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Another hit for EU-US trade – A WTO arbitrator allows the US to impose countermeasures against the EU in the amount of USD 7.5 billion per year

On 2 October 2019, the World Trade Organization (hereinafter, WTO) published the decision by the WTO arbitrator regarding the level of authorised countermeasures that the US may request with respect to the EU and certain EU Member States in relation to the case of *European Communities and Certain Member States — Measures Affecting Trade in Large Civil Aircraft* (DS316). The WTO arbitrator concluded that "*the level of countermeasures "commensurate with the degree and nature of the adverse effects determined to exist" during the 2011-2013 Reference Period amounts to USD 7,496.623 million per annum*", the highest arbitration award in the history of the WTO. The US already announced that it would implement tariffs on a multitude of products originating in the EU, or certain EU Member States, from 18 October 2019. Unrelated to other tariffs introduced by the US Administration in recent times, such as for aluminium and steel, this decision could further complicate the already strained EU-US trade relations and have strong implication for businesses in both the EU and the US.

This decision is perhaps the first climax of the two longstanding trade disputes over subsidies to airplane manufacturers *Airbus* and *Boeing* by the EU and the US, respectively. The disputes have been ongoing since 2004 and have since occupied adjudicators at all stages of WTO dispute settlement. Both disputes have now reached their respective final stages and, accounting for the fact that the WTO determined that both sides did not entirely comply with the rulings, WTO arbitrators have been tasked to determine the rights of the EU and the US to impose countermeasures on each other's products.

In this long-standing case, whose original request for consultations dates back to 6 October 2004, the US had claimed that certain subsidies paid to aircraft manufacturer *Airbus* for the production of the Airbus A350 and A380 passenger aircraft were inconsistent with the EU's obligations under the WTO Agreement on Subsidies and Countervailing Measures (hereinafter, SCM Agreement) and the General Agreement on Tariffs and Trade (GATT) 1994. On 18 May 2011, the WTO Appellate Body upheld the Panel's finding that certain subsidies provided by the EU and certain EU Member State Governments, namely France, Germany, Spain, and the UK, to *Airbus* were incompatible with Article 5(c) of the SCM Agreement because they had caused serious prejudice to the interests of the US. The dispute did not end there, as the US followed-up, in December 2011, by requesting a compliance panel on the

basis of Article 21.5 of the WTO Dispute Settlement Understanding (hereinafter, DSU), alleging the failure by the EU and the respective EU Member States to implement the recommendations and rulings adopted by the DSB, as well as a request for countermeasures under Article 22 of the DSU. The compliance panel report was published in 2016, finding that the EU and the respective EU Member States did indeed fail to implement the recommendations and rulings of the DSB to bring their measures into conformity with their obligations under the SCM Agreement. On 28 May 2018, the Compliance Appellate Body report was adopted by the DSB. The Compliance Appellate Body upheld, albeit for different reasons, the Panel's conclusions that the EU and certain EU Member States had "*failed to comply with the DSB recommendations and rulings*".

In parallel to the compliance proceedings, the US had requested, on 9 December 2011, authorisation by the DSB to take countermeasures under Article 22 of the DSU and Article 7.9 of the SCM Agreement. At a meeting of the DSB on 22 December 2011, the EU objected to the level of suspension of concessions or other obligations contained in the US' request and claimed that the principles and procedures set forth in Article 22.3 of the DSU had not been followed. The EU requested that the matter be referred to arbitration under Article 22.6 of the DSU. In January 2012, in view of the compliance proceedings, the US and the EU requested the arbitrator to suspend its work. Shortly after the decision of the Compliance Appellate Body, the US resumed its pursuit of authorisation for countermeasures. On 13 July 2018, the US requested the resumption of the work by the arbitrator, who has now reached a decision.

Article 22.4 of the DSU provides that the *"level of the suspension of concessions or other obligations authorized by the DSB shall be equivalent to the level of the nullification or impairment*". The decision of the arbitrator is three-fold, concluding that: 1) With reference to Articles 7.10 of the SCM Agreement, and Article 22.6 of the DSU, the level of countermeasures "*commensurate with the degree and nature of the adverse effects determined to exist*" during the 2011-2013 Reference Period amounted to USD 7,496.623 million per annum; 2) With reference to Article 22.3 of the DSU, the EU had not demonstrated that the US failed to follow the principles and procedures provided in Article 22.3 of the DSU in determining that it is not practicable or effective to suspend concessions or other obligations in trade in goods and that the circumstances are serious enough; and 3) With reference to Article 22.5 of the DSU, the EU had not demonstrated that the countermeasures proposed by the US are not allowed under the covered agreements at issue, namely the GATT and the General Agreement on Trade in Services. Finally, the decision states that these "*countermeasures may take the form of (a) suspension of tariff concessions and related obligations under the GATT 1994, and/or (b) suspension of horizontal or sectoral commitments and obligations contained in the United States' services schedule with regard to all services defined in the Services Sectoral Classification List, except for financial services*".

In recent months, the US had already prepared for this decision, working on a list of products that would be considered for additional tariffs. On 12 April 2019, the Office of the US Trade Representative (hereinafter, USTR) had published a preliminary list of products to be considered for inclusion on a final list of products that could be subject to additional *ad valorem* duties of up to 100%. In this first list, the US envisaged, *inter alia*, additional duties on EU's agro-food products, as well as on various metals, but also on products such as aircraft, helicopters, and handbags. A public hearing was held on 15 and 16 May 2019, at which more than 40 individuals provided their testimony. Additionally, more than 600 written submissions were filed. A number of public comments submitted in response to the notice of 12 April 2019 requested the USTR to consider additional products that were not included in the initial list for possible inclusion on the final list of products to be subject to additional duties. Thus, on 1 July 2019, the USTR proposed an additional list of products, which included further meat and dairy products, certain fruits and wine, and a number of chemical substances. A hearing on the supplemental list was held on 5 August 2019.

Before any tariffs may be imposed, the DSB will have to formally adopt the arbitrators' decision. Having anticipated the decision, on the same day that it was published, the USTR already requested that the WTO schedule a meeting on 14 October 2019 to approve a US request for

the authorisation to take countermeasures and announced that additional tariffs would be applied from 18 October 2019. Article 22.7 of the DSU provides that the DSB is to "*be informed promptly of the decision of the arbitrator and shall upon request, grant authorization to suspend concessions or other obligations where the request is consistent with the decision of the arbitrator, unless the DSB decides by consensus to reject the request*". The US also published the list of products that would be subject to additional tariffs. The list differentiates significantly between EU Member States, with tariffs on certain products only applicable to products from those EU Member States at which the WTO complaint had been addressed. In general terms, the additional tariffs will amount to 10% on large civil aircraft and to 25% on certain other products, clearly targeting certain specialty products. More specifically, the additional duties of 25% will, *inter alia*, affect Single-malt (or straight) Irish and Scotch Whiskies, as well as clothing products from the UK, tools and machinery from Germany, a variety of agro-food products from France, Germany, Spain and the UK (such as olives and wine). A number of cheeses, other dairy products (such as parmesan and pecorino cheese), as well as fruits, meat, and fish products, from all EU Member States will also be subject to the tariffs. As these examples show, the additional tariffs will not be limited to the aviation industry, but also concern other sectors and products.

Prior to the decision, the EU had continued efforts to reach a negotiated solution. European Commissioner for Trade *Cecilia Malmström* noted that, in July, the EU had shared "*concrete proposals*" with the US for a new regime on aircraft subsidies, and a way forward on existing compliance obligations on both sides, pointing out that, so far, the US had not reacted to the EU's proposals. It appears that the US preferred to first await the decision. In response to the arbitrator's decision, USTR *Robert Lighthizer* stated that the US now expects "*to enter into negotiations with the European Union aimed at resolving this issue in a way that will benefit American workers*", underlining that the US has the authority to increase the tariffs at any time, or change the affected products.

Importantly, there is no further recourse available to the decision of the arbitrator. Article 22.7 of the DSU provides that the parties are to "*accept the arbitrator's decision as final and the parties concerned shall not seek a second arbitration*". Also noteworthy is that, according to Article 22.8 of the DSU, the suspension of concessions or other obligations is only to be temporary and is only to be applied until such time as the measure found to be inconsistent with a covered agreement has been removed, or the respective WTO Member that must implement recommendations or rulings provides a solution to the nullification or impairment of benefits, or a mutually satisfactory solution is reached. Still, there is no specific time limit to the countermeasures, and all depends on the negotiations to be conducted between the EU and the US.

The EU also already prepared a preliminary list of products originating in the US that could be subject to additional duties when imported into the EU and once the WTO arbitrators have reached decision in the parallel case on *United States — Measures Affecting Trade in Large Civil Aircraft*. The list contains a number of agro-food products (*e.g.*, fish, fruit and vegetables, nuts, a multitude of processed food products, as well as wine and spirits), certain chemical substances, machinery, as well as playing cards and video game consoles. The decision by the WTO arbitrators in the parallel case is not expected until the Spring of 2020. With this decision still months away, the EU is reportedly reviewing earlier WTO cases in which the EU had been authorised to impose tariffs on goods originating in the US.

The authorisation of countermeasures is a rare occurrence in the history of the WTO, as trading partners typically pursue negotiated solutions to avoid the cascade of consequences of additional tariffs, or do not actually exercise their rights granted by WTO arbitrators. While addressed at products originating in the respective trading partner, the imposition of such additional tariffs can also have important domestic implications. Importers of EU products in the US, including US airlines that purchase and import Airbus aircraft, reportedly already urged the US Government to be sensitive of the US' own interests and to avoid "*collateral damage*" to the US economy.

Highly integrated global supply chains make businesses increasingly dependent on seamless trade. Businesses must monitor any development that could affect their supply chains, as trade measures, such as the forthcoming additional tariffs, as well as any new restrictive or discriminatory non-tariff measures, that could significantly disrupt trade flows and/or prove very costly for businesses and consumers around the world, are being proposed or adopted/applied. At the same time, if timely and properly addressed with the competent authorities, who may be unaware of the implications for certain sectors, such negative implications can often be avoided or mitigated. The decision on countermeasures in the *Airbus* case and the forthcoming tariffs will add to the tension in EU-US trade policy. Resolving this issue will likely become one of the first priorities of the incoming European Commissioner for Trade, *Phil Hogan*, when he takes office on 1 November 2019.

Low level of compliance before the new EU regulatory framework on medical devices comes into effect in May 2020 – A risk of critical shortages?

On 5 April 2017, the EU published *Regulation (EU) 2017/745 of 5 April 2017 of the European Parliament and of the Council on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC* (hereinafter, *Regulation on medical devices* or MDR) and *Regulation (EU) 2017/746 of 5 April 2017 of the European Parliament and of the Council on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU* (hereinafter, *Regulation on in vitro diagnostic medical devices* or IVDR), which entered into force on 25 May 2017 and will progressively replace the existing three directives on medical devices. The Regulation on medical devices will become fully applicable on 26 May 2020 and the Regulation on *in vitro* diagnostic medical devices on 26 May 2022. During the current transition period of three years for the MDR and of five years for the IVDR, manufacturers are still allowed to place devices on the market under both the currently applicable directives, as well as under the new regulations. According to a survey by the *Regulatory Affairs Professionals Society* (hereinafter, RAPS) and the tax, audit, and advisory firm *KPMG LLP*, only 27% of respondents said they would be fully compliant on 26 May 2020. The industry faces a fast-approaching deadline for compliance, which could result in a shortage of medical devices on the EU market.

In September 2019, European Commission (hereinafter, Commission) President-elect *Ursula von der Leyen* unveiled her new team of Commissioners-designate, including the addition of *Stella Kyriakides* to lead the health portfolio. In her mission letter to Commissioner-designate *Kyriakides*, President-elect *von der Leyen* noted that she wanted her to focus on the effective implementation of the new regulatory framework on medical devices, in order to protect patients and ensure that it addresses new and emerging challenges. *Von der Leyen* also announced a major shift, namely that the relevant part of Unit D.4 responsible for '*Health Technology and Cosmetics*' within the Commission's Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW) dealing with medical devices would move from DG GROW to the Commission's Directorate General for Health and Food Safety (DG SANTE).

'*Medical device*' is defined in Article 2(1) of the MDR as any instrument, apparatus, appliance, software, implant, reagent, material, or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes: 1) Diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease; 2) Diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability; 3) Investigation, replacement or modification of the anatomy or of a physiological or pathological process or state; and 4) Providing information by means of *in vitro* examination of specimens derived from the human body, including organ, blood and tissue donations; and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means. Medical devices include products, such as sticking plasters, contact lenses, dental

filling materials, x-ray machines, pacemakers, breast implants, or hip replacements. IVDs include products, such as devices used to ensure the safety of blood transfusion, detect infectious diseases (*e.g.*, HIV), monitor diseases (*e.g.*, diabetes), and perform blood chemistry (*e.g.*, cholesterol measurement). Medical devices should not be mistaken for medicinal products (often referred to as pharmaceuticals), which are subject to a separate EU regulatory framework. The main difference between medical devices and medicinal products is the principal mode of action, which is typically physical for a medical device (*inter alia*, mechanical action, physical barrier, replacement of or support to organs or body functions).

The reasons for the recast of the EU regulatory framework on medical devices in 2017 were four-fold: 1) There had been a major technological and scientific progress in the past years; 2) EU Member States do not always interpret and implement the current rules (set out in directives and not in directly applicable regulations) in the same way; 3) It is not always possible to trace medical devices back to their supplier (*i.e.*, rules on traceability are needed), and 4) Supervision of the independent conformity assessment bodies (the so-called '*notified bodies*') by EU Member States needs to be strengthened to ensure that all bodies have the necessary competence to carry out the pre-market assessment of medical devices. The circumstance that EU Member States appear to interpret and implement the current rules in different ways appears to have led to varying levels of patient and public health protection in the EU, also creating obstacles to the Single Market and reducing the benefits economic operators could obtain.

While the requirements of the three existing directives on medical devices were transferred to the new regulations, the MDR imposes additional requirements and stricter standards on medical device manufacturers and broadens the scope of product coverage. For example, Article 6 of the MDR covers medical devices, which are sold by distance sales (*e.g.*, online). In addition, the IVDR clarifies the scope with respect to genetic tests, companion diagnostics and diagnostic services offered at a distance. Compared with existing rules, the MDR reclassifies certain types of medical devices (*e.g.*, medical device standalone software) under stricter classification rules.

The new regulations contain a series of important improvements to modernise the current framework, including: 1) A stricter *ex-ante* control for high-risk devices via a new pre-market scrutiny mechanism with the involvement of a pool of experts at EU level; 2) The reinforcement of the criteria for designation and processes for oversight of notified bodies; 3) The inclusion of certain aesthetic devices that present the same characteristics and risk profile as analogous medical devices under the scope of the regulations; 4) A new risk classification system for *in vitro* diagnostic medical devices in line with international guidance; 5) An improved transparency through a comprehensive EU Database on Medical Devices (*i.e.*, Eudamed) and a device traceability system based on unique device identification (hereinafter, UDI); 6) The introduction of an '*implant card*' for patients containing information about implanted medical devices; 7) The reinforcement of the rules on clinical evidence, including an EU-wide coordinated procedure for authorising multi-centre clinical investigations; 8) The strengthening of post-market surveillance requirements for manufacturers; 9) An improved coordination mechanisms between EU countries in the fields of vigilance and market surveillance; and 10) The appointment by manufacturers of a person responsible for regulatory compliance.

On medical device traceability, to ensure identification within the supply chain, for medical devices, other than custom-made or investigational devices, economic operators are to be able to identify the following: 1) Any economic operator to whom they have supplied a device; 2) Any economic operator that has supplied them with a device; and 3) Any health institution or healthcare professional to whom they have supplied a device. The UDI system must allow the identification and traceability of devices. In this context, on 6 June 2019, the Commission adopted *Implementing Decision (EU) 2019/939 of 6 June 2019 designating issuing entities designated to operate a system for the assignment of Unique Device Identifiers (UDIs) in the field of medical devices*.

Medical devices are regulated by national competent authorities, but the European Medicines Agency (hereinafter, EMA) is also involved in the assessment of certain categories of medical devices. Medical devices in the EU have to undergo a conformity assessment to demonstrate that they meet legal requirements to ensure they are safe and perform as intended. EU Member States may designate accredited notified bodies to conduct conformity assessments. The conformity assessment usually involves an audit of the manufacturer's quality system and, depending on the type of device, a review of technical documentation from the manufacturer on the safety and performance of the device. Once a medical device has passed a conformity assessment, manufacturers may affix a CE (*i.e.*, *Conformité Européenne*) mark thereto. The MDR and the IVDR will change the EU legal framework for medical devices, introducing new responsibilities for the EMA and for national competent authorities.

Notified bodies must assess medical devices before they may be marketed. A notified body is an organisation designated by an EU Member State to assess the conformity of certain products before being placed on the market, when the applicable legislation requires a third-party assessment. It is the responsibility of the respective EU Member State to notify conformity assessment bodies within their jurisdiction according to principles laid down in *Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products*. Notified bodies are free to offer their conformity assessment services to any economic operator inside or outside the EU. *Inter alia*, notified bodies may carry out these activities on the territory of other EU Member States or non-EU countries; they must operate in a non-discriminatory, transparent, neutral, independent, and impartial manner; they must make adequate arrangements to ensure the confidentiality of the information obtained in the course of conformity assessment; and they must provide information to their notifying authority, the market surveillance authorities, and other notified bodies. Manufacturers are free to choose any notified body that has been legally designated to carry out the conformity assessment procedure. The Commission publishes a list of such notified bodies.

Unlike under the current framework for medical devices, there are currently only four notified bodies designated under the new rules (*i.e.*, the UK's *BSI Assurance UK Ltd*, Germany's *DEKRA Certification GmbH*, Italy's *IMQ Istituto Italiano del Marchio di Qualità S.P.A.*, and Germany's *TÜV SÜD Product Service GmbH Zertifizierstellen*). Reportedly, an expert from a notified body stated that, even if the Commission designated 20 notified bodies by May 2020, the workload would not be manageable. Furthermore, the expert noted that Commission guidance documents were adding requirements and burdens instead of explaining the MDR, while, for the IVDR, no guidance has yet been released. The expert also noted that, as the Commission was not providing any answers, a kind of common interpretation among notified bodies was being developed, which would be circulated and published. The low number of notified bodies designated so far is making medical device companies particularly worried because they perform a necessary part of the EU's device approval process. If there are too few notified bodies, or their capacity to assess devices under the MDR is inadequate to meet demand, it would create bottlenecks that could result in product shortages, including for critically important devices that patients depend on. On 6 September 2019, the *Irish Medtech Association*, according to which Ireland is Europe's second largest exporter of medtech products, totalling €12.6 billion in exports, with 38,000 people working in the sector, called on the Government of Ireland to take greater action on the MDR. Ireland's notified body, the *National Standards Authority of Ireland*, has yet to be designated. The Government of Ireland, alongside Germany, also flagged the issue at a meeting of EU Member States' Health Ministers earlier this year, claiming that there could be a shortage of devices on the market. In September 2019, a notified body has reportedly issued a conformity certificate to an inhaler under the MDR, the first of its kind under the new regulation. Under the current directives on medical devices, the product was regulated as a Class I device and did not require notified body review. Under the MDR with more stringent rules, the product is classified as a Class IIa device that necessitates review.

According to the *RAPS* and *KPMG* survey of 230 of the industry's regulatory affairs professionals, 46% of the companies participating in the survey would leverage the MDR's

transitional provisions to continue selling their current medical devices in the EU markets, while working on their compliance programs, placing additional work on companies to recertify products and manage inventory. 66% of companies surveyed have yet to develop a strategy to ensure compliance with MDR requirements. Nearly 48% of survey respondents had yet to develop a strategy for the EUDAMED database. More than 35% of organisations stated that the lack of notified bodies was a significant barrier to MDR compliance. The survey concluded that without adequate planning and budgeting, MDR compliance efforts could lead to strained resourcing, employee resistance, insufficient training, and communication failures across the companies, which would create barriers to get MDR-compliant products to the market.

On 10 September 2019, the Commission clarified its designation process for appointing expert panels that are supposed to support regulators, notified bodies, and other entities under the MDR and IVDR. According to *Commission Implementing Decision (EU) 2019/1396 laying down the rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards the designation of expert panels in the field of medical devices*, expert panels are intended to provide scientific, clinical and technical support related to either enforcement of or compliance with MDR and IVDR mandates. The MDR and IVDR require notified bodies to have recourse to expert panels, for example, for clinical evaluations of high-risk medical devices, as well as performance evaluations for some IVDs. The Commission and the Medical Device Coordination Group (MDCG) identified eleven key areas in need of expert panel support, including orthopaedics, neurology, circulatory and respiratory systems, endocrinology, obstetrics and gynaecology, and IVD devices. However, the Commission notes in its implementing decision that these areas, as well as lists of designated expert panels, may change on an as-needed basis, as effects of the new Regulations become more apparent, or as new scientific and/or clinical needs become apparent. The implementing decision establishes qualifications for expert panellist appointments, compensation and conflict-of-interest baselines, and confidentiality and transparency requirements. Medical device and IVD manufacturers planning to obtain or maintain CE marking under the MDR and IVDR should be aware of the role expert panels will play in affecting certifications for their products.

Stakeholders in the medical devices sector in the EU should carefully monitor developments on the new medical devices framework and its implementation and take action to ensure that their legitimate interests are voiced and represented within all relevant *fora*.

Germany will recommend the *Nutri-Score* front-of-pack nutrition labelling model – German Government presents results of a consumer survey

On 30 September 2019, the German Minister of Food and Agriculture *Julia Klöckner* presented the results of an official consumer survey, according to which German consumers understand best the *Nutri-Score* colour model of an extended front-of-pack (hereinafter, FoP) nutrition label for sugar, fat, and salt. Minister *Klöckner* called the consumer survey a "*milestone in nutrition policy*" and intends to respect its result and implement the *Nutri-Score* model as a "*recommendation*" for an additional voluntary FoP nutrition label. However, according to the Ministry, a legal obligation for manufacturers is not possible.

Nutrition labelling is often presented as an important tool in the fight against obesity and other non-communicable diseases. As the mandatory nutrition information presented in a panel on the back or side panel of food packaging is detailed and complex, additional, simplified and voluntary FoP labels on food products aim at empowering consumers to make more informed and healthier choices about their diets. While the European Commission (hereinafter, Commission) still intends to release a report on the topic in 2019, food manufacturers and retailers have already developed their own simplified FoP nutrition labels and a number of EU Member States has issued recommendations regarding specific schemes.

The *Nutri-Score* FoP nutrition labelling system was first recommended and introduced on a voluntary basis in France in 2017. *Nutri-Score* provides a rating to any food (except single-

ingredient foods and water), ranging from a dark green A (best) to a red E (worst), by weighing the prevalence of '*good*' and '*bad*' nutrients. The algorithm on which the *Nutri-Score* system is based appears to consider only a limited number of favourable and unfavourable elements. For example, certain nutrients which are essential for good health, such as iron, are not taken into account. Unlike so-called '*traffic light*' labels, first introduced in the UK in 2012, which rate the healthiness of a product by assessing the content of key nutrients (*i.e.*, salt, fat, saturated fat, sugar) and total calorie count, *Nutri-Score* provides only a single score for the entire product, giving consumers an overall assessment of the product, but without taking into account calories and recommended intakes. In August 2018, Belgium announced the intention to follow the French model (see *Trade Perspectives*, Issue No. 16 of 7 September 2018) and, on 13 November 2018, also the Spanish Government's Agency for Consumer Affairs, Food Security and Nutrition announced a number of measures aimed at tackling obesity, including the use of the *Nutri-Score* FoP nutrition labelling scheme. Other EU Members States, such as Portugal and Luxembourg, appear to be considering the introduction of *Nutri-Score*, while certain food manufacturers and retailers already market products with the *Nutri-Score* label in other EU Member States.

In Germany, since January 2019, the frozen food manufacturer *iglo* started implementing *Nutri-Score* voluntarily, without the guidance of any recommendation by the German Government. On 16 April 2019, the Hamburg Regional Court (*i.e.*, *Landgericht Hamburg*) issued a preliminary injunction against *iglo,* ordering it to refrain from placing the *Nutri-Score* FoP nutrition label on its products. The Court found that the *Nutri-Score* label violates EU food labelling regulations and is, therefore, illegal in commercial transactions (see *Trade Perspectives*, Issue No. 10 of 17 May 2019).

In the survey commissioned by the German Ministry of Food and Agriculture, carried out by the market research institute *Info GmbH*, four models, which the Ministry believed could withstand scientific requirements, had been put to a vote by consumers since mid-July. Overall, 57% of the more than 1,600 citizens interviewed favoured the *Nutri-Score* scheme. A model of the *Federal Max-Rubner Institute* (MRI) for nutrition research, which awards a star rating in the form of five honeycombs, came second with 28% of the votes, followed by the keyhole model used in Scandinavian countries, in which recommendable products are labelled with a green keyhole, with seven 7%, and a kind of pie chart developed by the *German Food Federation* (*i.e.*, *Lebensmittelverband Deutschland*) with 5%.

Prior to the survey, Minister *Klöckner* had explained that the survey would be the only decision criterion for the recommendation by the German Government. The approach to declare a consumer survey as binding and sole criterion for her decision, has been subject to criticism. *Peter von Philipsborn*, scientist from the *Pettenkofer School of Public Health* at the *Ludwig-Maximilians-University Munich*, commented that far-reaching political decisions of this nature should not depend on the outcome of a single survey. Another study by the *Allensbach Institute for Demoscopy* on behalf of the *German Food Federation* revealed in August 2019 that only 20% (out of 1,262 respondents) felt well or very well informed about the products by *Nutri-Score*. The consumer organisation *Foodwatch* and medical associations also recently submitted a survey that had yielded high approval ratings for *Nutri-Score*. The *German Food Federation*'s president *Philipp Hengstenberg* said that many consumers wanted labelling that would allow them to follow a balanced diet. A "*too simplified system*" would, however, not find approval.

EU law only permits additional voluntary FoP nutrition labelling schemes if certain requirements are met. According to Article 35 of *Regulation (EU) No 1169/2011 on the provision of food information to consumers* (hereinafter, FIR), in addition to the harmonised panel with '*nutrition information*', the energy value and the amount of nutrients may be indicated by other forms of expression and/or may be presented using graphical forms or symbols in addition to words or numbers. According to Article 35(2) of the FIR, EU Member States may recommend to food business operators (FBOs), providing the Commission with the details, the use of one or more additional forms of expression or presentation of the nutrition declaration that they consider as best fulfilling the following requirements: "*1) They are based*

on sound and scientifically valid consumer research and do not mislead the consumer; 2) Their development is the result of consultation with a wide range of stakeholder groups; 3) They aim to facilitate consumer understanding of the contribution or importance of the food to the energy and nutrient content of a diet; 4) They are supported by scientifically valid evidence of understanding of such forms of expression or presentation by the average consumer; 5) In the case of other forms of expression, they are based either on the harmonised reference intakes set out in Annex XIII of the FIR, or in their absence, on generally accepted scientific advice on intakes for energy or nutrients; 6) They are objective and non-discriminatory; and 7) Their application does not create obstacles to the free movement of goods".

As regards the *Nutri-Score* logo, there is no indication of the reference intakes. In comparison, the UK's '*traffic light*' scheme is a '*hybrid*' FoP scheme that includes reference intakes (formerly known as '*guideline daily amounts*', or GDAs) and colour coding in the logo. The *Nutri-Score* logo and its colour codes appear to simply categorise foods from '*good*' foods to '*bad*' foods, without taking into account how much energy and nutrients are consumed per day. Indeed, due to the calculation of an overall '*score*', based on an algorithm, the *Nutri-Score* label does not provide consumers with information on the individual nutrients. Regarding the requirement of Article 35 of the FIR, that these additional forms of expression be objective and non-discriminatory, it appears that only saturated fats and '*simple*' sugars are relevant for the negative component of the calculation of the nutritional score. This appears to be a discrimination towards products containing saturated fats (like certain oils and dairy products, which are not *per se* unhealthy) and presumably added sugars, which can also form part of a healthy diet, if consumed in moderation. It appears that apple juice would fall into the orange range (*i.e.*, C) of *Nutri-Score*. Apple juice is, however, a natural product. If fructose is taken out, it would no longer be a natural apple juice, which cannot be reformulated to obtain a better score. But '*Apfelschorle*' (*i.e.*, apple juice mixed with sparkling mineral water) would fall into *Nutri-Score*'s red range (*i.e.*, E), although it has fewer calories than apple juice. The German *Süddeutsche Zeitung* newspaper noted in a commentary that, although studies indicated that *Nutri-Score* allows a "*better decision*" in terms of a "*nutrient policy fixed on salt, fat and sugar, but ready meals world remains the same*. *Manufacturers have plenty of possibilities to play around with the ingredients without changing anything essential to the product. Slightly less salt and sugar, but more flavour enhancers and sweeteners. A little less bad fat, but still fat. In the end, even added some fibre, and the product shifts moves from a moderate yellow C in Nutri-Score to a healthy green A - animating to overconsumption*".

In fact, it appears that there is a risk that *Nutri-Score* only forces the industry to adjust the recipes of their products so that they receive a better assessment under the algorithm and that *Nutri-Score* is just another attempt to inform about diet and nutrition in a too simplified way. But it appears like nutrition is too complex to assess, with a single colour labelling, that a product is healthy, while another is not. Individual lifestyle and body conditions have a huge impact, too. Consumers should be better informed about diet and nutrition in general.

There are more legal questions. First, whether schemes like *Nutri-Score* are actually '*voluntary*' in nature or whether they implicitly force competing FBOs to apply the same labels, once one major operator has started doing so. Second, whether certain elements of these schemes can be classified as '*non-beneficial*' nutrition claims. Nutrition claims are by nature '*beneficial claims*' because operators, who place such claims on their products, intend to highlight something nutritionally '*positive*'. Accordingly, '*non-beneficial*' nutrition claims (like '*rich in fat*') do not fall under the scope of *Regulation (EC) No. 1924/2006 of the European Parliament and of the Council on nutrition and health claims made on foods*. A red "*E*" colour code could be considered as a '*non-beneficial*' nutrition claim having a negative connotation and, thereby, as being a claim and not a part of the nutritional declaration. Finally, the proliferation of different schemes across EU Member States may become an obstacle to the free movement of goods within the EU and be contrary to EU law (see on these questions *Trade Perspectives*, Issue No. 21 of 20 November 2015 and Issue No. 6 of 24 March 2016). It appears, though, that the *Nutri-Score* scheme is slowly gaining ground among EU Member States.

During the course of the month, Minister *Klöckner* plans to submit a proposal to the Federal Government for a recommendation of the *Nutri-Score* scheme. The Cabinet of Ministers would then adopt the recommendation as a regulation and notify it to the Commission for consideration. Approximately in April 2020, the recommendation should enter into force. Until then, in the opinion of the Hamburg Regional Court, the food manufacturers *iglo* is not allowed to use the Nutri-Score label. Whether this also applies to other manufacturers is not clear. *Iglo* has appealed the decision of the Hamburg Regional Court and a hearing has reportedly been scheduled at the Higher Regional Court Hamburg (*Oberlandesgericht Hamburg*) for 14 November 2019.

Stella Kyriakides, the Commissioner-designate for Health, endorsed the idea of common EU standards for nutrition labels. At her confirmation hearing on 2 October 2019, in front of the European Parliament's Committee on the Environment, Public Health and Food Safety, Commissioner-designate *Kyriakides* stated that she "*would like to see a common approach across member states*", noting that she wanted to wait until the Commission finishes its FoP review of food labelling laws before deciding on a specific proposal.

Stakeholders in the agro-food sector should monitor developments on FoP nutrition labelling and take action to ensure that their legitimate interests are voiced and represented within all relevant *fora*. In addition, given the unique situation of the EU Single Market, harmonised legislation regarding FoP nutrition labelling should arguably be adopted at the EU level, as piecemeal legislation across EU Member States would almost certainly have a negative (if not illegal) impact on the free movement of goods. The release of the Commission's report in 2019 will hopefully shed some light on this complex topic and guide the way for a harmonised approach across the EU.

Recently Adopted EU Legislation

Trade Remedies

- *Commission Implementing Regulation (EU) 2019/1662 of 1 October 2019 imposing a definitive anti-dumping duty on imports of ironing boards 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*

- *Commission Implementing Regulation (EU) 2019/1590 of 26 September 2019 amending Implementing Regulation (EU) 2019/159 imposing definitive safeguard measures against imports of certain steel products*

- *Commission Implementing Regulation (EU) 2019/1584 of 25 September 2019 initiating an investigation concerning possible circumvention of anti-dumping measures imposed by Council Implementing Regulation (EU) No 1343/2013 on imports of peroxosulphates (persulphates) originating in the People's Republic of China, and making such imports subject to registration*

Food and Agricultural Law

- *Commission Delegated Regulation (EU) 2019/1666 of 24 June 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council as regards conditions for monitoring the transport and arrival of consignments of certain goods from the border control post of arrival to the establishment at the place of destination in the Union*

- *Commission Implementing Regulation (EU) 2019/1604 of 27 September 2019 amending Regulation (EEC) No 2568/91 on the characteristics of olive oil and olive-residue oil and on the relevant methods of analysis*

- *Commission Delegated Regulation (EU) 2019/1602 of 23 April 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council concerning the Common Health Entry Document accompanying consignments of animals and goods to their destination*

Other

- *Decision No 2/2019 of the Joint Committee under the Agreement between the European Union and Japan for an Economic Partnership of 26 August 2019 on the establishment of the list of individuals who are willing and able to serve as arbitrators*

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