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In light of growing e-commerce worldwide, global differences in regulation inspire 83 WTO Members to negotiate common rules for digital trade

On 19 February 2020, the European Commission (hereinafter, Commission) published its Communication '*A European strategy for data*', which sets out to create a "*genuine single market for data, open to data from across the world*", in which data is secure and businesses have "*easy access to an almost infinite amount of high-quality industrial data, boosting growth and creating value*". A few days before, from 10 to 14 February 2020, representatives of 83 Members of the World Trade Organization (hereinafter, WTO), representing over 90% of global trade and over the half of the WTO's membership, held another round of negotiations regarding a plurilateral initiative on electronic commerce (hereinafter, e-commerce), seeking to establish a framework to facilitate cross-border e-commerce. The recent developments demonstrate the importance of the discussions regarding the current and future regulatory framework for international digital trade.

What is e-commerce? There is no single and recognised definition of the term. In its Work Programme on Electronic Commerce of 1998, the WTO defines e-commerce as "*the production, distribution, marketing, sale or delivery of goods and services by electronic means*". The OECD understands this definition to encompass all '*digitally enabled*' transactions of trade in goods and services, regardless of whether they are ultimately delivered in digital or physical form. Hence, the terms include, for example, digitally delivered software, e-books and databases services, as well as digitally enabled, but physically delivered goods and services, such as the purchase of a good on an online marketplace or the booking of a hotel through a matching service. Certain technological developments illustrate the complexity to properly define and regulate e-commerce. For instance, if a digital 3D-model for printing is sent across borders to be printed elsewhere, this entails the question of whether the sending of the file should be treated as the trade of a service or rather than the trade of the final product itself: While the creation of the model itself undoubtedly constitutes a service, the fact that the model constitutes the "*DNA*" of the final product and, therefore, already holds a part of its value, may cause controversial discussions. This categorisation issue has accompanied the trading community since the very start of the debate on digital trade, which was formalised with the WTO Work Programme on Electronic Commerce in 1998.

The reason why these uncertainties have not yet led to greater upheavals in international trade relations is that WTO Members agreed, in 1998, on a temporary *moratorium* on customs duties for electronic transmissions, that is for digitally delivered products. Until now, the *moratorium* has been continually extended. However, critical voices exist, especially coming from developing countries. As the share of tariff revenues as part of the GDP is usually considerably higher in developing countries than in developed countries, the former are more vulnerable to a diversion of trade flows from physical goods to, currently tariff-free, electronic transmissions.

Today, the question of customs duties on electronic transmissions is only one of many areas for which participants in the WTO e-commerce negotiations have recognised the need for increased harmonised international regulation. As the volume of international digital trade constantly grows (the United Nations Conference on Trade and Development (UNCTAD) estimated a growth of 13% in 2017 alone), so do the costs of a lack of standards in various related fields. Therefore, the topic has received increased attention in recent years. While the WTO's 1998 Work Programme was of an informative nature, without the objective to serve as a framework for international regulation, in 2017, a group of 71 WTO Members started exploratory discussions on the potential negotiation of trade rules on electronic commerce. These discussions led to the signing, by 76 WTO Members, of a Joint Statement on Electronic Commerce on 25 January 2019, which marked the starting point for the current WTO negotiations on e-commerce.

The topics discussed in the WTO negotiations on e-commerce mainly relate to market access, the principle of non-discriminatory treatment of digital products, customs duties on electronic transmissions, cross-border data flow regulation, the facilitation of electronic transactions (*e.g.*, electronic contracts and signatures), consumer protection, data protection and privacy, cybersecurity, access to government data and the protection of source codes. While some of these issues, such as the prohibition of unsolicited commercial electronic messages and the rules regarding the validity of electronic contracts, are of a rather technical nature and, therefore, less prone to controversy, there is a number of issues that will likely lead to confrontation between the parties engaged in the negotiations. These issues concern, *inter alia*, the topics of cross border data flows and so-called data localisation requirements (also referred to as local storage requirements), privacy invasions by data collectors, the transfer of source codes, the imposition of customs duties and internet taxes, as well as internet censorship. Article 3(5) of *Regulation (EU) 2018/1807 of the European Parliament and of the Council of 14 November 2018 on a framework for the free flow of non-personal data in the European Union* defines data localisation requirements as "*any obligation, prohibition, condition, limit or other requirement […] which imposes the processing of data in the territory of a specific […] State or hinders the processing of data in any other […] State"*.

The regulation of data flows and data localisation requirements provide an illustrative example of the conflicts lying ahead. Data flows include everything from the online streaming of films and music over the delivery of online courses to the transmission of performance data of a factory or data transmitted among different branches of a company. Data localisation requirements often concern Government data, personal data of national citizens or commercially sensitive data of domestically based companies. Countries' data policies vary, often reflecting the political approach and cultural preferences. Data localisation requirements are often based on a Governments' belief that data stored locally are more secure. In addition, such policies may also be motivated by economic and legal reasons, for example the ability to subject a data processing company to national law, thereby allowing both the enforcement of national law and, potentially, the creation of additional regulatory obstacles for foreign companies entering the national market. Therefore, policy approaches to cross-border data flow regulation and local storage requirements vary widely between WTO Members and constitute important non-tariff measures affecting trade.

China, for instance, has voiced reservations regarding free cross-border data flows because of national security considerations, even though it does not openly mention them in its Communication on e-commerce in the context of the WTO discussions. Article 37 of China's Cybersecurity Law (hereinafter, CCSL) states that *Critical Information Infrastructure Operators*

(hereinafter, CIIOs) may only transmit "*personal information and important data*" overseas after passing a Government security assessment and stipulates a local storage requirement. Article 31 of the CCSL defines CIIOs as *"important sectors including public telecommunication and information services, energy, transportation, water resource, finance, public services, e-government, as well as other critical information infrastructure that, if damaged, [or if they] lose functionality, or experience data leakage, could seriously jeopardize national security, national economy, people's livelihood, and public interest".* It remains unclear, however, what exactly is to be understood, for example, by the concepts of *"important data"* or *"public interest"*. The use of such vague language can serve as a legal basis for potentially far-reaching and non-transparent limitations to the free flow of data, leading to legal uncertainty for businesses and, in consequence, to impediments for international trade.

The communications on e-commerce of the EU (INF/ECOM/22) and of the US (INF/ECOM/23, not publicly available), on the other hand, support the principle of free cross-border data flows and the prohibition of data localisation requirements. It must be noted that also the communications of the EU and of the US include potentially far-reaching exceptions with regards to "*legitimate public policy objectives*" (in the case of the US) and with regards to the protection of personal data (in the case of the EU). This notwithstanding, China's approach, on the one hand, and the EU/US approach, on the other hand, follow two substantially different paradigms regarding the free flow of data, which will likely make it very difficult to reconcile the respective positions.

Similar controversies look poised to arise regarding other contested fields of negotiation, for example regarding the protection of personal data. While the US Communication states that *"Parties may take different legal approaches to protecting personal information"* and requires *"any restrictions on cross-border flows of personal information"* to be *"necessary and proportionate to the risks presented",* the EU Communication asks WTO Members to *"recognize that the protection of personal data and privacy is a fundamental right and that high standards in this regard contribute to trust in the digital economy and to the development of trade."* The EU goes on to stipulate that WTO Members "*may adopt and maintain the safeguards they deem 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*".

The EU's recently announced *'European strategy for data'* places further emphasis on this position, stating that the Commission was *"convinced that international cooperation must be based on an approach that promotes the EU's fundamental values, including protection of privacy*", which is supposed to apply to both EU citizen's personal data, as well as commercially sensitive data. Regarding personal data, the Communication goes on to specify that *"international transfers are done via adequacy decisions and other existing transfer tools which guarantee that the protection travels with the data no matter where the data is*". The adequacy requirement means that personal data may only flow from the EU to a third country without any further safeguard being necessary if the Commission has determined that the country offers an adequate level of data protection. So far, the Commission has adopted adequacy decisions for only 13 countries. Considering the EU's unequivocal position on the protection of personal data, it appears that the EU is ready to accept the potentially detrimental effects on data flow and digital trade that this might entail. Keeping in mind that the current US Administration also has a reputation for intransigence in international trade negotiations, the issue of data protection will most likely be another controversial matter in the course of the WTO negotiations on e-commerce.

Against this backdrop, it must be underlined that even a WTO agreement on e-commerce with a rather limited scope, which could serve to harmonise various elements pertaining to less contested fields of the digital trade agenda, would already be of great value to businesses and traders around the world. As Governments continue to regulate e-commerce domestically and negotiate at the WTO level, interested stakeholders should follow the developments and contribute to this important and often very technical debate.

French Court rules that organisms obtained via *in vitro* mutagenesis techniques should be subject to strict GMO regulation, while Italy expresses its interest in '*sustainable biotechnologies*', such as gene editing

On 7 February 2020, the French Conseil d'Etat (*i.e.*, Council of State), which is France's highest administrative court, ruled that organisms obtained via *in vitro* mutagenesis techniques should be subject to regulation as genetically modified organisms (hereinafter, GMOs). On the other hand, the Italian Minister of Agriculture *Teresa Bellanova* expressed her interest in "*sustainable biotechnologies*", such as gene editing. This article provides a follow-up to the preliminary judgment of the Court of Justice of the European Union (hereinafter, the CJEU) of 25 July 2018, in Case C-528/16 *Confédération Paysanne and Others v Premier Ministre and Ministre de l'Agriculture, de l'Agroalimentaire et de la Forêt*, in which the Court established, that organisms obtained by mutagenesis are GMOs and are, in principle, subject to the obligations laid down by *Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC* (hereinafter, Directive 2001/18).

There is a number of methods, including transgenesis and mutagenesis, that can be used in order to modify the genetic heritage of a living organism. Directive 2001/18 itself does not provide any general definition of these techniques. The CJEU's Advocate General, in Case C-528/16, referred to the relevant working definitions provided by the referring court, according to which transgenesis is a genetic engineering technique that consists of inserting one or more genes from one species into the genome of another species. Directive 2001/18 does not explicitly refer to the notion of transgenesis. However, substantively, the directive covers various techniques, which could be considered as transgenic. Mutagenesis does not entail the insertion of foreign DNA into a living organism. It nonetheless involves an alteration of the genome of a living species. Conventional or random methods of mutagenesis are applied *in vivo* (*i.e.*, within living organism) to entire plants (chemically and by irradiation) in order to select, from the resulting mutants, interesting deviations and to use them in breeding, without apparently creating any identifiable risks for the environment or health.

Gradually, new techniques have been developed. As further explained by the referring court, not only have random mutagenesis techniques been applied *in vitro* (*i.e.*, in a test tube) to plant cells, but targeted mutagenesis methods applying new genetic engineering techniques have also been devised, such as oligonucleotide-directed mutagenesis (ODM, which provides a means to alter a defined site within a region of cloned DNA) or directed nuclease mutagenesis (SDN1, which is based on small deletions or insertions at a precisely defined location in the genome). Whereas conventional mutagenesis involves random mutations, some of the new techniques cause a precise mutation in a specific gene. Directive 2001/18 (and its predecessor Directive 90/220) does not apply to organisms obtained by means of untargeted mutagenesis techniques listed in its Annex I B, namely those that have conventionally been used in a number of applications and have a long safety record. Some new genetic engineering methods, in particular CRISPR-Cas9, are not based on the introduction of foreign genetic material into the DNA, but cause more or less precise changes ("*targeted mutations*") of the DNA in order to change the properties of the organism. However, unlike traditional genetic engineering techniques, gene-editing does not involve the introduction of DNA from another organism. Indeed, it is virtually impossible to detect whether the DNA of a plant or animal has been edited or not, because the changes involved are indistinguishable from naturally occurring mutations.

The decision of the French Council of State of 7 February 2020 comes after nine associations and trade unions (*i.e.*, *Confédération Paysanne and Others*) asked the French Prime Minister to subject organisms obtained by mutagenesis to GMO regulations and to declare a *moratorium* on the use of herbicide-tolerant plant varieties obtained by mutagenesis in France. Following the Prime Minister's refusal, the matter was referred to the Council of State, which submitted a preliminary question to the CJEU, which in turn had held, on 25 July 2018, in Case

C-528/16, that plants obtained by new plant breeding techniques should, in principle, fall under Directive 2000/18.

In the related preliminary judgment in Case C-528/16 *Confédération Paysanne and Others v Premier Ministre and Ministre de l'Agriculture, de l'Agroalimentaire et de la Forêt*, the CJEU established, on 25 July 2018, that organisms obtained by mutagenesis are GMOs and are, in principle, subject to the obligations laid down by Directive 2001/18. The CJEU held that crops obtained by mutagenesis are GMOs, because the techniques and methods of mutagenesis alter the genetic material of a plant in a way that does not occur naturally. The CJEU states that it followed "*that those organisms come, in principle, within the scope of Directive 2000/18 and are subject to the obligations laid down by that directive*". The ruling came as a surprise, as it had been widely expected to follow the same line taken by the CJEU's Advocate General (hereinafter, AG) in charge of that case, who in his January 2018 opinion, had stated that organisms obtained by mutagenesis were, in principle, exempted from the obligations in Directive 2001/18. The CJEU's judgements often reflect and follow the AG opinions.

Drawing on the consequences of the judgment of the CJEU, the French Council of State ruled that the organisms obtained by means of mutagenesis techniques, which have appeared or have mainly developed since the adoption of Directive 2000/18 (the so-called new plant breeding techniques), must be subject to the obligations imposed on GMOs by Directive 2000/18. The Council of State specified that this was the case not only of targeted mutagenesis (*i.e.*, mutagénèse dirigée), but also of random mutagenesis *in vitro* (*i.e.*, mutagénèse aléatoire in vitro), used in particular to make plants, such as sunflower or rapeseed, tolerant to herbicides. On the other hand, varieties obtained by means of earlier techniques, whose safety has been proven for a long time, are not subject to these obligations.

Until now, the French Environmental Code only targets organisms obtained by transgenesis, excluding from the scope of GMO regulations all organisms obtained by mutagenesis. In particular, the Council of State tasked the Government to do the following: 1) Modify Article D. 531-2 of the Environmental Code in this sense within six months; 2) Identify, within nine months in the catalogue of varieties of agricultural plants, the ones that have been obtained by mutagenesis and which should have been subjected to the evaluations applicable to GMOs; 3) Better assess the risks associated with varieties of plants made tolerant to herbicides; and 4) Define growing conditions intended to limit the use of herbicides.

A statement on the Conseil of State's website states that, in accordance with the precautionary principle, the Prime Minister "*cannot refuse to take preventive measures for the use of plant varieties that have been made tolerant to herbicides*". In a joint statement, the French Ministry of Agriculture and Ministry of Environment indicated that the Government would now study how to implement the Court's ruling in line with EU legislation.

In Italy, on the other hand, the Minister of Agriculture *Teresa Bellanova* has expressed an interest in developing "*sustainable biotechnology*", such as gene editing, in the light of an agreement on next generation biotechnology that the Italian farmers' organisation *Coldiretti*, representing more than one and a half million members in Italy, and the Italian Society of Agricultural Genetics (*i.e.*, *Società italiana di genetica agrarian*, SIGA) intend to sign. She reportedly stated that "*the next-gen biotech do in less time what natural crossbreeding would do in several steps and more slowly*", adding that "*genetically modified organisms (GMOs) are the past and their cultivation is and will remain banned in Italy*".

The intended cooperation agreement concerns an entirely new field for the application of biotechnology in Italy's farming sector. The agreement will be titled '*Camici e Trattori*' (in English, freely translated, '*gloves and tractors*') and will focus on the application of the latest-generation biotechnology to typical Italian plant varieties. Such agreement appears to be a turning point in the relationship between the farming sector and biotechnology research in Italy, so far marked by a heated debate on GMOs. According to *Coldiretti*'s President *Ettore Prandini*, these are techniques that do not involve the use of foreign DNA in the plant and, for this reason, are able to protect the biodiversity of Italian agriculture while being more

sustainable by creating, for example, more resistant grape varieties that require less pesticide use. He reportedly also stated that "*cisgenesis and genome editing give the possibility to do it without changing identity and oenological profile. Using the next-gen biotech to protect typical varieties is a challenge that must be faced together with those who do research in Italy so that the results do not end up in the hands of a few multinationals*".

The idea of cooperation between the farming sector and public research bodies on issues such as gene editing appears interesting given the circumstance that most gene editing patents are currently owned by a few multinational companies and the authorisation procedures for GMOs under Directive 2000/18 are quite expensive and are within the reach of only a few biotechnology companies, but outside the reach of public research. It appears that something in the strict EU legal framework needs to change in order to make it easier to authorise new plant breeding techniques through gene editing. Such an approach could arguably be developed in the EU's forthcoming *Farm to Fork* strategy, something that European Commissioner for Health and Food Safety *Stella Kyriakides* had already hinted at. According to a leaked document, which is part of the Commission's internal consultation process regarding the draft biodiversity strategy led by the European Commission's Directorate-General for Environment, which has yet to be released, new breeding techniques are viewed as a way to manage pests in agriculture. The leaked document reportedly reads that the "*need to better target the use of pesticides*" could be addressed with a "*combined strategy of providing alternatives to the most dangerous ones and enhancing the introduction of alternative pest management through new breeding techniques, bio-controls, Integrated Pest Management, etc., and improving the monitoring of substance residues, including at farm level*".

Modern gene editing methods are lab-based genetic modification procedures. The CJEU and the French Council of State ruled that such technologies fall under the strict and burdensome rules applicable to GMOs. It may, however, be scientifically sound to distinguish between gene editing and transgenic GMOs with the consequence of applying different rules to the different techniques, taking into consideration the different levels of risks, if they exist. The EU's regulatory framework on genetic engineering and GMOs may indeed no longer be appropriate in view of scientific developments and technological advancements. Calls have been made to adjust the EU's regulatory framework to better address the relevant matters, such as gene editing. Interested stakeholders are advised to carefully monitor developments on gene editing in the EU and to seek adequate legal advice to take action and ensure that their legitimate interests are properly voiced and represented within all relevant *fora*.

New foods in EU retail shelves – the simplified EU procedure for the placing on the market of traditional foods from third countries as novel foods

On 17 February 2020, the EU published *Commission Implementing Regulation 2020/206 of 14 February 2020 authorising the placing on the market of fruit pulp, pulp juice, concentrated pulp juice from Theobroma cacao L. as a traditional food from a third country under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Implementing Regulation (EU) 2017/2470* in its Official Journal. Since the entry into force of the EU's revised Novel Food Regulation (*i.e.*, *Regulation (EU) 2015/2283 of 25 November 2015 on novel foods*, hereinafter, the NFR), a number of new novel foods, including traditional foods from third countries, have been authorised and placed on the EU market. This article provides an assessment of the simplified procedure for notifying the placing on the EU market of novel foods as traditional foods from a third country, and compares it to the general application and authorisation procedure established for all other categories of novel foods.

The NFR defines '*novel*' food as "*any food that was not used for human consumption to a significant degree within the Union before 15 May 1997*", which is when the previous Novel Food Regulation (*i.e.*, *Regulation (EC) 258/97 of the European Parliament and of the Council concerning novel foods and novel food ingredients*) had come into force. The EU's revised

NFR applies since 1 January 2018 and repealed and replaced *Regulation (EC) No 258/97* and *Regulation (EC) No 1852/2001 laying down detailed rules for making certain information available to the public and for the protection of information submitted pursuant to European Parliament and Council Regulation (EC) No 258/97*.

The NFR established a clear legal framework with the aim of allowing food business operators to more easily bring new and innovative foods to the EU market, while maintaining a high level of food safety for consumers. The new rules provide applicants with a simplified and centralised authorisation mechanism managed by the European Commission (hereinafter, Commission), which takes into account technological progress and includes a notification procedure for traditional foods from third countries having a history of safe food outside the EU. The risk assessment of a proposed novel food is carried out by the European Food Safety Authority (hereinafter, EFSA) and the Commission bases its authorisation decision on the EFSA's scientific evaluation. Additionally, novel foods may only be placed on the EU market if: 1) They do not pose any risk to human health; 2) They are not intended to replace another food with such a change in the nutritional value to mislead the consumer; and 3) They are not intended to replace another food in a way that its normal consumption would be nutritionally disadvantageous for the consumer.

Article 3(2)(a) of the NFR defines ten categories of novel foods, which may be summarised as follows: 1) Foods originating from plants, animals, microorganisms, cell cultures, minerals, etc. (Article 3(2)(a) (ii), (iii), (iv), (v), and (vi) of the NFR); 2) Specific categories of foods (*e.g.*, insects, vitamins, minerals, foods used exclusively in food supplements before 1997, *etc.*) (Article 3(2)(a) (ix) and (x) of the NFR); 3) Foods resulting from production processes and practices (Article 3(2)(a) (vii) of the NFR); and 4) Food developed through modern technologies (*e.g.*, foods with intentionally modified or new molecular structure, nanomaterials), which were not produced or used in the EU before 1997 and thus may be considered to be novel foods (Article 3(2)(a) (i) and (viii) of the NFR).

Articles 8 to 13 of the NFR provide for an authorisation procedure managed by the Commission, and the establishment of an EU list containing all authorised novel foods. According to Article 10 of the NFR, the procedure for placing on the market of a new novel food starts either on the basis of a Commission initiative or following an application to the Commission. The application for an authorisation must include the following elements: 1) The name and address of the applicant; 2) The name and description of the novel food; 3) The description of the production process; 4) The detailed composition of the novel food; 5) Scientific evidence demonstrating that the novel food does not pose a safety risk to human health; 6) Where appropriate, the analysis method(s); and 7) A proposal for the conditions of intended use and for specific labelling requirements, which do not mislead the consumer, or the verifiable justification as to why those elements are not necessary. Once the Commission has validated the application, it is forwarded to the EFSA with a request to deliver an opinion on the safety of the proposed novel food. Within seven months from the date of publication of the EFSA's opinion, the Commission submits to the EU's Standing Committee on Plants, Animals, Food and Feed a draft implementing act authorising the placing on the EU market of the proposed novel food. The authorisation measure must take into account the EFSA's opinion, any other relevant provision of EU law and any other relevant legitimate factor. The EFSA issued a '*Guidance on the preparation and presentation of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283*' providing the detailed description of the scientific information to be provided in the applications for authorisation of a novel food.

Notably, Articles 14 to 20 of the NFR provide for a mere notification system for '*traditional food from a third country*' on the basis of a history of safe food use. According to Article 3(2)(c) of the NFR, '*traditional food from a third country*' refers to food that has not been used for human consumption to a significant degree within the EU before 15 May 1997 other than novel food as referred to in Article 3(2)(a) (i), (iii), (vii), (viii), (ix) and (x) of the NFR and which is derived from primary production and has a history of safe food use in a third country. According to Article 3(2)(b) of the NFR, the "*history of safe food use in a third country*" means that "the *safety*

of the food in question has been confirmed with compositional data and from experience of continued use for at least 25 years in the customary diet of a significant number of people in, at least, one third country". If the safety of the traditional food can be established on the basis of evidence of a history of consumption in the third country, and if the EFSA and the EU Member States do not raise any safety concerns, the traditional food may be placed on the market within four months and without any authorisation procedure.

Article 14 of the NFR provides that notifications of a traditional food from a third country must state: 1) The name and address of the applicant; 2) The name and description of the traditional food; 3) The detailed composition of the traditional food; 4) The country or countries of origin of the traditional food; 5) Documented data demonstrating the history of safe food use in a third country; and 6) A proposal for the conditions of intended use and for specific labelling requirements, which do not mislead the consumer, or a verifiable justification as to why those elements are not necessary. Additionally, in September 2016, the EFSA issued a '*Guidance on the preparation and presentation of the notification and application for authorisation of traditional foods from third countries in the context of Regulation (EU) 2015/2283*', which provides an in-depth description of the technical and scientific requirements for notifications. Notifications must include the description of the production process, composition, stability data, specifications related to the identity of the novel food, data from the experience of continued use in a third country, and data on the proposed conditions of use of the food to be placed on the EU market.

Importantly, applicants seeking the authorisation of a novel food under Article 10 of the NFR are required to demonstrate the safety of the novel food on the basis of the submission of extensive safety data and toxicological studies, while applicants notifying a traditional food from a third country under Article 14 of the NFR are required to provide evidence of food safety mainly on the basis of data related to the history of consumption of the traditional food in a third country. More specifically, applicants notifying a request for an authorisation of a novel food as a traditional food from a third country must demonstrate, *inter alia*, the '*experience of continued use in a third country*' of the traditional food. In that respect, the EFSA Guidance advises to make references to "*scientific publications, scientific expert opinions, monographs, information from international or national organisations, governmental documentation, figures on cultivation/harvesting, and sales and trade*. *Further information might be obtained from cookbooks, recipes and anecdotal data*". Moreover, the document underlines the importance of "*characterising as much as possible the traditional modalities of use in terms of preparation type, extent of use and duration of the exposure*". Food business operators seeking an EU authorisation for traditional foods from third countries are advised to take into account the EFSA Guidance, as well as the *Commission Implementing Regulation (EU) 2017/2468 of 20 December 2017 laying down administrative and scientific requirements concerning traditional foods from third countries in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods*, which provides further elements on the structure, content and presentation of a notification.

Each new novel food authorised is added to the EU list by means of a Commission implementing regulation. Once a novel food is added to the EU list, it is automatically considered as being authorised and it may be placed on the EU market. *Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 on establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on Novel Foods* entered into force on 9 January 2018, a few days after the entry into force of the NFR. The list has been last updated on 3 February 2020 and currently counts 143 authorised novel foods. Following the adoption of *Commission Implementing Regulation 2020/206* on 14 February 2020, another update of the list can be expected. All authorisations for novel foods under the NFR are generic, which means that any food business operator may place a previously authorised novel food on the market, provided that the authorised conditions of use are respected.

Chia seeds originating in mountainous areas extending from West Central Mexico to Northern Guatemala were authorised under the previous Novel Food Regulation by *Commission*

Decision 2009/827/EC authorising the placing on the market of Chia (Salvia hispanica) seeds as a novel food ingredient. With the notification procedure for traditional foods from third countries already in place at that time, the authorisation would have been less arduous, in particular without the need for an EFSA opinion on chia seeds' safety. In recent times, the following traditional foods from third countries have been authorised as novel foods in the EU: 1) Syrup from *Sorghum Bicolor (L.) Moench,* having a history of safe food in the US, (authorised by *Commission Implementing Regulation (EU) 2018/2017 of 18 December 2018*); 2) Decorticated Grains of *Digitaria Exilis,* having a history of safe food in West Africa (authorised by *Commission Implementing Regulation (EU) 2018/2016 of 18 December 2018*) ; 3) Berries of *Lonicera Caerulea L.,* having a history of safe food in Japan (authorised under *Commission Implementing Regulation (EU) 2018/1991 of 13 December 2018*); and 4) Fruit pulp, pulp juice, concentrated pulp juice from *Theobroma Cacao L.* , with a history of safe food in Brazil (authorised by *Commission Implementing Regulation 2020/206 of 14 February 2020*). Furthermore, *Aristotelia Chilensis* from Chile, commonly known as *Powder of Maquiberry*, *Coffea arabica L. and/or Coffea Canephora Pierre ex A. Froehner* commonly known as Coffea Leaves, cultivated in Ethiopia, South Sudan, Liberia, Indonesia and Jamaica, *Roasted Sacha Ichi Seeds* from Peru, and Leaf *Powder of Moringa Stenopetala* from Ethiopia, are currently under evaluation.

Food business operators interested in placing novel foods on the EU market and third countries planning to support the export of their traditional products to the EU should carefully assess the relevant legal frameworks.

Recently Adopted EU Legislation

Trade Remedies

- *Commission Implementing Regulation (EU) 2020/230 of 19 February 2020 initiating an investigation concerning possible circumvention of anti-dumping measures imposed by Implementing Regulation (EU) 2015/83 on imports of monosodium glutamate originating in the People's Republic of China, and making such imports subject to registration*

Food and Agricultural Law

- *Commission Regulation (EU) 2020/279 of 27 February 2020 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of soybean hemicellulose (E 426)*

- *Commission Implementing Regulation (EU) 2020/278 of 27 February 2020 fixing the maximum amount of aid for private storage of olive oil within the tendering procedure opened by Implementing Regulation (EU) 2019/1882*

- *Commission Implementing Regulation (EU) 2020/277 of 26 February 2020 amending Regulation (EC) No 1484/95 as regards fixing representative prices in the poultrymeat and egg sectors and for egg albumin*

- *Commission Implementing Regulation (EU) 2020/207 of 14 February 2020 amending Regulation (EU) No 142/2011 as regards imports of petfood from Saudi Arabia*

- *Commission Implementing Regulation (EU) 2020/206 of 14 February 2020 authorising the placing on the market of fruit pulp, pulp juice, concentrated pulp juice from Theobroma cacao L. as a traditional food from a third country under*

Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Implementing Regulation (EU) 2017/2470

Other

- *Decision No 1/2019 of the EU-Ukraine Sanitary and Phytosanitary Management Sub-committee of 18 November 2019 modifying Annex V to Chapter 4 of the Association Agreement*

- *Commission Implementing Regulation (EU) 2020/269 of 26 February 2020 amending Regulation (EU) No 468/2010 establishing the EU list of vessels engaged in illegal, unreported and unregulated fishing (Part B – Vessels listed in Article 30 of Regulation (EC) No 1005/2008)*

Ignacio Carreño, Moritz Brandenburger, Fabrizio De Angelis, Tobias Dolle, Lourdes Medina Perez and Paolo R. Vergano contributed to this issue.

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