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New EU rules on voluntary digital labelling in the fertiliser sector: Reducing costs and complexities?

On 30 September 2024, the EU published *Regulation (EU) 2024/2516 of the European Parliament and of the Council of 18 September 2024 amending Regulation (EU) 2019/1009 as regards the digital labelling of EU fertilising products*, which aims at promoting the use of digital labelling for fertilising products in the EU, improving the readability of labelling and simplifying suppliers' labelling obligations. This article provides an overview of the EU's legal framework on the labelling of fertilising products, the digital labelling requirements introduced under *Regulation (EU) 2024/2516*, and the implications for businesses, as well for end-users.

The EU's legal framework for the labelling of fertilising products

In the EU, the labelling of fertilisers is regulated by *Regulation (EU) 2019/1009 of the European Parliament and of the Council laying down rules on the making available on the market of EU fertilising products*. Article 2(1) of *Regulation (EU) 2019/1009* defines '*fertilising product*' as "*a substance, mixture, micro-organism or any other material, applied or intended to be applied on plants or their rhizosphere or on mushrooms or their mycosphere, or intended to constitute the rhizosphere or mycosphere, either on its own or mixed with another material, for the purpose of providing the plants or mushrooms with nutrient or improving their nutrition efficiency*". According to Article 2(2) of *Regulation (EU) 2019/1009*, '*EU fertilising product*' means "*a fertilising product which is CE marked when made available on the market*".

Article 4(1) of *Regulation (EU) 2019/1009* provides that EU fertilising products are to be labelled in accordance with the labelling requirements defined in Annex III to the Regulation. Annex III includes general labelling requirements, including: 1) The designation of the *Product Function Category* (PFC); 2) The quantity of the EU fertilising product; 3) The iinstructions for intended use, including application rates, timing and frequency; 4) TheThe recommended storage conditions; 5) Any relevant information on measures recommended to manage risks to human, animal or plant health, to safety, or to the environment; and 6) A list of all ingredients above 5% by product weight or volume.

The extensive labelling requirements set out in *Regulation (EU) 2019/1009* mean that labels tend to be overloaded with information. While the provision of such detailed information caters to the appropriate use of products characterised by innovative components, as well as to the

growing interest in their environmental and health impacts, it also has an impact on the labels' readability. In 2020, the European Commission (hereinafter, Commission) published its report on the '*fitness check*' of the EU's most relevant chemicals legislation, including *Regulation (EU) 2019/1009*. Among its conclusions, the Commission noted that not all the opportunities to improve and simplify the communication of chemical hazards and safety information to consumers had yet been seized, including those presented by digital technologies (see *Trade Perspectives*, Issue No. 22 of 4 December 2023).

The new digital labelling rules for EU fertilising products

Regulation (EU) 2024/2516 amends *Regulation (EU) 2019/1009* by providing the option for voluntary digital labelling of EU fertilising products. In doing so, *Regulation (EU) 2024/2516* presents businesses placing EU fertilising products on the market with an opportunity to make the most of digital solutions without compromising the objectives of protecting public health and the environment. In July 2024, following the conclusion of the legislative process for *Regulation (EU) 2024/2516,* the Council of EU noted that "*digital labels are QR codes or bar codes that redirect the user to a web page where the information of the label is stored*".

Regulation (EU) 2019/1009, as amended by *Regulation (EU) 2024/2516*, contains new provisions concerning, *inter alia*, the forms of labelling, the requirements for digital labels, obligations of economic operators providing a digital label, and the evaluation of the digital labelling of EU fertilising products. Article 11a(1) of *Regulation (EU) 2019/1009* on "*Forms of labelling*" provides for two main forms of labelling of EU fertilising products: 1) A label indigital form ("*digital label*"); or 2) A label in physical form ("*physical label*"). The decision to use a digital label will be informed by two factors: whether the EU fertilising products are made available to economic operators or to end-users, and whether the products are provided with or without packaging.

Articles 11a(1) and (2) of *Regulation (EU) 2019/1009* allows all labelling elements referred to in Annex III to *Regulation (EU) 2019/1009* to be provided in a digital label only for the EU fertilising products supplied to economic operators, with or without packaging. Article 2(15) of *Regulation (EU) 2019/1009* defines economic operator as "*the manufacturer, the authorised representative, the importer and the distributor*". Regarding end-users, Article 11a(3) of *Regulation (EU) 2019/1009* specifies that, when EU fertilising products are made available to end-users in packaging and the provider uses a digital label, its content must be duplicated on the physical label. Article 11(a)(4) of *Regulation (EU) 2019/1009* provides for an exception concerning products made available on the market to end-users without packaging. For such cases, as an alternative to the leaflet accompanying the product, a digital label may be used. Recital 8 of *Regulation (EU) 2024/2516* notes that "*physical labels remain a preferred way for end-users to obtain key information about the use of EU fertilising products",* that, "*while professional users are well accustomed to fertilising products and often rely on consultancy for their fertilisation plans, they tend to belong to more advanced age groups, with a lower level of digital skills and might encounter difficulties in accessing the digital labels*", and that there is a higher possibility of unreliable internet access in rural areas.

Article 11(b) of *Regulation (EU) 2019/1009* spells out the '*Requirements for digital labels*' in terms of content, accessibility and usability. Notably, the digital label must digitally provide the manufacturers' and importers' name, registered trade name or trademark, and a contact postal address; the CE marking; and all labelling elements required in Annex III. Article 11b(4) of *Regulation (EU) 2019/1009* requires a digital label to be easily accessible free of charge, searchable, available for 10 years after the product is placed on the EU market, and "*easily and directly accessible through all major operating systems and browsers, without a need to register in advance, to download or install applications or to provide a password, and accessible to all potential users in the Union*", as well as "*presented in a way that also addresses the needs of vulnerable groups and supports, as relevant, the necessary adaptations to facilitate access by those groups, in particular those consisting of persons with disabilities*". Pursuant to Article 11b(5), the data carrier, such as QR code, used for the digital label, must be physically printed or placed on the product packaging or on an accompanying

document if the product is sold without packaging, "*in a way that it is externally visible, legible, and accessible to vulnerable groups, including persons with disabilities, and that allows that data carrier to be processed automatically by digital devices*".

Article 11c of *Regulation (EU) 2019/1009* on '*Obligations of economic operators providing a digital label*' requires economic operators providing a digital label not to "*track, analyse or use any usage information for purposes other than what is absolutely necessary for providing the relevant information digitally*". When EU fertilising products are supplied to end-users without packaging and the required information is provided through a digital label, the economic operator must display the manufacturer's and importer's details visibly at the point of sale.

Finally Article 42 of *Regulation (EU) 2019/1009*, as amended, requires the Commission, by 1 May 2027, to adopt delegated acts supplementing the requirements for digital labelling and the obligations for economic operators on issues such as the approved "*electronic technical solutions*" for providing the digital label, and the alternative means for providing the necessary information in case of the ilitytemporary unavailability of the digital label.

A trend towards digital labels and digital product passports

In recent times, the EU has adopted similar legislation introducing either digital labelling for specific products or legal obligations for product-specific information to be accessible digitally. Notable examples include the requirement for a '*digital battery passport*' for industrial batteries, light means of transport (LMT) batteries, and electric vehicle (EV) batteries, that provides information on a wide range of aspects, including battery manufacturing carbon intensity, repair and recycling processes, as well as a '*digital product passport'* setting out sustainability-related performance and information conditions (*i.e.*, the so-called '*ecodesign requirements*')for almost all categories of goods (see *Trade Perspectives*, Issue No. 7 of 11 April 2022). Digital labelling rules are also in place for medical devices, and are under preparation for, *inter alia*, detergents, hazardous chemicals, and packaging and packaging waste.

From a regulatory coherence perspective, in July 2023, in its paper calling for digital labelling for food and drink products, *FoodDrinkEurope*, an association representing the European food and drink industry, had argued that the growing number of digital labelling regulations across various consumer products creates a fragmented and disjointed system in the internal market. *FoodDrinkEurope* further contended that, without "*a horizontal and harmonised approach to digital labelling, the EU is facing an impermeable web of digital labelling that differs across different sectors and products, to the detriment of the consumer*".

A cost-effective solution for large and small businesses?

The deployment of digital solutions, such as QR codes, allows the provision of comprehensive information while decreasing labelling complexities and costs, simplifying content updates, and increasing the accessibility and readability of the information. Notably, the quantity and quality of the information that can be access through a digital label can be much higher compared to a physical label. Emphasising the cost saving advantage of digital labelling, the Council of the EU notes that digital labelling is expected to reduce annual costs by, on average, EUR 57,000 for a large company and EUR 4,500 for a small and medium-sized enterprise. Beyond the EU market, studies also show that digital labelling would "*avoid multiple compliance marks for products designed for the global market*" especially in countries where such labelling is already allowed, thereby, facilitating trade across borders.

Preparing to harness digital labelling

Regulation (EU) 2024/2516 will enter into force on 20 October 2024, but, pursuant to Article 2 thereof, it will only start applying after two years and seven months, namely from 1 May 2027. Businesses interested in placing fertilising products on the EU market, and interested in utilising digital labels, should expect further requirements and obligations, such as the alternative means for providing information in case of the temporary unavailability of the digital

label, to be set through delegated acts and should seek professional advice to ensure compliance with the requirements for digital labelling and the obligations for economic operators.

A German court repeals the withdrawal of the marketing authorisation of kava-containing medicinal products: Noble kava is not a chimera!

On 18 June 2024, the Administrative Court of Cologne (*Verwaltungsgericht Köln*), Germany, lifted a prohibition that had prevented kava from being marketed as a pharmaceutical product in Germany. For more than 20 years, decisions of Germany's *Federal Institute for Drugs and Medical Devices* (*Bundesinstitut für Arzneimittel und Medizinprodukte,* hereinafter, *BfArM*), the German regulatory authority responsible for the monitoring of risks related to medicinal products, prohibited kava-containing pharmaceutical products from being marketed in Germany.

Technically, kava may now be brought back to the German market under the marketing authorisations of January 2018, but with severe warning labels. This article reviews the recent court decision and also discusses kava as a food. In particular, on 25 September 2020 the Codex Alimentarius Commission adopted a *Regional Standard for Kava Products for use as a beverage when mixed with water* and the EU foresees a novel food notification procedure for traditional foods from third countries. "*Noble*" kava should now be supported internationally.

Kava

Kava is an important crop in the South Pacific Island Countries. The major exporting producers of kava among the South Pacific Islands Countries are Fiji, Samoa, Tonga, and Vanuatu. Kava, a social beverage prepared from the roots of *Piper methysticum*, is an essential part of South Pacific societies and culture. Kava is drunk in quantities of one to three cups per session and has relaxing, stress-releasing and anti-aggressive effects without otherwise altering the state of mind of its consumers. High doses of kava drinks cause sleepiness and muscle relaxation, but have no known adverse effects.

Due to the calming and relaxing properties of certain active ingredients of the plant, kava extracts have been used for the development of herbal medicinal products for the treatment of mostly situational anxiety, in particular in Europe. Scientific work has been undertaken to underline that kava and, in particular, "*noble*" kava cultivars, are safe. According to the *Vanuatu Kava Act*, "*noble kava means a variety of kava listed in Table 1 of the Schedule and includes their synonyms on other islands*". Table 1 lists 12 varieties. Also the recent Codex Standard provides a non-exhaustive list of "*vernacular terms used to describe some Noble varieties in the various regions*".

The withdrawal of the marketing authorisation for medicinal products containing kava

Medicinal products require a marketing authorisation. In Germany, this marketing authorisation is granted or denied by the *BfArM*. When the first case reports of liver toxicity related to kava occurred in 1999/2000, the *BfArM* had opened a so-called drug safety protocol, which resulted in 2002 in the withdrawal of the marketing authorisations for medicinal products containing kava extract with the argument of an intolerable risk.

On appeal, the *BfArM* suspended the marketing authorisations in 2005 and later withdrew them again in 2007. This was contested by manufacturers and, during the process, the *BfArM* changed its legal position and arguments several times. It appears that, when it was suitable for the *BfArM*, it raised the issue of safety, and when it was shown that there was no problem with the safety of kava, *BfArM* simply switched to a lack of efficacy.

The first Court cases in Germany

When pharmaceutical companies with marketing authorisations for kava extract-containing herbal medicinal products were finally allowed to go to court in 2012, a decision by the Administrative Court of Cologne in May 2014 was received, stating that the *BfArM*'s decision was unlawful and had to be lifted (see *Trade Perspectives*, Issue No. 13 of 27 June 2014). Essentially, the Court held that the *BfArM* was not allowed to withdraw the marketing authorisations merely on the basis of its undemonstrated doubts about the efficacy of such medicines, and because BfArM considered clinical studies on kava extracts as outdated.

In relevant part, the Court ruled that, if risk could not be clearly and scientifically corroborated, there was no justification for the withdrawal of a marketing authorisation. In a benefit-risk-ratio, the risk must be assessed in context, especially if the therapeutic alternatives bear a greater risk. Here, the Court found that the *BfArM* erred when it described benzodiazepines as a harmless alternative to kava. On 25 February 2015, the Higher Administrative Court of Münster (*Oberverwaltungsgericht Münster*) confirmed the decision.

New hurdles for kava

After the 2015 decision, kava was technically back on the market, but the *BfArM* prevented the marketing of medicinal products containing kava extracts because it was calling for changes to the safety information and for new dossiers for the marketing authorisations. The new dossiers were delivered in 2017, but the changes to the safety information that the *BfArM* had requested on side-effects, etc. were so severe that they would have prevented any possibility of sales.

In 2019, the *BfArM* took several approaches to make sure that kava stayed off the market. The *BfArM* re-opened a drug safety protocol, using the information from 2001, which already had been lifted in 2014/2015 by the Courts. Furthermore, the *BfArM* declared the newly submitted dossiers as insufficient for a number of reasons: 1) The quality of the kava material was said to have been changed to "*noble kava*", which, according to the *BfArM* does not exist (the representative of the *BfArM* questioned the existence of *noble kava* and stated in Court at the hearing on 18 December 2018 that: "*Noble kava is a chimera!*"); 2) Kava is not efficacious, as the efficacy against "*generalized anxiety disorder*" had not been proven. The *BfArM* had referred to Public Statement on kava of the *European Medicines Agency*'s (EMA) Committee for Herbal Medicinal Products (HMPC), which had argued for a lack of efficacy in generalised anxiety, whereas the applications for marketing authorisations had covered "*states of nervous anxiety and tension*", which is a different indication.

The most recent judgement – Noble kava is not a chimera!

The plaintiff, a German pharmaceutical company, filed a lawsuit on 19 February 2020 and the *BfArM*'s arguments were contested in Court at a hearing on 14 May 2024. With respect to the drug safety protocol, there was essentially no new data. The only "*new*" data that the BfArM had presented was an assessment report on *Piperis methystici rhizoma - herbal medicinal product* issued by the EMA's HMPC of 22 November 2017. As regards the lack of efficacy and quality, it was explained by the plaintiff that "*noble kava is not a chimera and is even part of the legislation in the South Pacific kava producing countries, including Codex Alimentarius*". With respect to the efficacy, the Court appears to have followed the plaintiff's arguments, especially the fact that the *BfArM* had excluded the risk of therapeutic alternatives. On 18 June 2024, the Administrative Court of Cologne, Germany, ruled that "*The action is well-founded. The decision of the BfArM of 20.12.2019 in the form of the objection notice of 28.01.2020 is unlawful and violates the plaintiff's rights*".

According to Article 30(1) of Germany's Medicinal Products Act (*Arzneimittelgesetz*, hereinafter, AMG), the marketing authorisation of a medicinal product is to be revoked if, *inter alia*, there is an unfavourable benefit-risk ratio. According to Article 4(28) of the AMG, this includes an assessment of the positive therapeutic effects of a medicinal product in relation to

the risk described in the context of the quality, safety, or efficacy for the health of patients or public health. The Court held that "*a different decision is only conceivable if there are additional circumstances of weight that justify a reassessment of the risk assessment. The authorisation authority bears the full burden of proof for this. This is because the authority bears the full burden of proof for the prerequisites for the revocation of an existing marketing authorisation (…). The evidence required under this for an unfavourable benefit-risk ratio that would justify a revocation has still not been provided: in particular, it does not result from the* assessment report *of the HPMC of 22 November 2017*". During the hearing, it was clarified that the aim of the HMPC's report on the matter was to prepare a monograph on the active substance. Naturally, this was not about the question of evaluation in the light of possible therapeutic alternatives. Nor does the assessment report prescribe a legal consequence resulting from a benefit-risk ratio that is assessed as unfavourable.

The Court held that, "*In addition, the scientific assessment by the HMPC (…) does not have a binding effect on the decision of the Member States*" and that "*This is a scientific statement on the active ingredient, not a recommendation on the legal consequences*". The Court permitted an Appeal and the *BfArM* filed its appeal on 23 July 2024. The main arguments were that the dossiers of 2017 had lacked clarity with respect to kava quality and the use of *noble kava* in the clinical trials, and that the Public Statement of the EMA had shown a lack of efficacy (in an indication that was never claimed for the products) and an existing risk, especially potential carcinogenicity. A decision on the appeal by the Higher Administrative Court of Münster is not expected within the next 12 to 24 months.

Kava as food: Codex Alimentarius standard for kava and EU Novel Foods Regulation

The safety concerns in relation to kava as an herbal medicine also had a great influence on its status as a food in the EU. In the meantime, the EU adopted *Regulation (EU) 2015/2283 of 25 November 2015 on novel foods*, (hereinafter, the Novel Foods Regulation, NFR), which foresees in Articles 14 to 20 a notification system for '*traditional food from a third country*' on the basis of a history of safe food use that kava could benefit from. 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 and that derives from primary production (*i.e.*, the production, rearing, or growing of primary products including harvesting, milking, and farmed animal production prior to slaughter, including hunting and fishing and the harvesting of wild products) and has a history of safe food use in a third country.

Another very important step was the approval on 25 September 2020 by the Codex Alimentarius Commission of the Codex Alimentarius *Regional Standard for Kava Products for use as a beverage when mixed with water*. Scientific work started in 2012 to map all kava cultivars, so that an international Codex standard could be developed and become the guarantee of kava quality and safety. "*The work started way back in 2004 in Apia, Samoa, and has taken 16 years to get here*", explained the representative of Vanuatu on behalf of the FAO/WHO Coordinating Committee for North America and South West Pacific (CCNASWP), the region where the standard will be used.

The regional standard applies to fresh or dried kava products that are used to prepare a beverage when mixed with potable water, intended for human consumption. The standard does not apply to the final kava beverage as such, or to kava products used for medicinal purposes, or as ingredients in foods or other tradable product, or for any other purposes. Section 3.1 on '*Raw materials*' states that "*Kava plants used as raw material for kava products shall be a Noble variety. The Noble variety shall be confirmed using their morphological characteristics. Kava of the wild, Piper wichmannii and Two-day (Tudei) varieties are excluded*". In this context, establishing a Geographical Indication to protect kava from the Pacific Island Countries is also being discussed.

Way forward

For years, kava, with over 3,000 years of safe historical, social, and ceremonial food uses, has been overshadowed by safety concerns, stemming from incidents of liver damage linked to kava-containing medicines. Kava's reputation as food has been repaired in recent years. As a result of the recent judgement in Germany, the status of the Marketing Authorisations for kava-containing pharmaceutical products might lead back to where it was in January 2018: legally on the market, but still with severe warning labels.

The future of lab-grown meat regulation in the EU: A beefy debate with political dimensions

On 26 July 2024, the French start-up *Gourmey* became the first applicant to submit an application for regulatory approval of lab-grown meat or cultured meat in the EU. Notably, the company is seeking to commercialise its cultivated duck *foie gras* in the EU, which is considered under EU legislation a "*novel food*". The European Food Safety Authority (hereinafter, EFSA) will now conduct a risk assessment of the product, after which the European Commission (hereinafter, Commission) shall decide on its approval for placement on the market, with the overall process expected to take at least 18 months.

This article dissects 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), its consistency with trade rules, and the debates and controversy that it has sparked within the EU and beyond.

Understanding artificial meat and its legal qualification in the EU

Cultured meat, also known as lab-grown meat, is grown from animal cells in a laboratory, constituting true animal tissues, unlike plant-based meat, which imitates meat. The process to grow cultured meat involves obtaining stem cells (*i.e.*, undifferentiated cells that have the potential to develop into any type of specialised cell in the body) from a live animal, placing them in large tanks called bioreactors (similar to those used for the fermentation of beer or yoghurt) with a nutrient-rich media, and guiding their differentiation into the three main components of meat: muscle, fat, and connective tissue. The nutrient-rich culture media in the bioreactors is a carefully formulated mixture of essential nutrients, including amino acids, vitamins, minerals, and growth factors, that provide the cells with everything they need to grow and develop. These cells are then organised into the desired meat structure (*e.g.*, a steak), often using a scaffolding material such as decellularised animal tissue or a synthetic polymer. In the specific case of *Gourmey*'s *foie gras*, the company takes cells "*out of a freshly laid duck egg*" and places them in a cultivator. Those same cells are then "*fed with proteins, amino acids and sugar, similar to the nutrients a duck would get from a diet of oats, corn and grass"* to finally be harvested and turned into *foie gras*.

In the EU, cultured meat (per opposition to regular meat, defined by EU law as "*the edible parts of animals, (…) including blood*" of domestic and game animals) is considered a novel food, which is defined by Article 3 of the NFR as "*any food that was not used for human consumption to a significant degree within the Union before 15 May 1997, irrespective of the dates of accession of Member States to the Union"* and which falls under the scope of one of the categories listed by that Article. 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. In particular, Article 3(2)(a)(vi) of the NFR differentiates a group of novel food "*consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, micro-organisms, fungi or algae",* to which cultured meat would correspond.

The EU's current framework: Risk assessment and risk management

The NFR establishes a scheme of pre-market approval for novel foods, which entails a centralised authorisation procedure managed by the Commission and divided into two phases: 1) The risk assessment phase; and 2) The risk management phase. The approval process begins with an application submitted to the Commission by the company wishing to commercialise a novel food product. The Commission proceeds to verify the validity of the application. Following the provisions of the EU's General Food Law (*i.e.*, *Regulation (EC) No 178/2002 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*), when the novel food is liable to have an effect on human health, the Commission will request the EFSA to carry out a risk assessment of the food based on a valid application. In assessing safety, the EFSA considers various factors, such as whether the novel food is as safe as comparable existing food categories on the market or if "*the composition of the novel food and the conditions of its use do not pose a safety risk to human health in the Union*".

Once the EFSA's opinion has been adopted and published, the Commission has seven months to submit a draft implementing act authorising the placing on the market of the novel food and updating the Union List of authorised novel foods, contained in the Annex to *Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods*, to the Standing Committee on Plants, Animals, Food and Feed (hereinafter, the PAFF Committee). The PAFF Committee is a committee of representatives from all EU Member States, presided by a Commission representative, that provides scientific and technical advice to the Commission. It is composed of national experts who give a second opinion based on the risk assessment undertaken by EFSA in its opinion.

The PAFF Committee reviews the provisions of the NFR, EU food law (notably the '*precautionary principle*') and "*any other legitimate factors relevant to the application under consideration*". Particularly, the NFR establishes in Article 7 on '*General conditions for inclusion of novel foods in the Union list'* that the Commission shall only authorise a novel food if: (a) it does not "*on the basis of the scientific evidence available, pose a safety risk to human health*;"; (b) its intended use "*does not mislead the consumer, especially when the food is intended to replace another food and there is a significant change in the nutritional value*;"; and (c) in the case the food intends to replace another food, "*it does not differ from that food in such a way that its normal consumption would be nutritionally disadvantageous for the consumer*". This is the risk management phase.

If the PAFF Committee delivers a positive opinion, the Commission shall typically approve the placement on the market of the novel food and update the Union List of authorised novel foods. The NFR further provides for the possibility that novel food authorisations may be subject to post-market monitoring to ensure ongoing safety or specific labelling requirements and provisions to protect the intellectual property rights of the product.

*A globally accepted approval scheme with the enemies "*at home*"*

According to the EU, the pre-market approval scheme that the NFR establishes was drafted on the basis of Article 8 and Annex C of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (hereinafter, SPS Agreement), which specifies the requirements that procedures of control, inspection and approval procedures for food to ensure safety must follow, as well as the proportionality mandated by Article 2.2 of the SPS Agreement. So far, no significant concerns regarding the NFR's approval scheme for cultured meat products have been raised at the WTO level and similar pre-market schemes also exist in other jurisdictions, such as in the US, where a system of "*pre-market consultation*" is carried out by the Food and Drug Administration (FDA) for products derived from cultured animal cells destined to human consumption, in coordination with the US Department of Agriculture (USDA) and Singapore, which applies a pre-market approval system reviewed by the *Singapore Food Agency* that analyses food safety risks, notably toxicity and production method safety.

The main opposition to the system as it stands comes from within the EU. In October 2023, the European Parliament adopted a Resolution stating that "*cell-based food […] presents*

ethical, social, environmental and economic challenges, and the Novel Food regulation is not fit for purpose". Italy went a step further and enacted a general prohibition on the production and sale of cultivated meat on 1 December 2023, the legality of which vis-à-vis the NFR and EU law core principles remains to be seen (see *Trade Perspectives*, Issue No. 6 of 25 March 2024).

In January 2024, the agriculture ministers of Austria, France, and Italy co-authored a Note to the Council of the EU supported by other delegations, such as Spain and Greece, questioning the "*current regulation as suitable legal framework*" to approve cultured meat-based products. In particular, these EU Member States argued that cultured meat threatened traditional European farming and called for a thorough discussion before allowing its production. More specifically, the Ministers raised concerns regarding the impact of such developments on rural areas, sustainability, consumer affordability, labelling, and the emergence of potential monopolies. In this regard, the Note proposes to launch, before any authorisation, "*a genuine and comprehensive public consultation on lab grown meat*", stricter rules (for instance, not allowing cell-based products to be called meat), and for the Commission to "*present a fact-based and comprehensive impact assessment on artificial meat prior to any authorisation for sale and consumption*". The latter should address "*ethical, economic, social and environmental questions, as well as, nutrition, health safety, food sovereignty and animal welfare concerns*".

A more restrictive approach with respect to the authorisation of lab-grown meat might, however, jeopardise the consistency of such measure with the EU's WTO commitments. Unless the EU could prove the existence of a risk related to the lab-grown meat, any restrictive measure would be difficult to justify.

What can businesses expect? Rough seas on the horizon

The current legislative framework for the approval of cultured meat products in the EU faces a bumpy ride in this new legislature of the European Parliament. With a notable share of EU Member States voicing reservations as to the emergence of this sector, the framework for cultured meat could be subject to strong challenges in the coming years. A more restrictive approach would negatively affect the emergence of a cultured meat sector in the EU and face significant challenges vis-à-vis its consistency with WTO rules, especially the SPS Agreement.

Recently adopted EU legislation

Trade Law

- *Notice concerning the entry into force of the Accession Protocol to the Framework Agreement on Comprehensive Partnership and Cooperation between the European Community and its Member States, of the one part, and the Republic of Indonesia, of the other part, to take account of the accession of the Republic of Croatia to the European Union*

- *Commission Delegated Regulation (EU) 2024/2104 of 27 June 2024 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council as regards the cases where and the conditions under which competent authorities may request operators to notify the arrival of certain goods entering the Union*

- *Council Decision (EU) 2024/2588 of 10 September 2024 on the signing, on behalf of the European Union, and provisional application of the Protocol on the implementation of the Fisheries Partnership Agreement between the European Community and the Republic of Guinea-Bissau (2024–2029)*

- *Notice concerning the provisional application of the Framework Agreement on Comprehensive Partnership and Cooperation between the European Union and its Member States, of the one part, and the Kingdom of Thailand, of the other part*

Customs Law

- *Commission Delegated Regulation (EU) 2024/2514 of 3 July 2024 supplementing Regulation (EU) 2022/2399 of the European Parliament and of the Council by specifying the data elements to be exchanged through the European Union Customs Single Window Certificates Exchange System and amending that Regulation as regards the list of Union non-customs formalities covered by the EU Single Window Environment for Customs*

- *Council Decision (EU) 2024/2606 of 23 September 2024 establishing the position to be taken on behalf of the European Union within the Partnership Council established by 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, as regards modifications to Annex 3 to that Agreement*

Food Law

- *Commission Implementing Regulation (EU) 2024/2610 of 30 September 2024 amending Annexes V and XIV to Implementing Regulation (EU) 2021/404 as regards the entries for Israel and the United States in the lists of third countries, territories or zones thereof authorised for the entry into the Union of consignments of poultry and germinal products of poultry, and of fresh meat of poultry and game birds*

- *Commission Implementing Regulation (EU) 2024/2607 of 27 September 2024 entering a name in the register of protected designations of origin and protected geographical indications (Ροδόσταγμα Αγρού / Rodostagma Agrou / Agros Rosewater (PGI))*

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