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Trade Perspectives© is honoured to welcome on the Editorial Board our two new colleagues in Jakarta, Indonesia: **Dr. Michelle Limenta**, Of Counsel at *FratiniVergano*, and **Ms. Alya Mahira**, Junior Lawyer at *FratiniVergano*. We look forward to working with them and reinforcing our ASEAN presence. Michelle and Alya will be regularly contributing to *Trade Perspectives*© with articles having primarily an ASEAN or Indonesian focus.

Happy Easter to all our readers! Stay safe, wherever you are.

The Covid-19 pandemic and the multilateral trading system

On 3 April 2020, the World Trade Organization (hereinafter, WTO) published a report on *Trade in Medical Goods in the Context of Tackling Covid-19*, which provides an overview of trade in medical goods, including personal protective products, references the tariffs imposed thereon, and traces global trade flows of such products. WTO Deputy Director-General *Alan Wolff* highlighted a number of trade-related measures and policy responses by Governments to address the Covid-19 pandemic and possible future trade policy responses. While some measures implemented by WTO Members across the world appear to be in line with the ideas highlighted by the WTO, export restrictions in various countries remain in place. As the greater implications of the Covid-19 pandemic on the global economy and on trade are still difficult to assess, global efforts within the multinational *fora* have been launched to mitigate the negative impact on trade.

On 24 March 2020, WTO Director-General *Roberto Azevêdo* had requested WTO Members to submit information to the WTO Secretariat regarding policies that they had introduced in response to the Covid-19 outbreak. Director-General *Azevêdo* pointed out the importance of transparency with regard to trade-related measures and argued that an overview of the measures taken by WTO Members "*would be particularly useful for the many countries that rely on imports for medical supplies*". Additionally, Director-General *Azevêdo* created a task

force of experts from across the WTO Secretariat to monitor the impact of Covid-19 on trade flows and the overall global economy. On 3 April 2020, the WTO published its report on *Trade in Medical Goods in the Context of Tackling Covid-19*. The report provides an overview of trade and tariffs imposed on medical goods, considered as relevant in the context of Covid-19. The report categorised the medical products into four groups: 1) Medicines (*i.e.*, pharmaceuticals); 2) Medical supplies (*e.g.*, alcohol, syringes, and gauze); 3) Medical equipment and technology; and 4) Personal protective products (*e.g.*, hand soap and sanitizer, face masks, and protective spectacles). According to the report, medical products accounted for approximately 5% of total world trade in 2019, while medicines represented 56% of the total value of medical product imports. The biggest importers of medical goods are the US, Germany and China, which together account for 34% of total world imports. The biggest exporters of medical products are Germany, the US, and Switzerland, which together supply 35% of medical products.

Overall, the report notes that tariffs on medical products are considerably low. According to the report, the average applied Most Favoured Nation (hereinafter, MFN) tariff for medical products is 4.8% and the majority of WTO Members applies tariffs below 5%. The WTO has contributed to the liberalisation of trade in these products by means of: 1) The tariff Schedules agreed at the time of establishment of the WTO in 1995; 2) The conclusion of the Plurilateral sectoral Agreement on Pharmaceutical Products; and 3) The expansion of the Information Technology Agreement (ITA) in 2015, which covers certain medical equipment. However, the report also notes that an average of 11.5% tariffs is applied on Covid-19 relevant personal protective products, which is partly attributed to the fact that most of these products are not included in any of the aforementioned arrangements. 40% of the exports in personal protective products originate in China, Germany and the US. More specifically, the report notes that products, such as face masks, hand gloves, and sanitizers, are subject to relatively high tariffs. For hand soap, the global average stands at 17% and, in some countries, such as Egypt, the tariff is set at as much as 56.7%. With respect to face masks, a third of all WTO Members applies tariffs between 10 and 15%. However, some Latin American countries, such as Argentina, Bolivia, Brazil, Ecuador, and Venezuela apply tariffs of between 19% and 20%.

In recent weeks, multilateral *fora* have been increasingly advocating for global action. According to WTO Deputy Director-General *Wolff*, a discussion paper of 11 March 2020, for a meeting of the so-called Ottawa Group of WTO Members, focused on WTO reforms and highlighted two topics of discussion: 1) Tariff reductions as a fiscal stimulus measure; and 2) Tariff eliminations as a direct response to the coronavirus outbreak. WTO Deputy Director-General *Wolff* underlined that there was "*neither sufficient time nor evident WTO Member desire to initiate and conclude a new round of tariff negotiations*" and that the "*only effective step would be to engage in autonomous coordinated tariff reduction*". Such tariff elimination should be reciprocal, with other WTO Members voluntarily replicating the approach. In order to ensure transparency, the WTO has put in place a webpage dedicated to Covid-19, providing up-to-date trade-related information and an updated list of the various notified measures adopted by WTO Members.

The WTO has also called on the Group of Twenty (hereinafter, G20), an international *forum* of the Governments and Central Banks' Governors from 19 countries and the EU, to increase international cooperation. The WTO requested G20 countries to: 1) Ask international organisations "*to establish coordinated norms and best practices to facilitate trade in Covid-19 related health products and health*"; 2) "*Pledge to cooperate to ensure sufficient supply and smooth cross-border circulation of goods and services*"; and 3) "*Agree that any recourse to export restrictions should be targeted proportionate, temporary and transparent and commit to sharing information about such measures with the WTO*". In a joint statement, countries in the G20 stated that they remained committed to international cooperation and to working together to facilitate international trade and to coordinate their responses. On 6 April 2020, the World Customs Organization (hereinafter, WCO) and the WTO issued a joint statement, noting that the WCO was willing "*to establish a coordinated approach in support of initiatives that facilitate cross-border trade in goods, in particular those key to combat COVID-19*".

In line with the WTO recommendations, a number of countries have already taken measures to eliminate tariffs and to facilitate trade flows. For instance, Argentina temporarily suspended anti-dumping duties on imports of hypodermic syringes from China, Brazil temporarily eliminated import tariffs on certain personal protective equipment, and Canada waived tariffs and sales taxes on all goods imported by or on behalf of public health agencies, hospitals, testing sites, and first response organisations. The EU also decided to suspend tariffs and VAT on specific goods under strict conditions and, on 3 April 2020, published *Commission Decision on relief from import duties and VAT exemption on importation granted for goods needed to combat the effects of the COVID-19 outbreak during 2020*. Reportedly, the US has the intention to suspend most favoured nation (hereinafter, MFN) tariffs on certain goods from countries with MFN status for three months. This would not apply to tariffs on goods import from China and the EU, which are subject to the additional tariffs under Section 301 of the US Trade Act of 1974 or to steel and aluminium products subject to Section 302 of the Trade Act of 1974. On 25 March 2020, the US published in its Federal Register a public consultation for "*comments on possible further modifications to remove duties from additional medical-care products*", which is open until 25 June 2020.

Regardless of the calls for international cooperation, export restrictions on personal protective equipment (see *Trade Perspectives*, Issue No. 6 of 27 March 2020) and certain food products remain in place in many countries. Export restrictions are generally prohibited by the WTO. Exceptions to this rule are only allowed in specific circumstances under Articles XI:2 and XX of the General Agreement on Tariffs and Trade (hereinafter, GATT). Article XI:2 of the GATT expressly allows "*export prohibitions or restrictions temporarily applied to prevent or relieve critical shortages of foodstuffs or other products essential to the exporting contracting party*" and Article XX(b) of the GATT allows measures "*necessary to protect human, animal or plant life or health*". Further, Article XXI(b)(iii) on '*Security exceptions*' states that nothing in the GATT must be construed to prevent any WTO Member "*from taking any action which it considers necessary for the protection of its essential security interests*". El Salvador and Honduras adopted a temporary export ban on certain dried leguminous vegetables, such as red beans, in order to guarantee domestic supplies. Kyrgyzstan implemented restrictions on certain food products, such as wheat and meslin (*i.e.*, a mixture of cereal species that are sown and harvested together), wheat flour, cooking oil, rice, pasta, chicken eggs, sugar and iodised table salt. On 9 April 2020, the Government of Romania issued an export ban of wheat, corn, rice, sunflower seeds, and other grains, vegetable oils, sugar, and various bakery products. The export ban is supposed to be in place during the Covid-19 state of emergency. In this regard, in a joint statement of the World Health Organization (WHO), the Food and Agriculture Organization (FAO) of the United Nations, and the WTO, noted that millions of people worldwide depend on international trade for their food security or livelihoods and that countries should ensure that trade-related measures do not disrupt food supply chains.

According to WTO Deputy Director-General *Wolff*, the WTO can be an essential *forum* for international cooperation to ensure that trade policies contribute to respond to the current crisis and reduce the disease's severe negative impact on the world economy. The Covid-19 pandemic will likely take months to overcome and the impact on trade will be significant. Traders around the world should monitor the trade-related developments linked to Covid-19, as the situation is changing dynamically and rapidly. Businesses should remain up to date on the measures in force and should seek adequate legal advice, also ensuring that their legitimate interests are properly voiced and represented within all relevant *fora*.

The Government of Indonesia starts to levy taxes from digital companies operating in the country – a violation of the WTO *Moratorium on e-commerce*?

On 31 March 2020, in an effort to reduce the economic impact of the Covid-19 outbreak, Indonesia's President *Joko "Jokowi" Widodo* signed *Government Regulation in Lieu of Law No. 1 Year 2020 on States' financial policies in handling the Covid-19 and/or facing threats to the national economy* (hereinafter, *Perppu* 1/2020), which immediately entered into force. A

Perppu is an '*emergency*' and temporary regulation issued by the President of Indonesia under circumstances of compelling urgency. The declaration of the Covid-19 pandemic as a global health emergency by the World Health Organization (WHO) appears to justify President *Jokowi's* action on issuing this emergency regulation. Although it immediately entered into force, under the current circumstances, the *Perppu 1/2020* will need to be approved by Indonesia's House of Representatives (hereinafter, DPR) in the near future. Once approved, the regulation would be converted into a law, while a rejection by the DPR would result in the revocation of the *Perppu*.

In brief, *Perppu 1/2020* legitimises State spending beyond the allowed maximum 3% of Indonesia's gross domestic product (GDP), as mandated by *Law No. 17 Year 2003 concerning the State Budget*, and allows the Government of Indonesia to allocate more funds to the public health sector in order to address the Covid-19 pandemic, including the establishment of tax policies. Articles 4(2), 6, and 7 of the *Perppu 1/2020* provide an unprecedented authority for the Government to collect taxes from digital companies operating in the country from 31 March 2020. Aside from the objective of collecting funds to address the economic impacts of the Covid-19 pandemic, another underlying objective of *Perppu 1/2020* is admittedly to improve the administration of internet-based trading activities by digital and e-commerce businesses.

For the past few years, the Government of Indonesia has been attempting to tax multinational enterprises operating within the country's growing digital market. Recently, Indonesia's Minister of Finance *Sri Mulyani* claimed that the Government was unable to collect taxes from foreign businesses due to their limited or non-existent presence in Indonesia. Pursuant to *Indonesia's Law No. 36 Year 2016 concerning Income Tax* (hereinafter, Income Tax Law), foreign digital companies cannot be taxed unless they have established a permanent business entity in Indonesia. In fact, there are many foreign companies that have been incurring substantial revenues from their digital sales in Indonesia without having a permanent entity and, consequently, without paying any taxes in Indonesia. Arguably, these foreign companies have a competitive advantage in the Indonesian market vis-à-vis Indonesian competitors and foreign companies with a permanent business entity in Indonesia.

To overcome this '*loophole*', the Government of Indonesia has been planning to revise relevant tax laws and require global digital companies operating in Indonesia to pay taxes, so as to create a level playing field between domestic and foreign companies. As noted by Indonesia's Minister of Communication and Information, *Johnny Gerard Plate*, this plan had been drafted under the *Omnibus Law on Taxation*, and submitted to the DPR for deliberation in February. The Law would redefine the concept of '*permanent entity*', so as to allow foreign tax subjects to be domestically taxed without having a physical presence in Indonesia. Taxation under the *Perppu 1/2020* appears to concern the sale and purchase of goods and services sold through electronic platforms provided by foreign companies (*i.e.*, foreign traders, service providers, and/or electronic trading providers), applying to intangible and physical goods and to services sold and transmitted by electronic means. Taking into account the Covid-19 pandemic, Indonesia's Minister of Finance *Sri Mulyani* admitted that the Government considered it necessary to start collecting the taxes sooner than scheduled through *Perppu 1/2020*.

Under Article 6(1) of the *Perppu 1/2020*, foreign companies will be charged with value added tax (VAT) on the sale of their products and services. In addition to VAT, the Government will also either charge the income tax or the electronic transaction tax (hereinafter, electronic tax) based on the activities carried out by foreign individuals or digital companies that fulfil the criteria of "*significant economic presence*" (hereinafter, SEP) in Indonesia. Article 6(8) of the *Perppu 1/2020* specifies that, in case levying income tax on foreign companies were to be contrary to Indonesia's commitments under a tax treaty (*e.g.*, a double taxation avoidance agreement), foreign companies with a SEP would be subject to the electronic tax based on the company's digital sales in Indonesia.

Indonesia is not the first country to apply such kind of tax method. For instance, Singapore has been charging goods and services tax (GST) on overseas digital services since 1 January 2020 and, under the *Finance Act 2019*, the Government of Nigeria has the authority to tax

digital businesses that have a SEP in Nigeria. The EU has recently underlined again the importance of agreeing to a global framework for digital taxation. The European Commissioner for Economy *Paolo Gentiloni* stated that the economic fallout caused by the Covid-19 pandemic could be a factor in persuading certain EU Member States to support a digital tax. Despite certain controversial initiatives by individual EU Member States, the EU has been addressing the issue of digital taxation mostly at the multilateral level, and discussions are supposed to continue at a G20/Organization for Economic Co-operation and Development (hereinafter, OECD) plenary session scheduled for July in Berlin.

The Indonesian concept of SEP referred to in the *Perppu 1/2020* is determined by three indicators: 1) A company's gross distribution; 2) The value of sales in Indonesia; and/or 3) The number of active users of their digital goods/services in Indonesia. Those companies that are considered to have a SEP in Indonesia will be considered as having established a permanent entity in Indonesia and will, therefore, be subject to domestic tax regulations. A similar provision is embedded in Article 7 of Indonesia's *Government Regulation No. 80 Year 2019 concerning E-commerce*, whereby foreign e-commerce or internet companies with a SEP in Indonesia are considered as Indonesian tax subjects. The Government has yet to issue the specific threshold/criteria for the SEP, as it is in the process of issuing a new Government Regulation and Minister of Finance Regulation clarifying the scope of the SEP, the tax calculation, and other mechanisms for the payment of income tax or electronic tax for companies, as mandated by *Perppu 1/2010*.

At the multilateral level, in 1998, Members of the World Trade Organization (hereinafter, WTO) established the *Work Programme on Electronic Commerce* and agreed, under the *Moratorium on e-Commerce,* not to impose customs duties on electronic transmissions. The *Moratorium* has been renewed at every subsequent WTO Ministerial Conference. At the 2017 WTO Ministerial Conference, the WTO General Council had agreed to extend the application of the *Moratorium on e-Commerce* until the 12th Ministerial Conference in June 2020, which has recently been cancelled due to the Covid-19 pandemic. While WTO Members agreed to extend the application of the *Moratorium on e-Commerce*, there is no agreed definition nor common understanding on the scope of '*electronic transmissions*' and, thereby, the *Moratorium*'s scope. Electronic transmissions are generally held to encompass anything from software, e-mails, video games, films, all of which can be delivered through electronic means. According to the UNCTAD and OECD, trade in electronic transmission excludes products that are ordered online but delivered physically. Questions have been raised on whether the *Moratorium* applies only to the '*electronic transmissions*' themselves (*i.e.*, the delivery of the digital products or services) or also to the '*content*' of the electronic transmissions. WTO Members, including Indonesia, interpret the scope of the *Moratorium* to only include the '*electronic transmission*' itself. This debate on the '*content*' or the '*electronic transmission*' is closely related to the debate on whether electronic transmissions should be treated as '*goods*' under the General Agreement on Tariffs and Trade 1994 (hereinafter, GATT) or as '*services*' in accordance with the General Agreement on Trade in Services (hereinafter, GATS). In recent years, countries such as Indonesia, India, and South Africa indicated their intention to end the *Moratorium on e-Commerce* and to begin imposing tariffs on cross-border digital trade.

The Government of Indonesia appears to have designed the taxes under the *Perppu 1/2020* as internal taxes, so as to avoid coming in conflict with the *Moratorium on e-Commerce*. The *Moratorium* concerns customs duties or border measures, which are defined as taxes imposed on the exportation or importation of goods. Under the *Perppu 1/2020*, VAT is levied on the sales of intangible goods and on services provided by foreign tax subjects, while the electronic tax is imposed on the digital transactions or sales of goods and services delivered from foreign tax subjects to Indonesian customers. A research paper from the United Nations Conference on Trade and Development (UNCTAD) on *'Growing Trade in Electronic Transmissions: Implications for the South'* showed that it is technically feasible for countries to levy customs duties on intangible imports through internal taxation, including VAT systems. The implementation of Indonesia's new taxation scheme should be closely monitored and, if it were to *de facto* operate as a system of customs duties on the imports of intangible goods and services, Indonesia's internal taxes could be considered as inconsistent with the WTO

Moratorium on e-Commerce.

Indonesia's new rules taxing foreign companies for their digital products and services purchased by Indonesian consumers must comply with Indonesia's international trade obligations, notably the WTO *Moratorium on e-Commerce* and the GATT/GATS principles of national treatment and non-discrimination. To date, there has been no complaint raised by WTO Members concerning the *Perppu 1/*2020, as countries' primary attention and resources are currently devoted to address the Covid-19 pandemic. As the efforts against the pandemic are likely to take months, stakeholders should closely monitor and remain up to date on the digital tax-related developments in Indonesia.

Towards the authorisation of certain insects as novel food in the EU? An opinion by the EFSA on the safety for human consumption is expected shortly

The European Food Safety Authority (hereinafter, EFSA) is reportedly soon expected to issue a scientific opinion on the safety for human consumption of whole or ground mealworms, lesser mealworms, locusts, crickets, and grasshoppers. A positive scientific opinion, which is expected, would then be followed by the final authorisation as novel food by the European Commission (hereinafter, Commission) before the products covered by the authorisation may be marketed in the EU. Businesses in the insect food sector may then freely market their products in the entire EU and not only in individual EU Member States, as it is currently the case.

Insects and insect-based products are already widely consumed around the world and, to a certain extent, in the EU, as well. The interest in using insects as food or as a source of protein has increased and there appears to be the potential for insect protein as an economically viable source for both human consumption and animal feed. The human use of insects as food, referred to as entomophagy, is already common in many parts of the world, with at least two billion people worldwide consuming insects on a regular basis. Experts agree that there are nutritional values to incorporating more insect-based protein into the diets of EU consumers. The United Nations' Food and Agriculture Organisation (FAO) has been advocating on issues related to edible insects since 2003. Edible insects typically contain a high level of calcium, high quality proteins, vitamins and amino acids. Insects are also rich in fibre, they represent a good source of healthy fats (omega-3), and have a high amount of nutrients such as iron, selenium, zinc and vitamin B12. Furthermore, insect consumption can be associated with environmental benefits, due to the limited resources necessary to rear them, compared to other animals.

In the EU, the consumption of insects is still considered something '*novel*'. Novel foods are foods that have not been consumed to any significant degree by humans in the EU before May 1997, when the first novel foods *Regulation (EC) No. 258/97* entered into force. In principle, in order to be able to commercialise novel insect foods in the EU, producers need to gain pre-market approval, which means that the food must be declared safe for consumption. This is achieved via the submission of a detailed dossier and the carrying out of a risk assessment of the product, according to *Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No. 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No. 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No. 1852/2001* (hereinafter, the Novel Foods Regulation, or NFR). Parts of insects (such as legs, wings, heads, etc.) were already included in the EU definition of novel food as food ingredients isolated from animals, while whole insects were not (see *Trade Perspectives*, Issue No. 3 of 6 February 2015 and Issue No. 11 of 29 May 2015). Most importantly, the NFR clarifies that whole animals, such as whole insects, if not consumed in the EU to a significant degree by humans prior to 15 May 1997, fall under the definition of novel food and require authorisation.

Article 35(2) of the NFR (on transitional measures) provides that foods not falling within the scope of *Regulation (EC) No. 258/97*, which were lawfully placed on the market by 1 January 2018 and which fall within the scope of the NFR (*e.g.*, whole insects), may continue to be placed on the market until a decision is taken (following an application for authorisation of a novel food or a notification of a traditional food from a third country), but no later than 2 January 2020. Although the timeline for the transitional measure has lapsed, some EU Member States, including Austria, Belgium, Denmark, Finland and the Netherlands, as well as the UK, appear to continue allowing insects to be reared and marketed for food purposes. This does, however, not apply to ingredients that were isolated or extracted from insects, such as protein isolates.

In accordance with the requirements laid down in Article 10(1) of the NFR, the Commission makes the summary of the novel foods applications publicly available based on the information concerning the name and address of the applicants, the name and description of the novel foods, and scientific evidence demonstrating that the novel foods do not pose a safety risk to human health. At least eight applications from Belgian, Dutch and French companies are currently pending at the Commission regarding crickets, locusts, grasshoppers, mealworms and lesser mealworms: 1) *Acheta domesticus* (house cricket); 2) *Locusta migratoria* (migratory locust); 3) Whole and ground grasshopper (*Locusta migratoria*); 4) Whole and ground *Alphitobius diaperinus* (lesser mealworm) larvae products; 5) Mealworm (*Tenebrio molitor*) flour; 6) Dried *Tenebrio molitor* (mealworms); 7) *Tenebrio molitor* (mealworm); and 8) Whole and ground mealworm (*Tenebrio molitor*) larvae. It appears that currently no applications are processed at the Commission regarding insects as traditional foods from non-EU countries, submitted within the meaning of Article 14 of the NFR, with a description demonstrating the history of safe food use in the non-EU country (see *Trade Perspectives*, Issue No. 3 of 12 February 2016).

Article 10 of the NFR concerns the procedure for authorising the placing on the market within the EU of a novel food and updating the EU list, which is initiated either on the Commission's initiative or following an application to the Commission. Upon request by the Commission, the EFSA is required to give its opinion as to whether the authorisation of the placing on the market within the EU of a novel food is liable to have an effect on human health. The procedure for authorising the placing on the market within the EU of a novel food and updating the EU list of novel foods ends with the adoption of an implementing act in accordance with Article 12 of the NFR and the respective amendment of Commission *Implementing Regulation (EU) 2017/2470 of 20 December 2017 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*.

With respect to the applications for approval of the insect foods mentioned above, the Commission has requested the EFSA's opinion as to whether authorising their placing on the market within the EU would be liable to have an effect on human health. Details as to where the procedure stands can be obtained at the EFSA's register of questions, where the different requests are either "*under consideration*", "*in progress*", or where "*additional data* (has been) *request*(ed)". Contrary to the previous novel food regulation, under the NFR there are strict timelines within which the EFSA's opinion on a novel food application is to be obtained. According to Article 11 of the NFR, where the Commission requests an opinion from the EFSA, it shall forward the valid application to the EFSA without delay, and not later than one month after having verified its validity. The EFSA is required to adopt its opinion within nine months from the date of receipt of a valid application. In duly justified cases, where the EFSA requests additional information from the applicant, the nine-month period may be extended.

In assessing the safety of novel foods, the EFSA is required, where appropriate, to consider whether: 1) The novel food concerned is as safe as food from a comparable food category already placed on the market within the EU; 2) The composition of the novel food and the conditions of its use do not pose a safety risk to human health in the EU; and whether 3) A novel food, which is intended to replace another food, does not differ from that food in such a way that its normal consumption would be nutritionally disadvantageous for the consumer.

The different applications mentioned above address the question of whether the insect food does or does not pose a safety risk to human health. For example, the summary of the application for whole and grinded lesser mealworm larvae products by a Dutch company notes that "*analyses and scientific studies show no safety concerns for heavy metals, mycotoxins, pesticides, prions, flame retardants, PCBs, DDT, and dioxin compounds*". Furthermore "*the microbial data does not exceed the limits as set in Regulation (EC) No 2073/2005 and the levels advised by NVWA. Concentrations of chitin are not likely to exceed the level mentioned in the EFSA Opinion on chitin-glucan (EFSA NDA, 2010) based on the calculated anticipated intake data*" and "*literature search did not reveal concerns regarding the absorption, digestion, metabolism and excretion of proteins, minerals, chitin and amino acids. Based on the low concentrations of undesired compounds, no toxicological studies have been performed*". However, the applications noted that there is a high allergenic potential, which "*warrants mandatory allergenicity labelling, as cross-reactivity exists with crustaceans, molluscs and house dust mite and the product contains gluten*". Similar considerations on contaminants, pesticides, microbiology, toxicity and allergenicity are made in the other applications as well. It is now for the EFSA to assess the applications and adopt the respective scientific opinions.

Article 12 of the NFR concerns the authorisation of a novel food and updates of the EU list. Within seven months from the date of publication of the EFSA's opinion, the Commission is to submit to the EU's Standing Committee on Plants, Animals, Food and Feed (PAFF Committee) a draft implementing act authorising the placing on the market within the EU of a novel food, including the authorised conditions of use, labelling requirements, and other specifications.

The International Platform of Insects for Food and Feed (hereinafter, IPIFF), representing the EU insect sector, has anticipated that the EFSA is likely to make a decision on approving whole or ground mealworms, lesser mealworms, locusts, crickets and grasshoppers as being safe for human consumption. "*These have a good chance of being given the green light in the coming few weeks*", the IPIFF's Secretary General reportedly said, adding that "*these authorisations will be a breakthrough for the sector so we are looking for those authorisations quite impatiently. They are taking the necessary time, they are very demanding on information, which is not bad. But we believe that once we have the first novel food given a green light from EFSA, that will have a snowball effect*". Many companies are reported to be preparing to increase their operations. "*We have many of our members building bigger factories because the key to success is to upscale your companies and produce on a mass scale*" IPIFF's Secretary General said, adding that "*the next few years will be very interesting ones and obviously the novel food authorisations will definitely help*".

Under the NFR, all authorisations are generic, which means that any food business operator, not just the applicants, may place an authorised novel food on the EU market, following its listing in Commission *Implementing Regulation (EU) 2017/2470*, provided that the authorised conditions of use, labelling requirements, and other specifications set out in *Regulation (EU) 2017/2470* are respected.

If the EFSA soon publishes the long-awaited scientific opinion on the safety of certain insect species for human consumption, finding that they are safe for human consumption, the authorisation by the Commission can be expected before the end of this year. Interested stakeholders are advised to monitor the respective developments and are encouraged to be prepared to navigate the procedures and to work with their legal advisors prior to submitting new novel food dossiers for other insect species or products to the Commission.

The EFSA confirms that increasing the current EU maximum levels for aflatoxins in food would not substantially change the impact on human health

On 9 March 2020, the European Food Safety Authority (hereinafter, EFSA) published a scientific opinion providing a *Risk assessment of aflatoxins in food*, largely confirming earlier conclusions that aflatoxins are genotoxic and carcinogenic. Aflatoxins, which are naturally

occurring contaminants of the family of mycotoxins (*i.e.*, toxic chemical compounds generating in moulds that grow in decaying vegetations, hay, and grains) have been found to be generally harmful to human health at a certain level of exposure. In 1998, the EU introduced maximum limits for these contaminants in a certain number of products with no substantial changes implemented to date. The current maximum levels are often considered as being too strict and the disproportionate enforcement of related import rules can further complicate trade.

Aflatoxins occur mainly in tree nuts (*i.e.,* almonds, Brazil nuts, cashews, hazelnuts, pecans, pistachios and walnuts), ground nuts (*i.e.*, peanuts), figs, other dried fruits, crude vegetables oils, cocoa beans, and maize and are primarily caused by two types of moulds (*i.e.*, *Aspergillus flavus* and *Aspergillus parasiticus)* that especially develop in warm and humid conditions. Additionally, aflatoxins may also develop in improperly stored staple commodities, such as cassava, chili peppers, millet, rice, sesame seeds, sorghum, sunflower seeds, wheat and a variety of spices. Finally, aflatoxin contamination occurs in eggs, milk products, and meat, when the animals are fed contaminated grains. The four main aflatoxins found in contaminated products pertain to the groups B1, B2, G1 and G2, which are metabolites of various strains of *Aspergillus flavus* and *Aspergillus parasiticus.* According to studies, aflatoxin B1 is the most common aflatoxin found in food and among the most potent genotoxic and carcinogenic mycotoxins. High levels of aflatoxins exposure may result in chronic liver damage or liver cancer, as well as to stunted growth and delayed development in children. In 1992, the International Agency for Research on Cancer (IARC) classified aflatoxin B1 as a "*human carcinogenic*" and aflatoxins B2, G1, and G2 as "*probable human carcinogenic*".

In the EU, the basic principles regarding contaminants in food are regulated by *Council Regulation 315/93/EEC laying down Community procedures for contaminants in food*, which establishes that: 1) Food containing a contaminant to an amount unacceptable from the public health viewpoint, and in particular at a toxicological level, is not to be placed on the market; 2) Contaminant levels must be kept as low as it can be reasonably achieved following recommended good working practices; and 3) Maximum levels must be set for certain contaminants in order to protect public health. Maximum levels of aflatoxins B1, B2, G1 and G2 were established by *Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs.*

At the international level, the *Codex General Standard for Contaminants and Toxins in Food and Feed* (CODEX STAN 193-1995), which was amended and revised several times between 1995 and 2019, establishes maximum levels for total aflatoxins B1, B2, G1 and G2 in almonds, Brazil nuts, hazelnuts and pistachios ranging from 10 to 15 µg/kg, depending on whether they are ready-to-eat products or intended for further processing. For peanuts and dried figs, maximum levels are set at 15 µg/kg and 10 µg/kg irrespective of their intended use. For the same products, the EU has adopted an alternative approach, establishing much lower (*i.e.*, stricter) maximum levels for the total aflatoxins B1, B2, G1 and G2 ranging from 4 to 15 µg/kg and introducing dedicated maximum levels for aflatoxin B1 ranging from 0.1 µg/kg to 8 µg/kg. In the US, the Food and Drug Administration (hereinafter, FDA) has established a general maximum level of total aflatoxins B1, B2, G1 and G2 in food intended for human consumption at 20 µg/kg. In 2016, the Joint FAO/WHO Expert Committee on Food Additives (hereinafter, JECFA) conducted an assessment of different maximum levels of aflatoxins in ready-to-eat peanuts and concluded that "*enforcing a maximum limit of 10, 8 or 4 µg/kg for ready to-eat peanuts would have little further impact on dietary exposure to total aflatoxins for the general population, compared with setting a maximum limit of 15 µg/kg*".

In 2007, following discussions within the *Codex Alimentarius Committee for Food Additives and Contaminants* (CCFAC) concerning the suitability of setting maximum levels for total aflatoxins at 15 µg/kg for unprocessed almonds, hazelnuts, and pistachios, and at 8 µg/kg for these three ready-to-eat nuts, the European Commission (hereinafter, Commission) requested the EFSA to provide a scientific opinion on the health risks linked to the possible increase (*i.e.*, relaxation) of the existing maximum levels of aflatoxins in these foodstuffs. The EFSA's Panel on Contaminants in the Food Chain (hereinafter, CONTAM Panel) concluded that "*increasing the current EU maximum levels of 4 µg/kg total aflatoxins in these three nuts to 8 or 10 µg/kg*

total aflatoxins would have minor effects on the estimated dietary exposure, cancer risk and the calculated margins of exposure". However, in the same opinion, the EFSA's CONTAM Panel confirmed previous conclusions that "*exposure to aflatoxins from all sources should be kept as low as reasonably achievable because aflatoxins are genotoxic and carcinogenic*". In 2009, the EFSA conducted a similar assessment regarding nuts other than almonds, hazelnuts and pistachios, which led to the conclusion "*that public health would not be adversely affected by increasing the levels for total aflatoxins from 4 µg/kg to 10 µg/kg*". However, the EFSA's CONTAM Panel reiterated that *"exposure to aflatoxins from all sources should be as low as reasonably achievable, because aflatoxins are genotoxic and carcinogenic, and that priority should be given to reducing the numbers of highly contaminated foods reaching the market, irrespective of the commodity involved*".

The scientific opinion issued by the EFSA in March 2020, following a request by the Commission, confirms the EFSA's previous conclusions on the basis of broader exposure data and of a more comprehensive assessment. The opinion estimates the dietary exposure of the EU population to aflatoxins and assesses the related risk to human health within the EU population. The exposure assessment was carried out using food consumption data from 38 dietary surveys carried out in 22 EU Member States available in the EFSA's Comprehensive European Food Consumption Database. Differently from the EFSA's assessment carried out in 2007, the most recent assessment also analysed data related to the toxicity for humans of aflatoxins pertaining to the group M1, concluding that aflatoxin B1 is around ten times more potent than aflatoxin M1 with respect to liver carcinogenicity. Aflatoxin M1 is the hydroxylated metabolite of Aflatoxin B1 and is found in milk and dairy products obtained from livestock that has ingested contaminated feed, as well as in human milk. The data on Aflatoxin M1 were excluded from the EFSA's previous assessments due to the fact that these were targeted to nuts and their derived products, and that almost all values on the concentration of aflatoxin M1 in the commercial milk samples considered were below 0.05 µg/kg and the carcinogenic potency of Aflatoxin M1 is much lower than of Aflatoxin B1.

The scientific community agrees on the fact that the presence of aflatoxins in food is harmful only if the level of aflatoxins exceeds certain levels. In that respect, the JECFA, the FDA, and the EFSA confirmed that maximum levels of aflatoxins higher than those established by EU legislation would not substantially change the impact on human health. Still, the EU appears to maintain its maximum levels of aflatoxins. In particular, the unilateral establishment by the EU of maximum levels for aflatoxin B1, which is not provided for in the relevant *Codex* standard, results in exporters having to face product rejections or having to bear the costs of reducing aflatoxin contamination intended only for the EU market, thereby increasing the costs of crop management and food processing. According to Article 3 of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (hereinafter, SPS Agreement), WTO Members are required to base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist. WTO Members may only resort to stricter measures if there is scientific justification, or as a consequence of the level of sanitary or phytosanitary protection that a WTO Member scientifically determines to be appropriate in accordance with the SPS Agreement. Importantly, in accordance with Article 5(6) of the SPS Agreement, WTO Members are required to ensure that their SPS measures "*are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection*". Arguably, the measures maintained by the EU are more trade-restrictive than necessary. Consequently, the EU should take action to better align its regulatory framework with relevant international standards, particularly in light of the EFSA's findings that such alignment to higher (*i.e.*, less strict) maximum levels would not jeopardise food safety and human health, but would facilitate trade.

Import controls are crucial in verifying compliance of products with the relevant requirements, including with the EU maximum levels for aflatoxins. In the EU, the vast majority of products of relevance for the food chain is not subject to mandatory checks. An exception to this regime concerns food and feed of non-animal origin, which are, typically temporarily, subject to mandatory border controls due to the existence of an identified risk. Under *Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls*

and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, which repealed *Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules,* the EU applies four different import control regimes for foods of plant origin: 1) Pre-export checks for food products with the lowest risk; 2) Foods under no specific import regime for which the general rules of Regulation 2017/625 apply; 3) Increased controls based on emerging or known risks; and 4) Emergency measures in cases of the highest perceived risk. Most recently, *Commission Implementing Regulation (EU) 2019/1793 of 22 October 2019 on the temporary increase of official controls and emergency measures governing the entry into the Union of certain goods from certain third countries*, establishes for which countries increased controls and emergency measures apply due to aflatoxin contamination. For example, for peanuts from Ghana, Brazil nuts in shell from Brazil, pepper from Ethiopia, and watermelon seeds from Nigeria, a frequency of physical and identity checks of 50% of import consignments has been established.

Considering the recent scientific findings, regulators around the world should review their standards for aflatoxins and ensure that they are not more trade-restrictive than necessary, scientifically justified and based on the existing relevant international standards. Businesses exporting to the EU affected food products should closely monitor relevant import requirements and seek legal guidance in order to avoid delays or border rejections.

Recently Adopted EU Legislation

Market Access

- *Commission Implementing Regulation (EU) 2020/502 of 6 April 2020 on certain commercial policy measures concerning certain products originating in the United States of America*

Trade Remedies

- *Commission Implementing Regulation (EU) 2020/508 of 7 April 2020 imposing a provisional anti-dumping duty on imports of certain hot rolled stainless steel sheets and coils originating in Indonesia, the People's Republic of China and Taiwan*

- *Commission Implementing Regulation (EU) 2020/477 of 31 March 2020 amending Commission Implementing Regulation (EU) 2020/39 imposing a definitive anti-dumping duty on imports of peroxosulphates (persulphates) 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*

Food and Agricultural Law

- *Commission Implementing Regulation (EU) 2020/500 of 6 April 2020 authorising the placing on the market of partially defatted chia seed (Salvia hispanica) powders as novel foods under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470*

- *Commission Implementing Regulation (EU) 2020/484 of 2 April 2020 authorising the placing on the market of lacto-N-tetraose as a novel food under Regulation*

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

- *Commission Implementing Regulation (EU) 2020/478 of 1 April 2020 correcting Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods*

- *Commission Implementing Regulation (EU) 2020/479 of 1 April 2020 amending Regulation (EC) No 1235/2008 laying down detailed rules for implementation of Council Regulation (EC) No 834/2007 as regards the arrangements for imports of organic products from third countries*

Other

- *Commission Implementing Regulation (EU) 2020/466 of 30 March 2020 on temporary measures to contain risks to human, animal and plant health and animal welfare during certain serious disruptions of Member States' control systems due to coronavirus disease (COVID-19)*

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