FRATINIVERGANO
EUROPEAN LAWYERS
TRADE PERSPECTIVES©

Issue No. 23 of 17 December 2021

Season's Greetings

2021 has been another difficult year all over the world and our thoughts go to all those that have suffered personal or professional losses due to the *Covid-19* pandemic. All of us in the International Trade and Food Law practice of *FratiniVergano* would like to wish you, your colleagues and families all the best for a peaceful holiday season and for healthy and prosperous 2022.

We hope that you have enjoyed *Trade Perspectives*© in 2021 and that you have always found it stimulating and timely. As always, we have published a total of 23 issues and invested considerable time and energy in this undertaking. We have done it with our usual passion and drive, eager to play a small but constant role in protecting the multilateral trading system and the rule of law from the temptations of unilateralism and protectionism.

In the new year, we will continue with our editorial efforts, beginning with the publication of the next issue of *Trade Perspectives*© on 14 January 2022. *Trade Perspectives*© is circulated to thousands of recipients worldwide this fills us with pride, but also with a deep sense of commitment and discipline towards our readers' expectations.

Thank you for your interest in *Trade Perspectives*© and for helping us to make it a better and more useful tool of discussion. We look forward to hearing from you regularly and to another year of international trade and food law developments. You can follow us on *Twitter* *@FratiniVergano* and find all previous issues of *Trade Perspectives*© on our website at http://www.fratinivergano.eu/en/trade-perspectives.

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Addressing the '*weaponisation*' of trade: The European Commission publishes its Proposal against "*measure of economic coercion*" by third countries

On 8 December 2021, the European Commission (hereinafter, Commission) published its Proposal for a *Regulation on the protection of the Union and its Member States from economic coercion by third countries* (hereinafter, proposed Regulation). The proposed Regulation aims at deterring EU trading partners from using economic coercion to pursue their interests by putting at the Commission's disposal a number of tools to dissuade those third countries "*from engaging in economic coercion, in the first place, or to dissuade them from continuing the*

economic coercion, if economic coercion occurs". While the Commission hopes that the very existence of such '*anti-coercion*' instrument would already dissuade third countries from taking such steps, it would also allow the Commission to take significant countermeasures that might have important implications for international relations, as well as for businesses around the world.

Reacting to the 'weaponisation' of trade measures

The now proposed '*anti-coercion*' instrument has been on the legislative horizon for more than a year and follows developments in recent years that have seen trade policy becoming increasingly weaponised in the pursuit of other policy objectives. Reference can be made to the measures introduced by the previous US Administration establishing additional tariffs on steel and aluminium, supposedly for purposes of national security interests, and that were then used to negotiate bilateral solutions with certain trading partners (see *Trade Perspectives*, Issue No. 22 of 3 December 2021). Another example is the recent blockage of exports from Lithuania to China, which are perceived as being enacted in response to Lithuania's policies regarding Taiwan.

In the context of her 2020 State of the Union speech, the President of the Commission *Ursula von der Leyen* listed an "*Instrument to deter and counteract coercive actions by third countries*" under the "*Key new initiatives for 2021*" in her Letter of Intent to the President of the European Parliament and to the President of the Council of the EU. Subsequently, in the context of the EU's legislative process to update the EU's *Enforcement Regulation*, which enables the EU to suspend or withdraw concessions or other obligations under international trade agreements to respond to breaches by third countries of international trade rules, the European Parliament and a number of EU Member States had again voiced their concern with respect to the issue of economic coercion, which was shared by the Commission. These discussions led to the adoption of a *Joint Declaration of the Commission, the Council and the European Parliament on an instrument to deter and counteract coercive actions by third countries*. In their Joint Declaration, the Commission confirmed "*its intention to further examine a possible instrument, which could be adopted in order to dissuade or offset coercive actions by third countries and which would allow the expeditious adoption of countermeasures triggered by such actions*". In turn, the European Parliament and the Council of the EU "*committed to fulfil their institutional role as co-legislators and to consider the proposal in a timely manner, taking into account the Union's obligations under public international law and WTO law as well as relevant developments in international trade*".

The Commission's Proposal

In accordance with Article 2(1) of the proposed Regulation, this instrument would apply in case a third country: 1) "*interferes in the legitimate sovereign choices of the Union or a Member State by seeking to prevent or obtain the cessation, modification or adoption of a particular act by the Union or a Member State*"; 2) "*by applying or threatening to apply measures affecting trade or investment*". In simple terms, the proposed Regulation foresees a "*two-step response*" by the EU to instances of third country economic coercion: 1) Non-interventionist measures: Namely determining that a third country act falls within the scope of the Regulation, as well as making efforts to diplomatically engage with the third country; and 2) The adoption of countermeasures, as "*last resort*", which would have to comply with certain criteria and follow a defined procedure. More specifically, Articles 3 to 5 of the proposed Regulation detail the elements of the first step in the EU action.

Firstly, the Commission would assess the third country measure "*on its own initiative or following information received from any source*". As part of this assessment, the Commission must determine whether the conditions and criteria laid down in Article 2 of the proposed Regulation are met. Secondly, for such assessment, Article 2(2) of the proposed Regulation stipulates a number of criteria that must be taken into account, namely: *"(a) the intensity, severity, frequency, duration, breadth and magnitude of the third country's measure and the pressure arising from it*"; *"(b) whether the third country is engaging in a pattern of interference*

seeking to obtain from the Union or from Member States or other countries particular acts"; "*(c) the extent to which the third-country measure encroaches upon an area of the Union's or Member States' sovereignty*"; *"(d) whether the third country is acting based on a legitimate concern that is internationally recognised*"; and "*(e) whether and in what manner the third country, before the imposition of its measures, has made serious attempts, in good faith, to settle the matter by way of international coordination or adjudication, either bilaterally or within an international forum*". Only if those conditions are met, the Commission is allowed to proceed to the next step and issue a "*Decision determining whether the measure of the third country concerned meets the conditions set out in Article 2(1)*".

Following the determination that a third country measure constitutes a measure of economic coercion, the Commission is called upon to "*engage on behalf of the Union with the third country concerned, to explore options with a view to obtaining the cessation of the economic coercion*". Additionally, the Commission is also called upon to consult or cooperate with "*any other country affected by the same or similar measures of economic coercion*", which may involve coordination in relevant international *fora*.

In case the engagement with the third country has not led to the cessation of economic coercion or has not led to the reparation of the injury caused to the EU, and where "*action is necessary to protect the interests and rights of the Union and its Member States in that particular case*" and "*in the Union's interest*", as a second step and "*last resort*", the Commission is allowed to pursue a "*response measure*". Such response measure would be taken by means of an implementing act, allowing the Commission to act on its own, following the consultation of a committee composed of EU Member State representatives. Article 7 of the proposed Regulation lays down the specific rules and conditions that must be followed when adopting such "*response measures*". Annex 1 to the proposed Regulation provides an exhaustive list of measures that the Commission can take, including the suspension of tariff concessions, as well as the suspension of applicable international obligations related to a wide array of sectors, such as trade in goods, trade in services, public procurement, and intellectual property. Importantly, in addition to a measure that applies to the third country as a whole, the proposed Regulation provides that such measure can also apply with regard to specific natural or legal persons. Article 7 further defines a number of procedural aspects, requiring the Commission to notify the concerned third country of the implementing act and, continuing on the non-interventionist measures, to again offer a negotiated solution. The response measure is to apply until the third country ceases to apply economic coercion measures.

The response measure can be amended, suspended, and terminated in line with the relevant provisions under the proposed Regulation.

Successful dissuasion or negative side effects for businesses?

It remains to be seen whether or not the mere existence of the proposed Regulation would indeed dissuade and deter third countries for pursuing trade measures that the EU considers as economic coercion measures. It is clear that trade and trade policy have, in recent years, often been weaponised to pursue certain economic objectives and to '*incentivise*' or '*coerce*' trading partners to adopt a certain behaviour or policy. It may be questionable though that existing international legal frameworks, such as within the multilateral trading system under the World Trade Organization (hereinafter, WTO) or under preferential trade agreements, do not provide adequate means to address such measures. It appears that the EU intends to act quickly and unilaterally instead of relying on lengthy dispute settlement procedures within those multilateral or bilateral *fora*. Both the "*measures of economic coercion*" and the EU's "*response measures*" may be subject to scrutiny in light of the applicable WTO obligations and/or of the commitments under preferential trade agreements, likely triggering WTO dispute settlement proceedings or recourse to the dispute settlement mechanism under specific preferential trade agreements.

One aspect that should not be neglected in the debate about the proposed Regulation is the potential for significant impacts on businesses in the affected countries. In addition, in view of

today's globally interconnected supply chains, impacts could be felt also by EU businesses and businesses around the world. Recent trade measures have clearly demonstrated how trade disputes, which are confined to a specific sector, can, due to the adopted countermeasures and counterbalancing measures, suddenly affect completely unrelated business sectors. While the Commission's interest to act swiftly is comprehensible, which was again confirmed by European Commission Vice-President and European Commissioner for Trade *Valdis Dombrovskis* and the Chair of the European Parliament's Committee on International Trade *Bernd Lange*, a dedicated consultation mechanism to avoid important collateral negative impacts on EU businesses should also be part of the process.

A difficult legislative procedure ahead?

The Commission's Proposal is only the departure point of the EU legislative procedure, and it can be expected that substantial changes will be brought to the proposed legislation during the '*trilogue*' negotiations. While, as indicated in the *Joint Declaration*, the broader objectives of the Proposal appear to be supported by both the European Parliament and EU Member States, certain aspects are poised to be particularly controversial. Notably, the Commission has based its proposal on Article 207(2) of the Treaty on the Functioning of the European Union, which relates to measures defining the framework for implementing the EU's common commercial policy and legislation where the EU has exclusive competence. However, it appears that certain EU Member States consider that, in view of the potentially significant foreign policy implications, the decision-making for the "*response measures*" should follow the EU's regular approach on foreign policy matters, namely decision by unanimity of EU Member States. This would, notably, bring the anti-coercion response measures in line with broader foreign policy sanctions against third countries or individuals. Apart from such procedural questions, certain EU Member States also voiced their concerns regarding the implications of the proposed Regulations and the potential negative impacts on trade relations.

The proposed Regulation will now follow the EU's ordinary legislative procedure and will have to be agreed and adopted by the European Parliament and the Council of the EU. More specifically, the European Parliament and Council of the EU will now internally develop their respective positions, before entering into so-called '*trilogue'* negotiations with the assistance of the Commission. Until 8 February 2022, interested stakeholders can submit comments to the proposed Regulation, as part of the Commission's feedback period. Interested stakeholders in the EU and beyond should closely follow this legislative procedure, submit comments to the proposed Regulation, and engage in the appropriate *fora*.

The Government of Indonesia enacted a new regulation to facilitate import licensing through Indonesia's *National Single Window*

In order to reduce its import requirements, the Government of Indonesia issued *Ministry of Trade Regulation No. 20 of 2021* (hereinafter, *MOT Regulation No. 20/2021*), which was enacted on 1 April 2021, and which entered into force on 15 November 2021. This regulation revoked 39 import regulations that were related to the control and importation of strategic products, corresponding to 4,085 tariff headings under the harmonised system (HS). *MOT Regulation No. 20/2021* establishes a new import licensing system via the *Indonesia National Single Window System* (*i.e.*, *Sistem Indonesia National Single Window*, SINSW). However, some provisions of the new regulation appear to be causing confusion among importers and may be inconsistent with other regulations.

Overview of MOT Regulation No. 20/2021

MOT Regulation No. 20/2021 is part of the implementing regulations to *Law No. 11 of 2020 concerning Job Creation. MOT Regulation No. 20/2021* regulates, *inter alia,* the procedures for the issuance of import licenses. The three main changes brought about by *MOT Regulation No. 20/2021* are the following: 1) Export and import licensing will now be based on the

commodity balance; 2) Export and import applications must be made via an integrated *Single Submission System*; and 3) Introduction of the '*fictitious positive*' approval of import and export licensing, which means that import/export permits will automatically be issued 5 days after submission, unless they are expressly denied.

MOT Regulation No. 20/2021 also provides the following obligations for importers: 1) Importers must obtain a Business Registration Number (*i.e.*, *Nomor Induk Berusaha*, NIB) that is valid as an importer identification number (*i.e.*, *Angka Pengenal Importir*, API); 2) Importers must obtain a confirmation of Taxpayer Status (*i.e.*, *Konfirmasi Status Wajib Pajak*, KSWP); and 3) Importers must have access rights by registering through the SINSW.

Import licensing through the Indonesia National Single Window System *(SINSW)*

One of the important changes introduced by *MOT Regulation No. 20/2021* is the implementation of a *Single Submission System* for import licensing through the SINSW. Article 6(1) of *MOT Regulation No. 20/2021* stipulates that an application for an import license must be submitted electronically to the Ministry of Trade through the SINSW.

The SINSW is an electronic platform that integrates various systems and information related to the process of handling customs documents, quarantine documents, licensing records, port/airport documents, and other documents related to the exportation and importation of goods. It ensures data and information security and automatically integrates the information flows and processes among the internal systems of various authorities.

Indonesia's new import licensing system, carried out through the SINSW, integrates data between all relevant ministries and agencies, in order to avoid repetitions and duplications of permit-issuing procedures. For instance, INATRADE, which is the integrated trade system operated by Indonesia's Ministry of Trade, is now integrated into the SINSW system. Furthermore, in order to achieve greater convenience for applicants of import and export licenses, the *Single Submission System* also uses an electronic signature (digital signature) and barcode to guarantee the authenticity and security of data and information in the licensing document. Following the submission of an application, Indonesia's Ministry of Trade shall process the application and issue the import permit through the SINSW, based on the Commodity Balance. Indonesia's Commodity Balance refers to a list issued by the Government that provides the commodities that may be exported and imported. The data used for the commodity balance is determined through a coordination meeting organised by Indonesia's Coordinating Ministry for Economic Affairs, together with related ministries and institutions. The list of commodities established at the coordination meeting is made available on the SINSW.

The utilisation of the SINSW is also part of Indonesia's commitment in the context of the Association of Southeast Asian Nations (hereinafter, ASEAN) Single Window (hereinafter, ASW), which is a regional electronic platform that facilitates ASEAN economic integration by allowing ASEAN Member States to electronically exchange border trade-related documents and information. The ASW connects and integrates the National Single Windows of all ASEAN Member States.

Start-up difficulties or inherent problems?

On 23 November 2021, Indonesia's Ministry of Trade conducted an event to familiarise importers with *MOT Regulation No. 20/2021*. Importers mostly inquired about the technical incompleteness of the system, as some options still need to be added into the system, technical problems exist (*e.g.,* difficulty to log in or to create a new account), and certain issues regarding the submission of applications affect the usage. These technical issues mainly occurred during the initial implementation stage and Indonesia's Minister of Trade clarified that there had indeed been technical problems related to the system's integration with pre-existing platforms. More specifically, some of the data submitted through the SINSW system did not match the elements in the INATRADE system. Consequently, this caused the submitted import

license applications to be unable to be forwarded to the INATRADE system and they could not be further processed by the Ministry of Trade. Reportedly, more than 2,000 applications for import and export approval permits were unable to be processed by the system. Indonesia's Ministry of Trade and the National Single Window Agency (*i.e.*, *Lembaga National Single Window*, LNSW) are reportedly working to resolve these technical start-up glitches so as not to continue affecting trade.

Inconsistency of import licensing requirements leading to legal uncertainty for importers

Even though *MOT Regulation 21/2021* aims at facilitating imports and exports through the new licensing system via the SINSW, some importers noted that there were overlapping regulations, leading to uncertainties with respect to the importation of certain products. For instance, with respect to the importation of garlic, the Head of the *Indonesian Garlic and Vegetable Tuber Business Actors (Pusbarindo), Pak Valentino*, noted that there remained dual and conflicting rules. More specifically, *Ministry of Agriculture Regulation No. 15 of 2021 concerning Standards for Business Activities and Product Standards in the Implementation of Risk-Based Business Licensing in the Agricultural Sector* provides that the *Recommendation for Import of Horticultural Products* (*i.e.*, *Rekomendasi Impor Produk Hortikultura*, RIPH), a written statement confirming that the horticultural product meets the administrative and technical requirements, is one of the documents that must be submitted for the issuance of an import approval. However, *MOT Regulation No. 20/2021* does not list the RIPH as one of the requirements for the issuance of an import approval for garlic.

In this context, the *Indonesian National Importers Association* (GINSI) urged Indonesia's Ministry of Trade to clarify *MOT Regulation No. 20/2021,* in order to address the procedural inconsistency and to avoid confusion among importers. The *Indonesian National Importers Association* considers that the Ministry of Trade must ensure that the SINSW is adequately configured and does not cause any problems for importers during the application process. The Acting Director-General of Foreign Trade within Indonesia's Ministry of Trade, *Indrasari Wisnu,* stated that licensing issues were not caused by regulatory problems, but that the *Single Submission System* is still new for importers, which led to the confusion. However, the possible instances of inconsistency between *MOT Regulation No. 20/2021* and *Ministry of Agriculture Regulation No. 15 of 2021* were also raised at the event on 23 November 2021 and representatives from Indonesia's Ministry of Trade noted that the Ministry would clarify these issues.

Outlook

As *MOT Regulation No. 20/2021* only recently entered into force, it remains to be seen how this regulation would affect imports in the upcoming years and whether it will indeed facilitate trade. Further clarifications and awareness-raising for the new system are still needed in order to avoid confusion among importers. Given the possible inconsistencies vis-à-vis other regulations, Indonesia's Ministry of Trade should further clarify those provisions in *MOT Regulation 20/2021,* so as to avoid confusion and legal uncertainties for traders. Businesses in Indonesia and their global trading partners should make use of the new system and flag any problems to the relevant Government agencies.

After introducing allergen labelling for pre-packed foods for direct sale, the UK is considering standardised '*precautionary*' allergen labelling

On 6 December 2021, the UK's Food Standards Agency (hereinafter, FSA) has launched a consultation to gather views from businesses and consumers on the use of '*precautionary*' allergen information and labels, often indicated with statements such as "*may contain...*". In addition, since 1 October 2021, the so-called *Natasha*'s law applies in the UK, introducing allergen labelling for pre-packed foods for direct sale (hereinafter, PPDS). In the EU, there are no harmonised rules on allergen labelling for PPDS. In case the UK also adopted specific rules

on '*precautionary*' allergen labelling, it would be the second field of regulation in which different rules on food information on allergenic ingredients apply in the EU and in the UK following '*Brexit*'. This article compares the UK legislation and the FSA initiative with the current regulatory framework in the EU.

*'*Precautionary*' allergen labelling (PAL)*

Further to the intended presence of ingredients that are allergens, the realities of food production cannot avoid the unintended presence of allergens, which can pose a risk to susceptible people. Allergenic substances may be inadvertently present in food products, due to cross-contamination during transport, storage, or processing. Precautionary and voluntary allergen labelling has evolved as a tool for food manufacturers to communicate to consumers that certain allergens could be present unintendedly. This is increasingly communicated on pre-packaged foods by statements like "*may contain…*" or "*produced in a factory which uses...*" or "*produced on shared equipment…*". '*Precautionary*' allergen labelling may, however, not give a clear indication to consumers of what the precise risk is. Food manufacturers, control authorities and regulators know that the allergen is not always present in the finished product, nor is it necessarily present at a consistent level throughout the production batch, production run, or even in the individual product. In some EU Member States and in the UK, regulatory agencies (*e.g.*, the Danish Veterinary and Food Administration and the UK Food Standards Agency) have advised businesses that precautionary allergen labelling should only be applied following a thorough risk assessment, rather than being used as an automatic default position (see *Trade Perspectives*, Issue No. 18 of 6 October 2017).

The regulation of allergen labelling in the EU and the UK

For many years, EU and UK legislation require that food manufacturers declare the use of major allergenic foods and ingredients on their product labels. The first harmonised EU rules on the labelling of food allergens were established by *Directive 2003/89/EC of the European Parliament and of the Council as regards indication of the ingredients present in foodstuffs*, which introduced Annex IIIa to *Directive 2000/13/EC on the labelling and presentation of foods*. The rules entered into effect in 2005 (see *Trade Perspectives*, Issue No. 1 of 9 January 2015). *Regulation (EU) No. 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers* (hereinafter, the FIR) then replaced *Directive 2000/13/EC* and set out rules relating to ingredients that can cause food allergies and/or intolerances. Annex II to the FIR lists the substances or products causing allergies or intolerances: 1) Cereals containing gluten; 2) Crustaceans; 3) Eggs; 4) Fish; 5) Peanuts; 6) Soybeans; 7) Milk; 8) Nuts; 9) Celery; 10) Mustard; 11) Sesame seeds; 12) Sulphur dioxide; 13) Lupin; and 14) Molluscs. The name of the substance or product as listed in Annex II is to be emphasised in the list of ingredients of pre-packed foods through a typeset that clearly distinguishes it from the rest of the list of ingredients, for example by means of the font, style, or background colour.

The FIR defines '*prepacked food*' as "*any single item for presentation as such to the final consumer and to mass caterers, consisting of a food and the packaging into which it was put before being offered for sale, whether such packaging encloses the food completely or only partially, but in any event in such a way that the contents cannot be altered without opening or changing the packaging; 'prepacked food' does not cover foods packed on the sales premises at the consumer's request or prepacked for direct sale*". Adopted before '*Brexit*', the *Food Information Regulations 2014 (S.I. 2014/1855)* transposed the allergen food information requirements of the FIR into UK law and still applies.

*Applicable legal framework to '*precautionary*' allergen labelling (PAL)*

In the EU, there is currently no specific legislation that determines when precautionary allergen labelling (hereinafter, PAL) should or must be provided. In general, food safety in the EU is regulated by *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* (General Food Law Regulation, or GFL). Article 14 of the GFL provides that food must not be placed on

the market if it is '*injurious to health*'. In determining whether any food is injurious to health, according to Article 14(4)(c) of the GFL, regard shall be given, *inter alia*, to the particular health sensitivities of a specific category of consumers. However, according to researchers, the "*amount of an allergen which is considered to be injurious to health is an area of uncertainty and inconsistency, due to the lack of consensus on agreed reference doses on which actions can be based to drive labelling decisions*". Article 36 of the FIR sets out a framework, which can be used to implement a comprehensive, consistent, and science-based approach to PAL. According to Article 36(2)(c) of the FIR, the European Commission (hereinafter, Commission) has the option to introduce, by means of an implementing act, new rules on the following voluntary information: "*information on the possible and unintentional presence in food of substances or products causing allergies or intolerances*". As a general rule, Article 36(2) of the FIR provides that food information provided on a voluntary basis must meet the following requirements: 1) It must not mislead the consumer; 2) It must not be ambiguous or confusing for the consumer; and 3) It must, where appropriate, be based on the relevant scientific data.

UK consultation on '*precautionary*' allergen labelling

The FSA notes that recent studies have found that people who live with food allergies, intolerances, or coeliac disease appreciate precautionary allergen information or labelling. At the same time, the FSA states that consumers can be confused by the range of precautionary labelling statements on pre-packed foods, such as chocolate bars, biscuits, and other products sold in supermarkets, where the wording can differ between products, and it may not be clear precisely what the risk is. The purpose of the FSA's consultation is, therefore, to seek feedback on the issues faced by interested parties so that the information is: 1) Communicated "*more clearly and consistently, in an understandable and meaningful way to consumers, in terms of the form and content of the information*"; and 2) Based on proportionate and standardised processes "*for assessing, managing, and communicating the risk of allergen cross-contamination by food businesses*". The FSA notes that precautionary allergen information is difficult for both businesses and for the local authorities responsible to enforce the law.

Precautionary allergen labelling only after a thorough risk assessment

It is important to note that the application of PAL should only be made after a thorough risk assessment has been performed and if it is considered that there is a real risk to the food-allergic or food-intolerant consumer. The use of PAL, when there is not a real risk, could be considered as misleading. Reportedly, there is evidence demonstrating that there is limited or no correlation between such warnings and the actual risks. Many products with zero or negligible risk carry warnings, and products without warnings sometimes contain high levels of allergens.

The EU currently has no harmonised quantitative criteria or benchmarks for PAL in foods or drinks, meaning that EU Member States are free to carry out their own risk assessments and set their own benchmarks for risk levels that must be labelled. According to a '*non-paper*' on *Precautionary Allergen Labelling (PAL): a science-based approach based on Quantitative Risk Assessment* (*i.e.*, Version 2 of January 2021 thereof) by *FoodDrinkEurope*, which is the trade association representing Europe's food and drinks producers, there is mounting evidence that PAL is increasingly losing credibility among stakeholders, including critically those for whom it is primarily intended (*i.e.,* allergic consumers). In its summary recommendations on PAL, *FoodDrinkEurope* calls for a defined framework for the application of PAL that meets the requirements of Article 36(2) of the FIR. It should be clear (*i.e.*, a single statement with a single meaning, easy to translate into EU languages, *i.e.*, "*may contain [allergen]*"); and not misleading (*i.e.*, PAL should only be applied where a defined, appreciable risk has been identified through a quantitative risk assessment).

FoodDrinkEurope further requests that the framework be based on relevant scientific data and that the "*Voluntary Incidental Trace Allergen Labelling (VITAL®) system*" be identified as the most fully elaborated system, since it has been subjected to extensive peer review and has also been recognised by several European national authorities (such in France and in the UK).

FoodDrinkEurope suggests that it should be taken into account that analytical methods have limitations with regard to sensitivity and accuracy, and that quantitative benchmarks (*i.e.*, reference doses) require the development of capable protocols and methodologies. In addition, consumers need to be informed, using multiple channels of communication, such as websites, customer care lines, etc. (*i.e.*, not just through labelling), that products have undergone a risk assessment and that the presence or absence of the PAL is a consequence of that process.

Natasha's law on allergen labelling for pre-packed foods for direct sale (PPDS) in the UK

In the UK, the *Food Information (Amendment) (England) Regulations 2019* introduced a new regulation 5A, providing that food that is pre-packed for direct sale, whether supplied to a final consumer or to a mass caterer, must have a list of ingredients provided directly on the package or on a label attached to the package. Also known as '*Natasha's Law*', the changes were made following the death of a teenager named Natasha from an allergic reaction caused by a pre-packed sandwich which, at the time, did not require allergen labelling. These Regulations came into force on 1 October 2021 and any food business selling PPDS foods in the UK is now required to provide a full ingredients list on the product label with allergenic ingredients emphasised within that list.

In the EU, the FIR only partially harmonised mandatory allergen information for non-prepacked food in Article 44, which states that "*1. Where foods are offered for sale to the final consumer or to mass caterers without prepackaging, or where foods are packed on the sales premises at the consumer's request or prepacked for direct sale: (a) the provision of the particulars specified in point (c) of Article 9(1) is mandatory;(…) 2. Member States may adopt national measures concerning the means through which the particulars or elements of those particulars specified in paragraph 1 are to be made available and, where appropriate, their form of expression and presentation*". The *Commission Notice of 13 July 2017 relating to the provision of information on substances or products causing allergies or intolerances as listed in Annex II to Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers* clarifies that EU Member States remain competent to adopt national provisions on the means through which allergen information is to be made available on such foods: "*In principle all means of communication as regards the provision of allergen information, are allowed to enable the consumer to make an informed choice, e.g. a label, other accompanying material, or any other means including modern technology tools or verbal communication (i.e. verifiable oral information)*". In the absence of those national measures, the provisions of the FIR concerning pre-packed food are applicable to non-pre-packed food. Accordingly, in accordance with Article 13 of the FIR, the information about allergens must be easily visible, clearly legible and, where appropriate, indelible and provided in a written form. The Commission's Notice concludes that "*it is not possible to provide allergen information only upon request by the consumer*".

Outlook and conclusion

After introducing allergen labelling for pre-packed foods for direct sale (PPDS), the UK is considering standardised '*precautionary*' allergen labelling (PAL). The consultation by the UK FSA is open until 14 March 2022. Within three months of a consultation ending, the FSA aims at publishing a summary of the responses received. Interested parties should consider participating in the consultation and should closely monitor any developments and the potentially upcoming regulatory initiatives on PAL in the EU, in order to ensure that their legitimate interests are duly taken into account.

Recently adopted EU legislation

Trade Law

- *Council Decision (EU) 2021/2234 of 29 November 2021 on the conclusion, on behalf of the Union, of the Agreement in the form of an Exchange of Letters between the European Union and 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*

- *Agreement in the form of an Exchange of Letters between the European Union and 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*

- *Commission Implementing Regulation (EU) 2021/2240 of 15 December 2021 amending Annexes V and XIV to Implementing Regulation (EU) 2021/404 as regards the entries for the United Kingdom in the lists of third countries authorised for the entry into the Union of consignments of poultry, germinal products of poultry and fresh meat of poultry and game birds (1)*

Trade Remedies

- *Commission Implementing Regulation (EU) 2021/2239 of 15 December 2021 imposing a definitive anti-dumping duty on imports of certain utility scale steel wind towers originating in the People's Republic of China*

Customs Law

- *Commission Implementing Regulation (EU) 2021/2246 of 15 December 2021 amending Implementing Regulation (EU) 2019/1793 on the temporary increase of official controls and emergency measures governing the entry into the Union of certain goods from certain third countries implementing Regulations (EU) 2017/625 and (EC) No 178/2002 of the European Parliament and of the Council (Text with EEA relevance)*

Food Law

- *Commission Delegated Regulation (EU) 2021/2244 of 7 October 2021 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with specific rules on official controls as regards sampling procedures for pesticides residues in food and feed (1)*

- *Commission Delegated Regulation (EU) 2021/2245 of 12 October 2021 amending Delegated Regulation (EU) 2017/891 as regards the calculation of the value of marketed production of producer organisations in the fruit and vegetable sector*

- *Commission Implementing Regulation (EU) 2021/2247 of 15 December 2021 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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