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Preventive measures: New EU law aimed at curbing the spread of animal diseases takes effect

On 15 January 2022, *Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health* (hereinafter, the Animal Health Law), became fully effective, thus completing a multi-year process aimed at both synthesising existing animal health and safety standards and expanding and strengthening said standards across the entire agri-food chain. Possessing a broad scope, the Animal Health Law provides a host of new rules and principles, including requirements, both substantive and administrative, that impact exporters of a variety of animal and fish products into the EU.

A Brief Summary of the Animal Health Law

From 2007 until 2013, the European Commission (hereinafter, Commission) operated under an Animal Health Strategy known as "*prevention is better than cure*", in which preventive measures, disease surveillance, and disease-related research were the primary *foci*. It was within this larger strategic framework that the Animal Health Law was initiated.

Early draft proposals of the law had a very ambitious scope, seeking to incorporate a number of animal health-related concerns such as public health, environmental protection, food security and animal welfare into the core of the would-be legislation (see *Trade Perspectives,* Issue No. 4 of 21 February 2014). Over time, the scope of the proposals narrowed somewhat. For example, substantive requirements relating to the *welfare* of animals were discarded. Similarly, provisions aimed at regulating specific aspects of veterinary care (*e.g.*, the setting of educational standards and the scope of acceptable veterinary medications and medicated feed) were left to be regulated in other pieces of legislation.

The version that was ultimately adopted on 9 March 2016, while slightly less bold than earlier iterations, still retained a number of noteworthy attributes. Arguably, the most significant of these is the streamlining of the EU legal framework on animal health. This was a welcome development that brought an end to the previous piecemeal approach, wherein the relevant provisions were scattered over 30 EU directives and regulations. Now, general principles for dealing with transmissible animal diseases and more specific animal health rules relating to

disease prevention, disease surveillance, control, and eradication, are housed under one regulation.

This is not to say that the Animal Health Law, which aims primarily at preventing the spread of transmissible animal diseases among humans and/or animals, is merely a rehash of old rules in a new consolidated document. On the contrary, there are a number of innovations in the regulation, as well. Among the new elements introduced by the Animal Health Law are: 1) Enhanced guidance for creating lists of animal diseases '*of concern*' to the EU; 2) The establishment of basic responsibilities of animal keepers and veterinarians with respect to preventing and detecting animal diseases; and 3) The creation of a new system for EU notification and reporting of animal diseases, the *Animal Disease Information System*. Also noteworthy are the concerted efforts made within the body of the Animal Health Law to have greater convergence with international standards on animal health, as set forth by the World Organisation for Animal Health (hereinafter, OIE), the organisation recognised by the World Trade Organization (hereinafter, WTO) in animal health-related matters. This is potentially a wise gambit, as the relevant international trade agreement in this sphere, the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (hereinafter, SPS Agreement), incentivises '*conformity*' with international standards by presuming the consistency of such '*conforming*' measures with WTO obligations (see Article 3.2 of the SPS Agreement).

Importantly, much of the Animal Health Law became operational in the Spring of 2021. However, as discussed more fully below, conformity with the regulations among exporters to the EU was delayed until 15 January 2022.

Trade Impacts of the Animal Health Law Generally

The area of the Animal Health Law most directly impactful on trade flows into and out of (and within) the EU is found largely in Part V of the Animal Health Law, entitled "*Entry into the Union and Export*" (hereinafter, Part V). Part V of the Animal Health Law has been further effectuated through the *Commission Delegated Regulation (EU) 2020/692 of 30 January 2020*, and a quartet of implementing regulations. Three of the implementing regulations concern certification requirements. In particular, *Commission Implementing Regulation (EU) 2020/2235 of 16 December 2020* provides model animal health certificates, model official certificates and model animal health/official certificates, for the entry into the EU and movements within the EU of consignments of certain categories of animals and goods, including, *inter alia*, composite products, germinal products, animal by-products, sprouts for human consumption, and seeds intended for the production of sprouts for human consumption. The second, *Commission Implementing Regulation (EU) 2020/2236 of 16 December 2020* deals with consignments of certain categories of terrestrial animals and germinal products thereof, and the third, Commission Implementing Regulation (EU) 2021/403 of 24 March 2021, concerns consignments of aquatic animals and of certain products of animal origin from aquatic animals. The fourth implementing regulation, namely *Commission Implementing Regulation (EU) 2021/404 of 24 March 2021*, sets forth the list of third countries, territories, and/or particular zones within said countries or territories, from which the entry into the EU of animals, germinal products, and products of animal origin is permitted.

In essence, the new requirements contained in the implementing regulations represent a revamping of certain certificates and declarations for movement both for the entry into the EU of the aforementioned products and for their transport across EU Member States. Indeed, collectively, the *Commission Implementing Regulations 2020/2235*, *2020/2236*, and *2021/404* now act as the repositories of the certification requirements, providing information in the three documents that was previously spread across a plethora of different directives, regulations, and decisions.

While there are efficiency gains for impacted countries (and their exporters) in having a more centralised group of regulations to navigate, there are also administrative challenges associated with the new certification requirements, a point which is discussed in greater detail below. In recognition of those challenges, a transitional period has been in effect since the

Spring of 2021, when the Animal Health Law first officially came into force. This transitional period, which was initially supposed to conclude in October of 2021, was ultimately extended to 15 January 2022.

A Closer Look: Impact of the Animal Health Law on Exporting Fish Products into the EU

The impact of the Animal Health Law on exporters to the EU can perhaps be seen more clearly by focusing on a particular industry. Consider the elements of the Animal Health Law that may affect fish and seafood exporters to the EU, including: (re)classification of certain species; new substantive rules; and more onerous certification requirements.

One potentially impactful aspect of the Animal Health Law for fish and seafood exporters concerns the instances in which certain products have been re-categorised. For example, under the law, scallops and processed shellfish have been reclassified from '*fishery products*' to '*live bivalve molluscs and their products*'. This has the effect of bringing these species under more intense disease controls. Similarly, new substantive obligations are clearly relevant to seafood exporters. For example, there is a new rule that requires that certain species be '*listed*' as containing a heightened risk for carrying certain diseases. These '*listed*' species are required to be inspected and certified as '*disease-free*' by an official veterinarian before their exports to the EU. Finally, new certification requirements can prove challenging. In the context of *Commission Implementing Regulation (EU) 2020/2236*, seafood exporters are required to provide information meant to improve traceability and biosecurity. This can increase the time burdens and costs associated with exportation. These requirements add to the existing obligations under the EU's rules on illegal, unreported, and unregulated (IUU) fishing by virtue of *Council Regulation (EC) No 1005/2008 of 29 September 2008 establishing a Community system to prevent, deter and eliminate illegal, unreported and unregulated fishing*.

As the EU's new Animal Health Law takes effect, the affected industries and the relevant exporting country agencies are working to adapt. For example, the *Canadian Food Inspection Agency* recently issued a notice to those in the fish and seafood industries in Canada that "*advanced requests for export certification of each shipment prior to export will be required for live and fresh seafood leaving for the EU on, and after, January 15, 2022*". This is very likely being done to accommodate the requirements related to the aforementioned '*listed*' species. Similar communiques are likely being extended in a host of other countries throughout the world and operators around the world should closely review the new rules to avoid having their goods rejected upon importation into the EU.

A Look Ahead

For a world which is now two years into a global pandemic, the need for regulations like the Animal Health Law is relatively intuitive. Still, such a broad piece of legislation is apt to have points of complementarity and also points of friction with other policy endeavours. Where trade law and policy is concerned, there are opportunities for the Animal Health Law to act as a facilitator of strong international health standards, in conformity with the OIE, and perhaps even serve to create efficiency gains, insofar as it streamlines regulatory content. However, there is also the possibility that the Animal Health Law will create burdens to trade facilitation and/or will be viewed in some quarters as a source for hidden protectionism. With the law now in full effect, the coming weeks, months, and years shall provide the source material for the story to be told.

The EU and Singapore launch negotiations for a Digital Partnership: Towards greater regulation of digital trade and more trade facilitation?

In recent times, electronic commerce (hereinafter, e-commerce) and digital trade have grown substantially, but the relevant legal frameworks are lagging behind and efforts, domestically, as well as internationally, are underway for the rules to catch up. On 7 December 2021, the EU and Singapore announced in a *Joint Statement* their shared intention to advance towards

a comprehensive EU-Singapore Digital Partnership. The growing importance of digital trade creates significant commercial opportunities, but the legal challenges at the domestic and international level, due to the divergences in regulatory approaches, negatively affect trade and underline the importance of international cooperation and negotiations to develop common approaches.

Growing importance of e-commerce and digital trade

Efforts are underway, both domestically and internationally, for the rules to catch up with the fast-paced growth of digital trade that has swept through global markets, also as a reaction to the constraints inflicted by the *Covid-19* pandemic. Broadly speaking, the Organisation for Economic Co-operation and Development (OECD) defines '*digital trade*' as "*digitally enabled trade in goods and services, whether digitally or physically delivered, covering cross-border trade and data flows*". '*E-commerce*' is considered as an element of digital trade that specifically addresses the sale and purchase of goods or services via digital platforms.

Notably, as digital trade plays an increasingly large role in terms of trade and trade volumes, developing common approaches on certain aspects, such as data flows (*i.e.*, the "*movement of data through a system comprised of software, hardware or a combination of both*"), digital connectivity (*i.e.*, network connections), interoperability (*i.e.*, *the ability of a system to exchange and make use of information*), data localisation (*i.e., mandatory requirements directly or indirectly stipulating that data be stored or processed, exclusively or non-exclusively, within a specified territory)*, and data privacy at the international level, appear to be actions of critical urgency. Essentially, common approaches to digital trade governance could allow for compatible rules on digital trade that, in turn, would facilitate and expand global trade. In this context, the *Joint Statement* by the EU and Singapore states that the Digital Partnership would "*further deepen digital ties and expand bilateral trade and investments, ensuring that workers and businesses, especially small and medium-sized enterprises, benefit from opportunities in the growing global digital economy".*

Increasing regulation of digital trade aspects at the international level

Efforts to develop common rules on digital trade are ongoing, notably in the context of the plurilateral negotiations for a World Trade Organization (WTO) Agreement on Trade-Related Aspects of Electronic Commerce (see *Trade Perspectives*, Issue No. 17 of 24 September 2021). On 14 December 2021, the participating WTO Members announced the finalisation of a clean text on certain issues, such as online consumer protection, electronic signatures and authentication, open government data, and electronic contracts. The participating WTO Members expect to secure convergence on the majority of the remaining issues, such as customs duties on electronic transmissions, cross-border data flows, data localisation, cybersecurity, and electronic invoicing, by the end of 2022.

In parallel, countries around the world are also resorting to develop rules to facilitate digital trade through dedicated provisions and chapters in their Preferential Trade Agreements (hereinafter, PTAs). This approach is in line with recent trade liberalisation trends and has led to bilateral and regional rules on key issues, such as data flows, digital connectivity (*i.e.*, network connections), interoperability, and data privacy. These rules allow businesses within the countries that are parties to such PTAs to have greater legal certainty in their digital cross-border trading activities. Moreover, rules prohibiting requirements to establish local computing facilities as a condition for market access are important commitments, given the significant costs involved in such data localisation requirements.

In the past, the EU has included limited rules on e-commerce in its trade agreements but has, more recently, developed a template chapter on '*Digital Trade*', which is becoming a standard element in the EU's approach for its preferential trade agreements with third countries. As opposed to focusing merely on aspects related to e-commerce, the EU's approach to digital trade has also included, *inter alia*, the prohibition on customs duties on electronic transmissions, rules on data flows, the regulation of data localisation, and the protection of

software codes. The EU-UK Trade and Cooperation Agreement is the first PTA in which the EU agreed to commitments on cross-border data flows.

At the same time, Singapore is involved in developing a more digital-friendly legal framework through bilateral agreements, as well as in the context of regional integration within the Association of Southeast Asian Nations (hereinafter, ASEAN), which groups Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, the Philippines, Singapore, Thailand, and Viet Nam. Collectively, ASEAN Member States have developed various legal instruments in an effort to enhance and facilitate cross-border e-commerce transactions within the region. Most importantly, on 12 November 2018, ASEAN Member States signed the *ASEAN Agreement on Electronic Commerce*, which was adopted on 22 January 2019 (see *Trade Perspectives*, Issue No. 7 of 9 April 2021). Additionally, Singapore is Party to the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (hereinafter, CPTPP), and the Regional Comprehensive Economic Partnership (hereinafter, RCEP) that contain detailed commitments on key digital trade aspects, such as '*Personal information protection'*, '*Cross-border transfer of information by electronic means'*, the '*Location of computing facilities',* and the protection of software codes.

A new approach: Singapore's Digital Economy Agreements

Most recently, Singapore has placed particular emphasis on negotiating so-called '*Digital Economy Agreements'* or '*Digital Economy Partnership Agreements'*. According to Singapore's Ministry of Trade and industry, a *'Digital Economy Agreement*' (hereinafter, DEA) "*establishes digital trade rules and digital economy collaborations between two or more economies*". Through the DEAs with key trading partners, Singapore seeks "*to develop international frameworks to foster interoperability of standards and systems and support businesses, especially SMEs, engaging in digital trade and electronic commerce*". So far, Singapore has concluded negotiations on four DEAs, namely: 1) The *Digital Economy Partnership Agreement* (DEPA) with Chile and New Zealand, in force since 7 January 2021; 2) The *Singapore-Australia Digital Economy Agreement* (SADEA), in force since 8 December 2020; 3) The *UK-Singapore Digital Economy Agreement* (UKSDEA), signed on 9 December 2021, but not yet in force; and 4) The *Korea-Singapore Digital Partnership Agreement* (KSDPA), signed on 15 December 2021, and also not yet in force). The DEPA, the UKSDEA, and the KSDPA are stand-alone digital agreements, while the SADEA introduces a new Chapter 14 relating to '*Electronic commerce*' into the existing Singapore-Australia Free Trade Agreement.

Essentially, Singapore's DEAs are very detailed and broad in scope, covering commitments relating to various aspects of digital trade and the related trade facilitation. More specifically, the DEAs include detailed provisions on '*Paperless trading*' (*i.e.*, accepting electronic versions of administrative documents, such as phytosanitary certificates) and on emerging trends and technologies, such as cooperation on '*Fintech*' and Regulatory Technology ('*Regtech*'), as well as '*Artificial intelligence'*. The DEAs also contain clear commitments relating to personal data protection, cross-border data transfers, and a prohibition on data localisation requirements, as well as the protection of software codes.

The future EU-Singapore Digital Partnership

On 7 December 2021, the EU and Singapore announced in a *Joint Statement* their shared intention to advance towards a comprehensive EU-Singapore digital partnership. According to the *Joint Statement*, "*this marks the EU and Singapore's shared vision of bringing their strong bilateral trade partnership into the digital future, building on the entry into force of the* EU-Singapore Free Trade Agreement *in 2019*". EU and Singapore officials were tasked to start technical discussions and identify the relevant digital trade elements. According to the *Joint Statement*, "*to maximise the benefits of the digital economy for workers, businesses and societies, it is important to ensure the connectivity and interoperability of digital markets and policy frameworks, to lift barriers and facilitate digital trade, as well as to provide legal certainty for businesses and to protect consumers*".

The provisions of the *EU-Singapore Free Trade Agreement* (hereinafter, EUSFTA) on electronic commerce are very limited in scope and in the depth of their coverage, mostly providing for cooperation and regulatory dialogue on electronic signatures, the liability of intermediary service providers with respect to the transmission or storage of information, the treatment of unsolicited electronic commercial communications, and the protection of consumers. Therefore, modernising the EUSFTA provisions on electronic commerce with clear language on key digital trade issues, such as cross-border data flows, data protection, and on the trends and innovations in the recent agreements, such as Singapore's DEAs, could be a significant upgrade of the EU's approach to digital trade rules in PTAs, and could also enable businesses to benefit from commercial opportunities in the EU and Singapore. In this context, the *Joint Statement* notes that "*today, over 60% of global GDP is already digital, and both parties recognise that jobs and growth opportunities in the digital economy will become increasingly important in the future*".

The future EU-Singapore Digital Partnership is an opportunity for the EU to contribute to the global standard-setting of digital trade and with respect to other countries in the ASEAN region. In this context, the *Joint Statement* affirms that "*the joint announcement signals the EU's commitment to deepen digital cooperation with like-minded partners in the Indo-Pacific region, coming after the EU Indo-Pacific Strategy that states the EU's interest to explore the launch of negotiations on a Digital Partnership Agreement with Singapore*". The EU's *Strategy for cooperation in the Indo-Pacific*, adopted by the Council of the EU on 19 April 2021, aims, *inter alia*, at developing standards in new technologies. Apart from Singapore, the EU has also committed to negotiate digital partnership agreements with Japan and Korea.

Towards greater regulation of digital trade?

Digital transactions have literally revolutionised the world and have evolved rapidly over the past few years, with important implications for international trade. At the same time, domestic rules, for example on data localisation, risk to negatively affect trade and demonstrate the importance of bilateral, plurilateral, and multilateral agreements or coordination regarding the relevant rules. The EU should use the important opportunity of the negotiations for partnership agreements with Japan, Korea, and Singapore to achieve ambitious agreements and forward-looking rules on digital trade, which set the standards for similar agreements or chapters in PTAs with other trading partners. All interested stakeholders should closely monitor the related developments and engage with negotiators to put forth their industry's positions and needs.

The EU removes the authorisation to use titanium dioxide (E 171) in foods and studies deleting it from the EU list of additives for the use as colour in medicinal products

On 14 January 2022, the European Commission (hereinafter, Commission) adopted *Regulation (EU) 2022/63 amending Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the food additive titanium dioxide (E 171)*. *Regulation (EU) 2022/63* removes the authorisation to use titanium dioxide (E 171) in foods and states that the Commission considers deleting it from the EU's list of additives for the use as colour in medicinal products within three years. The article looks at the different uses of titanium dioxide and why it is difficult to replace it, particularly in medicinal products.

Titanium dioxide and its uses

Titanium dioxide is the naturally occurring oxide of titanium, with the chemical formula TiO_2. Titanium dioxide is listed as food colourant E171 in part B of Annex II (*i.e.*, the EU list of additives approved for use in foods and the conditions of their use) of *Regulation (EC) No 1333/2008 on food additives*. In addition, *Commission Regulation (EU) No 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008* provides for technical specifications for E171 relating to origin, purity criteria, and

any other necessary information. The colourant has no nutritional value and is predominantly used in confectioneries, such as candy covered chocolates, in sweets, chewing gums, bakery products and sauces, to give the product a white, opaque or cloudy effect. The use of titanium dioxide (or E171) in food products must be indicated on the products' ingredient list. It is also used in sunblock because it reflects UV light, as well as in toothpastes and medicines. Titanium dioxide, as a common chemical, is also widely used in other products such as paints, paper, plastics, printing inks, or cosmetic products.

Ban of titanium dioxide as food additive

On 6 May 2021, the European Food Safety Authority (hereinafter, EFSA) published a scientific opinion on the safety assessment of titanium dioxide (E 171) as a food additive. Further to new relevant information, the opinion takes into account data on the potential genotoxicity of titanium dioxide nanoparticles published before 2016, which had not previously been identified as relevant for the earlier re-evaluation in 2016. In its opinion, the EFSA indicated that, based on all the evidence available, a concern for genotoxicity could not be ruled out, which means that there is a possibility that the use of titanium dioxide as a food additive might cause DNA or chromosomal damage. Given the many uncertainties, the EFSA concluded that titanium dioxide can no longer be considered safe when used as a food additive. The EFSA neither identified nor recommended any new studies that could alleviate the genotoxicity concerns and other remaining uncertainties.

In light of the conclusion of the EFSA's 2021 opinion about the safety of titanium dioxide (E 171) when used as a food additive, the Commission considered it appropriate to remove the authorisation to use titanium dioxide (E 171) in foods. As titanium dioxide (E 171) would no longer be authorised for use in foods, *Regulation (EU) 2022/63* also removes the reference to it from the entry on the use of potassium aluminium silicate (E 555) in Part 1 of Annex III to *Regulation (EC) No 1333/2008*.

However, given that the EFSA did not identify an immediate health concern linked to titanium dioxide (E 171) used as a food additive and, in order to allow for a smooth transition, according to Article 2 of *Regulation (EU) 2022/63*, foods that contain titanium dioxide (E 171) used in accordance with the rules applicable before 7 February 2022 may still be placed on the market until six months after that date. Those foods may then continue to be marketed until their date of minimum durability or '*use by*' date.

The use of titanium dioxide in medicines

The new EFSA opinion assessed titanium dioxide when used as an additive in foods. In medicinal products, titanium dioxide will still be authorised for use until other suitable alternatives are found. This is to avoid causing shortages of medicinal products that could negatively impact public health or animal health and welfare. This approach is supported by the European Medicines Agency's (hereinafter, EMA) analysis on the use of titanium dioxide in medicines, which was published on 8 October 2021.

Titanium dioxide is extensively used as an opacifier and colourant in medicines due to its multiple functionalities. According to comments submitted to the EMA on 2 July 2021 by three European associations representing the human medicines manufacturers (*i.e.*, the *Association of the European Self-Care Industry* (AESGP), the *European Federation of Pharmaceutical Industries and Associations* (EFPIA), and *Medicines for Europe*, which represents the European generic, biosimilar and valued added pharmaceutical industries), approximately 91,000 human medicinal products in the EU contain titanium dioxide. Titanium dioxide is used frequently in oral solid dosage forms (*e.g.*, tablets, soft capsules, and hard capsules), and in oral semi-solid dosage forms (*e.g.*, oral paste). According to the industry, 69.75% of tablets contain titanium dioxide. It is present in many essential medicines including antidiabetics, antibiotics, and several veterinary medicinal products. Further to its use as a colourant, titanium dioxide serves, *inter alia*, as a masking agent for taste and smell, to improve product appearance by ensuring that the tablet coating is smooth and easy to swallow, and it prevents

water absorption into the tablet. The EMA stresses that, historically, there is a legislative link allowing the use of colourants listed in Annex II to *Regulation (EC) No 1333/2008* in human and veterinary medicinal products without further justification. According to the EMA, this has effectively resulted in the function of titanium dioxide "*being typically described as a 'colourant' in marketing application dossiers although TiO_2 exhibits multiple (highly advantageous) functionalities from a pharmaceutics perspective*", which is "*one reason for the widespread use of TiO_2*".

To date, no single material has been identified that provides the same combination of properties that are unique to titanium dioxide. Possible alternatives identified so far include calcium carbonate, talc and starch. However, a number of disadvantages have also been identified with these alternatives (*e.g.*, inability to obtain sufficiently thin films, supply chain issues, mined materials with an associated elemental impurity risk). Therefore, the EMA could not confirm the feasibility of replacing titanium dioxide with those alternative substances. Each affected medicinal product will need an individual review and assessment, which will require investigation of alternatives, product reformulation, generation of new data related to manufacture, dissolution, stability, and potentially new clinical data, which subsequently will all have to be assessed by the national competent authorities and the EMA. The EMA warns that "*direct and indirect impacts on medicines for human and veterinary use are expected to be aggravated in the scenario, where Europe would be the only region globally to ban TiO_2 as excipient in medicines, which would require industry to develop new formulations for the majority of oral solid dose products potentially for the EU only, with titanium dioxide continuing to be used in the majority of medicines globally*".

An acceptable transition period for phasing-out titanium dioxide in medicines is currently difficult to estimate. The time needed to reformulate each individual product could be several years, depending on the level of formulation and studies required, to be followed by the necessary regulatory procedures for assessment and approval. In this respect, the EMA refers to the pharmaceutical industry, which estimates timeframes of seven to twelve years. Considering the scale of the use of titanium dioxide, the time and costs involved in the reformulation and the volume of products impacted, the EMA considers that "*any requirement to replace TiO_2 in medicines will almost certainly cause significant medicines shortages and discontinuations/withdrawals of medicines from the EU/EEA market with major implications for patients and animals. Particular concerns arise in relation to certain vulnerable classes/types of products such as paediatric medicines, orphan medicines, low sales volume products, bee products, etc.)*".

The impact on trade of a ban of titanium dioxide in food and possibly in medicines

The removal of titanium dioxide from Annex II of *Regulation (EC) No 1333/2008 on food additives* was not a surprise for the food industry, as titanium dioxide has been under review for a considerable time. Even more generally, the food industry has been phasing out artificial colours and is turning to natural, plant-based colours. However, deleting titanium dioxide from the EU list of additives for the use in medicinal products will almost certainly have an impact on trade, as most pharmaceutical companies provide products to both EU and non-EU markets. Maintaining parallel production of products with and without titanium dioxide for different markets may, according to the industry, not always be "*justifiable for companies from the patient, technical and economical perspective*". Supply chains are global and any proposed restriction would lead to a challenge for companies manufacturing and supplying products for the EU. Furthermore, it would affect world-wide supply for affected products and may lead to drug shortages for existing products, as well as to delays in the introduction of new innovative drugs. This will inevitably impact other (non-EU) markets, which rely on EU approved medicines.

The way forward

Foods that contain titanium dioxide as a food additive may be placed on the market until 7 August 2022 and may then continue to be marketed until their date of minimum durability or

'*use by*' date. The Commission, together with the EMA, will re-evaluate the situation regarding titanium dioxide in medicines in the near future. In this regard, Article 3 of *Regulation (EU) 2022/63* states that the Commission, following consultation with the EMA, is to review the necessity to maintain titanium dioxide or to delete it from the *Union list of food additives for the exclusive use as colour in medicinal products* in Part B of Annex II to *Regulation (EC) No 1333/2008,* within three years after 7 February 2022.

Recital 18 of *Regulation (EU) 2022/63* provides that this review is to be based on an updated assessment of the EMA, to be performed before 1 April 2024, and is to take into account the progress made during this period to develop alternatives to titanium dioxide in medicinal products both for new products and for replacing it in authorised products, and the possible impacts on quality, safety and efficacy, as well as on the availability of medicinal products. The pharmaceutical industry is, therefore, invited to accelerate the research and development of alternatives to titanium dioxide, and to submit the necessary changes to the terms of the marketing authorisations concerned. However, the timeframes envisaged by the Commission are significantly shorter than the timeframes of seven to twelve years reasonably expected by the pharmaceutical industry to reformulate and approve every product.

Interested stakeholders are advised to carefully monitor developments on titanium dioxide 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*.

Recently adopted EU legislation

Trade Remedies

- *Commission Implementing Regulation (EU) 2022/116 of 27 January 2022 imposing a definitive anti-dumping duty on imports of acesulfame potassium originating in the People's Republic of China, following an expiry review pursuant to Article 11(2) of Regulation (EU) 2016/1036 of the European Parliament and of the Council*

Customs Law

- *Regulation (EU) 2022/111 of the European Parliament and of the Council of 25 January 2022 amending Regulation (EU) 2019/216 as regards the Union tariff rate quota for high-quality beef from Paraguay*

Food Law

- *Commission Delegated Regulation (EU) 2022/126 of 7 December 2021 supplementing Regulation (EU) 2021/2115 of the European Parliament and of the Council with additional requirements for certain types of intervention specified by Member States in their CAP Strategic Plans for the period 2023 to 2027 under that Regulation as well as rules on the ratio for the good agricultural and environmental condition (GAEC) standard 1*

- *Commission Implementing Regulation (EU) 2022/129 of 21 December 2021 laying down rules for types of intervention concerning oilseeds, cotton and by-products of wine making under Regulation (EU) 2021/2115 of the European Parliament and of the Council and for the information, publicity and visibility requirements relating to Union support and the CAP Strategic Plans*

- *Commission Implementing Regulation (EU) 2022/114 of 26 January 2022 granting a Union authorisation for the single biocidal product 'SchwabEX-Guard' (1)*

- *Commission Implementing Regulation (EU) 2022/130 of 24 January 2022 entering a name in the register of protected designations of origin and protected geographical indications 'Bračko maslinovo ulje' (PDO)*

- *Commission Implementing Regulation (EU) 2022/131 of 24 January 2022 entering a name in the register of protected designations of origin and protected geographical indications 'Carne Ramo Grande' (PDO)*

- *Commission Implementing Regulation (EU) 2022/115 of 26 January 2022 amending Regulation (EC) No 1484/95 as regards fixing representative prices in the poultrymeat and egg sectors and for egg albumin*

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