the use of land to satisfy the global demand for vegetable oils. Such measure could thereby accelerate ground degradation, which could cause more flora and fauna damage and increase CO_2 emissions. The Council of Palm Oil Producing Countries (hereinafter, CPOPC) stated that the claims against palm oil and the decision taken by *Iceland* were misleading consumers on the environmental benefits of other vegetable oils. Researchers

from the Durrell Institute of Conservation and Biology (hereinafter, DICE) of the University of Kent published their concerns vis-à-vis *Iceland*'s decision, underlining that banning palm oil from products was actually a step backwards in the effort to prevent deforestation and to promote sustainability. Currently, researchers at DICE are working with palm oil certification bodies and companies to improve the way in which oil palm cultivation interacts with the environment. The work at DICE seeks to demonstrate the advantages of connecting high-quality rainforest patches in oil palm plantations to allow wildlife to move freely. If sustainability certification of palm oil became more widespread, this would benefit the environment a lot more than switching to other vegetable oils. According to the research at DICE, *Iceland* should work with the industry to find sustainably sourced solutions, highlighting that "*[e]nvironmentally conscious consumers should demand palm oil from certified sources, but avoiding it altogether runs the risk of putting pressure on other crops that are equally to blame for the world's environmental problems"*.

The issue of sustainability is already being addressed by palm oil-producing countries, often in concerted efforts with the relevant industries and NGOs. Establishing sustainability certification and implementing such standards is the main tool to improve the environmental impact of palm oil production, as it is for all other forms of human activity that have environmental impacts. The statement by *Iceland*'s Managing Director that there was no such thing as "*sustainable palm oil*" clearly contradicts the important efforts already underway, such as the initiative in palm oil-producing countries (*e.g.*, the Indonesian Sustainable Palm Oil (ISPO) and the Malaysian Sustainable Palm Oil (MSPO) standards), the concerted efforts within the CPOPC, and the initiatives by the Roundtable on Sustainable Palm Oil (RSPO).

Palm oil producers and palm oil-producing countries clearly recognise the need for improving the sustainability of palm oil production. The overall importance of environmental protection is also undisputed. However, discriminatory and denigrating measures taken with respect to one specific product, whether they are '*private*' or '*public*' in nature, clearly do not achieve the desired result. The small effect by *Iceland*'s action is already demonstrated by the neglectable amount it would remove from overall UK palm oil imports. A number of other products also impact the environment and, in many cases, probably more so than palm oil. Why is *Iceland* not taking action against those products? Is it perhaps because palm oil is an easy scapegoat and convenient target that is not cultivated in the UK or the EU? For instance, soy is one of the crop alternatives to produce vegetable oil. However, on average, eight hectares of soybeans are needed to produce the same amount of vegetable oil that can be achieved with one hectare of oil palm. Beef is another important example, the production of which also has a big impact on the environment. Cattle farms, are being accused of deforestation and of ever-increasing methane emissions contributing to climate change, but we do not see many campaigns of the type that are being waged in Europe against palm oil. Will removing palm oil from Iceland's products help the environment? Clearly not, despite the rather hypocritical illusion that is being marketed by its proponents.

Another worrisome aspect of *Iceland*'s campaign concerns its intention to attach a '*no palm oil*' sticker on its packaging. In principle, businesses are free to decide which kind of raw materials they use in their products, free to choose whether or not to use palm oil. However, waging denigrating marketing campaigns and attaching unauthorised labels to food products might violate the law. Since 13 December 2014, *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, the Food Information Regulation, FIR) provides that the specific vegetable oils must be indicated in the list of ingredients (see *Trade Perspectives*, Issue No. 23 of 12 December 2014). Any consumer can read in the list of ingredients whether a product does or does not contain palm oil, which can no longer be '*hidden*' behind the generic term '*vegetable oils*'. Therefore, since the specific origin of the vegetable oil used in any given foodstuff must be declared, '*palm-oil free*' claims are arguably unnecessary, irrelevant and illegal pursuant to Article 7(1)(c) of the FIR. When made in a nutritional context, or in case of accompanying further nutritional or environmental allegations, they often appear to be unsubstantiated misleading generalisations, and could

also be considered misleading pursuant to Article 7(1)(a) of the FIR. Finally, '*palm oil-free*' claims are arguably not permitted nutrition claims in the sense of Article 8(1) of *Regulation (EC) No 1924/2006 of the European Parliament and of the Council on nutrition and health claims made on foods*, which, for instance, allows the claim '*saturated fat-free*'.

Iceland's decision to eliminate palm oil from its own-brand products is obviously legitimate as a company decision, but it is arguably a discriminatory form of denigration against palm oil and, in view of other products' impact on the environment, such as soy or beef, clearly hypocritical. Efforts by palm oil producers and palm oil-producing countries should be recognised and encouraged by paying a premium for sustainable palm oil. Instead, palm oil is used as an easy scapegoat and denigrated as a whole. Legal avenues against misleading advertising and misleading food product labelling are available and should be considered to ensure that consumers are not deceived.

Spain adopts decree with a detailed list of substances that may be used in the preparation of food supplements

On 27 March 2017, Spain published in its Official Journal the *Royal Decree 130/2018*, of 16 March, which modifies *Royal Decree 1487/2009*, of 26 September, relating to food supplements (*i.e.*, *Real Decreto 130/2018, de 16 de marzo, por el que se modifica el Real Decreto 1487/2009, de 26 de septiembre, relativo a los complementos alimenticios*, hereinafter, *R.D. 130/2018*). As a novelty, *R.D. 130/2018* includes a detailed list of substances other than vitamins and minerals that may be used in the preparation of food supplements.

'*Food supplements*' are defined in Article 2(a) of *Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements* (as last amended by *Commission Regulation (EU) 2017/1203*) as "*foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities*". *Directive 2002/46/EC* only harmonises, at the EU level, the rules on labelling and on authorised vitamins and minerals and their forms. Important aspects in the marketing of food supplements, such as maximum and minimum levels of vitamins and minerals or the use of other substances, such as botanical extracts, essential fatty acids or fibre, are not harmonised at EU level.

Recitals 6 to 8 of *Directive 2002/46/EC* describe the original plan of the EU legislator. It acknowledged that there is a wide range of nutrients and other ingredients that might be present in food supplements, including, but not limited to, vitamins, minerals, amino acids, essential fatty acids, fibre and various plants and herbal extracts. As a first stage, *Directive 2002/46/EC* laid down specific rules for vitamins and minerals used as ingredients of food supplements. It was planned that specific rules concerning nutrients, other than vitamins and minerals, or other substances with a nutritional or physiological effect used as ingredients of food supplements would be laid down at a later stage, provided that adequate and appropriate scientific data about them became available. Until such specific EU rules are adopted, national rules concerning nutrients or other substances with nutritional or physiological effects used as ingredients of food supplements apply.

In accordance with Article 4(8) of *Directive 2002/46/EC*, the European Commission (hereinafter Commission), submitted, on 5 December 2008, a report to the Council of the EU and the European Parliament on the use of substances other than vitamins and minerals in food supplements. In that report, the Commission points out that, "*in general terms, despite certain limitations, mutual recognition is a useful instrument for facilitating the free movement*

of the products concerned". The Commission concluded that it did not consider it opportune to lay down specific rules for substances other than vitamins or minerals for use in food supplements. However, since substances other than vitamins or minerals, including substances derived from plants, are now being added to ordinary foodstuffs and not only to food supplements, the Commission does not rule out the possibility, at a later state, of carrying out supplementary analysis to the report, examining the conditions for the addition of these substances to foodstuffs in general.

Therefore, the principle of mutual recognition is extremely relevant for the marketing of food supplements in the EU. This means that a food supplement containing a certain substance may be lawfully placed on the market in one EU Member State and would subsequently have to be accepted by other EU Member States that still maintain more restrictive national legislation. However, the mutual recognition principle does not apply if the authorities of an EU Member State can successfully invoke the protection of health and life of humans as a reason to deny the marketing. However, this may only take place under strict conditions, including an in-depth risk assessment based on the most reliable scientific data available and on the basis of the most recent results of international research, which must show that there is a risk to health associated with a product, as well as proportionality.

In *R.D. 130/2018*, Spain argues that the conclusions of the Commission's 2008 report, which indicated that mutual recognition was sufficient, were not shared by many EU Member States. In fact, in the absence of a perspective of harmonisation at the EU level, EU Member States have opted to establish lists of substances that may be used in the elaboration of food supplements. Substances other than vitamins and minerals are indeed subject to legislation at the national level. For instance, in Belgium, the *Ministerial Decree of 19 February 2009 on the production and placing on the market of food supplements containing substances other than nutrients and plant or plant preparations* (*i.e.*, *Arrêté ministériel du 19 février 2009 relatif à la fabrication et au commerce de compléments alimentaires contenant d'autres substances que des nutriments et des plantes ou des préparations de plantes*), lists three substances (*i.e.*, choline, carnitine, ubiquinone) for which the use in food supplements is subject to conditions. Italy lists various other substances, including caffeine, carnitine, creatine, lycopene, flavonoids and some enzymes, in the Health Ministry's revised list (of November 2007) of nutrients and substances with a nutritional or physiological effect *(i.e.*, *Ministero della Salute: Altri nutrienti e altre sostanze ad effetto nutritivo o fisiologico, revisione novembre 2017*). France has adopted an Order on 26 September 2016 establishing a list of substances authorised in food supplements for nutritional or physiological purposes (*i.e.*, caffeine, carnitine, creatine, lycopene) and the conditions for their use *(i.e.*, *Arrêté du 26 septembre 2016 établissant la liste des substances à but nutritionnel ou physiologique autorisées dans les compléments alimentaires et les conditions de leur emploi, Version consolidée au 29 janvier 2018*).

In this context, the elaboration in Spain of a national list of substances that may be used in food supplements has been considered necessary in order to ensure consumer protection, without undermining the competitiveness of national food companies in the EU market. Since the publication of *R.D. 1487/2009*, Spanish legislation on food supplements has focused on the use of vitamins and minerals as ingredients for their manufacture. Spain considers its legislation no longer sufficient, since today there are an estimated 400 different substances for the manufacture of these supplements. About 50 other substances, divided into eight new categories of ingredients for food supplements, have been introduced by *R.D. 1487/2009*: 1) Fatty acids; 2) Amino acids (and their salts of Na, K, Ca, Mg and HCl) and other nitrogen compounds; 3) Dipeptides and peptides; 4) Coenzymes; 5) Flavonoids and carotenoids; 6) Nucleotides; 7) Polysaccharides and oligosaccharides; and 8) Other substances (*e.g.*, glucosamine (as sulfate or hydrochloride), wheat germ, pollen and brewer's yeast). For these substances, maximum daily doses have been established and in some cases, warning messages need to be labelled like "*not be consumed by pregnant or lactating women, nor by children*" when astaxanthin of crustaceans and fish (category 5: flavonoids, carotenoids) are used.

In preparing *R.D. 130/2018*, Spain has taken the reports of the Scientific Committee for Food (SCF) and the European Food Safety Authority (EFSA) into account, as well as other bodies of recognised scientific authority. The safety of the substances and the doses established in *R.D. 130/2018* have been evaluated by the Scientific Committee of the Spanish Agency for Consumer Affairs, Food Safety and Nutrition (*i.e.*, the Comité Científico de la Agencia Española de Consumo, Seguridad Alimentaria y Nutrición), except for those that have traditionally been considered as dietetic or have been traditionally consumed in Spain, like royal jelly (*i.e.*, *jalea real*, a honey bee secretion).

R.D. 1487/2009 has incorporated a new additional provision to expressly address mutual recognition: "*The requirements of this royal decree shall not apply to food supplements legally manufactured or marketed in other Member States of the European Union, or products originating in the countries of the European Free Trade Association (EFTA) which are contracting parties to the Agreement on the European Economic Area (EEA), or to those States which have a Customs Association agreement with the European Union*". In this context, it should be stressed that, since 13 May 2009, refusals of mutual recognition are subject to the conditions laid down in *Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State*.

Besides the matter of '*other substances*' in food supplements, there are two other major areas of regulation on food supplements in the EU that have not been harmonised: 1) Botanical substances; and 2) Maximum amounts of vitamins and minerals. '*Other substances*' introduced by Spain's *R.D. 130/2018*, do not specifically include permitted botanical substances in food supplements. Botanical preparations have a wide variety of applications and can fall under different regulatory regimes, depending on their intended use and presentation (*e.g.,* as food supplements or medicines). The use of botanicals in food supplements may be subject to legislation at EU Member State level. Some EU Member States like Belgium, France and Italy have adopted lists of prohibited and/or authorised plants and plant parts in their legislation. Germany has developed a reference guide for authorities and food business operators. Most EU Member States do not have specific regulations on the use of botanicals. The second contentious matter is that of the maximum amounts of vitamins and minerals. Article 5 of *Directive 2002/46/EC* provides that maximum amounts of vitamins and minerals present in food supplements, per daily portion of consumption as recommended by the manufacturer, shall be set, taking the following into account: 1) Upper safe levels of vitamins and minerals established by scientific risk assessment based on generally accepted scientific data, taking into account, as appropriate, the varying degrees of sensitivity of different consumer groups; and 2) Intake of vitamins and minerals from other dietary sources. However, such EU harmonised minimum and maximum levels of vitamins and minerals have not yet been adopted.

In the absence of harmonisation, national rules and guidance apply in certain EU Member States, including 1) In the UK, *Safe Upper Levels for Vitamins and Minerals of May 2003* by the Expert Group on Vitamins and Minerals; 2) In France, Decree of 6 May 2006 on nutrients to be used in the production of food supplements (*i.e.*, *Arrêté du 9 mai 2006 relatif aux nutriments pouvant être employés dans la fabrication des compléments alimentaires, Version consolidée au 17 avril 2018*); 3) In Belgium, Royal Decree of 3 March 1992 on the placing on the market of nutrients and foods with added nutrients (*i.e.*, *Arrêté Royal du 3 mars 1992 concernant la mise dans le commerce de nutriments et de denrées alimentaires auxquelles des nutriments ont été ajoutés, modifié par A.R. du 24 avril 2014*); and 4) In Italy, daily levels of vitamins and minerals allowed in food supplements by the Ministry of Health, revision of May 2017 (*i.e.*, *Apporti giornalieri di vitamine e minerali ammessi negli integratori alimentary, revisione maggio 2017*). This tendency for EU Member States to '*do it alone*', with restrictive individual maximum levels for vitamins and minerals in food supplements, may reportedly eliminate the therapeutic effect of vitamin supplements and have long-term negative impacts on consumers' health.

Besides the matter of '*other substances*' in food supplements, which has now been addressed in Spain, the use of botanical substances in food supplements and maximum amounts of vitamins and minerals in the EU are increasingly regulated by EU Member States, due to the lack of EU harmonisation. Clearly, this piecemeal approach does not do the EU Single Market justice. Only a coordinated approach and harmonised rules on the relevant issues would allow for the necessary degree of trade facilitation intended by EU law. All interested stakeholders should carefully analyse the relevant rules in EU Member States and reach out to relevant interlocutors in view of increased harmonisation efforts.

Recently Adopted EU Legislation

Customs Law

- *Commission Implementing Regulation (EU) 2018/604 of 18 April 2018 amending Implementing Regulation (EU) 2015/2447 as regards the procedural rules to facilitate the establishment in the Union of the preferential origin of goods, and repealing Regulations (EEC) No 3510/80 and (EC) No 209/2005*

- *Council Decision (EU) 2018/601 of 16 April 2018 on the conclusion, on behalf of the European Union, of the Agreement between the European Union and New Zealand on cooperation and mutual administrative assistance in customs matters*

- *Council Decision (EU) 2018/600 of 10 October 2016 on the signing, on behalf of the European Union, of the Agreement between the European Union and New Zealand on cooperation and mutual administrative assistance in customs matters*

- *Agreement between the European Union and New Zealand on cooperation and mutual administrative assistance in customs matters*

- *Council Regulation (EU) 2018/581 of 16 April 2018 temporarily suspending the autonomous Common Customs Tariff duties on certain goods of a kind to be incorporated in or used for aircraft, and repealing Regulation (EC) No 1147/2002*

- *Commission Implementing Regulation (EU) 2018/579 of 16 April 2018 amending Council Regulation (EC) No 312/2003 as regards an additional Union tariff quota for certain agricultural products originating in Chile*

Trade Remedies

- *Commission Implementing Regulation (EU) 2018/607 of 19 April 2018 imposing a definitive anti-dumping duty on imports of steel ropes and cables originating in the People's Republic of China as extended to imports of steel ropes and cables consigned from Morocco and the Republic of Korea, whether declared as originating in these countries or not, following an expiry review pursuant to Article 11(2) of Regulation (EU) 2016/1036 of the European Parliament and of the Council*

Other

- *Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties*

- *Commission Implementing Regulation (EU) 2018/578 of 13 April 2018 amending Council Regulation (EC) No 2368/2002 implementing the Kimberley Process certification scheme for the international trade in rough diamonds*

- *Commission Implementing Decision (EU) 2018/576 of 15 December 2017 on technical standards for security features applied to tobacco products*

- *Commission Implementing Regulation (EU) 2018/574 of 15 December 2017 on technical standards for the establishment and operation of a traceability system for tobacco products*

- *Commission Delegated Regulation (EU) 2018/573 of 15 December 2017 on key elements of data storage contracts to be concluded as part of a traceability system for tobacco products*

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