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Implementing the EU's digital agenda: Agreement on data flows reached with Japan, while negotiations on binding digital trade rules start with Korea

In recent months, the EU has concluded several partnerships to further enhance its digital trade relations with partner countries, particularly those in the Indo-Pacific region. On 28 October 2023, the European Commission (hereinafter, Commission) announced that, the EU and Japan had concluded discussions on cross-border data flows "*to make doing business in the online world easier, less costly and more efficient*". Additionally, on 31 October 2023, the EU and the Republic of Korea, issued a *Joint Statement on the launch of negotiations for an EU-Korea Digital Trade Agreement*, which is to "*provide legal certainty for businesses and consumers engaged in digital trade, enhance their protection in digital transactions, and foster an open, free and fair online environment*". This article provides an overview of the EU's and its trading partners' efforts to facilitate digital trade, particularly when it comes to rules on cross-border data flows, and identifies the implications of these commitments for businesses and consumers.

The EU's evolving approach to regulating digital trade

The growing importance of digital trade has been reflected in the Commission's *2021 Communication on An Open, Sustainable and Assertive Trade Policy*, which highlights that the EU needs to "*step up bilateral engagement and explore stronger frameworks for cooperation on trade-related digital issues with like-minded partners*". As part of this overall approach, the EU has pursued *Digital Partnerships* with its key partners in the Indo-Pacific region, which, in general terms, provide an overarching framework for bilateral cooperation in the digital field. To date, the EU has concluded *Digital Partnerships* with Japan, the Republic of Korea, and Singapore, which were signed in May 2022, November 2022, and February 2023, respectively (see *Trade Perspectives*, Issue No. 15 of 31 July 2023).

Additionally, the EU concluded *Digital Trade Principles* with Japan, Korea, and Singapore, which are an essential deliverable of the *Digital Partnerships*. The *Digital Trade Principles* are "*non-binding instruments that reflect a common understanding on key issues relevant to digital trade and a joint commitment to an open digital economy, free of unjustified barriers to*

international trade" (see *Trade Perspectives*, Issue No. 3 of 13 February 2023 and Issue No. 15 of 31 July 2023).

While the EU's *Digital Partnerships* and *Digital Trade Principles* are an essential step forward to developing common regulatory approaches on digital trade, they remain non-binding. Building on these non-binding instruments, the EU has been pursuing binding commitments on digital trade, which are intended to '*modernise*' the rules on electronic commerce in the PTAs concluded with Japan, Singapore, and the Republic of Korea.

New rules on cross-border data flows for the EU-Japan EPA

In October 2022, the EU and Japan agreed to start negotiations to include rules on cross-border data flows in the *EU-Japan Economic Partnership Agreement* (hereinafter, EPA), which have now been concluded. As a basis for the negotiations, Japan had proposed the disciplines provided in the *Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP)* and the EU proposed its text that it had tabled in the agreements recently concluded with Chile, New Zealand, and the UK, although the specific coverage differs depending on the parties' respective interests and negotiations. The Commission notes that the final text was a mixture of both the CPTPP and the EU's framework, but was largely based on the latter, particularly regarding the protection of personal data and privacy.

More specifically, the EU and Japan successful negotiated two articles for the EU-Japan EPA on cross-data flows, notably one providing for a ban of data localisation requirements and one on data protection. While the agreed text has not yet been made publicly available, Commission officials provided some details on the agreed provisions. In addition to the four prohibitions common to the EU's framework on digital trade rules, which provide "*that cross-border data flows shall not be restricted between the Parties by: a. requiring the use of computing facilities or network elements in the Party's territory for processing, including by imposing the use of computing facilities or network elements that are certified or approved in the territory of the Party; b. requiring the localisation of data in the Party's territory for storage or processing; c. prohibiting storage or processing in the territory of the other Party; d making the cross-border transfer of data contingent upon use of computing facilities or network elements in the Party's territory or upon localisation requirements in the Party's territory*"), the agreed article on data localisation contains new clauses, including a prohibition on measures requiring companies to obtain prior approval for data transfers.

The Commission notes that the agreed text balances the prohibitions on data localisation requirements with a clause that preserves the policy space needed for legitimate public policy objectives. While a similar clause is found in Article 12.4 of the EU-New Zealand FTA, it appears that the text agreed between the EU and Japan goes a step further by clarifying what constitutes legitimate public policy objectives, one of which, according to Commission, is cyber security.

Negotiations on comprehensive digital trade disciplines for the EU-Korea FTA

With regard to the Republic of Korea, on 14 April 2023, the Commission adopted a *Recommendation for a Council Decision authorising the opening of negotiations for digital trade disciplines with the Republic of Korea and with Singapore*. The Recommendation highlights that, while bilateral trade between the EU and Singapore and the Republic of Korea "*have already been liberalised and enhanced by the Free Trade Agreements (FTAs) concluded between the EU and the Republic of Korea in 2011 and between the EU and Singapore in 2019*", they do not yet provide comprehensive rules on digital trade. On 27 June 2023, the Commission announced that the Council of the EU had adopted the negotiating directives for negotiations on digital trade disciplines with Singapore and the Republic of Korea and, on 20 July 2023, negotiations were already officially launched with Singapore (see *Trade Perspectives*, Issue No. 15 of 31 July 2023). On 31 October 2023, the EU and the Republic of Korea issued a *Joint Statement on the launch of negotiations for an EU-Korea Digital Trade Agreement*. The EU proposed the same text for the Agreement on digital trade with Korea and

Singapore, respectively. The text proposals contain 31 articles and provide, *inter alia*, for a prohibition of customs duties on electronic transmissions, a commitment on ensuring cross-border data flows, commitments on digital trade facilitation (*e.g.*, on the conclusion of contracts by electronic means and electronic authentication and electronic trust services), and commitments on establishing business trust (*e.g.*, a prohibition against a requirement to transfer or access the source code of software). Article 5 of the proposed texts covers the four prohibitions on data localisation common to the EU's framework on digital trade rules.

The evolving role of data flows in regulating trade in services

Digital trade and trade in services are closely intertwined. Notably, digital trade encompasses "*digitally enabled trade in goods and services that can either be digitally or physically delivered, and that involves consumers, firms, and governments*". Data flows are relevant for almost every service delivered electronically. Digital trade is "*profoundly transforming the world services trade, as the exports of mode 1 services (i.e., cross-border trade in services) are booming*". Therefore, restrictions on cross-border data flows, imposed through measures such as data localisation requirements, can significantly affect trade in services.

Essentially, regulators impose data localisation requirements for various reasons, namely for the protection of privacy, security, economic development of local businesses, and to support domestic law enforcement. These objectives inform the different exceptions applied to trade rules concerning cross-border data flows. However, measures taken to achieve such objectives can be perceived as protectionist in nature, intended to protect local service providers from the competition of '*like*' foreign services and service providers. In this context, the Commission notes that the agreed provisions on cross-border data flows with Japan "*lay the foundation for a common approach on digital trade, sending a strong message against digital protectionism and arbitrary restrictions".* The Commission adds that, *"from a trade perspective, unjustified data localisation requirements can raise the cost of conducting business across borders*" and provides the example of "*mandating companies to keep data within a certain territory or making the cross-border transfer of data contingent upon the use of computing facilities or network elements in the country's territory, for protectionist reasons".*

Article 6 of the text proposed by the EU to Korea would allow the Parties to adopt and maintain measures deemed "*appropriate to ensure the protection of personal data and privacy including through the adoption and application of rules for the cross-border transfer of personal data*". To justify the EU's exception to cross-border data flows, the Commission notes that *"regulating data protection safeguards, including with respect to cross-border data transfers, foster the trust of consumers and as such benefit the digital economy which critically depends on such trust*". A similar exception is provided in Article XIV(c)(ii) of the World Trade Organization's General Agreement on Trade in Services (hereinafter, GATS) on '*General Exceptions*', which permits WTO Members to adopt or enforce measures "*necessary to secure compliance with laws or regulations.(..)*", when intended to protect "*the privacy of individuals in relation to the processing and dissemination of personal data and the protection of confidentiality of individual records and accounts*".

Unlocking business potential?

The services sector constitutes a substantial part of the EU's economy and, according to the Commission, "*the EU is the world's largest exporter of services; 48% of them (excluding investment) are digital*". Advancing digital trade disciplines in the EU's FTAs could strengthen this position. The Commission notes that, with the prohibition of data localisation requirements, "*companies are not required to physically store their data locally*", which "*would not only entail additional costs and complexities, as businesses might have to build and maintain data storage facilities in multiple places and duplicate the data they use, with a negative impact on their competitiveness, but could also undermine the security of such data*". The Managing Director of the *European Services Forum* (ESF), a network of representatives from the European services sector, *Pascal Kerneis*, stated that the ESF welcomed "*the agreement reached between the EU and Japan on cross-border data flows*", which "*finally completes the digital*

trade chapter of the Economic Partnership Agreement and demonstrates the leading role of the EU and Japan in setting global rules in this domain".

Next steps

The Commission notes that, once ratified, the agreed provisions on cross-border data flows between the EU and Japan would be included in the *EU-Japan Economic Partnership Agreement* and that "*similar negotiations with Korea and Singapore are due to follow*". Interested stakeholders should actively follow the negotiations and make their interests heard.

Singapore's Court of Appeal rules that the Geographical Indication *Prosecco* may be registered in Singapore and used exclusively for wines produced in Italy

On 8 November 2023, the Singapore's Court of Appeal issued a judgement in the case *Consorzio di Tutela della Denominazione di Origine Controllata Prosecco V Australian Grape and Wine Incorporated*, which cleared the way for the term *Prosecco* to be registered and used in Singapore as a geographical indication (hereinafter, GI) exclusively for wines produced in Italy. The judgement by Singapore's Court of Appeal overturned the ruling of Singapore's High Court, which had accepted the argument by *Australian Grape and Wine Incorporated* (hereinafter, AGWI) that the registration of *Prosecco* as a GI *"would be likely to mislead the consumer"*. In this context, the Court of Appeal ruled that, while *AGWI* had demonstrated that *Prosecco* was the name of a grape variety, it failed to show that the registration of *Prosecco* as a geographical indication would likely mislead Singaporean consumers regarding the true geographical origin of the wine. So far, 165 EU GIs have been registered in Singapore, following a commitment under the *EU-Singapore Free Trade Agreement* (hereinafter, EUSFTA).

What is a Geographical Indication?

A geographical indication (GI) is a type of intellectual property right that consists of a label used on certain products that have a specific geographical origin and that possess certain qualities or a reputation linked solely to that specific origin. Products benefitting from a GI are subject to particular legal protection. At the international level, GIs are protected under the WTO Agreement on *Trade-Related Aspects of Intellectual Property Rights* (hereinafter, TRIPs Agreement), which provides the procedures and remedies *"for the enforcement of intellectual property rights"* by laying down certain general principles that are applicable *"to all IPR enforcement procedures"*. Provisions regarding the protection of GIs are contained in Articles 22 to 24 of the TRIPs Agreement. Notably, Article 22 of the TRIPs Agreement mandates WTO Members to protect GIs in order to prevent misleading the public and unfair competition. Furthermore, Article 23 concerns '*Additional Protection for Geographical Indications for Wines and Spirits*', notably that WTO Members are to "*provide the legal means for interested parties to prevent use of a geographical indication identifying wines for wines not originating in the place indicated by the geographical indication in question*".

The EUSFTA charts the course for Singapore's Geographical Indications Act 2014

As a signatory to the *TRIPs Agreement,* Singapore has the obligation to confer protection to GIs and, on 15 January 1999, Singapore enacted its first *Geographical Indications Act*. Most importantly, in view of the commitments contained in the EUSFTA, namely that each Party *"shall provide the legal means for interested parties"* to prevent the infringement of GIs, Singapore repealed the *Geographical Indications Act 1999* and enacted the Singapore *Geographical Indications Act 2014 (No 19 of 2014)*. Under the Chapter on Intellectual Property Rights of the EUSFTA, Singapore had agreed to enhance its existing regime on the protection of geographical indications and the *Geographical Indications Act 2014* was implemented in order to comply with these obligations. The *Geographical Indications Act 2014* only entered into force in 2019, following the entry into force of the *EUSFTA* in the same year.

The *Geographical Indications Act 2014* introduced several key changes, notably: 1) The establishment of a registration system, as mandated by Article 10.17 of the EUSFTA. Previously, the registration and recognition of GIs in Singapore could only be made through a court application. The registration system facilitates the registration of GIs and provides greater transparency and legal certainty; 2) Enhanced protection for agricultural products and foodstuffs by extending the protection of GIs to a wide variety of consumer products, not only wine and spirits, but also covering beers, meats, seafood, edible/non-edible oils, fruits, cheeses, spices and condiments, confectionery, baked goods, flowers, and natural gum; and 3) Border enforcement mechanisms for registered GIs, which requires *Singapore Customs* to detain imported and exported goods that are suspected of infringing the rights of GI-registered and -protected products. In this context, Article 10.49 of the EUSFTA provides that EU companies may request *Singapore Customs* to seize counterfeit GI goods.

Singapore's new GI Registry

The *Geographical Indications Act 2014* foresees the establishment of a GI Registration System and, in 2019, Singapore established the Office of the *Registrar of Geographical Indications*, which has control of the *Registry of Geographical Indications* and oversees the registration of GIs. To register a GI, businesses must submit their application to the Registrar and the Registrar will examine the application and determine whether the application contains any deficiency or faces any opposition. In case a third party opposes the registration of the GI, an opposition proceeding is to be conducted. Once a GI has been registered, the GI is protected for ten years from the date of registration, and the registration may be renewed upon expiry of that period. The detailed rules on, *inter alia,* the registration and publication of geographical indication applications, are provided under the *Geographical Indications Rules 2019*, which is the implementing regulation of the *Geographical Indications Act 2014.*

The case against Prosecco

On the basis of Annex 10-A of the EUSFTA, Singapore has the obligation to recognise 196 GIs concerning EU products, including *Prosecco* wine. *"Conegliano – Prosecco / Conegliano Valdobbiadene – Prosecco / Valdobbiadene – Prosecco"* is listed under No. 164 of Annex 10-A to the EUSFTA as wine originating from certain regions of Italy. While under the EUSFTA, Singapore has the obligation to recognise the EU's GIs listed in Annex 10-A thereof, Article 10.17(2)(c) of the EUSFTA allows an objection procedure in order for "*the legitimate interests of third parties to be taken into account*". Such procedures and relevant legal grounds are contained in Section 4, Part 2 of the *Geographical Indications Act 2014.*

On 3 May 2019, the *Consorzio di Tutela della Denominazione di Origine Controllata Prosecco* (hereinafter, Consorzio), a trade body established in Italy and responsible for protecting, promoting, marketing and overseeing the use of the term *Prosecco,* had applied to register *Prosecco* as a GI in Singapore. The claimed geographical area for the production of *Prosecco* wines was the *"North East region of Italy"* and included the entire territories of Belluno, Gorizia, Padova, Pordenone, Treviso, Trieste, Udine, Venice, and Vicenza. On 21 June 2019, *Prosecco* was registered in Singapore and published in the *Geographical Indications Journal* under Geographical Indication No 50201900088S.

On 9 September 2019, *AGWI*, a representative body for grape growers and winemakers in Australia, filed a notice of opposition against the registration of *Prosecco* as a GI, with two grounds of opposition: First, that *Prosecco "contained the name of a plant variety and was likely to mislead the consumer as to the true origin of the product"*. *AGWI* argued that *Prosecco* is the name of a plant variety, "*Prosecco grape*" as opposed to a name that refers to wine from Italy. *AGWI* based this argument Section 41(1)(f) of the *Geographical Indications Act 2014*, which provides grounds for refusal of registration of a GI. Notably, Section 41(1)(f) states that a proposed GI may be refused if it contains *"the name of a plant variety or an animal breed and is likely to mislead the consumer as to the true origin of the product"*. Second, AGWI argued that *Prosecco "did not fall within the meaning of a "geographical indication" as defined*

in Section 2(1) of the Geographical Indications Act 2014", which defines GI as *"any indication used in trade to identify goods as originating from a place, provided that the place is a qualifying country or a region or locality in a qualifying country; and a given quality, reputation or other characteristic of the goods is essentially attributable to that place"*.

Prosecco as a plant variety

The *AGWI*'s arguments were dismissed by the *Principal Assistant Registrar of Geographical Indications* (hereinafter, PAR), operating under the *Intellectual Property Office of Singapore* (IPOS), which ruled that *"neither ground of opposition had been made out"*. According to the PAR, it is unlikely that Singaporean consumers would be misled by the registration of *Prosecco* as a wine from Italy, as *"the length of time that Italian "Prosecco" wine had been sold in Singapore (since 2011) and the amount sold over eight years (387,100 litres in 2018 alone)*", thus the popularity and reputation of Italian *Prosecco* wines, are well-established in Singapore. On the other hand, the PAR noted that Australian *Prosecco* wines "*had only been introduced into the Singapore market in 2015 and the quantity of such wine sold here was significantly lower (9,657 litres in 2018)".*

AGWI then appealed the ruling by the PAR to the Singapore High Court, which ruled in 2022 in favour of *AGWI*, accepting the argument that *Prosecco* is the name of a plant variety and not of a wine and that, therefore, the registration of *Prosecco* was likely to mislead consumers. It should be noted that, on 30 November 2009, the European Commission had officially changed the name of the grape plant variety *"Prosecco"* to *"Glera"*, which means that the EU no longer considers *Prosecco* as a grape plant variety, but rather as a GI of wine originating from Italy. In this context, the High Court noted the evidence that *Prosecco* was the name of a grape plant variety prior to it being renamed by the EU in 2009 and concluded that the *"name change from "Prosecco to Glera applied only to the EU"*. The High Court concluded that, since *Prosecco* contained the name of a plant variety, the registration of *Prosecco* as a wine from Italy would likely mislead consumers. In response, the *Consorzio* took the case to Singapore's Court of Appeal, which overturned the ruling by the Singapore High Court.

The Singapore Court of Appeal, as the *"final arbiter of the law in Singapore",* ruled that the GI *Prosecco "must be allowed to proceed to registration"* and that *AGWI "failed to establish"* that the application of *Prosecco* as a GI was likely to mislead Singapore consumers on the true geographical origin. The Court of Appeal recognised that *Prosecco* had indeed been recognised as the name of a grape variety in the EU prior to 2009. However, the Court of Appeal then examined whether Singaporean consumers were in fact aware that *Prosecco* as a plant variety was involved in the production of *Prosecco* wine and concluded that Singaporean consumers were ignorant of the type of grape used in the production of *Prosecco* wines and that, therefore, the registration of *Prosecco* as a GI for wine originating from Italy would not mislead Singaporean consumers.

The importance of the recognition of GIs

The EU comprehensively protects GIs not only at the EU-level, but also increasingly in third countries through its Preferential Trade Agreements. The EU's various trade agreements with trading partners provide comprehensive provisions that require the administrative enforcement of GI-protected products in third countries, such as measures to handle GI infringement at the border. Through such provisions in trade agreements with third countries, EU GIs can be selectively protected outside of the EU, allowing such EU products with GIs to be sold in third countries and being protected from infringement of products marketed with the same denominations. While this aims at ensuring that consumers are informed of the authenticity, distinctiveness, and quality of the product linked to the GI, it also allows such products, which are typically marketed at a premium price, to be protected against competitors and the issue has, therefore, become a rather contentious issue in certain trade negotiations, notably in case products with the same name exist in both jurisdictions.

The outcome is a major win for the EU and for Italy's *Consorzio di Tutela della Denominazione di Origine Controllata Prosecco*, which testifies to the importance of preferential trade agreements to open markets for EU producers, protect and enforce their rights in such markets, and deliver meaningful commercial advantages and dividends. EU producers of GI products need to remain involved during the negotiations of new EU trade agreements with third countries, especially in important emerging markets in Asia, and in the subsequent monitoring and enforcement of their implementation to ensure compliance.

Italy prohibits the production and importation of cell-based synthetic food, notably cultured meat

On 16 November 2023, with 159 votes in favour, 53 against, and 34 abstentions, Italy's Chamber of Deputies (*i.e.*, the lower house of Italy's Parliament) approved a Bill on *Provisions on the prohibition of the production and placing on the market of food and feed consisting of, isolated or produced from cell or tissue cultures derived from vertebrate animals and on the prohibition of the name of meat for processed products containing vegetable proteins*. With this new Law, the Government of Italy aims at prohibiting the country's food industry from producing cell-based foods in order to "*protect culinary heritage*". In April 2023, the Bill had been presented by Italy's Minister of Agriculture, Food Sovereignty and Forestry and Italy's Minister of Health to the Senate. On 19 July 2023, the Bill was approved by Italy's Senate. For the Bill to be approved, it still had to be adopted by Italy's Chamber of Deputies. The article provides an overview of the Bill and addresses the regulatory issues related to cultured meat in the EU, notably with respect to *Regulation (EU) No 2015/2283 on novel foods* (hereinafter, the NFR).

The prohibition of cultured meat

Article 2 of the Bill states that "*On the basis of the precautionary principle laid down in Article 7 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002, it is prohibited for food business operators and feed business operators to use in the preparation of food, beverages and feed, to sell, to hold for sale, import, produce for export, supply or distribute for food consumption or promote for such purposes, food or feed consisting of, isolated from, or produced from cell or tissue cultures derived from vertebrate animals*". Article 5(1) of the Bill establishes '*Sanctions*' and provides that *"food and feed business operators that infringe the provisions of Article 2 shall be subject to an administrative fine*", ranging from between EUR 10,000 and 150,000, depending on the annual turnover of the business. In addition to the monetary fine, a business' production plants may be closed for one to three years.

Cultured meat in the EU and the EU's Novel Foods Regulation

Cultured meat, which is 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 proteins in order for them to continue growing and developing tissues, which then become the cultured meat.

In the EU, cultured meat is considered a novel food, which refers to a food that was 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. According to Article 3(2)(a)(vi) of 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. 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. One of the main features and improvements of the NFR compared to the previous regulatory framework concerns the expanded category of novel foods, now including food consisting of, isolated from or produced from cell culture or tissue culture.

The NFR provides for a centralised authorisation procedure managed by the European Commission (hereinafter, Commission), while centralised safety evaluations of the novel foods are 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. On the topic of cultured meat, the Commission noted, in its answer to the written question of a Member of the European Parliament (MEP) of 8 October 2018, that cultured meat may fall in the category of Article 3(2)(a)(vi) of the NFR 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 novel foods before they are placed on the market for specific labelling requirements to ensure a high level of health protection and consumer information about specific characteristic or food properties. 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.

No application for the authorisation of *in vitro* meat has been received so far by the Commission in the context of novel food. Some experts think that there is likely to be an application for an authorisation soon, whereas others think that it could still be several years until cultured meat may be placed on the EU market. Before that, and according to reports, the EFSA will assess the safety of cultured meat, with elements such as growth factors and hormones, culture conditions, antimicrobials, hygiene measures, equipment and potential by-products, impurities, or contamination risks all forming part of the assessment.

At the request of the Commission's Directorate-General for Research and Innovation, a 2018 independent expert report on *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 "*[…] meat […] 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 […] with relevant nutritional profiles and sustainability footprints. […] Examples are: underutilised crops […] or alternative proteins sources in our daily diets (e.g., plant proteins, mycoprotein, in-vitro lab meat, algae, seaweed, insects)*".

According to media reports, the latest life-cycle assessment shows that, compared to conventional beef production, cultivated beef could result in a reduction of 92% of the carbon footprint if renewable energy were to be used in the production process, a reduction of 95% of land use, and a reduction of 78% of water requirements.

The reliance on the Precautionary Principle for banning cultured meat in Italy

Italy's Minister of Health, *Orazio Schillaci*, says that Italy intends "*to protect citizen's health*" and that the Bill was "*based on the precautionary principle because there are no scientific studies yet on the effects of synthetic foods*" on consumers' health. According to Italy's Minister of Agriculture, Food Sovereignty and Forestry, *Francesco Lollobrigida*, *"Italy will be the first country free of synthetic food and wants to set an example of how it can be regulated*", adding that Italy had expressly "*chosen the precautionary principle"* as a basis for the Bill. *Coldiretti*, an association representing Italian agriculture, noted that "*The general mistrust confirms the need to respect the precautionary principle in the face of a new technology with many unknowns, which risks changing people's lives and the environment*" and called on EU institutions to be more vigilant and "*in authorization processes not to equate laboratory products to new food products, but rather to pharmaceutical products".*

Article 7 of the EU's General Food Law (*i.e.*, *Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 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*) establishes the general requirement for the application of the '*Precautionary principle*'. Article 7(1) states that, "*In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment*". Importantly, after assessing the available information, the possibility of harmful effects on health must have been identified. Under Article 7(1) of *Regulation (EC) No 178/2002*, the precautionary principle may only be applied following an assessment of the available information and where the possibility of harmful effects on health is identified, provided that scientific uncertainty persists. An *ex-ante* prohibition of cultured meat produced with a relatively new technology, without the identification of possible harmful effects on health, as Italy envisages, appears to be, from a legal point of view, unnecessary and arguably not in compliance with the NFR.

Regarding the application of the precautionary principle, it must be noted that, under the NFR, novel foods are to be authorised by the Commission after a thorough safety assessment by the EFSA. In this regard, Recital (20) of the NFR states that "*Novel foods should be authorised and used only if they fulfil the criteria laid down in this Regulation. Novel foods should be safe and if their safety cannot be assessed and scientific uncertainty persists, the precautionary principle may be applied*". Article 7(2) of *Regulation (EC) No 178/2002* states that measures based on the precautionary principle must be "*proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community"* and must be reviewed "*within a reasonable period of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment*". These are all elements that do not appear to have been considered in the context of Italy's Bill.

Recital 42 of the NFR makes reference to the principle of subsidiarity, stating that "*Since the objectives of this Regulation, in particular the laying down of rules for the placing of novel foods on the market within the Union, cannot be sufficiently achieved by the Member States but can rather be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 TEU*". This may suggest that Italy is arguably not competent to legislate in this field.

Outlook and implications of a ban for businesses

The prohibition is poised to have major implications for the developing cell-based foods industry. Although there has been progress in cultured meat in recent years, production appears to remain small. To date, Singapore is the only country to have allowed the sale of cultured chicken, while companies in the US have been granted regulatory clearance to produce lab-grown chicken. European countries, including the UK, the Netherlands, and Spain, as well as Israel, have announced investments in research and development of cell-based foods.

The prohibition could damage the opportunity of Italy to take part in cell-based innovations in view of fragile supply chains, increased domestic and international supply constraints, and for Italy's competitiveness in the global agri-food industry. Cultivated meat appears to be a nascent industry that also has the potential to become a major economic driver, creating new jobs and business opportunities. Questions should also be asked in relation to the competence and legal basis for individual EU Member States to take actions with respect to this novel food industry, as their actions may be short-lived, damaging, and leading to regulatory and industrial fragmentation of the EU market.

Recently adopted EU legislation

Trade Law

- *Council Decision (EU) 2023/2467 of 23 October 2023 on the position to be taken on behalf of the Union within the Joint Committee on Mutual Recognition of Professional Qualifications established under the Comprehensive Economic and Trade Agreement (CETA) between Canada, of the one part, and the European Union and its Member States, of the other part, as regards the adoption of a decision on an agreement on the mutual recognition of professional qualifications for architects*

- *Declaration by the Union Within the Joint Committee established by the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community of 28 September 2023 pursuant to Article 23(4), point (a), of Decision No 1/2023 of the Joint Committee*

- *Decision No 4/2023 of the Joint Committee established by the Agreement on the Withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community of 28 September 2023 adding two newly adopted Union acts to Annex 2 to the Windsor Framework [2023/2471]*

- *Commission Implementing Decision (EU) 2023/2484 of 9 November 2023 amending Implementing Decision 2012/715/EU as regards the inclusion of Taiwan in the list of third countries established by that Decision*

- *Decision No 1/2023 of the EU-Central America Association Council of 29 June 2023 modifying Appendix 2 (List of working or processing required to be carried out on non-originating materials in order that the product manufactured can obtain originating status) and Appendix 2A (Addendum to the list of working and processing required to be carried out on non-originating materials in order that the product manufactured can obtain originating status) to Annex II (Concerning the Definition of the Concept of Originating Products and Methods of Administrative Cooperation) to the Agreement establishing an Association between the European Union and its Member States, on the one hand, and Central America on the other [2023/2442]*

- *Commission Delegated Regulation (EU) 2023/2515 of 8 September 2023 amending Delegated Regulation (EU) 2020/688 as regards certain animal health requirements for movements within the Union of terrestrial animals*

- *Council Decision (EU) 2023/2577 of 9 November 2023 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 Kingdom of Norway amending the Agreement of the European Union and the Kingdom of Norway pursuant to Article XXVIII of the General Agreement on Tariffs and Trade (GATT) 1994 relating to the modification of concessions on all the tariff-rate quotas included in the EU Schedule CLXXV as a consequence of the United Kingdom's withdrawal from the European Union*

- *Commission Delegated Regulation (EU) 2023/2497 of 15 November 2023 amending Directive 2014/23/EU of the European Parliament and of the Council in respect of the thresholds for concessions*

Customs Law

- *Commission Implementing Regulation (EU) 2023/2489 of 30 October 2023 concerning the classification of certain goods in the Combined Nomenclature*

- *Commission Implementing Regulation (EU) 2023/2490 of 30 October 2023 concerning the classification of certain goods in the Combined Nomenclature*

- *Commission Implementing Regulation (EU) 2023/2491 of 8 November 2023 concerning the classification of certain goods in the Combined Nomenclature*

- *Council Decision (EU) 2023/2505 of 26 July 2022 on the position to be taken on behalf of the European Union within the Trade Specialised Committee on Customs Cooperation and Rules of Origin as regards the consultation laid down in Article 63(3) of the Trade and Cooperation Agreement between the European Union and the European Atomic Energy Community, of the one part, and the United Kingdom of Great Britain and Northern Ireland, of the other part*

- *Commission Implementing Regulation (EU) 2023/2519 of 30 October 2023 concerning the classification of certain goods in the Combined Nomenclature*

Food Law

- *Commission Delegated Regulation (EU) 2023/2464 of 17 August 2023 amending Regulation (EU) No 1308/2013 of the European Parliament and of the Council, as regards marketing standards for eggs*

- *Commission Delegated Regulation (EU) 2023/2465 of 17 August 2023 supplementing Regulation (EU) No 1308/2013 of the European Parliament and of the Council as regards marketing standards for eggs, and repealing Commission Regulation (EC) No 589/2008*

- *Commission Implementing Regulation (EU) 2023/2455 of 7 November 2023 concerning the non-renewal of the approval of the active substance metiram, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) No 540/2011*

- *Commission Implementing Regulation (EU) 2023/2466 of 17 August 2023 laying down rules for the application of Regulation (EU) No 1308/2013 of the European Parliament and of the Council as regards marketing standards for eggs*

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