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As the EU reports on the implementation of its trade agreements, the EU-Singapore FTA will finally enter into force on 21 November 2019

On 8 November 2019, the Council of the European Union (hereinafter, Council) adopted the Council Decision on the conclusion of the Free Trade Agreement between the European Union and the Republic of Singapore. The EU-Singapore Free Trade Agreement (hereinafter, FTA) will enter into force on 21 November 2019 and is the first trade agreement with a country in South East Asia, thereby strengthening the cooperation between the Association of Southeast Asian Nations (hereinafter, ASEAN) and the EU. The EU-Singapore FTA will enlarge the EU trade network, which currently includes 41 FTAs covering 72 countries. In October, the European Commission (hereinafter, Commission) had published its '*Report on Implementation of Free Trade Agreements*', which is an essential part of the Commission's commitment to monitor and improve the implementation of FTAs. The compliance of FTA parties with the agreed rules and the enforcement of trade agreements, now soon including the EU-Singapore FTA, has been made a priority for the incoming European Commission.

Over the past twenty years, the global focus of trade negotiations has increasingly shifted from the multilateral level within the WTO to regional, bilateral, and *region-to-region* trade agreements. Perhaps somewhat reluctantly at first, given its traditional preference for the multilateral approach at the WTO, the EU then fully embraced this trend. In its 2015 '*Trade for all – Towards a more responsible trade and investment policy*' strategy, the Commission had laid out its detailed trade policy objectives with respect to key trading partners. The Commission's 2015 strategy noted that the Asia-Pacific region was "*crucial to European economic interests*" and, already back then, the Commission noted that the conclusion of negotiations with Singapore and Viet Nam had "*set a second benchmark for engaging with other partners*", such as Indonesia, Malaysia, the Philippines, and Thailand. The Commission's 2015 strategy also already pointed out the importance of the implementation of EU's FTAs to ensure parties take full advantage of the agreements. The Commission's 2015 strategy noted that implementation is a responsibility not only of the Commission, but also of EU Member States, the European Parliament, and of external stakeholders. To improve implementation, the Commission committed to "*report annually on the implementation of the most significant FTAs and give more in-depth analysis ex-post of the effectiveness of EU trade agreements, looking at sectors and Member States and the impact on the economies of partner countries in selected cases*". The first report on the implementation of the EU's FTAs was published in December 2017 and was followed by reports in 2018 and, more recently, in October 2019.

Originally, the EU and ASEAN initiated negotiations to conclude a '*region-to-region*' agreement, but the parties agreed to put those discussions on hold, due to the complexity and

sensitivity of the negotiations and some political externalities. Instead, the Council of the EU decided to pursue bilateral negotiations with individual ASEAN Member States. Although the strategic objective of the '*region-to-region*' agreement has notionally been maintained (see *Trade Perspectives*, Issue No. 9 of 4 May 2012), the focus is currently clearly on bilateral negotiations (on the possible relaunch of trade negotiations with Thailand, see *Trade Perspectives*, Issue No. 20 of 1 November 2019).

Negotiations for the EU-Singapore FTA were launched in 2010 and concluded in October 2014. However, following the conclusion of the negotiations, a controversy about the competence to conclude and sign the agreement had prompted the Commission to lodge a request for an advisory opinion to the Court of Justice of the EU (hereinafter, CJEU) in July 2015. The Commission asked the CJEU whether the EU had "*the requisite competence to sign and conclude alone the Free Trade Agreement with Singapore"* or whether it also required ratification by all EU Member States. On 16 May 2017, the CJEU published its opinion on the division of competences between the EU and its Member States with respect to the EU-Singapore FTA, and determined that "*the provisions of the agreement relating to non-direct foreign investment and those relating to dispute settlement between investors and States do not fall within the exclusive competence of the EU*", so that the EU-Singapore could not, as it stood, be concluded without the ratification by EU Member States' Parliaments. All other contentious areas were deemed by the CJEU to be of exclusive EU competence (see *Trade Perspectives*, Issue No.10 of 19 May 2017). The EU-Singapore FTA was subsequently divided into the EU-Singapore FTA, to be ratified only by the EU and Singapore, and the EU-Singapore Investment Protection Agreement, which will only enter into force once ratified by all EU Member States. Consequently, the adoption of the EU-Singapore FTA was subject to numerous delays until 8 November 2019, when the Council finally adopted the decision on the conclusion of the agreement. Already in February of this year, the European Parliament had adopted the agreement.

The EU-Singapore FTA is one of the EU's first so-called '*new generation*' FTAs. '*New generation*' agreements are those that, in addition to the removal and reduction of tariffs and non-tariff barriers for trade in goods and services, also include provisions on intellectual property rights, public procurement, competition, and sustainable development. The agreement will remove all remaining tariffs currently imposed by the Government of Singapore on certain EU products, such as alcoholic beverages, and maintain the current duty-free access for all other EU products. With respect to EU market access, more than 80% of imports from Singapore to the EU will be duty-free. Singapore is the EU's 14th largest trade in goods partner and the EU's largest ASEAN partner. In 2017, total trade in goods between the two parties amounted to EUR 53.3 billion and to EUR 51 billion for trade in services in 2017. Additionally, Singapore is a major destination for European investments in Asia and Singapore is the third largest Asian investor in the EU. Over 10,000 EU-based companies are established in Singapore and use it as the centre to serve the Asia-Pacific region. Key sectors that will benefit from the removal of tariffs and non-tariff barriers from the day the agreement enters into force are, *inter alia*, electronics, pharmaceuticals, petrochemicals and processed agricultural products. Tariffs on certain types of textiles or carpets will be eliminated in three years counting from the day the agreement enters into force. Tariffs on bicycles, fruits, and cereals will be eliminated after five years. The agreement also aims at enhancing Customs cooperation with the objective to simplify, harmonise, standardise, and modernise procedures in order to further reduce transaction costs for businesses.

Another important element in the EU-Singapore FTA is the recognition of rules of origin and the enhanced protection of intellectual property rights. For instance, under the EU-Singapore FTA, 196 geographical indications (GIs) will be protected. With respect to rules of origin, the agreement includes the concept of '*ASEAN cumulation*' in Article 3 of Annex 10, the '*Protocol 1 concerning the definition of the concept of "originating products" and methods of administrative co-operation*'. This concept will allow Singapore-based manufacturers to include components originating in other ASEAN Member States as originating content when determining whether a specific product meets the EU rules of origin requirements. Further key features of the agreement are: 1) The opening-up of services and investment markets in the

fields of telecommunications, environmental services, engineering, computing and maritime transport; and 2) Binding commitments on trade and sustainable development, including requirements concerning environmental protection and social development, in the agreement's Chapter on Trade and Sustainable Developments.

As the EU-Singapore FTA shows, the EU continues its efforts to negotiate and conclude comprehensive trade agreements with its key trading partners. In the mission letter addressed to Commissioner-designate *Phil Hogan*, the President-elect of the European Commission *Ursula von der Leyen* pointed out that Mr. *Hogan*'s mission as the future Commissioner for Trade would be, *inter alia*, to conclude ongoing negotiations, notably with Australia and New Zealand. Additionally, the letter notes that, where conditions are met, the Commissioner is supposed to "*propose to open negotiations on new bilateral or multilateral agreements*". In view of the various agreements now concluded, an important focus will also be the implementation and enforcement of existing agreements. In this regard, President-elect *von der Leyen* notes that the College of Commissioners would appoint a *Chief Trade Enforcement Officer* to work under the direct guidance of the Commissioner for Trade in order to monitor and improve trading partner's compliance with the EU's trade agreements.

In the context of implementation and enforcement of trade agreements, on 14 October 2019, the Commission published its annual report on the implementation of the EU's FTAs for the period from 1 January to 31 December 2018. The report notes that, despite the difficult global economic climate, the EU's trade network had increased. According to the report, in 2018, this network covered 31% of the EU's trade exchanges. As more trade agreements enter into force, such as the EU-Singapore FTA, this figure looks poised to increase significantly. In 2018, EU exports to and imports from trade agreements' partners showed positive developments, with a continued growth of 2% and 4.6%, respectively, with a strong performance of EU agri-food exports. Overall, in 2018, EU agri-food exports increased by 2.2% compared to 2017, with the main export sectors being beverages, food preparations, and preparations of cereals. Non-agricultural exports increased by 1.9%, where the stronger sectors (by value) were machinery and transport equipment, followed by chemicals. Overall, agri-food imports decreased by 0.5%, with plant products being the main import product, and non-agricultural imports increasing by 5.2%. The main non-agricultural imports were mineral products, machinery and appliances. The report notes that EU trading partners continued to make use of the preferences granted under the agreements with an average preference utilisation rate of 87%.

The report notes that implementation is crucial and that benefits can be seen from the early stage following the entry into force of an agreement. For instance, with respect to the Comprehensive Economic and Trade Agreement (CETA) between the EU and Canada, the report notes that, after only one year of implementation, bilateral trade in goods had increased by 10.3% and that the EU's trade surplus with Canada increased by 60%. EU exports to Canada, in sectors where import tariffs were still high, such as for pharmaceuticals, machinery or organic chemicals, increased by 15%. Overall, the report summarises that the EU's FTAs "*continue to contribute to developing a rules-based trading system and they improved market access for EU products and investments in partner countries. They also contribute to economic diversification and growth in developing partner countries*". Finally, the report notes that FTAs are beneficial not only to improve trade and market access, but also to promote European values related to workers' rights and environmental protection, including climate change mitigation. Still, the report also notes that many trade barriers remain in place and that there continues to be a need to increase efforts to raise awareness of the opportunities that trade agreements offer and ensure appropriate compliance with the commitments undertaken.

On 21 November 2019, the EU-Singapore FTA will enter into force. The implementation of the agreement is key for both parties to finally benefit from the agreement, for which negotiations were concluded five years ago. The EU-Singapore FTA will be one of the agreements that DG Trade's new *Chief Trade Enforcement Officer* will be tasked to monitor and ensure proper compliance of. All relevant stakeholders in the EU, in Singapore and in all other EU trading partners should take advantage of the agreements in place, support ongoing negotiations and raise issues of implementation that should be addressed by the parties.

An update on the regulatory developments regarding cannabidiol (CBD) at EU and global level

Recently, the Slovak Republic has undertaken steps to reform legislation related to cannabidiol (hereinafter, CBD). In the US, trade associations are strongly advocating for the US Congress to grant an exception for CBD derived from hemp under the provisions of the Food, Drug and Cosmetic Act, which regulates the use of ingredients in both drugs and foods. In August 2019, the Government of Thailand announced that it would allow hemp to be used in herbal products, food, and cosmetics. The regulation of CBD and hemp-derived products around the world continues changing and a global piecemeal approach persists.

Products, derived from the hemp plant, in particular CBD, are increasingly marketed in the EU and elsewhere. CBD products, notably CBD oils, have seen a notable rise in consumer demand in recent years, leading to an influx of products available largely online, in high street health food stores, and in pharmacies. CBD, as well as tetrahydrocannabinol (hereinafter, THC), are some of at least 113 cannabinoids identified in the cannabis plant. Cannabinoids are the chemicals that give the cannabis plant its medical and recreational properties. THC is the most abundant cannabinoid before CBD. CBD, which accounts for up to 40% of the plant's extract, does not appear to have any psychoactive effects, such as those caused by THC. Hemp, or industrial hemp, is a variety of the *Cannabis sativa L.* plant species, which is cultivated specifically for the industrial uses of its derived products. CBD oil is a natural botanical extract of the common hemp plant and is produced from high-CBD, low-THC hemp, unlike medical marijuana products, which are usually produced from plants with high concentrations of THC. Because hemp contains only trace amounts of THC, these hemp oil products are non-psychoactive. In hemp, THC is only present in trace amounts, while CBD dominates the plant's chemical makeup. Therefore, CBD is considered a safer and less controversial alternative to THC, while still offering significant health benefits, such as a downregulating impact on disordered thinking and anxiety. However, potential uses of CBD are still the subject of ongoing research. While CBD use is considered to be safe, a 2017 scientific review recommended larger and longer human trials before a definitive conclusion could be reached. CBD oils are almost always produced from industrial hemp.

Currently, in the European retail market, CBD products with low levels of THC are sold mainly as food supplements. However, regulatory issues are becoming more prevalent due to a lack of clear regulation from EU Member States. With the aim of clarifying the regulatory framework surrounding CBD, 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*' into *Regulation (EU) No 2015/2283 on novel foods* (hereinafter, the NFR). All extracts of hemp and derived products containing cannabinoids are now described as novel food and require an authorisation under the NFR (see *Trade Perspectives*, Issue No. 6 of 22 March 2019). The amendments to the novel food catalogue now classify CBD as a novel food, since the compound does not have a long-standing history of consumption in the EU. Therefore, producers wishing to sell food and drink products containing CBD in the EU are required to follow the procedure described by the NFR and present a dossier showing that CBD does not pose a safety risk to human health. This change in EU rules is now being implemented in EU Members States. Recently, the Federal Government of Germany confirmed in an official statement that CBD is to be classified as novel food. This statement followed a ruling by the Administrative Court of Düsseldorf, Germany, which rejected the argument that hemp-derived CBD cannot be considered as a novel food, because the NFR also applies to manufactured food products whose source (*i.e.*, hemp) is not novel in itself.

While some EU Member States strictly enforce the interpretation on novel foods, others do not appear to do so. In the UK, more than 6 million citizens are reportedly consuming CBD-related products and, although around 20 applications on CBD products are currently being processed

by the EFSA, no novel foods licences have been granted in the UK for CBD to date. In order to contribute to ensuring compliance with the law and in view of quality control, the *Centre for Medical Cannabis*, the UK's industry membership body for stakeholders operating in the cannabis-based medicinal products and cannabidiol wellness market, announced, in August 2019, that the signatories of the *Cannabinoid Industry Quality Charter* are required to pursue the necessary authorisation to be granted permission to legally distribute cannabinoid products. Businesses are encouraged to follow the novel food authorisation process in close collaboration with the UK's Food Standard Agency.

Slovakia is another EU Member State that has recently taken initiatives concerning CBD products, joining the majority of EU countries that legally permit the sale of CBD-related products such as supplements, tinctures and tablets. The *Bill amending Act no. 139/1998 coll. on narcotic drugs, psychotropic substances and preparations* (hereinafter, the Act on psychotropic substances) updates the status of CBD from psychotropic to non-psychotropic ingredient, therefore excluding it from Group 2 of the list contained in the Act on psychotropic substances. This change now exempts CBD from certain mandatory requirements for handling, import and export. The draft provision must still be adopted by the Slovak Parliament and is scheduled to come into force on February 2020.

In the US, there have been quite some changes regarding the regulation of medical cannabis over the last 15 years, but focusing on THC products, while CBD was considered as a regulated substance and, until 2018, the cultivation of hemp was prohibited in the US. So far, the US Food and Drug Administration (hereinafter, FDA) has not yet approved any safety, purity, manufacturing or ingredient standards for CBD. The 2018 *Farm Bill* authorised the growing and processing of hemp for the development of CBD finished goods. The *Farm Bill* further specifically prevented the FDA from regulating these products and the FDA also made it clear that a new regulatory framework for CBD products based on a health hazard evaluation aiming at determining a safe daily exposure level, would take at least three to five years to complete. This means that, given the growing marketplace of CBD products, thousands of CBD products are inundating the US market, the legality of which remains unclear.

Trade associations in the US have long been asking the US Congress to grant an exception for CBD derived from hemp under the provisions of the *Food, Drug and Cosmetic Act*, which regulates the use of ingredients in both drugs and foods. However, the FDA stated that an application requesting the investigation for the use of CBD as a drug was impeding further regulatory actions to authorise it as a food product. It is worth noting that, for CBD derived from hemp to be granted the requested exception, CBD would have to be derived from hemp as defined by the 2018 *Farm Bill* and any dietary supplement containing hemp-derived CBD would have to comply with the requirements for new dietary ingredients under the *Food, Drug and Cosmetic Act* and the FDA's implementing regulations, which include requirements on product labelling, good manufacturing practices, as well as the prohibition of making any drug claim.

In Southeast Asia, since 27 August 2019, the Government of Thailand allows hemp to be used in herbal products, food, and cosmetics. According to the relevant modified provision of the *Narcotic Act B.E. 2522 of 22 April 1979*, hemp extracts that contain THC not exceeding a level of 0.2% by weight are no longer considered narcotics and may be used in herbal products and drugs. Thailand also removed cannabis and hemp extracts with a THC content of less than 0.2% from the list of banned narcotics substances, with the aim of allowing extracts to be used in medicines, cosmetics, and food and of supporting hemp cultivation. Finally, the new provision establishes that only licensed local producers may trade CBD-based products in Thailand during the next five years, in a move that has attracted significant controversy and may lead to trade litigation.

In China, the law allows the sale of hemp seeds and hemp oil, however, CBD used in food and medicines is not permitted and, according to an official declaration released by China's Deputy Director of the National Narcotics Control Commission, in relation to the legalisation of hemp and CBD products in other countries, the Chinese authorities would now "*strengthen the supervision of industrial cannabis*".

The progressive regulation of CBD and hemp-derived products around the world continues and regulatory developments aimed at regulating one of the fastest-growing industries worldwide are resulting in a piecemeal approach through often diverging national laws and regulations. Legal and scientific uncertainties are poised to result in significant obstacles to trade and manufacturers might find themselves in the obligation of seeking professional advice on the functioning and interaction of the different legal frameworks. In general terms, regarding the regulation of hemp-derived products, such as CBD, regulators around the world should pursue a more harmonised and trade-facilitative approach, while traders and operators must exercise extreme caution and due diligence.

Regulatory issues on cultured meat in the EU: novel foods, GMOs, labelling

In recent times, the idea of cultured or '*laboratory-grown*' meat is gaining supporters, who are interested in enjoying a diet that includes meat, but without the linked environmental and animal welfare issues. Cultured meat appears to offer a solution to this perceived '*problem*'. This article addresses regulatory issues related to cultured meat in the EU and draws a comparison to the situation in the US.

Cultured meat (also known as synthetic, artificial or *in vitro* meat) is a product obtained by harvesting muscle cells from animals, then placing the harvested cells in a breeding medium and finally into a bioreactor, similar to that used for the fermentation of beer or yogurt, which supports the growth of muscle tissue fibres. The animal cells are '*fed*', *inter alia*, with minerals, salt and protein in order to keep growing and developing tissues, which then become the cultured meat. According to media reports, the first '*synthetic hamburger*' was reportedly already "*produced in 2013 by researchers at a Dutch university, at a cost of hundreds of thousands of dollars*". Costs appear to be significantly lower now: "*With the help of cells from a single cow*", scientists can reportedly now "*produce* 175 million hamburgers. In a question for written answer by the European Commission (hereinafter, Commission) on 18 April 2019, a Member of the European Parliament (hereinafter, MEP) stated that "*under ideal conditions, two months of in vitro meat production from just ten muscle cells from a pig could deliver 50,000 tonnes of in vitro meat, with a much lower environmental impact than that produced by butchered meat*". Moreover, the MEP stated that *in vitro* meat would be less exposed to bacteria and less likely to decay, as its production would be more controlled than that of conventional meat and as it would not be exposed to toxic chemicals, such as pesticides and fungicides.

In a reply to another question for written answer by an MEP, the Commission noted on 8 October 2018 that it is aware of numerous studies in the context of cultured meat, which are available in scientific literature. At the request of the Commission's Directorate-General for Research and Innovation, a 2018 independent expert report *Recipe for change: An agenda for a climate-smart and sustainable food system for a healthy Europe* identified the development of new meat alternatives as an important pathway to achieving the Commission's *Food 2030 Initiative*, which aims at delivering a climate-smart and sustainable food system for a healthy Europe. The report makes express reference to '*in-vitro lab meat*' and states, *inter alia*, that "*The main source of protein in our diets consists of meat, that accounts for 15% of greenhouse gas emissions, consumes 10% of the world's fresh water and uses more than one quarter of the planet's ice-free surface. On the other side, there is a large diversity of crops and other protein sources suitable for human consumption with relevant nutritional profiles and sustainability footprints that are not produced or processed in sufficient amounts. Examples are: underutilised crops (e.g., lupin, peas, quinoa) or alternative proteins sources in our daily diets (e.g., plant proteins, mycoprotein, in-vitro lab meat, algae, seaweed, insects)*".

According to Article 3(2)(a)(vi) of *Regulation (EU) No 2015/2283 on novel foods* (hereinafter, the NFR), "*food consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, micro-organisms, fungi or algae*" falls within the scope of the NFR which applies since 1 January 2018, repealing and replacing *Regulation (EC) No 258/97* and

Regulation (EC) No 1852/2001. The NFR aims at improving conditions so that food businesses can easily bring new and innovative foods to the EU market, while a high level of food safety for consumers is maintained. Novel foods are foods that were not used for human consumption to a significant degree within the EU before 15 May 1997, irrespective of the dates of accession of EU Member States. This includes newly developed, innovative food, or food produced using new technologies and production processes, as well as food traditionally consumed outside of the EU. The first EU rules on novel foods established by *Regulation (EC) No 258/97* needed to be updated to simplify the current authorisation procedures 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).

One of the main features and improvements of the NFR is the expanded category of novel foods, including food consisting of, isolated from or produced from cell culture or tissue culture. Under the NFR, all authorisations are generic, as opposed to the previous applicant-specific, restricted novel food authorisations. As a consequence, any food business operator may place an authorised novel food on the EU market, provided that the authorised conditions of use, specifications and labelling requirements are respected. Food industry sources have described the generic nature of the authorisations as not being an incentive for companies to invest in a lot of safety investigations for the novel product and have stated that it would depend on what companies can do to protect their intellectual property. However, Article 26 of the NFR foresees that, upon request, an applicant may be granted an individual authorisation for the placing on the market of a novel food if it is based on newly developed scientific evidence and proprietary data. Such data shall not be used for the benefit of a subsequent application during a period of five years from the date of the authorisation of the novel food without the agreement of the initial applicant.

The NFR provides for a simplified, centralised authorisation procedure managed by the Commission. Centralised, safety evaluations of the novel foods are to be carried out by the European Food Safety Authority (hereinafter, EFSA). The Commission consults the EFSA on the applications and bases its authorisation decisions on the outcome of the EFSA's evaluations. Industry sources state that the major problem of the previous system was time, with on average three and a half years to achieve a novel food approval and, in some cases, even five or six years. The new procedure aims at improving efficiency and transparency by establishing deadlines for the safety evaluation and authorisation procedure, thus reducing the overall time spent on approvals to 18 months. *Commission Implementing Regulation (EU) 2017/2469 of 20 December 2017 laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods* sets out the administrative, technical and scientific requirements that must be included in a novel food application and dossier. In addition, the EFSA has issued, on 21 September 2016, detailed guidance. Both the legal text of the implementing act and the EFSA guidance are expected to assist food business operators and facilitate the preparation and submission of a novel food application.

On the topic of cultured meat, the Commission noted, in its answer to the written question of an MEP on 8 October 2018, that it is aware of the new technologies intended to produce cultured meat using cell cultures and referred to Article 3(2)(a)(vi) of the NFR. According to the Commission, cultured meat may fall in this category and would require a pre-market authorisation, which would include a safety assessment performed by the EFSA. The NFR contains provisions for the safety assessment of such foods before they are placed on the market and for specific labelling requirements to ensure a high level of health protection and consumer information about specific characteristic or food property. In addition, the Commission may also, for safety reasons, and taking into account the opinion of the EFSA, impose post-market monitoring requirements for novel foods. The Commission noted, at that time, that no application for the authorisation of *in vitro* meat had been received so far in the context of novel food.

Interestingly, in the answer to a written question by an MEP on 18 June 2019, the Commission noted that the pre-market authorisation procedure for cultured meat under the NFR does

exceptionally not apply "*where the technique used falls under the scope of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, in which case the latter applies*". Indeed, although the production of cultured meat does not appear to require, in principle, techniques of genetic engineering, there are, reportedly, discussions among researchers about utilising such techniques to improve the quality and sustainability of cultured meat.

As regards the eventual labelling of cultured meat, novel foods are subject to the general labelling requirements laid down in *Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers* (hereinafter, FIR). The NFR notes that, in certain cases, it may be necessary to provide for additional labelling information, in particular regarding the description of the food, its source, its composition or its conditions of intended use to ensure that consumers are sufficiently informed of the nature and safety of the novel food, particularly with regard to vulnerable groups of the population. Article 6(2) of the NFR states that, when novel foods are added to the EU's list of authorised novel food, there can be requirements regarding labelling, in order to fully inform the consumer, for instance by describing the food or its composition. It can be expected that specifications will be added for cultured or *in vitro* meat. A likely controversial issue is whether the term '*meat*' may be used in labelling and advertising. According to point 17 of Part B of Annex VII of the FIR, the definition of meat, for food labelling purposes, is: "*Skeletal muscles of mammalian and bird species recognised as fit for human consumption with naturally included or adherent tissue, where the total fat and connective tissue content does not exceed [certain values] and where the meat constitutes an ingredient of another food*".

As cultured meat is food, it is also subject to the general principles and requirements of food law established in *Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety*, in terms of, for example, responsibilities of food business operators and traceability of the food.

The US still needs to set up a regulatory framework regarding cultured meat. However, the roles of US Government agencies have recently been clarified. On 7 March 2019, the US Food and Drug Administration (hereinafter, FDA) and the US Department of Agriculture's (hereinafter, USDA) Food Safety and Inspection Service concluded a formal agreement on their cooperation to oversee the production of cell-based meat from livestock and poultry. The purpose of the Agreement is to determine the intended roles of the FDA and the USDA with respect to the oversight of human food produced using animal cell culture technology, derived from cell lines of USDA-amenable species and required to bear a USDA mark of inspection. Essentially, according to the agreement, the FDA is competent to oversee cell culture and production up to the harvest of the cultured meat cells, whereas the USDA takes over responsibility, as of harvest, up to and including the actual production of cell-based meat products. The Agreement does not determine which regulatory framework would apply to cultured meat. This still needs to be settled. Nevertheless, it has been welcomed by the market players concerned. On 8 March 2019, the *Good Food Institute*, which works with scientists, investors, and entrepreneurs, focussing on "*clean meat and plant-based alternatives to animal products – foods that are more delicious, safer to eat, and better for the planet than their outdated counterparts*" issued a press release, stating that "*The agreement is a significant step forward in providing a transparent and predictable regulatory path to market for cell-based meat, which will help to ensure that the U.S. does not fall behind Israel, China, Japan, the Netherlands, Singapore, and other countries that are moving quickly to ensure a clear path to market for this method of meat production*".

Some would like to see the '*problem*' of meat consumption being addressed with an emphasis on organic farming, sustainable sources of animal feed and respect of animal welfare. But scientific and technological advancements appear to provide other sources of protein needed to contribute to the necessary intake by humans, which cannot be met by plant-based production or traditional meat only. Interested stakeholders are encouraged to be prepared to navigate the approval procedures for cultured meat and to work with their legal advisors prior

to submitting new novel food dossiers or, as the case may be, a dossier for genetically modified food, to the Commission in the EU or other competent authorities around the world.

Recently Adopted EU Legislation

Customs Law

- *Council Decision (EU) 2019/1864 of 24 October 2019 on the signing, on behalf of the Union, of the Agreement in the form of an Exchange of Letters between the European Union and the Swiss Confederation in the context of negotiations under Article XXVIII of the GATT 1994 on the modification of Switzerland's WTO concessions with regard to seasoned meat*

Trade Remedies

- *Commission Implementing Regulation (EU) 2019/1860 of 6 November 2019 amending Commission Implementing Regulation (EU) No 1313/2014 imposing a definitive anti-dumping duty on imports of certain prepared or preserved citrus fruits (namely mandarins, etc.) originating in the People's Republic of China following an expiry review pursuant to Article 11(2) of Council Regulation (EC) No 1225/2009*

Food and Agricultural Law

- *Commission Regulation (EU) 2019/1901 of 7 November 2019 amending Regulation (EC) No 1881/2006 as regards maximum levels of citrinin in food supplements based on rice fermented with red yeast Monascus purpureus*

- *Commission Implementing Regulation (EU) 2019/1872 of 7 November 2019 amending Annex I to Regulation (EC) No 798/2008 as regards the entry for Japan in the list of third countries, territories, zones or compartments from which certain poultry commodities may be imported into or transit through the Union*

Other

- *Notice concerning the date of entry into force of the Free Trade Agreement between the European Union and the Republic of Singapore*

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