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France considers taxing large global digital technology companies – a breach of international trade obligations?

On 6 March 2019, the French Minister of the Economy and Finance, Bruno Le Maire, submitted a Bill concerning the establishment of a new tax on digital services and modifying the scope of corporate tax reductions (*i.e.*, *Projet de loi portant création d'une taxe sur les services numériques et modification de la trajectoire de baisse de l'impôt sur les sociétés*, hereinafter, the Bill), to the lower house of the bicameral French Parliament (*i.e.*, the *Assemblée nationale*). The Bill aims at taxing digital services by internet and technology businesses based on their digital sales. The US immediately expressed its concerns *vis-à-vis* the legislative proposal, noting that it would mainly affect US-based companies, and has raised the Bill's potential inconsistencies with international trade rules.

The proposed law aims at addressing the global tax optimisation policies that some internet and technology companies have adopted in order to leverage their worldwide profits. Indeed, many large technology companies have established their European headquarters in Ireland, a country with lower taxes applicable to the revenue of such companies, compared to other EU Member States. These companies often transfer their revenues to Ireland in order to benefit from the lower taxes there. These practices are increasingly subject to criticism and considered as "*unfair taxation*" methods, as underlined by the recent '*yellow vests*' movement in France. Considering these circumstances, the French Government has deemed it necessary to take steps to impose higher taxes on such companies, mitigating their transfer of revenues to countries with lower tax rates.

At the multilateral level, within the context of the *Inclusive Framework on Base Erosion and Profit Shifting* (hereinafter, BEPS), the Organisation for Economic Co-operation and Development (hereinafter, OECD) has been working on proposals for an international legal scheme that would multilaterally address the taxation of technology companies. In fact, the OECD announced, on 29 January 2019, that countries had "*agreed to explore potential solutions that would update fundamental tax principles for a twenty-first century economy, when firms can be heavily involved in the economic life of different jurisdictions without any significant physical presence and where new and often intangible drivers of value become more and more important*". In general terms, the OECD's BEPS plan intends to support Governments by providing domestic and international instruments to address the global phenomenon of tax avoidance. In this regard, French Minister Le Maire already noted that, if an agreement were to be reached at the multilateral level, France would revoke the proposed tax.

In parallel, the EU has also been discussing the issue. On 21 March 2018, the European Commission (hereinafter, the Commission) published a *Proposal on the common system of a digital services tax on revenues*. Ireland, which hosts the European headquarters of several US-based digital technology companies, leads a small group of otherwise mostly Nordic EU Member States that argue that a new tax specifically targeting these digital technology companies could lead to reprisals against EU companies and further complicate the already strained trade relationship with the US. Consequently, these EU Member States countries vetoed any progress on this matter. Considering that the issue is currently not moving forward at the EU level, France and other EU Member States have been unilaterally moving ahead towards establishing domestic measures aimed at taxing global technology companies. In France, the proposed tax has been referred to as the '*GAFA tax*' indicating that it is intended to address mainly practices by US technology companies *Google*, *Apple*, *Facebook* and *Amazon*. According to projections released by the French weekly newspaper *La Tribune*, fewer than ten French companies would currently be affected by the proposed tax.

According to Article 1 of the Bill, the provision, by means of electronic communications, of a digital interface allowing internet users to contact and interact with other internet users, notably in view of the supply of goods and services directly between these users, would be subject to the new tax. Pursuant to Article 1(2) of the Bill, the services marketed to advertisers, or their agents, aimed at placing targeted advertising messages on a digital interface based on data relating to the user that consults it, and collected or generated during the consultation of such interfaces, would be subject to the tax. These services may include services for the purchase, storage and/or distribution of advertising messages, advertising control and performance measurement, as well as services for the management and transmission of user data.

The Bill also provides for a number of important exclusions, such as: 1) The provision of a digital interface by a person, who uses it primarily to provide users with digital content, communication services or payment services; 2) Regulated financial services, listed by the Minister for Economic Affairs, when they are provided by financial service providers that are subject either to authorisation and supervision, pursuant to EU harmonisation measures for financial services regulation, or to supervisory frameworks considered equivalent, in accordance with an EU legal act, to such harmonisation measures. Pursuant to Article 1(33) of the Bill, the tax rate would be established at 3%. Most notably, the Bill provides that the tax would only apply to companies, whatever their place of establishment, for which the amount of the revenue collected for taxable services exceeds the two following thresholds: 1) EUR 750 million for services provided globally; and 2) EUR 25 million for services provided in France. Calculations show that this would deliver an annual tax revenue of around EUR 500 million. On the other side of the Atlantic, the initiative has already caused strong reactions. Lafayette G. "*Chip*" Harter, Deputy Assistant Secretary for International Tax Affairs at the US Department of the Treasury, stated that the tax appeared to be "*highly discriminatory*" towards US companies. He further added that the US Department of the Treasury, the Office of the US Trade Representative, and US lawmakers were "*studying whether the discriminatory impact would give us rights under trade agreements".*

The proposed measure, once adopted, would likely come under scrutiny within the context of the applicable WTO rules, possibly even by means of WTO dispute settlement, as already indicated by the US. More specifically, the US Department of the Treasury noted that the US might consider challenging the future tax at the WTO under the WTO's General Agreement on Trade and Services (hereinafter, GATS) arguing that the tax violated France's commitments not to impose measures that discriminate between domestic and foreign services and service suppliers.

The Uruguay Round of multilateral trade negotiations resulted in the establishment of the WTO and the extension of international trade rules to trade in services. Since then, under the GATS Agreement, WTO Members have committed to granting other WTO Members non-discriminatory conditions in terms of market access and national treatment obligations. In simple terms, under the so-called '*national treatment*' obligation, a WTO Member is required to grant other WTO Members the same treatment that it grants its own '*like*' services and

service suppliers. Pursuant to Article XVII of the GATS on national treatment, WTO Members, in conformity with their Schedules of Concessions for services, are to "*accord to services and service suppliers of any other Member*" treatment no less favourable than that which they accord to their own '*like*' services and service suppliers. The national treatment obligation under the GATS differs from Article III of the General Agreement on Tariffs and Trade (hereinafter, the GATT), which provides for the national treatment obligation regarding trade in goods. The national treatment obligation under Article III of the GATT has general application *vis-à-vis* all measures affecting trade in goods, while the national treatment obligation under the GATS only applies to measures affecting trade in services to the extent that the WTO Member has explicitly committed itself to grant such '*national treatment*' in respect of specific services sectors and sub-sectors. The main purpose of the national treatment obligation of Article XVII:1 of the GATS is to ensure equal competitive opportunities for '*like*' services and '*like*' service suppliers in the respective sectors.

If the proposed tax were to come under WTO scrutiny, it would have to be determined whether the proposed tax is consistent with the WTO commitments under the GATS to which France, as part of the EU, is bound. According to WTO jurisprudence, in order to determine whether a measure is consistent or not with Article XVII:1 of the GATS, four elements must be addressed: 1) It must be determined that the WTO Member committed to provide national treatment with regard to the services sector and mode of supply at issue; 2) The measure at issue must affect trade in services; 3) The foreign and domestic services or service suppliers at issue must be '*like services*' or '*like service suppliers*'; and 4) The foreign services or service suppliers must not have been granted '*treatment less favourable*' than what domestic services or service suppliers actually received. As noted above, the national treatment obligation only applies to the extent that a WTO Member has committed to grant such treatment for this particular services sector in its Schedule of commitments. As the EU has exclusive competence on trade, the relevant Schedule against which commitments are to be analysed is that of the EU. It appears that, with respect to the EU's commitments in the category of "*Computer and Related Services*" of its Schedule, the EU has not listed any specific limitation regarding the national treatment obligation related to the commercial presence of third countries' companies in the EU. Therefore, it appears that the EU has committed to grant national treatment to all other WTO Members regarding "*Computer and Related Services*".

The second element relates to the question of whether the WTO Member's measure at issue affects trade in services, thereby falling under the material scope of the GATS. In the case *Canada – Autos* (DS142), the WTO Appellate Body set out two keys issues to be examined to determine whether a measure is one '*affecting trade in services*'. First, there must be a measure regarding '*trade in services*'. Secondly, the measure must '*affect*' such trade in services. With regard to the first question, the scope of the concept of '*trade in services*' is very broad since, according to Article I:3 of the GATS, it entails all services except services supplied in the exercise of governmental authority. With regard to the second question, a measure affects trade in services when the measure bears upon the conditions of competition for the supply of a service, as noted by the WTO Appellate Body in the case US – FSC (DS108). Considering the impact that such tax might have on the concerned companies, it would likely be deemed to "*affect*" trade in services.

The third element of the test of consistency relates to the question of whether the foreign and domestic services or service suppliers constitute '*like services*' or '*like service suppliers*'. Services are '*like*' if "*it is determined that the services in question in a particular case are essentially or generally the same in competitive terms*". Any determination of likeness is appreciated on a case-by-case basis and considering all the circumstances of the case. In the case of the proposed tax, it appears that the digital technology companies to which it would apply would likely be considered '*like service suppliers*'.

The fourth and final element relates to the requirement of a '*treatment no less favourable*'. Pursuant to Article XVII:3 of the GATS, the treatment, whether it is formally identical or formally different, is considered less favourable if "*it modifies the conditions of competition in favour of services or service suppliers of the Member compared to like services or service suppliers of*

any other Member". In other words, a Member may give formally identical treatment to foreign and domestic services or service suppliers and still be in breach of the national treatment obligation. Therefore, it appears that the jurisprudence construed a criterion to assess the existence of such "*treatment no less favourable*", namely the conditions of competition. In the case of China – Electronic Payment Services (DS413), the Panel examined this fourth element in two steps: First, it analysed whether the measures at issue provided for different treatment between domestic services and service suppliers and '*like*' services and service suppliers of other Members. Secondly, the Panel assessed whether any different treatment amounted to a *de facto* less favourable treatment. While the proposed French Bill applies indistinctly to the digital technology companies fulfilling the criteria and thresholds set forth in the text, it would need to be determined if the applicable thresholds do or do not constitute a *de facto* discrimination of certain companies.

Elaborated by the French Government, the Bill was submitted to the French Parliament and is now at the stage of the first reading. The Bill will follow the regular legislative process towards another reading in the lower house in mid-April, before it is transmitted to the Senate, the upper house of the French Parliament. The two houses of the French Parliament have to agree on a text of the Bill before it can become law. Supposing that the two houses of the French Parliament agree on the terms of the Bill, it would be voted and become law in the following months. Pursuant to Article 1(75) of the Bill, it would apply retroactively from January 2019.

US Government officials clearly noted their concerns with the proposed Bill. In fact, there appear to be important questions with regards to the consistency with international trade rules that should be considered before France moves ahead further with this legislative initiative. Interested stakeholders should carefully monitor the debate in France and the next steps.

The EU reached agreement on operationalising the EU's accession to the Geneva Act of the Lisbon Agreement to better protect geographical indications

On 14 March 2019, the European Parliament, the European Commission (hereinafter, Commission) and the Council of the EU (hereinafter, Council) reached political agreement on the accession of the EU to the *Geneva Act of the Lisbon Agreement on Appellation of Origin and Geographical indications* (hereinafter, Geneva Act). On the same day, the Council published the respective legislative proposal. The Geneva Act reforms the *Lisbon Agreement on Appellation of Origin*, which extends the scope of the Agreement to geographical indications (hereinafter, GIs). With its accession, the EU intends to improve the protection of GIs in parallel to its efforts to include rules on GIs in its trade agreements with third countries, often a particularly sensitive aspect of the EU's trade negotiations.

GIs are defined in Article 22 of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights of 1994 (hereinafter, TRIPs Agreement) as "*indications which identify a good as originating in the territory of a Member, or a region or locality in that territory, where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin*". GIs were originally only protected through domestic laws. However, this protection was then limited to the respective State's territory and products were often imitated outside the country of origin. As a result of international cooperation and negotiation, a number of agreements regarding the protection of intellectual property rights and the appellation of origin were established, including the *Paris Convention for the Protection of Industrial Property* of 1883 (hereinafter, Paris Convention) (see *Trade Perspectives*, Issue No 5 of 6 March 2015 and the *Lisbon Agreement for the Protection of Appellations of Origin and their International Registration* (hereinafter, Lisbon Agreement), signed on 31 October 1958.

The Lisbon Agreement was established to protect certain product names from violations or misuse in the other signatory countries and aims at ensuring that appellations of origin (*i.e.,* a special kind of GI, which refers to a specific quality or characteristics that are essentially due to the geographical environment in which they are produced) receive protection in all Parties'

jurisdictions insomuch as they are protected in their country of origin. The Lisbon Agreement, established an International Register of Appellations of Origin, which is managed by the World Intellectual Property Organization (WIPO) (see *Trade Perspectives*, Issue No 20 of 3 November 2017). Currently, the Lisbon Agreement has 28 members, seven of which are EU Member States (*i.*e., Bulgaria, the Czech Republic, France, Italy, Hungary, Portugal and Slovakia). From 2009 to 2015, the Lisbon Agreement was revised with the objective to: 1) Refine its current framework; 2) Include provisions specifying that the Lisbon system also applies to GIs; and 3) Include a provision allowing inter-governmental organisations, such as the EU, to also accede to the agreement. On 20 May 2015, a diplomatic conference in Geneva, attended by an EU delegation, adopted the revising act of the Lisbon Agreement (*i.e.*, the Geneva Act), which was then opened for signatures the day after its adoption.

Given that pre-existing international agreements, such as the Lisbon Agreement and the International Register, had generally been viewed as ineffective tools, the inclusion of rules on GIs in the 1995 WTO TRIPs Agreement was a significant step forward. Article 22(2) of the TRIPs Agreement provides that WTO Members are required to allow interested parties a means to prevent the use of a product name or designation, which misleads the public as to the geographical origin of a good, and to prevent any use of GIs which would constitute an "*act of unfair competition contrary to honest practices in industrial or commercial matters*". Additionally, Article 23(1) of the TRIPs Agreement grants a particularly high standard of protection to geographical names of wines and spirits. In that regard, any use of misleading indications is prohibited, even if the true origin of the goods is stated, or if the GI is used as a translation or accompanied by expressions such as '*kind*', '*style*' or '*type*'. Article 24(4) of the TRIPs Agreement constitutes a grandfathering clause, which protects GIs used by any WTO Member's nationals or domiciled residents in a continuous manner for at least ten years before 15 April 1994, or in good faith prior to that date.

In 1997, on the basis of Article 23(4) of the TRIPs Agreement, WTO Members began negotiations aimed at establishing a multilateral register for wines and spirits. In the context of the WTO *Doha Round* of trade negotiations, two issues relating to GIs figured on the agenda: 1) The establishment of a multilateral register for wines and spirits; and 2) Extending the increased level of protection of Article 23 of the TRIPs Agreement to products beyond wines and spirits. From 1997 until now, three sets of proposals have been submitted: 1) A proposal by the EU for a registry and a "*rebuttable presumption*" that any GI registered in the system would be protected in all WTO Members' territories; 2) A '*joint proposal*' signed by 20 WTO Members including Canada, Chile, Japan, Mexico, New Zealand, South Africa, and the US supporting a voluntary system in which notified GIs would be registered in a database; and 3) A compromise proposal, under which registered GIs would be protected in those WTO Members' territories that choose to participate in the system. Until now, WTO Members have remained divided over the two issues (*i.e.*, the multilateral registry for wine and spirits and the extension of higher level of protection beyond wine and spirits) and no further developments have occurred.

The EU has established a system of GI protection for wines (*Regulation (EU) No.1308/2013*), spirits (*Regulation (EC) No. 110/2008*), aromatised wine (*Regulation (EU) No. 251/2014*) and other agricultural products and foodstuffs (*Regulation (EU) No. 1151/2012*). On the basis of these regulations, the protected names benefit from a comprehensive protection throughout the EU, which is based on a single application process. The EU has been working on ensuring the protection of GIs at the multilateral and the bilateral level. At the multilateral level, the EU is one of the main supporters of the WTO '*Doha Round*' and has been very involved in the TRIPs negotiations for a multilateral registry for wines and spirits. At the bilateral level, the EU increasingly aims at achieving the protection of GIs in its trade agreements, either on the basis of stand-alone sectoral agreements, such as the EU-US Wine Agreement, or in the context of the EU's comprehensive preferential trade agreements (hereinafter, PTAs), such as the EU-Canada Comprehensive Economic and Trade Agreement (CETA). The protection of GIs through PTAs has become a standard element of EU trade negotiations. However, negotiations concerning the protection of GIs are often very sensitive and often contribute to delays in the negotiations.

Before the conference in Geneva and the adoption of the Geneva Act, the Commission had submitted, on 30 March 2015, a draft for a decision by the Council authorising the opening of negotiations for the revised Lisbon Agreement, which the Council adopted on 7 May 2015. However, the Council based its decision on Article 114 of the Treaty on the Functioning of the European Union (hereinafter, TFEU) on the approximation of national laws, stating that the system of protection for appellation of origin and GIs was a shared competence between the EU and its Member States. The Commission contested the Council's decision before the Court of Justice of the European Union (hereinafter, CJEU) (see *Trade Perspectives*, Issue No 20 of 3 November 2017). On 25 October 2017, the CJEU in *Case C-389715 Commission v Council* clarified that the Geneva Act was "*essentially intended to facilitate and govern trade*" between the EU and third countries and that "*it is such as to have direct and immediate effects on such trade, so that negotiations fell within the exclusive competence confers to the [EU]*" as established under Article 3(1) of the TFEU.

On 14 March 2019, the three EU Institutions finally reached political agreement on the accession of the EU to the Geneva Act. The respective legislative proposal lays down the rules on how the EU would operate as a contracting party to this multilateral treaty. The legislative proposal states, first, that EU Member States would be allowed to ratify or accede the Geneva Act. However, the EU would remain responsible for ensuring compliance with the commitments and obligations established under the Geneva Act. Second, the EU and any EU Member State that ratifies or accedes to the Geneva Act must be represented by the Commission. In addition, all notifications to the Geneva Act must be done by the Commission. The Commission would be the Competent Authority responsible for the administration of the Geneva Act within the EU and for the communications with the International Bureau of the WIPO, which is responsible for the examination of international applications, possible irregularities, and the response to irregularities. Third, in the Assembly of the Special Union, composed of the members of the Lisbon Agreement and the contracting parties to the Geneva Act, the EU would vote, while EU Member States that have acceded to the Geneva Act, may not exercise their right to vote. Moreover, Article 5 of the legislative proposal states that the accession document addressed to the Director General of the WIPO must contain a document specifying that, for the protection of appellations of origin or GIs in the EU, an application must fulfil further requirements in addition to the mandatory requirements provided in the Lisbon Agreement, such as information on the reputation and connection with the geographical area.

The Geneva Act reforms the Lisbon Agreement and, in terms of the substantive aspects, most notably extends the scope to also include the protection to GIs. The Geneva Act establishes a GI register for agricultural and non-agricultural products. Importantly, the move into non-agricultural GIs would be a main shift for the EU. Currently, there is no system for the recognition and protection of non-agricultural GIs at the EU level and non-agricultural GIs are only protected by certain EU Member States on the basis of their domestic laws. In this regard, non-governmental organisations, such as the Organization for an International Geographical Indications Network (*i.e.*, oriGIn), expressed support for the EU's accession to the Geneva Act, but pointed out that the EU should "*embark with no further delay on a serious discussion to recognize and protect non-agricultural GIs in the EU*". The Geneva Act provides for a flexible international registration system allowing the contracting parties to use any type of legislation to protect products registered under the Lisbon system, provided that the legislation fulfils the requirements of the Geneva Act. Regarding the grounds for the invalidation of a registered product, the Geneva Act does not provide for invalidity grounds, allowing contracting parties to address this in its domestic rules. This is in line with EU legislation, which does not operate with a list of invalidation grounds. Finally, the Geneva Act also provides for better protection of third-party rights, allowing anyone whose interest were to be affected by the international registration of a GI or appellation of origin to request to its Competent Authority to notify a refusal of protection relating to the registration.

GIs are important intellectual property rights because they have the potential to add value and promote rural socio-economic development. Any change with respect to the protection of GIs could have an impact on businesses that depend on the use of GIs as a distinctive advantage

of their products. Therefore, the accession of the EU to the Geneva Act could bring a number of advantages, in particular by extending the protection of GIs to the current and future parties of the Geneva Act. The EU's accession could also incentivise other countries to join the Geneva Act and further expand the related protection. Once the EU has acceded to the Geneva Act, it could refer to the Lisbon System in its bilateral trade negotiations (if the respective trading partner is part of the Lisbon Agreement) instead of negotiating a detailed case-by-case protection of GIs. However, the success and impact of the reformed Lisbon Agreement will clearly depend on the number of countries or inter-governmental organisations that become part of it.

The European Parliament is expected to approve the legislative proposal during its plenary meeting on 16 April 2019. Once the European Parliament has given its consent, the Council will adopt its decision authorising the EU's accession to the Geneva Act. The accession of the EU to the Geneva Act would be a step further for the protection of GIs at the global and multilateral level. Interested stakeholders should monitor the next steps, in particular as they relate to the protection of non-agricultural products through GIs.

European Commission considers cannabinoids as novel food

On 15 January 2019, the European Commission (hereinafter, Commission) modified the entries relating to '*Cannabis sativa*' and '*Cannabidiol (CBD)*' in the EU's '*Novel Food Catalogue*' and added an entry on '*Cannabinoids*'. All extracts of hemp and derived products containing cannabinoids are now described as novel food and require an authorisation under *Regulation (EU) 2015/2283 of 25 November 2015 on novel foods* (hereinafter, the Novel Foods Regulation or NFR). Hemp seeds, flour and seed oil remain permitted without such pre-market approval. In recent months, hemp and CBD products, as well as shops selling such products, have increasingly appeared across the EU, but now face an important impediment.

Under EU law, 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. If foods and/or food ingredients were used exclusively in food supplements, new uses in other foods also require authorisation under the NFR. The NFR applies since 1 January 2018 and replaced *Regulation (EC) No 258/97 on novel foods*. The aim of the NFR is to establish a clear legal framework allowing food businesses to easily bring new and innovative foods to the EU market, while maintaining a high level of food safety for consumers. The rules needed to be updated to simplify the current authorisation procedures (including a notification procedure for new traditional foods from third countries) and to take account of recent developments in EU law and technological progress (see *Trade Perspectives*, Issue No. 11 of 29 May 2015 and Issue No 18 of 9 November 2015).

Products derived from the hemp plant (*i.e.*, *Cannabis sativa L.*), in particular cannabidiol (hereinafter, CBD), are increasingly marketed in the EU and elsewhere. CBD is one of 113 chemical compounds (*i.e.*, cannabinoids) that are found in the hemp plant and which give the cannabis plant its medical and recreational properties. CBD can be extracted and mixed with a carrier oil, often hemp seed or coconut oil, to create CBD oil. Hemp seeds are reportedly a good source of protein and have proven useful in human nutrition with the seed's oil being rich in omega-3 and omega-6 fatty acids. The seeds can be used to produce protein powder, as well as bread and cereals. Likewise, the oil is also used, *inter alia*, in food supplements and for the production of margarine, salad dressing and cosmetics. CBD accounts for up to 40% of the plant's extract and does not appear to have any psychoactive effects, such as those caused by tetrahydrocannabinol (THC), the most abundant cannabinoid contained in the hemp plant. What makes CBD interesting are its alleged analgesic (*i.e.*, pain-relieving), neuroprotective (*i.e.*, recovering or regenerating the nervous system, its cells, structure and function), and anti-inflammatory (*i.e.*, reducing pain and inflammation) effects.

According to Article 4 of the NFR, food business operators are responsible for verifying whether or not the food they would like to place on the EU market is considered a novel food. If a food business operator is unsure of the novel food status of the food after consulting all available information (including the NFR, the EU List of Novel Foods, and the EU Novel Food Catalogue), the food business operator is supposed to check the status of the food with the authorities in the EU Member State in which the food is supposed to be marketed first. The process for consulting EU Member States' authorities to clarify the novel food status is governed by *Commission Implementing Regulation (EU) 2018/456 of 19 March 2018 on the procedural steps of the consultation process for determination of novel food status in accordance with Regulation (EU) 2015/2283 on novel foods*.

The EU Novel Food Catalogue is an informal tool on the Commission's website, providing a searchable catalogue that lists plant and animal products and other substances that are subject to the NFR. Along with a description of the food product, it also provides information on the novel food status of the product, based on information provided by the EU Member States. It is a non-exhaustive list and serves as orientation on whether a product would require authorisation under the NFR. For food and food ingredients, the status may be either "✓" (*i.e.*, not novel in foods), "*FS*" (*i.e.*, not novel in food supplements) or "*X*" (*i.e.*, "*there was a request whether this product requires authorisation under the NFR. According to the information available to EU Member States' competent authorities, this product was not used as a food or food ingredient before 15 May 1997. Therefore, before it may be placed on the market in the EU as a food or food ingredient, a safety assessment under the NFR is required"*).

The entry for *Cannabis sativa L*. notes the status "✓", meaning that the product was on the EU market as a food or food ingredient and consumed to a significant degree before 15 May 1997, and provides that: *"In the European Union, the cultivation of Cannabis sativa L. varieties is permitted provided they are registered in the EU's 'Common Catalogue of Varieties of Agricultural Plant Species' and the tetrahydrocannabinol (THC) content does not exceed 0.2% (w/w). Some products derived from the Cannabis sativa plant or plant parts such as seeds, seed oil, hemp seed flour, defatted hemp seed have a history of consumption in the EU and therefore, are not novel. Other specific national legislation may restrict the placing on the market of this product as a food or food ingredient in some Member States. Therefore, it is recommended to check with the national competent authorities*". The sentence "*Some products derived from the Cannabis sativa plant or plant parts such as seeds, seed oil, hemp seed flour, defatted hemp seed have a history of consumption in the EU and therefore, are not novel*" has been recently added to the description. Thus, its access to the market is not subject to the NFR, but EU Member States may still regulate and restrict the placing on the market of this product as a food or food ingredient.

The previous version of the EU Novel Foods Catalogue had contained an explicit entry on "*Cannabidiol: Extracts of Cannabis sativa L, in which cannabidiol (CBD) levels are higher than the CBD levels in the source Cannabis sativa L, are novel in food. Cannabidiol (CBD) is one of the cannabinoids in Cannabis sativa plant. In the European Union, the cultivation of Cannabis sativa L. varieties is granted provided they are registered in the EU's 'Common Catalogue of Varieties of Agricultural Plant Species' and the tetrahydrocannabinol (THC) content does not exceed 0.2 % of the plant*". After the recent changes in January 2019, the updated entry for cannabidiol (CBD) now states "*please consult*" the entry for the broader class of "*cannabinoids*", which states that: "*The hemp plant (Cannabis sativa L.) contains a number of cannabinoids and the most common ones are as follows: delta-9-tetrahydrocannabinol (Δ9-THC), its precursor in hemp, delta-9-tetrahydrocannabinolic acid A (Δ9-THCA-A), delta-9-tetrahydrocannabinolic acid B (Δ9-THCA-B), delta-8-tetrahydrocannabinol (Δ8-THC), cannabidiol (CBD), its precursor in hemp cannabidiolic acid (CBDA), cannabigerol (CBG), cannabinol (CBN), cannabichromene (CBC), and delta-9-tetrahydrocannabivarin (Δ9-THCV). Without prejudice to the information provided in the novel food catalogue for the entry relating to Cannabis sativa L., extracts of Cannabis sativa L. and derived products containing cannabinoids are considered novel foods as a history of consumption has not been*

demonstrated. This applies to both the extracts themselves and any products to which they are added as an ingredient (such as hemp seed oil). This also applies to extracts of other plants containing cannabinoids. Synthetically obtained cannabinoids are considered as novel".

The changes to the EU Novel Foods Catalogue came after a meeting of representatives of the competent authorities of the EU Member States and of the Commission within the *Working Group Novel Foods* on 16 October 2018. At the meeting, the European Industrial Hemp Association (hereinafter, EIHA) and the Cannabis Trades Association UK (CTA UK) were invited to outline the traditional food use of hemp extracts. It appears that no new information on the history of use of CBD was provided and that the Commission was not convinced to confirm a non-novel status of CBD. Media reports identified France, Germany, Italy, the Netherlands, and the UK as the countries asking for an update to the catalogue, citing ambiguity concerning the regulation of CBD and other hemp-derived products. After the meeting, the EIHA reiterated its position by saying that the Commission should recognise the aerial parts of the industrial hemp plant and hemp extracts with naturally occurring CBD levels as traditional in food and not as novel food. The EIHA argues that "*hemp extracts and tinctures were indeed made and sold in products, which would nowadays be 'supplements' up to 80 years ago*". Other evidence showed the use of hemp green parts (flowers, leaves) in products such as '*hemp-beer*' and herbal infusions/teas. The EIHA further argues that hemp flowers used for the production of beer-like beverages had been recognised as food ingredients by the Commission since 1998. On 12 March 2019, at the most recent meeting of the EU's Novel Foods Working Group, the EIHA presented 14 examples of '*traditional cannabinoid-rich products*', including medieval references and cookbooks from Italy, a German recipe for a hemp soup for monks, Swedish '*Hampfroeextract*' (hemp extract used 1894 in the preparation of the '*Maltos Cannabis*' nourishing food remedy), and examples from Poland and Slovakia.

During the first three months of 2019, a number of food incidents regarding official controls performed by EU Member States' authorities were notified through the EU's Rapid Alert System for Food and Feed (hereinafter, RASFF). In four instances, Spain notified the "*unauthorised novel food ingredient cannabidiol (CBD)*" in coffee with hemp flowers from Italy, in oil drops from Slovenia, in sublingual oil spray from the UK and in a food supplement from Spain. Austria notified the "*unauthorised novel food ingredient cannabidiol (CBD)*" in milk and dark chocolates from Hungary (1,750 mg/kg - ppm) and in a food supplement from Austria, produced in the Netherlands (44,200 mg/kg - ppm). The products were withdrawn from the market or, in the case of CBD in oil drops from Slovenia, returned to the consignor. It appears that the Spanish and Austrian authorities take a particular strict stance on CBD products. On 4 December 2018, the Austrian Ministry for Labour, Social Issues, Health and Consumer Protection adopted a Decree, which categorically states that cannabinoid-containing extracts, which are placed on the market in food, in particular as food supplements (*e.g.*, CBD oil) were novel foods and required authorisation. In the Netherlands, several operators have been severely fined for marketing CBD food supplements with claims linked to its effects against Parkinson's disease, Alzheimer or diabetes. Such claims are delicate as health claims (*i.e.*, *any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health*) are strongly regulated and, in general, Article 7(3) of *Regulation (EU) No 1169/2011 on the provision of food information to consumers* provides that food information shall not attribute to any food the property of preventing, treating or curing a human disease, nor refer to such properties (*i.e.*, medical claims).

The qualification in the EU Novel Foods Catalogue is a guidance for food business operators, but not a definitive interpretation of EU law, which ultimately is for the Courts to determine. It was previously argued that, depending on how products derived from the hemp plant are manufactured, in particular, hemp oils and CBD oils, they might require authorisation under the NFR before being placed on the EU market. Furthermore, hemp oil obtained by cold-pressing the seeds or other parts of the hemp plant does arguably not require pre-market authorisation as a novel food because it was already on the market before 1997. If, however, the natural CBD content of hemp oil is selectively increased using certain forms of extraction or purification techniques, then a novel food authorisation might be required. Due to the new qualification of food products containing extracts of *Cannabis sativa L.* and derived products

containing cannabinoids as novel foods, in particular based on the assumption that *"a history of consumption has not been demonstrated*", the increased trade in these products is currently at risk, considering that any novel food has to obtain a market authorisation in order to allow market access. Cannabinoid food products currently being marketed in EU Member States might become subject to enforcement measures, unless they benefit from the transitional regime laid down in the NFR. According to Article 35(2) of the NFR, foods not falling within the scope of the previous Novel Food Regulation, and lawfully marketed before the entry into force of the NFR on 1 January 2018, for which an application for market authorisation is filed before 2 January 2020, continue to be allowed to be marketed until an authorisation decision is taken.

The European Food Safety Authority (hereinafter, EFSA) is currently considering a novel food application for authorisation to place on the market trans-cannabidiol as a novel food in food supplements for adults. The application to the Commission is based on publicly available (not proprietary) safety and toxicological information and toxicity reviews, including acute and long-term toxicity studies in animals, and tolerance studies in humans. The overall data package, as submitted to the EU authorities with the application, aims at supporting the safety of cannabidiol as a novel food in food supplements for adults. Reportedly, an EFSA opinion is expected to be issued during March 2019. Under the NFR, if it is consulted by the Commission, the EFSA shall adopt its opinion within nine months from the date of receipt of a valid application. According to Article 12 of the NFR, within seven months from the date of publication of the EFSA's opinion, the Commission is required to submit to the Standing Committee on Plants, Animals, Food and Feed (hereinafter, SCPAFF), composed of representatives the EU Member States and chaired by the Commission, a draft implementing act authorising the placing on the market within the EU of the respective novel food and to update the EU list.

Many products have been deemed safe by passing a safety assessment under the NFR and authorised to be placed on the EU market (*e.g.*, Antarctic Krill oil, Sacha Inchi oil, Vitamin K, Baobab fruit, as well as Chia oil and seeds). Under the NFR, all authorisations (new and existing) are generic, which means that any food business operator, not only the applicant, may place an authorised novel food on the EU market, following its listing in *Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 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*, provided that the authorised conditions of use, labelling requirements, and other specifications set out in *Regulation (EU) 2017/2470* are respected. CBD manufacturers could pursue this approach and determine whether the current application for authorisation to place trans-cannabidiol on the market as a novel food in food supplements in the EU, if approved as a novel food, can be used generically. Certain specifications might still be amended at a later stage, like in the case of the maximum level of phospholipids in Antarctic Krill.

The marketing of food products derived from *Cannabis sativa* L. in the EU has been considerably restricted since cannabinoids, including food products containing CBD, were recently catalogued as novel foods. However, arguably, not all cannabis-derived food products require market authorisation. In the previous version of the EU Novel Foods Catalogue, in the entry for cannabidiol, products with '*natural*' levels of CBD had been considered '*traditional*' foods and not novel. Food Business Operators have been acting based on guidance provided in the Novel Food Catalogue. Pending the evaluation of the novel food application for authorisation to place trans-cannabidiol on the market as a novel food, the next steps for other CBD food products to be marketed need to be considered. CBD food products should be carefully marketed in order to avoid any unauthorised health claims and possibly illegal medical claims.

Recently Adopted EU Legislation

Customs Law

- *Commission Implementing Regulation (EU) 2019/455 of 20 March 2019 making imports of mixtures of urea and ammonium nitrate originating in Russia, Trinidad and Tobago and the United States of America subject to registration*

- *Commission Implementing Regulation (EU) 2019/398 of 8 March 2019 amending Regulation (EC) No 616/2007 as regards some additional tariff quotas in the sector of poultrymeat and derogating from that Regulation for the quota year 2018/2019*

- *Commission Implementing Regulation (EU) 2019/386 of 11 March 2019 laying down rules with regard to the apportionment of tariff rate quotas for certain agricultural products included in the WTO schedule of the Union following the withdrawal of the United Kingdom from the Union and with regard to import licences issued and import rights allocated under those tariff rate quotas*

Trade Remedies

- *Commission Implementing Regulation (EU) 2019/464 of 21 March 2019 initiating an investigation concerning possible circumvention of anti-dumping measures imposed by Council Implementing Regulation (EU) No 412/2013 on imports of ceramic tableware and kitchenware originating in the People's Republic of China, and making such imports subject to registration*

Food and Agricultural Law

- *Commission Implementing Decision (EU) 2019/470 of 20 March 2019 repealing Decision 2005/779/EC concerning animal health protection measures against swine vesicular disease in Italy*

- *Commission Implementing Regulation (EU) 2019/456 of 20 March 2019 authorising the change of the specifications of the novel food coriander seed oil from Coriandrum sativum under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470*

- *Commission Implementing Regulation (EU) 2019/446 of 19 March 2019 amending and correcting 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*

- *Commission Delegated Regulation (EU) 2019/428 of 12 July 2018 amending Implementing Regulation (EU) No 543/2011 as regards marketing standards in the fruit and vegetables sector*

Other

- *Council Decision (EU) 2019/407 of 4 March 2019 on the conclusion, on behalf of the European Union, of the Agreement to Prevent Unregulated High Seas Fisheries in the Central Arctic Ocean*

- *Agreement to prevent unregulated high seas fisheries in the Central Arctic Ocean*

- *Council Decision (EU) 2019/385 of 4 March 2019 on the conclusion of the Protocol on the implementation of the Fisheries Partnership Agreement between the European Union and the Republic of Côte d'Ivoire (2018-2024)*

- *Decision No 1/2019 of the Trade and Development Committee established under the Economic Partnership Agreement between the European Union and its Member States, of the one part, and the SADC EPA States, of the other part of 18 February 2019 on the establishment of a list of arbitrators*

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