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The EU introduces exceptions to the protection of medicines through *Supplementary Protection Certificates* to the benefit of biosimilar and generic medicines' producers

On 11 June 2019, the EU published *Regulation (EU) 2019/933 of the European Parliament and of the Council of 20 May 2019 amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products*. *Regulation (EU) 2019/933* will enter into force on 1 July 2019 and will introduce an exception to the protection granted to an original medicine by a so-called *Supplementary Protection Certificate* (hereinafter, SPC) for export purposes and/or for stockpiling. This exception is an important measure to the benefit of EU-based manufacturers of biosimilar and generic medicines, who will soon be entitled to manufacture a biosimilar or generic version of a medicine that is still covered by an SPC.

A biosimilar medicine is defined as a biologic medicine that contains a version of the active substance of an already authorised biological medicinal product (*i.e.*, the '*reference*' medicine) and which is marketed following the expiry date of exclusivity rights on the '*reference*' medicine. The active substance is of biological origin, which means that it is made by or derived from a biological source, such as a bacterium or yeast. Generic medicines are '*copies*' of a medicine that has already been authorised and that have exactly the same dosage, intended use, effects, side effects, route of administration, risks, safety, and strength as the '*reference*' medicine.

The SPCs were introduced in the EU in 1992, as an extension to a patent right. They are intended to offset the loss of effective patent protection for medicines, which occurs due to the compulsory and time-consuming testing and clinical trials that such products require before obtaining regulatory marketing approval. In the EU, an SPC can extend patent rights with an additional exclusivity of a maximum of five years. More specifically, the aim of SPCs is to avoid that the term of patent protection be shortened by the period between the filing date of the patent application and the date of the authorisation to place the product on the market in the EU. While aiming at rewarding investment in innovation and protecting intellectual property, SPCs can, at the same time, put biosimilar and generic medicines' manufacturers at a disadvantage with competitors in third countries, in particular when the protection of intellectual property rights expires earlier than in the EU. Currently, during the period of SPC protection of a product in the EU, EU-based generic and biosimilar medicines manufacturers may not manufacture for any purpose, including for export outside of the EU to countries, where SPC

protection has expired or does not exist, while manufacturers based in non-EU countries may do so.

It has, therefore, been argued that biosimilar and generic medicines manufacturers located in countries outside of the EU, with more relaxed patent protection rules, had a competitive advantage vis-à-vis EU biosimilar and generic medicines manufacturers. During the SPC term, a generic or biosimilar medicines manufacturer may also not manufacture a protected medicine for stockpiling reasons and to prepare for '*day 1*' entry in the domestic market following the expiry of the SPC. This has been considered to place EU-based manufacturers of biosimilars and generics at a disadvantage compared to manufacturers located in other countries that may prepare stocks for a timely market entry. EU-based biosimilar and generic medicines' manufacturers note that, due to the current restrictions of the SPC, they would be forced to delocalise production to non-EU countries, such as Canada, China, India, or the US.

Following more than three years of discussions and preparatory legislative deliberations, the EU now intends to address these issues by amending *Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products* through *Regulation (EU) 2019/933*. In 2016, the European Commission published the study *Assessing the economic impacts of changing exemption provisions during patent and SPC protection in Europe*, which had been commissioned to external consultants. The study aimed at assessing "*the economic impacts on the European pharmaceutical industry as well as wider impacts on employment and spending on pharmaceuticals, of a number of changes to exemption provisions during the patent and Supplementary Protection Certificate (SPC) term in Europe on medicines for human use*". One of the approaches addressed by the study were "*the potential impacts of allowing manufacturing of SPC protected medicines in protected (domestic) markets for purposes of: i) exporting to third countries where the corresponding patent or SPC has expired, ii) exporting to other EU Member States where the corresponding patent or SPC has expired, iii) preparing for timely entry in the domestic market subsequent to patent or SPC expiry (stockpiling)*". The study found that an EU SPC waiver would, *inter alia*: 1) Create 20,000 to 25,000 additional manufacturing jobs in Europe by 2025; 2) Increase the net sales for the EU-based pharmaceutical industry by EUR 7.3 to EUR 9.5 billion by 2025; 3) Ensure faster entry of biosimilar and generic competition in the EU after the expiry of an SPC, thereby improving access to medicines by patients; and 4) Enable savings in pharmaceutical expenditures of EUR 1.6 to EUR 3.1 billion thanks to enhanced competition.

The study was then followed by a public consultation, which was launched by the Commission and was open for feedback from 12 October 2017 to 4 January 2018. The Commission received 231 replies and prepared a summary. While biosimilar and generic medicines manufacturers confirmed the problems due to the SPCs and supported the introduction of a waiver, manufacturers of the original medicines rather noted their opposition to the idea of a waiver and argued that the current SPC framework did not "*put EU-based generics/biosimilars manufacturers at a particular disadvantage compared with foreign-based manufacturers*". On 28 May 2018, the Commission published its proposal for what would become *Regulation (EU) 2019/933*. Most importantly, the proposal limited the exception to the SPC to any act comprising the "*(i) making for the exclusive purpose of export to third countries; or (ii) any related act that is strictly necessary for that making or for the actual export itself*". Considering that the study had also addressed the manufacturing for "*preparing for timely entry in the domestic market subsequent to patent or SPC expiry (stockpiling)*", an intense debate strongly focused on that aspect.

In its opinion to the responsible Committee for Legal Affairs (hereinafter, JURI), the European Parliament's Committee for the Environment, Public Health and Food Safety (ENVI Committee) stated that it "*supports introducing a stockpiling waiver, giving generic and/or biosimilar manufacturers more incentives to manufacture within the Union and not in third countries*". On 29 January 2019, the JURI Committee's report was tabled for the plenary and, on 17 April 2019, the text was adopted by the European Parliament's plenary. The draft tabled for the plenary included an amendment regarding the exception also for stockpiling, providing an exception for "*making a product, or a medicinal product containing that product, for the*

purpose of storing it in the Member State of making, during the final 2 years of validity of the" SPC. This aspect was amended again in the final text adopted by the European Parliament in its last session on 17 April 2019, before the European election, notably reducing the period of time for such manufacturing to six months before the expiry of the SPC.

On 20 May 2019, the Presidents of the Council of the EU and of the European Parliament, respectively, signed the Regulation, and on 11 June 2019, *Regulation (EU) 2019/933* was published in the EU's Official Journal. The agreed text of the Regulation provides the following exceptions, that are to be included in Article 5(2)(a) of *Regulation (EC) No 469/2009*: "*(i) the making of a product, or a medicinal product containing that product, for the purpose of export to third countries; or (ii) any related act that is strictly necessary for the making, in the Union, referred to in point (i), or for the actual export; or (iii) the making, no earlier than six months before the expiry of the certificate, of a product, or a medicinal product containing that product, for the purpose of storing it in the Member State of making, in order to place that product, or a medicinal product containing that product, on the market of Member States after the expiry of the corresponding certificate; or (iv) any related act that is strictly necessary for the making, in the Union, referred to in point (iii), or for the actual storing, provided that such related act is carried out no earlier than six months before the expiry of the certificate*". Finally, it must be noted that this exception does not apply retroactively. Article 5(10) of Regulation (EC) No 469/2009 is amended to provide that Paragraph 2 applies to: 1) SPCs that are applied for on or after 1 July 2019; 2) SPCs that have been applied for before 1 July 2019 and that take effect on or after that date, but only to such certificates from 2 July 2022; and 3) SPCs that take effect before 1 July 2019.

The recent developments regarding the EU's SPCs and the exceptions introduced by *Regulation (EU) 2019/933* must also be seen in the broader context of intellectual property rights, patent protection and international trade. Clearly, a balance must be found between the interests of patent holders and the development of biosimilar and generic medicines. The debate must also take greater public health considerations into account, notably the access of patients to affordable medicines around the world. The introduction of the exceptions to the SPC in the EU is an important success for the biosimilar and generic medicines industry. However, it concerns only one of many important legal questions in the context of intellectual property rights and trade disciplines. Basic rules are provided in the *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPs), which applies between all Members of the World Trade Organization. However, as more and more trade disciplines are negotiated outside of the WTO, within the contexts of bilateral, regional, and plurilateral trade agreements, the debate has strongly shifted to the provisions that are included in such agreements. Again, a balance must be pursued to safeguard the rights of patent holders, but also to allow biosimilar and generic medicines' manufacturers to develop medicines at affordable prices benefitting patients.

Striking the right balance is not always easy and it is often subject to case by case evaluations. The upcoming introduction of the exceptions to the SPC in the EU is an important step in achieving such a balance. Many further issues remain and the multitude of ongoing trade negotiations demonstrates the continued relevance to address these issues and to reconcile the diverging positions of various competing sectors.

The California Office of Environmental Health Hazard Assessment holds that acrylamide in coffee does not pose a significant risk of cancer

On 7 June 2019, the California Office of Environmental Health Hazard Assessment (hereinafter, OEHHA) adopted '*Title 27, California Code of Regulations, Section 25704 Exposures to Listed Chemicals in Coffee Posing No Significant Risk*', which states that the exposure to chemicals in coffee, including acrylamide, does not pose a significant risk of cancer. Notably, this decision by the OEHHA will exempt coffee from carrying warning labels, which coffee retailers were required to affix to their coffee products on the basis of a 2018

Court ruling. Regulating acrylamide has led to debates and divergent opinions between legislators and industries. Despite calls in a number of countries, as well as in the EU, to take a tougher stance on maximum levels of acrylamide in food products and to place warning messages on certain products, it appears that California's authorities preferred to grant exceptions, while the EU has established benchmark levels, rather than maximum permitted levels.

Acrylamide, is a chemical that has been shown to be present in food as a result of cooking practices, some of which have been used for centuries. Acrylamide can have negative effects on human health. Therefore, finding ways to reduce the levels of its ingestion has proved complex. In the EU, *Commission Regulation (EU) 2017/2158 of 20 November 2017 establishing mitigation measures and benchmark levels for the reduction of the presence of acrylamide in food* defines acrylamide as "*a low molecular weight, highly water soluble, organic compound which forms from the naturally occurring constituents asparagine and sugars in certain foods when prepared at temperatures typically higher than 120 °C and low moisture*". According to Recital 3 of *Regulation (EU) 2017/2158*, it forms mainly in baked or fried carbohydrate-rich foods, where raw materials contain its precursors, such as cereals, potatoes and coffee beans.

Countries around the world are increasingly addressing the issue of acrylamide in food. In the US, in March 2016, the *Food and Drug Administration* (hereinafter, FDA) issued the *Guidance for Industry: Acrylamide in Foods,* intended to help growers, manufacturers, and foodservice operators to reduce acrylamide levels in certain foods. The guidance recommends that companies be aware of the levels of acrylamide in the foods they produce and consider adopting approaches, if feasible, that reduce acrylamide in their products. The non-binding guidance focuses on raw materials, processing practices, and ingredients pertaining to potato-based foods (such as French fries and potato chips), cereal-based foods (such as cookies, crackers, breakfast cereals, and toasted bread), and coffee, all of which are sources of acrylamide exposure. The guidance suggests a range of possible approaches to reducing acrylamide levels rather than identifying specific approaches to effectively reduce acrylamide levels. The guidance does not provide for any specific maximum recommended level or action level for acrylamide.

In the US State of California, '*Proposition 65, Safe Drinking Water and Toxic Enforcement Act of 1986*' (hereinafter, *Proposition 65*) requires warning signs on foods and beverages containing acrylamide. In general terms, *Proposition 65* aims at protecting drinking water sources from toxic substances that cause cancer and birth defects, and at generally reducing or eliminating exposures to those chemicals, for example in consumer products, by requiring warnings in advance of exposure. A so-called '*Prop 65 warning*' must be applied to any product containing a listed chemical (such as acrylamide), unless the level of exposure is below the regulatory '*safe harbour level*'. The content of the warning should include the words "*This product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause cancer/birth defects or other reproductive harm*".

The OEHHA, California's lead State agency for the assessment of health risks posed by environmental contaminants and lead agency for the implementation of *Proposition 65*, has established over 300 '*safe harbour levels*', which are daily exposure limits in micrograms (µg) per day. These levels include *No Significant Risk Levels* (NSRLs) for cancer-causing chemicals (for example, 0.2 µg/day for acrylamide) and *Maximum Allowable Dose Levels* (MADLs) for chemicals causing reproductive toxicity (for example, 140 µg/day for acrylamide). '*Safe harbour levels*' are different to the chemical total content of a product and there is no way to directly convert one figure into the other, as they refer to different conceptual measurements.

On 28 March 2018, the Superior Court of the State of California for the County of Los Angeles had issued its ruling in the case *Council for Education and Research on Toxics vs Starbucks Corporation, et. al.* In its ruling, the Superior Court found that the defendants "*failed to meet their burden of proof on their Alternative Significant Risk Level affirmative defence*". The *Alternative Significant Risk Level* (ASRL) affirmative defence is an exemption to the cancer

hazard warning requirement under the California Health and Safety Code Section 25249.6. The exemption in Section 25249.10(c) states that Section 25249.6 must not apply if an "*exposure for which the person responsible can show that the exposure poses no significant risk assuming lifetime exposure at the level in question for substances known to the state to cause cancer*…". In its ruling, the Court noted that acrylamide had been listed under '*Proposition 65*' as a chemical known to the State of California as carcinogenic. The Court noted that when "*coffee beans are roasted, a chemical reaction occurs (the Maillard reaction) causing the asparagine and sugars in green coffee beans to produce the chemical acrylamide. As coffee is brewed, the acrylamide in the ground roasted coffee beans dissolves in water, resulting in acrylamide being present in brewed coffee*". Therefore, in order to be granted with an exemption, the defendants would have needed to comply with a quantitative risk assessment, where "*sound considerations of public health support an alternative level*". The Court concluded that the defendants failed to prove that acrylamide presented "*no significant risk level*". In addition, the Court stated that the defendants did not conduct "*a quantitative assessment of the risk of cancer from exposure to acrylamide in coffee*" and which "*quantitatively compared any alleged health benefits with any adverse effects of coffee consumption*". The decision by the Court required that the defendants, namely *Starbucks*, *7-Eleven* and *Target*, post cancer warnings on their coffee products sold in California.

Following the Court's decision, the OEHHA proposed, on 15 June 2018, to add Section 25704 to the California Code of Regulations, which is supposed to clarify that "*cancer warnings are not required for coffee under Proposition 65*". On 7 June 2019, the OEHHA adopted the new Section 25704, which states that "*exposures to chemicals in coffee… that are created by and inherent in the processes of roasting coffee beans or brewing coffee do not pose a significant risk of cancer*". The OEHHA stated that the "*very large number*" of scientific studies, including the 2018 Monograph on Drinking Coffee by the International Agency for Research on Cancer, an authoritative body for purposes of *Proposition 65*, does not support "*an association between the complex mixture of chemicals that is coffee and a significant risk of cancer*". Therefore, the OEHHA notes that "*providing warnings for such exposures would not be 'clear and reasonable' or consistent with the purpose of Proposition 65*".

Shortly after the OEHHA had proposed to add Section 25704, the US Food and Drug Administration (hereinafter, FDA) issued a statement supporting the OEHHA's proposal for exempting coffee from California's cancer warning law. In its statement, the FDA recalled that one of its objectives is ensuring that the labelling of food products does not contain "*false or misleading statements*" about food safety or nutrition. The FDA went on to state that, if a US State law purported *"to require food labelling to include a false or misleading statement*", the FDA could decide to "*step in*". The FDA pointed out that requiring cancer warnings on coffee due to the presence of acrylamide, would be more likely to mislead consumers rather than to inform them. More specifically, the FDA stated that such a warning could mislead consumers to believe that drinking coffee would be dangerous for their health while, according to the FDA, it could actually provide health benefits.

This is not the first time that the FDA expresses its concern regarding warnings on food products due to acrylamide. In 2003 and 2006, the FDA had issued similar statements regarding the proposal to impose a cancer warning on whole-grain cereals. The FDA stated that, while some of those products might contain acrylamide, labelling all whole-grain cereals with a cancer warning could cause consumers to avoid food that would be beneficial for their health.

The recently adopted Section 25704, exempting coffee from a warning label, which the Court had imposed, demonstrates once again the complexity of regulating acrylamide in California. In the EU, *Commission Regulation (EU) 2017/2158* establishes mitigation measures and benchmark levels for the reduction of the presence of acrylamide in food, but does not set maximum permitted levels, as the EU has established for other chemical contaminants in certain foods, such as those set in *Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs* for 3-

monochloropropane-1,2-diol (3-MCPD), glycidiol and polycyclic aromatic hydrocarbons (PAH) (see *Trade Perspectives*, Issue No. 8 of 19 April 2019).

Stakeholders in the food industry should continue to closely monitor any development relating to acrylamide, as further changes to the current rules can be expected. Stakeholders should be in a position to quickly assess any new proposals, for instance regarding maximum permitted levels, develop their position, and engage with the key stakeholders and competent authorities.

Seaweeds as food – regulatory hurdles on novel foods, health claims and food contaminants remain in the EU

On 9 May 2019, the PHYCOMORPH European Guidelines for a Sustainable Aquaculture of Seaweeds (hereinafter, PEGASUS) report was released by the European Commission's (hereinafter, Commission) Joint Research Centre (hereinafter, JRC), which is the Commission's science and knowledge service that provides independent scientific advice and support to EU policy, as well as a team of experts of the international academic PHYCOMORPH network, which comprises research teams dedicated to the identification of the biological events governing the development of macroalgae (*i.e.*, a collective term used for seaweeds and other marine algae attached to the marine bottom). The authors of the PEGASUS report analysed the current EU policy framework for seaweed aquaculture, identifying challenges, including regulatory hurdles, and how they can be solved to make the most of this resource in a sustainable way.

Seaweeds are plant-like organisms that play a key ecological role in coastal ecosystems: seaweed support the marine food web, protect coasts from erosion, remove nitrogen or phosphate and possible pollutants, and sequestrate CO_2. The European continent is characterised by its large coastal territory and large range of climates. The PEGASUS report notes that, although the European marine flora has one of the highest diversity of species in the world, the commercial production of seaweeds is still at the beginning, with only 1% of the world's production. At the same time, interest in seaweed-based industrial applications (*e.g.*, food supplements, cosmetics like skincare, as well as herbal remedies) is on the rise. According to the PEGASUS report, the estimated value of the global seaweed production industry currently amounts to more than about EUR 8 Billion (for 30 Million metric tonnes) and will continue to increase. By 2050, the edible bioresource biomass (*i.e.*, the total quantity or weight of organisms in a given area or volume, essentially '*food*') will have to satisfy the 9 billion people predicted to live on the planet. Seaweed aquaculture can help to address global challenges related to nutrition, health and a sustainable circular economy. Today, there is growing need for the development, improvement and diversification of seaweed aquaculture practices, the report states.

Seaweeds are thus a promising bioresource for the future and the demand for high-value seaweed-derived compounds is growing in Europe. However, the report notes that European production lags behind Asian countries, where seaweeds have been used for centuries to benefit from their nutritional properties, due to their unique flavours. In Western countries, macroalgae have not been a significant food source over the past centuries, while industrial applications have long been limited to the extraction of *phycocolloids* (*i.e.*, algal colloids, *e.g.*, alginate, agar and carrageenan, used as gelling agents, thickeners or stabilising and emulsifying agents) for the food industry. However, northeast Atlantic countries show historical records of seaweed consumption, with the red alga *Palmaria palmata* being an important source of minerals and vitamins in ancient times. The tradition has survived only in Iceland and Ireland, where this red seaweed is still consumed, dried as a snack or mixed into salads, bread dough, and curds.

The PEGASUS report provides scientific guidance to help meet a growing global demand for seaweeds, while also protecting resources and the environment, calling for the development,

improvement and diversification of seaweed aquaculture practices in Europe. Currently, the production of seaweeds in Europe is largely based on the harvesting of wild stocks. However, climate change and disturbance from human activity is putting pressure on these populations, with commercially important species and essential coastal habitats significantly decreasing in certain areas of Europe. For example, in the southerly areas of Europe, where they normally grow, several species of kelp, used for food, animal feed and fertilisers, are starting to disappear. To protect these wild seaweed resources and to satisfy the market demand for seaweed biomass, the report states that aquaculture production (*i.e.*, farming) is becoming increasingly common. This also has potential environmental and ecological impacts, including the change to ecosystem dynamics caused by introducing non-native species or modifying the interaction between species. The report notes that developing the sector also depends on overcoming technological, market and regulatory constraints, such as upscaling production and simplifying legal procedures. As this is an emerging sector in the EU, there is currently no framework to guide the development of seaweed aquaculture in Europe that considers all these aspects. With this in mind, the PEGASUS report recommends: 1) Harmonising EU regulation and simplifying procedures across EU Member States; 2) Adopting a risk assessment approach to the cultivation of non-native species; 3) Improving standardisation and traceability frameworks; 4) Adapting food security monitoring programmes for seaweeds; and 5) Dedicated research to support market claims.

From a regulatory perspective, recommendations 1) and 5) above are particularly interesting. The report describes the national regulatory framework and the current status of development of the seaweed-aquaculture sector for seven European countries (*i.e.*, Denmark, France, Ireland, Norway, Portugal, Scotland/UK, and Spain) and identifies the main challenges that such countries need to overcome towards the sustainable development of the seaweed-aquaculture industry at the national level. These challenges include, *inter alia*, access to information about the regulatory framework (or the lack thereof), simplification of licencing procedures, availability of marine space for cultivation, and social acceptability.

Under EU harmonised legislation, some seaweed species are considered to be novel foods (such as the brown seaweed species *Cladosiphon okamuranus* or *Mosuku* and *Durvillaea antarctica* or *Cochayuyo*) and need to be authorised under *Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods*, while other seaweed species were consumed as food (or food supplements) to a significant degree within the EU before 15 May 1997 and do not require pre-market authorisation (like the brown seaweed *Alaria esculenta* or *Winged Kelp*, as well as the red seaweed *Chondrus crispus* or *Irish moss*). However, the report notes that there is no updated and complete list of seaweed species authorised as food in the EU. It must be noted that the seaweed species mentioned above as novel foods appear to be currently imported into the EU and could therefore benefit from the simpler novel food approval procedure under *Regulation (EU) 2015/2283* for traditional foods from third countries (see *Trade Perspectives*, Issue No. 1 of 12 January 2018).

Seaweeds accumulate very well minerals, metals, and also, unfortunately, heavy metals, if these are present in the surrounding environment. The latter include mercury, cadmium, and lead. However, EU law does currently not establish maximum levels for heavy metals in seaweed. *Commission Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs* establishes, for example, a maximum level of 3,0 mg/kg for cadmium in food supplements consisting exclusively or mainly of dried seaweed, as well as products derived from seaweed. According to the PEGASUS report, more specific levels for heavy metals and iodine in seaweed have been established in the US and recommended in France. However, the EU is planning to set harmonised levels in the future and already adopted *EU Recommendation 2018/464 on the monitoring of metals and iodine in seaweed, halophytes and products based on seaweed*, according to which the EU Member States, in collaboration with food and feed business operators, are to monitor, during the years 2018 to 2020, the presence of arsenic, cadmium, iodine, lead, and mercury in seaweed, halophytes (*i.e.*, salt-tolerant plants growing in waters of high salinity), and products based on seaweed. These collected values are to be reported to the European Food Safety Authority (EFSA).

As regards contaminants, the PEGASUS report states that most of the heavy metals in seaweed are organic and therefore harmless for humans, but regulations in some countries do not distinguish between organic and inorganic heavy-metal compounds, such as arsenic and cadmium, which can be found in some seaweeds. This would create unnecessary debates over the appropriateness of eating seaweed. However, the report argues that the consumption of seaweeds in China, for example, is many times higher than that of the EU, but that there are no detectable negative health effects.

Under point 5), the report recommends dedicated research to support market claims. This refers to the issue of seaweed and nutrition and the discussion on nutrition and health claims in the marketing of seaweeds and seaweed products, including food supplements. Seaweeds are known for their high nutritional properties. However, being very diverse, their nutritional composition varies by species, geography, environment, and season, and even within populations. Nutrients, enzymes, metabolites and other compounds from marine bio-resources are also used in the development of functional foods. Seaweeds are a good source of vitamins (*e.g.*, A, K, B12), minerals, and trace elements that are essential for human nutrition. *Regulation (EC) No 1924/2006 on nutrition and health claims made on foods* provides in its Annex for nutrition claims (*e.g.*, "*source of [name of vitamin/s]*", "*source of [name of mineral/s]*", "*high [name of vitamin/s]*" and/or "*high [name of mineral/s]*"), which are authorised if the respective product fulfils certain established requirements.

A number of health claims, for example for iodine, magnesium, calcium, and iron have also been approved in the EU under *Regulation (EC) No 1924/2006*. It can, for example, be claimed that iodine contributes to normal cognitive function, normal energy-yielding metabolism, normal functioning of the nervous system, the maintenance of normal skin, normal production of thyroid hormones, and normal thyroid function and normal growth of children. It must be determined, however, whether a specific seaweed or seaweed product (including food supplements) meets the strict conditions for making such health claims. In this respect, the PEGASUS report rightly states that "*more scientific research to define the potential of seaweed as bioactive food is needed. At present, companies claim effects, but more research is needed to support these claims and feed the market. It is recommended that scientific proof leads to risk-benefit analyses on health. For claims on seaweed as being nutraceuticals, bioactive foods, superfoods or even pharmaceuticals, more research and clinical proof is needed*". Therefore, in respect to market (nutrition and health) claims for seaweeds or seaweed products (including food supplements), unsubstantiated claims that may put the consumer at risk, but also damage the reputation of the sector in the long term, should be avoided.

The PEGASUS report provides the first European guidelines for the sustainable aquaculture of seaweeds, making a number of recommendations, including the adoption of a risk assessment approach to the cultivation of non-native species, improving standardisation and traceability frameworks, and adapting food security monitoring programmes for seaweeds. From a regulatory perspective, harmonisation in the EU, in particular in the field of food contaminants, should be carefully monitored by stakeholders. Adequate legal advice, *inter alia*, on health claims and the authorisation of novel foods (including traditional foods from third countries) should be sought to ensure that legitimate interests are properly voiced and represented within all relevant *fora*.

Recently Adopted EU Legislation

Food and Agricultural Law

- *Commission Implementing Decision (EU) 2019/950 of 7 June 2019 amending the Annex to Implementing Decision 2014/709/EU concerning animal health control measures relating to African swine fever in certain Member States (notified under document C(2019) 4357) (Text with EEA relevance.)*

Trade-Related Intellectual Property Rights

- *Commission Implementing Decision of 4 June 2019 on the publication in the Official Journal of the European Union of an application for amendment of a specification for a name in the wine sector referred to in Article 105 of Regulation (EU) No 1308/2013 of the European Parliament and of the Council (Vigneti delle Dolomiti/Weinberg Dolomiten (PGI))*

Other

- *Regulation (EU) 2019/933 of the European Parliament and of the Council of 20 May 2019 amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products*

- *Directive (EU) 2019/904 of the European Parliament and of the Council of 5 June 2019 on the reduction of the impact of certain plastic products on the environment*

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