FRATINIVERGANO
EUROPEAN LAWYERS

TRADE PERSPECTIVES©

Issue No. 6 of 26 March 2021

- **An *EU carbon border adjustment mechanism* based on the Emission Trading System? The European Parliament agreed its position**
- **Greater investment opportunities in Indonesia? The '*Job Creation Law*' and the important changes regarding special economic zones**
- **The European Food Safety Authority issues guidance for novel food authorisations in view of the imminent applicability of new transparency rules**
- **Recently Adopted EU Legislation**

An *EU carbon border adjustment mechanism* based on the Emission Trading System? The European Parliament agreed its position

On 10 March 2021, the European Parliament adopted its resolution on '*A WTO-compatible EU carbon border adjustment mechanism*'. The Carbon Border Adjustment Mechanism (hereinafter, CBAM), which aims at ensuring that "*the price of imports reflects more accurately their carbon content*", is considered to be a key piece of EU legislation in the framework of the *European Green Deal*. The resolution underlines that "*the EU's increased ambition on climate change must not lead to carbon leakage*" and that it should be WTO-compatible. The challenge remains to create an instrument that would be compatible with WTO rules avoiding discrimination between '*like*' products and among countries. The details of the EU's envisaged CBAM are not yet defined. In this resolution, the European Parliament lays out its position, which should be taken into account by the European Commission (hereinafter, Commission) as it works towards the publication of a legislative proposal by June 2021.

The road so far

In 2020, the Commission held a public consultation on the *EU Green Deal (carbon border adjustment mechanism)*. According to the Commission's Inception Impact Assessment (the legislative '*Roadmap*'), the future CBAM would aim at ensuring "*that the price of imports reflect more accurately their carbon content*" (see *Trade Perspectives*, Issue No. 17 of 18 September 2020). Notably, the CBAM would only apply to imports into the EU. The public consultation listed four options for the CBAM: 1) "*A tax applied on imports at the EU border on a selection of products whose production is in sectors that are at risk of carbon leakage*"; 2) "*An extension of the EU Emissions Trading System to imports*" (hereinafter, ETS); 3) "*The obligation to purchase allowances from a specific pool outside the ETS dedicated to imports, which would mirror the ETS price*"; and 4) "*Carbon tax (e.g. excise or VAT type) at consumption level on a selection of products whose production is in sectors that are at risk of carbon leakage*". However, until now, there is no clarity on the design of the Commission's legislative proposal and on how a future CBAM could work in practice.

In the EU, certain emissions are currently regulated through the EU's ETS. The ETS is based on the '*cap-trade system*' principle, which means that a limited cap is set on the total amount of certain greenhouse gas emissions that can be emitted by defined industry sectors. Within

the cap, companies can receive or buy allowances that can be traded with other companies. The cap is then linearly reduced over time so that the total emissions decrease (see *Trade Perspectives*, Issue No. 5 of 10 March 2017). The Commission now intends to design a new policy that aims at reducing EU carbon emissions, addressing '*carbon leakage*', and incentivising other countries to join emission reduction efforts. Carbon leakage refers to the situation in which EU production would move to non-EU countries that have less ambitious emission rules and have lower costs of production related to climate policies.

The European Parliament's position

On 10 March 2021, the European Parliament adopted its resolution on '*A WTO-compatible EU carbon border adjustment mechanism*'. The resolution was adopted with 444 votes in favour, 70 against and 181 abstentions. The resolution provides the European Parliament's position regarding such mechanism. The resolution underlines that the European Parliament supports the introduction of a CBAM "*provided that is compatible with WTO rules and EU free trade agreements (FTAs) by not being discriminatory or constituting a disguised restriction on international trade*" and that a CBAM "*should be exclusively designed to advance climate objectives and not to be misused as a tool of protectionism, unjustifiable discrimination or restriction*".

The resolution acknowledges that the Commission is currently assessing a multitude of options for a CBAM. However, on the basis of the resolution, it can be understood that, while the European Parliament has assessed the four options being considered by the Commission, the resolution focuses on the options 1 (import tax), 3 (a system mirroring the EU's ETS), and 4 (a "*carbon tax*"). The resolution encourages the Commission to pursue option 3 and to propose a CBAM based on the EU's ETS, in order to mirror the carbon costs paid by EU producers. In this context, the resolution states that, in order to address the potential risk of carbon leakage while complying with WTO rules, the CBAM would need "*to charge the carbon content of imports in a way that mirrors the carbon costs paid by EU producers*". The European Parliament further "*stresses that carbon pricing under the CBAM should mirror the dynamic evolution of the price of EU allowances under the EU ETS while ensuring predictability and less volatility in the price of carbon*". Additionally, the European Parliament is of the opinion that the Commission should consider a system that would allow importers to buy allowances from a separate pool of allowances to the EU ETS "*whose carbon price corresponds to that of the day of the transaction in the EU ETS*". Furthermore, the resolution notes that the scope of a CBAM should cover all imports of products and commodities covered by the ETS.

While there have been discussions on a possible transition period for the application of a CBAM regarding all products covered by the ETS, the resolution states that, "*as a starting point*", by 2023, a CBAM should cover the power sector and energy-intensive industrial sectors, such as cement, steel, aluminium, oil refinery, paper, glass, chemicals, and fertilizers. Additionally, the resolution states that the introduction of a CBAM should be accompanied by the necessary measures in non-ETS sectors, as well as a reform of the EU's ETS.

Regarding options 1 and 4, the resolution highlights that the option of an excise duty (option 4) on the carbon content of all consumed products, domestic and imported, would not "*fully address the risk of carbon leakage*". The resolution notes that it would be "*technically challenging given the complexity of tracing carbon in global value chains and might place a significant burden on consumers*". The resolution acknowledges that a fixed duty or tax on imports (option 1) could be a simple tool and would also provide "*a strong and stable environmental price signal for imported carbon*". However, the European Parliament considers that it would be a less flexible tool "*to mirror the evolving price of the EU ETS*". Additionally, the European Parliament notes that, if a CBAM were to be of a fiscal nature, unanimity would be required in the Council of the EU. The resolution "*stresses that the CBAM should ensure that importers from third countries are not charged twice for the carbon content of their products*" and that "*Least Developed Countries and Small Island Developing States should be given special treatment*".

Towards a WTO-compatible mechanism?

Despite the clear objective of the CBAM, many legal uncertainties remain. As the CBAM would likely constitute an innovative policy tool and as many details remain unclear, the legal viability of the concept has yet to be determined. Clearly, the EU will have to develop a mechanism that complies with relevant WTO disciplines. How the EU designs the CBAM will be crucial for determining its consistency with WTO rules, especially if the EU were to apply a border measure that only applies to imports.

The compatibility of the future measures with WTO rules is already a matter of concern. The General Agreement on Tariffs and Trade (hereinafter, GATT) prohibits WTO Members from imposing tariffs and charges in excess of the levels committed in their respective Schedule of Concessions. In addition, the GATT prohibits levying internal taxes or charges in excess of those applied to '*like*' domestic products. The European Parliament proposes a CBAM based on the EU's ETS, so as to ensure that the proposed CBAM applies to '*like*' domestic products and in order to ensure that both domestic producers and importers pay the same carbon price. However, a difficulty when assessing whether the charge levied on the imported product is equivalent to that applied to the domestic product, arises, for example, where the importing country does not maintain a simple tax scheme, but a more complex emissions trading scheme, such as the EU's ETS. Additionally, with respect to the issue of '*likeness*' under Article III of the GATT on '*National Treatment on Internal Taxation and Regulation*', currently, processing methods cannot be used to classify two products as different (or not '*like*'). Therefore, a CBAM would run the risk of being inconsistent with WTO rules.

That being said, Article XX of the GATT on '*General exceptions*' does allow WTO Members to adopt certain (otherwise discriminatory) measures when they are justified in order to protect human, animal or plant life or health, or relating to the conservation of exhaustible natural resources (Article XX(b) and (g) of the GATT, respectively). The resolution notes that the CBAM's "*rationale should be solely and strictly environmental – reducing global CO_2 emissions and preventing carbon leakage*". However, both exceptions are subject to strict requirements. Over the years, in the majority of WTO disputes, WTO Members failed to justify their environment-related measures under Article XX of the GATT. In particular, in relation to Article XX(b) of the GATT, a measure would need to pass the necessity test, which would determine whether a measure is '*necessary*' to achieve the policy objectives being pursued.

What is clear is that any future EU CBAM should be implemented in the least trade restrictive way possible. Any such mechanism, regardless of its design, will most likely be challenged by other WTO Members. On 23 March 2021, the US Special Presidential Envoy for Climate *John Kerry* stated that a CBAM should be considered a measure of last resort and called on the EU to work together with trading partners such as the US. Special Presidential Envoy for Climate *Kerry* urged the EU to refrain from introducing a CBAM until after the COP26 Climate Change Conference in Glasgow, which will take place in November 2021. Special Presidential Envoy *Kerry* stated that a CBAM "*does have serious implications for economies, and for relationships, and trade*".

EU Member States pushing towards a Council position

On 23 March 2021, Ministers from nine EU Members States published an op-ed stating their position and support for a CBAM, calling on the Commission to put forward a concrete WTO-compatible CBAM proposal by the summer. Ministers from Austria, Czech Republic, Denmark, France, Lithuania, Luxembourg, the Netherlands, Slovakia and Spain encouraged the Commission to put forward a CBAM proposal that would ensure non-discrimination and "*a good articulation*" with the EU's ETS, which could mirror the EU carbon market.

The position by the various ministers supports in a way the proposed option by the European Parliament. The op-ed states that the proposal "*must also take into account the climate policies and level of development of third countries by including them in the design and monitoring of the mechanism*".

The way forward

The Commission is expected to present its legislative proposal for a CBAM by June 2021. Additionally, the Commission also looks poised to present a proposal on how to use the revenues generated through the CBAM for purposes of financing parts of the EU budget. Businesses in the EU and around the world should closely monitor the upcoming legislative proposal and carefully review the WTO consistency of the proposed measures.

Greater investment opportunities in Indonesia? The '*Job Creation Law*' and the important changes regarding special economic zones

Indonesia's *Law No. 11 Year 2020 concerning Job Creation* (also known as the '*Omnibus Law*'), which was enacted on 2 November 2020 to improve the ease of doing business and increase the flow of foreign investment into Indonesia, contains a Chapter XI that specifically addresses the issue of special economic zones (hereinafter, SEZs). Notably, it amended the existing *Law No. 39 Year 2009 concerning Special Economic Zone* (hereinafter, *SEZ Law*) in an effort to provide greater business opportunities for investors, as well as to enhance Government support for the development of SEZs. To further elaborate the provisions on SEZs under the *Job Creation Law*, on 2 February 2021, the Government of Indonesia issued *Government Regulation No. 40 Year 2021 concerning Organization of Special Economic Zones* (hereinafter, *GR No. 40/2021*), which implements a number of important changes to Indonesia's SEZs regime.

Indonesia's special economic zones

In 2009, the Government of Indonesia had established a new location-based concession called '*Special Economic Zone*', which provides preferential regulatory requirements in order to channel investment into specific parts of the country with distinct superior resources, such as for plantations, logistics, and tourism activities. In general terms, SEZs are defined as areas equipped with geo-economic and geo-strategic advantages in which the special facilities or incentives are provided to attract investment and increase economic growth. Essentially, the main objectives of establishing SEZs are to: 1) Maximise industrial, export and/or import activities; 2) Accelerate regional development; 3) Create a model for area development; and 4) Foster job creation.

As of 2020, Indonesia had established 11 SEZs (*i.e.*, Sei Mangkei, Tanjung Lesung, Palu, Mandalika, Galang Batang, Arun Lhokseumawe, Tanjung Kelayang, Bitung, Morotai, Maloy Batuta Trans Borneo, and Sorong) and four additional SEZs that are currently in the development phase (*i.e.,* Tanjung Api-Api, Singhasari, Kendal, and Likupang). In June 2020, 29 companies were established in these SEZs, corresponding to an investment value of approximately IDR 87,509 trillion (approximately EUR 5.13 billion) and employing 8,862 people.

Indonesia's President *Joko "Jokowi" Widodo* aims at attracting more than USD 50 billion worth of investments into the SEZs over the next ten years. While the development of SEZs is progressing, many investors still appear to be reluctant to launch business activities in Indonesia, despite the incentives promised by the Government. To overcome this issue, the Government of Indonesia considers it to be crucial to establish more detailed and comprehensive rules on SEZs, concerning, *inter alia*, their establishment, determination, operation, management, and incentives, all of which have been addressed in *GR No. 40/2021.*

Location, and criteria for special economic zones

Pursuant to Article 3 of *GR No. 40/2021,* locations that may be proposed for the establishment of a SEZ are: 1) New areas; 2) Existing SEZs that will be further expanded, or 3) All or parts

of the locations of certain free-trade areas and free ports (particularly in Batam, Bintan, and Karimun). The establishment of a SEZ may be proposed to the National Council of SEZs, which administers the SEZs and is headed by Indonesia's Coordinating Ministry of Economic Affairs, by several parties, namely by State-owned enterprises, region-owned enterprises, cooperatives, private-owned business entities in the form of limited-liability companies, or joint-ventures/*consortia*.

Previously, the *SEZ Law* required the location proposed for the establishment of an SEZ to be near an international trade route or close to an international shipping lane, or to be located in an area of potential superior resources (*i.e.*, marine and fisheries, plantation, mining, or tourism). This requirement was removed by the *Job Creation Law*, reflecting the Government of Indonesia's plan to address the economic disparities that exist between different regions in Indonesia and opening up possibilities for future SEZs covering a wider range of sectors and, thereby, opening greater investment opportunities for both domestic and foreign investors. Once the location of an SEZ has been determined, the construction of such zones is to be finished within a maximum period of three years.

In each of the SEZs, the National Board of SEZs may determine one or more business activities considered as "*primary"* activities, whose supply chains will be the main focus of the SEZ. For instance, the primary business activities of the *Sei Magkei SEZ* include palm oil processing, rubber processing, tourism, and logistics, while the *Bitung SEZ* focuses on fisheries, the oil industry, as well as certain logistical support sectors. The type of primary activities is a relevant benchmark to determine the form of incentives and facilities that may be provided to the relevant business actors.

Expansion of business activities that may operate in special economic zones

According to the previous *SEZ Law*, there were only seven types of business activities that could be conducted in the SEZs, namely export processing, logistics, industry, technology development, tourism, energy, and other economic activities, as determined by the National Board of SEZs. Article 150 point (2) of the *Job Creation Law*, as further clarified by *GR No. 40/2021*, widened the scope of the business sectors. Under the new regime, business activities that may be carried out in the SEZs now expressly include the sectors of production, distribution, digital economy, education, health, sports, financial services, and creative industry business activities.

GR No. 40/2021 states that the criteria and requirements of education-related business activities are yet to be determined by Indonesia's Minister of Education and Culture, while the criteria for health-related business activities are to be set by Indonesia's Minister of Health. The Deputy for Investment Climate Development within Indonesia's Investment Coordinating Board *Yuliot Tanjung* announced that the Government of Indonesia planned to promote investment particularly in the sectors of education, financial technology, software development, and research and innovation start-ups.

Additional facilities and incentives

With respect to the facilities and incentives, *GR No. 40/2021* provides for rules similar to those set under the previous legal framework. Any business entity and business actor that carries out its activities in a SEZ is entitled to receive facilities and incentives in the areas of: 1) Taxation, customs and excise; 2) Traffic of goods; 3) Employment; 4) Immigration; 5) Land and spatial planning; 6) Business licensing; and/or 7) Other facilities and conveniences. Additionally, *GR No. 40/2021* introduced new incentives in the form of, *inter alia*, an exemption of value-added tax (VAT) for the imports of consumer goods into a tourism SEZ and the granting of limited-stay visas for foreigners involved in a start-up business established in a SEZ.

In relation to taxation, customs and excise, the facilities that may be granted to businesses concern income tax, VAT, luxury goods sales taxes, import duties, taxes in relation to imports,

and excise taxes. With respect to the income tax, business entities and business actors that carry out investments in the SEZs' primary business activities may receive a deduction of the corporate income tax with respect to the income obtained from such activities. Meanwhile, business entities and business actors that carry out investments in primary business activities, but that do not obtain the income tax deduction, or that invest in any non-primary business activity, may also benefit from income tax facilities. With respect to VAT and luxury goods sales taxes, such taxes are not collected on, *inter alia*: a) The delivery of certain tangible taxable goods from other places within Customs areas, free areas or bonded storage areas; 2) Imports of certain tangible taxable goods into SEZs; and 3) Imports of consumer goods into tourism SEZs.

For consumer goods, other than the exemption of VAT for imports, Article 150 point (25) of the *Job Creation Law* allows companies, which do not primarily engage in the production and processing business activities, to benefit from import facilities, namely the exemption from import duties and import taxes for the importation of consumer goods. As clarified in *GR No. 40/2021,* consumer goods that may receive facilities provided under the Regulation must fulfil the following requirements: 1) The consumer goods must be required by business actors in tourism SEZs as raw materials; 2) The utilisation period of such goods is relatively short and the existence and/or function will be lost once the goods are used in the production process; and 3) The consumer goods are not intended to be used outside of the SEZ. The type of consumer goods that fall within these requirements will be listed in the list of goods proposed by the administrator of a SEZ, as determined by the SEZs National Council.

With respect to the traffic of goods, Article 101 of *GR No. 40/2021* specifies that the restrictions and prohibitions that apply to the importation of certain goods, as well as the requirement to fulfil relevant Indonesian National Standards, do not apply to those goods that are imported into the territory of a SEZ. Nevertheless, if imported goods endanger health, safety, security and/or the environment, the restrictions may still be applied.

In general, the facilities provided for SEZs, which encourage exports, might conflict with World Trade Organization (WTO) rules, specifically the *Agreement on Subsidies and Countervailing Measures*. The measures include the exemption for businesses and/or manufacturers from paying import duties for raw materials and/or capital goods specifically for export purposes, as well as an export share requirement, in order to benefit from certain incentives. On the basis of the future implementation, it will have to be determined whether the facilities and incentives offered by the Government of Indonesia could be considered as export subsidies prohibited under the relevant WTO disciplines.

Exemption of capital investment requirements for tech-based start-ups

For the past few years, the high minimum foreign capital investment requirement in Indonesia has been considered as a barrier and an important restriction for investors planning to expand their business activities in the country. *Presidential Regulation No. 10 Year 2021 concerning Capital Investment Business Field* (*PR No. 10/2021*) maintains that foreign investment may only be carried out by business entities engaging in large scale business activities, referring to investments with an investment value of above IDR 10 billion (*i.e.*, around USD 700,000), excluding land and building), the same requirement as under the previous legal framework. In line with President *Jokowi*'s intention to increase the role of technology in his administration, foreign investment in technology-based start-ups located within the SEZs are now exempt from the IDR 10 billion minimum capital investment requirement. The removal of this requirement can be considered as good news for Indonesia's tech ecosystem, as well as for allowing the development of SEZs where start-ups and venture capital firms could cooperate and expand.

Additionally, the restrictions to investment under *PR No. 10/2021*, related to the business sectors open only for domestic investment, the business fields subject to a limitation regarding foreign capital ownership, and the business fields subject to special licenses, also do not apply

to investments carried out in Indonesia's SEZs.

Key takeaways

The amendments to the *SEZ Law* introduced by the *Job Creation Law* and by *GR No. 40/2021* are intended to provide greater legal certainty for the development of SEZs and related investments. Overall, the expansion of business sectors that may operate in SEZs, the exemption from the IDR 10 billion capital investment requirement for technology-based start-ups, and the exemption from certain investment requirements (*e.g.*, foreign ownership limitation), constitute significant positive developments that could increase investments and economic development in Indonesia. Businesses intending to invest in Indonesia or expand their activities should carefully assess the new rules.

The European Food Safety Authority issues guidance for novel food authorisations in view of the imminent applicability of new transparency rules

On 27 March 2021, *Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC* (hereinafter, the Transparency Regulation) will become applicable. The new rules contained therein will have an impact on the authorisation procedures for the so-called "*regulated*" products mentioned in the Transparency Regulation, namely genetically modified food and feed, additives for use in animal nutrition, smoke flavourings, food contact materials, food additives, enzymes and flavourings, plant protection products, and novel foods. The European Food Safety Authority (hereinafter, EFSA) already issued a first updated *Administrative Guidance* for the submission of novel foods applications.

The impact of the Transparency Regulation

The Transparency Regulation was adopted in June 2019 as a consequence of the review of *Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety* (the EU's Regulation on General Food Law, hereinafter, GFL Regulation) under the EU regulatory fitness and performance program (hereinafter, REFIT). The REFIT programme is an EU initiative aimed at evaluating the performance of EU legislation and ensuring that it maximises the benefits for EU citizens and businesses, while minimising unnecessary burdens. The REFIT evaluation of the GFL Regulation found that risk communication, a fundamental part of the risk analysis principle together with the risk assessment and the risk management, was not sufficiently effective. The adoption of the Transparency Regulation followed, in particular, the controversy surrounding the (re-)evaluation of certain products, such as the herbicide *glyphosate*, which had a significant impact on consumers' confidence on the proper functioning of the risk analysis process. The Transparency Regulation amends the GFL Regulation and establishes new rules aimed at making the EU risk assessment for food safety more transparent and sustainable. Furthermore, the Transparency Regulation amends, *inter alia*, the EU legal framework regulating the placing on the EU market of novel foods in relation to the notification of studies commissioned by applicants, the introduction of a mechanism of pre-submission advice, the rules governing the confidentiality of the information contained in the scientific dossiers presented by manufacturers to the EFSA for assessment, and the submission of each application to a public consultation (see *Trade Perspectives*, Issue No. 22 of 29 November 2019) .

The new EU rules on novel foods

The placing on the EU market of novel foods is governed by *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, Novel Foods Regulation). Article 10 of the Novel Foods Regulation establishes that the procedure for authorisation of the placing on the EU market of a novel food starts with the submission of an application to the European Commission (hereinafter the Commission). The application will then be forwarded by the Commission to the EFSA, which will provide an opinion as to whether the novel food might have an adverse effect on human health. According to Article 12 of the Novel Foods Regulation, within seven months from the publication by the EFSA of an opinion, the Commission will submit to the EU's Standing Committee on Plants, Animals, Food and Feed a draft implementing act authorising the placing on the EU market of the new novel food.

With the aim of supporting applicants in the placing on the EU market of novel foods, the EFSA adopted, on 15 February 2021, an *Administrative Guidance* regarding the preparation of applications on novel foods pursuant to Article 10 of the Novel Foods Regulation. The document describes the requirements applying to novel foods applications following the modifications, *inter alia*, in the GFL Regulation and the Novel Foods Regulation on the basis of the new Transparency Regulation. From 27 March 2021, the new provisions will apply in the pre-submission phase and in the application procedure for novel foods. More specifically, the Transparency Regulation introduces a system of general pre-submission advice, the mandatory notification of information related to studies commissioned or carried out to support the applications, the public disclosure of the non-confidential version of the scientific dossiers submitted to the Commission in support of the applications, and a mechanism of public consultation for each submitted application.

The General Pre-Submission Advice

Article 32a(1) of the GFL Regulation, as amended by the Transparency Regulation, provides applicants with the possibility to request advice from the EFSA prior to the submission of an application with respect to certain rules of the application process. In that respect, the EFSA's *Administrative Guidance* recommends submitting the request for advice at least six months before the submission of the application and clarifies that the following items are outside of the scope of the general pre-submission advice procedure: "1*) the design of the studies to be submitted and questions related to hypotheses to be tested, unless the advice concerns guidance documents developed by EFSA in which study design is addressed; 2) risk management questions; and 3) any aspects going beyond the information available in the legislation, rules, guidance documents or guidelines applicable to the applications*". The system of pre-submission advice has reportedly been considered by the food industry as a useful improvement in the authorisation procedure, mainly for addressing problems related to the criteria to demonstrate the safety of the novel foods, which are considered too vague.

The EU database of studies

As regards the notification of the information related to studies commissioned or carried out to support applications in accordance with Article 32b to the GFL Regulation, the *Administrative Guidance* states that potential applicants, laboratories, and other testing facilities located in the EU have the obligation to notify to the EFSA the following information: "*1) title and scope of the study; 2) laboratory or testing facility carrying out the study; and 3) starting and planned completion dates of the study*". Notifications must be submitted to the common database of studies through EFSA's website. The EFSA's *Administrative Guidance* warns applicants that a justification must be provided in case of notifications submitted to the EFSA after the starting date of the study and that non-compliance with the obligations related to the notification of studies may result in a delayed EFSA opinion or in the invalidation of the application.

New rules on the confidentiality of information

In the effort of strengthening the transparency of the risk assessment, the new Article 32(b) of the GFL Regulation, as amended by the Transparency Regulation, introduces a general principle of transparency of information, studies, and data submitted to the EFSA for scientific evaluation. By way of derogation from this principle, the EFSA may grant confidential status to certain items of the application dossier at the request of the applicant. Applicants are required to submit requests for confidentiality supported by verifiable justification showing that the disclosure of the information may potentially harm their interests to a significant degree.

The food industry reportedly welcomed these new rules, noting that the protection of trade secrets is crucial to preserve innovation in the EU food chain. However, the disclosure of information does not imply permission for its re-use, reproduction or exploitation in breach of existing rules concerning intellectual property rights or exclusivity of data. A further layer of protection in that respect is assured by Article 26 of the Novel Foods Regulation, which protects proprietary data supporting the applications for a period of five years from the date of the authorisation.

Public consultations on the information contained in the application

In order to ensure access to all relevant scientific data on the novel food subject of each application, the EFSA is now required to launch a public consultation on its website to identify whether additional scientific data, studies and other information supporting the application is available. Relevant comments are to be considered during the risk assessment phase.

What lies ahead

Business operators wishing to submit applications for the placing on the EU market of novel foods are advised to seek legal advice when submitting an application to the Commission in order to correctly apply the advice provided by the EFSA *Administrative Guidance*. More specifically, they are advised to seek qualified guidance regarding the technical dossier in order to avoid unnecessary delays in obtaining authorisations and for purposes of defining the correct strategy for securing the protection of their commercial secrets. Interested stakeholders should also note that, after the entry into force of the Transparency Regulation, further updated *Administrative Guidance* documents will likely be issued by the EFSA for the submission of applications of other regulated products.

Recently Adopted EU Legislation

Trade Law

- *Council Decision (EU) 2021/524 of 22 March 2021 on the signing, on behalf of the Union, of the Agreement in the form of an Exchange of Letters between the European Union and the Islamic Republic of Pakistan pursuant to Article XXVIII of the General Agreement on Tariffs and Trade (GATT) 1994 relating to the modification of concessions on all the tariff-rate quotas included in the EU Schedule CLXXV as a consequence of the United Kingdom's withdrawal from the European Union*

- *Council Decision (EU) 2021/515 of 22 March 2021 on the signing, on behalf of the Union, of the Agreement in the form of an Exchange of Letters between the European Union and the Commonwealth of Australia pursuant to Article XXVIII of the General Agreement on Tariffs and Trade (GATT) 1994 relating to the modification of concessions on all the tariff-rate quotas included in the EU Schedule CLXXV as a consequence of the United Kingdom's withdrawal from the European Union*

- *Council Decision (EU) 2021/516 of 22 March 2021 on the signing, on behalf of the Union, of the Agreement in the form of an Exchange of Letters between the European Union and the Republic of Indonesia pursuant to Article XXVIII of the General Agreement on Tariffs and Trade (GATT) 1994 relating to the modification of concessions on all the tariff-rate quotas included in the EU Schedule CLXXV as a consequence of the United Kingdom's withdrawal from the European Union*

Customs Law

- *Commission Implementing Regulation (EU) 2021/521 of 24 March 2021 making specific arrangements to the mechanism making the exportation of certain products subject to the production of an export authorisation*

Food Law

- *Commission Implementing Regulation (EU) 2021/533 of 24 March 2021 amending Regulation (EC) No 1484/95 as regards fixing representative prices in the poultrymeat and egg sectors and for egg albumin*

Other

- *Corrigendum to Commission Implementing Regulation (EU) 2020/1812 of 1 December 2020 laying down rules on the online data exchange and the notification of EU type-approvals under Regulation (EU) 2018/858 of the European Parliament and of the Council (Official Journal of the European Union L 404 of 2 December 2020)*

Ignacio Carreño, Fabrizio De Angelis, Simone Dioguardi, Tobias Dolle, Michelle Limenta, Alya Mahira, Lourdes Medina Perez and Paolo R. Vergano contributed to this issue.

Follow us on twitter @FratiniVergano

To subscribe to *Trade Perspectives*©, please click here. To unsubscribe, please click here

FRATINIVERGANO specialises in European and international law, notably WTO and EU trade law, EU agricultural and food law, EU competition and internal market law, EU regulation and public affairs. For more information, please contact us at:

FRATINIVERGANO – EUROPEAN LAWYERS
Boulevard Brand Whitlock 144, 1200 Brussels, Belgium. Telephone: +32 2 648 21 61, Fax: +32 2 646 02 70. www.fratinivergano.eu

Trade Perspectives© is issued with the purpose of informing on new developments in international trade and stimulating reflections on the legal and commercial issues involved.
Trade Perspectives© does not constitute legal advice and is not, therefore, intended to be relied on or create any client/lawyer relationship.

To stop receiving *Trade Perspectives*© or for new recipients to be added to our mailing list, please contact us at TradePerspectives@fratinivergano.eu

Our privacy policy and data protection notice is available at http://www.fratinivergano.eu/en/data-protection/