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The EU intends to amend its Enforcement Regulation – wide-ranging proposals from the European Parliament

On 6 July 2020, the European Parliament's Committee on International Trade (hereinafter, INTA Committee) adopted the *Report on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EU) No 654/2014 of the European Parliament and of the Council concerning the exercise of the Union's rights for the application and enforcement of international trade rules*. The INTA Committee's report provides for a number of amendments to the proposal prepared by the European Commission (hereinafter, Commission). The amendments to *Regulation (EU) No 654/2014* are in line with the Commission's priority of improving the enforcement and implementation of EU trade agreements.

The EU Enforcement Regulation

On 8 May 2014, the Council of the EU (hereinafter, Council) adopted *Regulation (EU) No 654/2014 of the European Parliament and of the Council of 15 May 2014 concerning the exercise of the Union's rights for the application and enforcement of international trade rules and amending Council Regulation (EC) No 3286/94 laying down Community procedures in the field of the common commercial policy in order to ensure the exercise of the Community's rights under international trade rules, in particular those established under the auspices of the World Trade Organization* (hereinafter, EU Enforcement Regulation). The Regulation creates a common legislative framework, which empowers the Commission to take swifter action when enforcing the EU's rights under international trade agreements. Previously, the EU enforced its rights under international trade agreements through the Council's adoption of regulations on a case-by-case basis, following proposals by the Commission (see *Trade Perspectives*, Issue No. 1 of 11 January 2013 and Issue No. 10 of 16 May 2014).

The EU Enforcement Regulation applies in four situations: 1) After the adjudication of a trade dispute, when the EU is authorised to suspend concessions or other obligations under agreements covered by the World Trade Organization's (hereinafter, WTO) Understanding on Rules and Procedures Governing the Settlement of Disputes (hereinafter, DSU); 2) Following the adjudication of a trade dispute under other international trade agreements, such as regional or bilateral agreements; 3) For the rebalancing of concessions or other obligations, in accordance with Article 8 of the WTO Agreement on Safeguards, or similar provisions in other international trade agreements; and 4) When no compensatory adjustments were agreed when another WTO Member modified its concessions under Article XXVIII of the General Agreement on Tariff and Trade (hereinafter, GATT). The EU Enforcement Regulation allows the

Commission to increase customs duties, to set import quotas or to impose limitations on the access to public contracts in the EU. By allowing the Commission to take these kinds of measures, the EU intends to pressure third countries to comply with their obligations under international trade agreements to which they are a party.

The Commission's proposal

On 12 December 2019, the Commission published its proposal to amend the EU Enforcement Regulation. The Commission's proposal primarily responds to the currently dysfunctional WTO Appellate Body, which ceased functioning on 11 December 2019, as a result of the nomination process of new judges being blocked. Consequently, the WTO Appellate Body is currently unable to hear new appeals and, as the Commission notes in its Explanatory Memorandum, WTO Members would be able to avoid binding rulings by appealing panel reports, which has been referred to as the appealing '*into the void*'. Since the Appellate Body cannot adjudicate any appeal, the Commission underlines these cases would fall in a "*legal void*" and, hence, "*remain unresolved*". In such situation – in which international rules cannot be enforced – the economic interests of the EU could be compromised. A number of WTO Member States agreed to mitigate this unfortunate situation by setting up an *interim* appeal arbitration under Article 25 of the WTO DSU.

To further address this situation, the Commission's proposal aims at expanding the scope of the EU Enforcement Regulation to two situations: 1) Cases when the EU has obtained a favourable ruling from a WTO dispute settlement panel, but when the process is blocked due to an appeal '*into the void*' by another party and such party has not agreed to *interim* appeal arbitration under Article 25 of the WTO DSU; and 2) In trade disputes relating to other international trade agreements, including regional or bilateral agreements, when an adjudication is not possible due to the third country's failure to take the necessary steps to establish a functional dispute settlement procedure.

On 8 April 2020, the Council adopted its position regarding the Commission's proposal and agreed that, due to "*the current paralysis of the WTO Appellate Body, the existing rules needed to be updated*" in order to allow the Commission to act in the instances when WTO dispute settlement cannot move forward. While the Council's position remains close to the Commission's proposal, it adds a review clause calling on the Commission "*to assess the functioning of the new rules and assess a potential need for extending the scope to services and intellectual property rights at the latest within three years from adoption of the regulation*".

The INTA Committee report

On 6 July 2020, the INTA Committee adopted the report concerning the Commission's proposal to amend the EU Enforcement Regulation with 32 votes in favour, 3 against and 3 abstentions. As the Council, the INTA Committee has been generally supportive of the Commission's proposal. However, the INTA Committee proposed various significant amendments to the proposal: 1) In addition to the currently allowed measures in the areas of goods and public procurement, the inclusion of services and intellectual property rights in the scope of trade policy measures taken to enforce EU rights; 2) Expanding the scope of the EU Enforcement Regulation to allow EU countermeasures "*in the event of the adoption by a third country of commercial policy measures that threaten or impair the commercial interests of the Union or jeopardise the Union's strategic autonomy, and constitute a clear breach of international law or a clear violation of its trade obligations towards the Union, provided that the Union has appropriately challenged these measures at the WTO or in front of the relevant dispute settlement body*"; and 3) A review of the revised EU Enforcement Regulation no later than two years after it has entered into force. Additionally, the INTA Committee's report proposes to reference the Chapters on Trade and Sustainable Development contained in the EU's preferential trade agreements with third countries in the recitals of the EU Enforcement Regulation, which should reiterate that provisions on trade and sustainable development fall within the exclusive competence of the EU and that the "*Commission should make proposals to strengthen the enforcement of sustainable development commitments*".

Notably, the *Rapporteur* of the report, *Marie Pierre Vedrenne*, Member of the Renew Europe group, as well as the Chair of the INTA Committee, *Bernd Lange*, stated that the EU Enforcement Regulation should allow the EU to act, at least provisionally, in case of manifest violations of international trade rules and "*without having recourse to a formal legal dispute such as a WTO panel ruling*". *Rapporteur Vedrenne* justified this position underlining that, "*through the enforcement regulation and the proposal to take temporary measures, we can tell our farmers and our small and medium-sized enterprises that the EU is there to defend their interests*". According to *Rapporteur Vedrenne*, such approach would also provide more confidence in EU enforcement and facilitate the ratification process of trade agreements in EU Member States.

Members of the INTA Committee from the Group of Greens/European Free Alliance voted against the report and Member of the European Parliament *Reinhard Bütikofer* critically stated that, with the vote, the majority of the INTA Committee had discarded "*the defence of WTO centered trade multilateralism*" and opted instead "*for a unilateralist approach*". The amendments proposed by the INTA Committee also raised concerns that the EU could act against WTO rules and trigger unnecessary trade wars or take protectionist actions.

Effective enforcement of international trade rules is and should always be an integral part of a rules-based trade policy. When third countries do not comply with their legal obligations and commitments under bilateral, plurilateral and multilateral trade agreements, the EU must be able to defend its interests. However, in the absence of a final and binding ruling of a competent dispute settlement body, countermeasures should arguably only be taken either: 1) After the EU has obtained a favourable ruling from a WTO panel and if the WTO appeal process is blocked due to an appeal '*into void*'; or 2) Because a third country is preventing a dispute settlement mechanism to properly function under a bilateral or regional trade agreement. The INTA Committee's proposal, only requiring "*that the Union has appropriately challenged these measures at the WTO or in front of the relevant dispute settlement body*", arguably, provides the Commission with too much power beyond the confines of the rules-based trading system.

Indeed, the EU should not abandon the principles, rules and procedures of the WTO system, even at a time when most other countries and regions are conveniently disregarding them or shifting to unilateral approaches that are not rule-based. It takes a second to lose the '*moral high grounds*', but the damage to one's credibility and to the multilateral system would be long-lasting. At the same time, however, as we have often invoked here on *Trade Perspectives*©, the EU should increasingly negotiate and equip its preferential trade agreements with leaner, faster and more enforceable mechanisms to immediately take away preferences and force compliance within those bilateral contexts and legal frameworks when its trading partners are not honouring their commitments, obligations, and concessions. Several such tools exist, and others could be engineered to achieve a higher degree of compliance and enforcement. Without it, EU Member States' and their domestic business constituencies' patience will wear thin and the risk is that the real victim will be the faith in the multilateral system, in the rule of law and in due process.

Enforcement and implementation as key priorities for the Commission

During a recent Civil Society meeting, *Sabine Weyand*, Director-General of the Commission's Directorate General for Trade, reiterated that one of the Commission's priorities was the implementation and enforcement of EU trade agreements, which had also been highlighted by European Commissioner for Trade, *Phil Hogan*, since he took office in 2019. The EU Enforcement Regulation complements the other existing EU trade defence instruments, such as the anti-dumping and anti-subsidy regulations, which the EU has been reinforcing under the previous Commissioner for Trade, *Cecilia Malmström*. Furthermore, an EU Chief Trade Enforcement Officer is supposed to be appointed soon (see *Trade Perspectives*, Issue No. 17 of 20 September 2019).

Next steps

The INTA Committee's report will be tabled for a vote at the next plenary meeting of the European Parliament, which will take place in September 2020. Once adopted, the report will become the European Parliament's position for the inter-institutional discussions to achieve a common text. All relevant stakeholders and EU trading partners should closely monitor the legislative procedure, engage in the discussions, and ensure that their interests are duly considered.

To promote its domestic pharmaceutical industry, the Government of Indonesia issued a local content regulation for pharmaceutical raw materials

In an effort to promote the development of the domestic upstream pharmaceutical industry and reportedly to reduce import dependence of raw materials, the Government of Indonesia issued *Ministry of Industry Regulation No. 16 Year 2020 concerning Provisions and Procedures for the Calculation of Local Component Level for Pharmaceutical Products* (hereinafter, *MOI Regulation No. 16/2020*), which entered into force on 29 May 2020. *MOI Regulation No. 16/2020* outlines the procedures for calculating the local content value of pharmaceutical products, as well as the procedures for obtaining a local content certificate. With the implementation of the regulation, it is expected that Indonesia's dependence on imports of active pharmaceutical ingredients (hereinafter, APIs) will decrease by up to 15% in 2021.

Calculating the local content of pharmaceutical products

In general, local content value refers to the magnitude or percentage of domestic components in goods, services, and/or a combination of both. With regard to pharmaceutical products, Article 4 of *MOI Regulation No. 16/2020* provides that the local content value of such products is calculated based on four components, namely:

Component and percentage	Sub-component and percentage
Raw material contents (50%)	• Active raw materials (*i.e.*, active pharmaceutical ingredients, APIs) (65%) • Excipient/additional raw materials (35%)
R&D process (30%)	• Development of new drug (25%) • Clinical trial (30%) • Formulation (35%) • Bioavailability/bioequivalence (10%)
Production process (15%)	• Mixing process (60%) • Dosage forming (40%)
Packaging (5%)	• Batch release (50%) • Primary packaging (40%) • Secondary packaging (10%)

The calculation above is referred to as a *'processed-based method'*, which was designed to recognise and value the specific and complex formula, as well as the Research and Development (R&D) process, for every pharmaceutical product. To determine the local content value of pharmaceutical products, Indonesia's Ministry of Industry has the authority to conduct a calculation and verification of such value, as represented by an independent verification agency. The Head of the Center for Enhancement of Domestic Products Utilization within Indonesia's Ministry of Industry then issues the local content certificate, which is valid for two years.

Notably, *MOI Regulation No. 16/2020* does not affect the sale, purchase, import, and/or distribution of pharmaceutical products in Indonesia's market, as it does not specify nor mandate a local content requirement with which pharmaceutical companies or manufacturers must comply. The Regulation also does not provide for sanctions for not obtaining the local

content certificate. Rather, *MOI Regulation No. 16/2020* follows an incentive approach in the form of an advantage in the context of Government procurement projects.

A certain local content value required for certain Government procurement benefits

The local content certificate is the documentary proof required to obtain certain advantages in the context of Indonesia's Government procurement of goods and/or services. According to *Presidential Regulation No. 16 Year 2018 concerning Government Procurement of Goods and/or Services*, a price preference is an incentive accorded to a provider of domestic products in the form of an '*acceptable price excess*' in the Government procurement selection processes. Such price preference provides a bidder, in particular companies that have met a 25% local content value or higher, or those that commit to achieving a 30% local content value or higher, a better position at winning the tender vis-à-vis other bidders that do not meet the local content requirements. The '*acceptable price excess*' reduces the Government of Indonesia's calculation of a companies' bidding price, known as final evaluation price. Companies provided with the price preference are likely to be selected, as the winner of Government procurement projects is determined based on the lowest final evaluation price. The exact value/percentage of such reduction is determined through a discretionary process on *case-by-case* basis. When implemented, public contracts in the pharmaceutical sector will most likely be awarded to companies that meet the domestic components requirements, including requirements for the domestic sourcing of APIs.

The rationale: Indonesia's reliance on imported pharmaceutical raw materials

It has been the Government of Indonesia's intention and plan to transform Indonesia's pharmaceutical industry into a competitive and self-reliant industry. Currently, Indonesia's pharmaceutical industry relies heavily on imported raw materials, particularly APIs, the biologically active components of pharmaceuticals. In fact, 90 to 95% of APIs and other chemical ingredients are imported, making the domestic pharmaceutical industry vulnerable to price fluctuations and uncertainties regarding API production overseas. China accounts for around 60% of API imports to Indonesia, while India accounts for another 20%.

The Government of Indonesia considers this import dependence, in particular with respect to APIs, to be a serious concern. The Covid-19 epidemic exposed vulnerabilities in the global medicine supply chain of essential drugs, most notably when China, the biggest API manufacturer in the world, reduced its production and restricted its exports due to the pandemic. Consequently, the availability of pharmaceutical products in Indonesia and other countries was limited due to reduced and delayed imports from China.

MOI Regulation No. 16/2020 was issued as a means to pursue the Government's long-standing commitment in promoting the development of Indonesia's domestic API industry and to reduce its reliance on imported pharmaceutical products and relevant raw materials. During his first presidential term, Indonesia's President *Jokowi* unveiled the *11th Economic Stimulus Package* in March 2016, with which the Government aimed at supporting the local production of medicines' raw materials, particularly in relation to biotechnology, vaccines, herbal extracts, APIs, and medical devices, stating that, at the time, 95% medicines' raw materials and 90% of medical equipment were imported. In the previous *10th Economic Stimulus Package,* issued in February 2016, the Government had removed the pharmaceutical industry from the negative investment list, which allowed 100% foreign ownership in related companies, with the hope of attracting investment of API manufacturing in Indonesia.

In 2016, Indonesia's President *Jokowi* issued *Presidential Directive No. 6 Year 2016 concerning the Acceleration of the Development of the Pharmaceutical and Medical Equipment Industry*. More specifically, the Directive instructed Indonesia's Ministry of Health to increase the independence and development of raw material production to meet domestic and export needs, facilitate the development of pharmaceutical and medical equipment industry with respect to biopharmaceuticals, vaccines, and APIs, and prioritise the use of local pharmaceutical and medical equipment supply via Government procurement. Pursuant to the

Directive, Indonesia's Ministry of Industry was mandated to issue, monitor and evaluate the implementation of the local content rule in pharmaceutical and medical equipment sectors.

By implementing the mandate laid out in the Presidential Directive, the Ministry of Health issued *Regulation No. 17 Year 2017 concerning Action Plan for the Development of the Pharmaceutical and Medical Equipment Industry* (hereinafter, *MOH Regulation No. 17/2017*), which requires the pharmaceutical and medical equipment industry in Indonesia to prioritise the use of raw materials produced domestically. By not making the local content certificate mandatory and only linking it to certain benefits in procurement procedures, it remains to be seen how *Regulation No. 16/2020* could make a material contribution in promoting Indonesia's pharmaceutical industry.

Potential inconsistencies with WTO disciplines?

The Government of Indonesia's approach on local content requirements with respect to pharmaceutical raw materials, with the aim of promoting domestic industries, can be characterised as an import substitution measure, defined by Article 3.1(b) of the Agreement on Subsidies and Countervailing Measures (hereinafter, SCM Agreement) as subsidies contingent upon the use of domestic over imported products. The measure also aims at developing Indonesia's domestic API industry, including for export purposes. Therefore, the measure will potentially affect international trade and Indonesia's obligations under the World Trade Organization (hereinafter, WTO) rules and, more specifically, the SCM Agreement.

In general terms, Article 1.1 of the SCM Agreement defines a subsidy as a "*financial contribution by a government or public body*", or an income or price support that confers a benefit to its recipient. Subsidies that require recipients to meet certain export targets, or to use domestic goods, are prohibited, as they are likely to negatively affect other countries' trade.

Article 3.1(a) of the *SCM Agreement* prohibits subsidies contingent upon export performance, such as direct export subsidies and export retention schemes, which involve a bonus on exports. As an illustration, the WTO Appellate Body in *Canada – Autos* concluded that an import duty exemption that was only available to a manufacturer that exports motor vehicles was contrary to Article 3.1(a) of the SCM Agreement, as the exemption was conditional upon the exportation of products. If, in order to support production of pharmaceutical products for exports, the Government of Indonesia were to issue a price preference, bonus, or any tax incentive, this would likely conflict with Article 3.1(a) of the SCM Agreement.

Moreover, import-substitution subsidies are prohibited under Article 3.1(b) of the SCM Agreement. Often, such schemes take the form of local content requirements. According to the WTO Appellate Body in *US – Tax Incentives*, '*goods*' within the meaning of this article may refer to '*goods*' used by the subsidy recipient, such as, *inter alia,* parts or components that are incorporated into another good. As the provision of a price preference for Government procurement of pharmaceutical products is contingent upon the fulfilment of certain local content value, including the use of domestic APIs, potential legal issues with Article 3.1(b) of the SCM Agreement could arise.

What's next?

Currently, domestic pharmaceutical companies control over 70% of the Indonesian market for pharmaceuticals. However, as the industry relies heavily on imported raw materials, the Government of Indonesia has introduced a number of regulations including local content requirements, coupled with incentives, for purposes of supporting the upstream sectors, such as the domestic manufacturing of APIs, as well as research and development. It is expected that further regulations to strengthen the upstream pharmaceutical industry will be issued in the near future to implement the mandates provided in *Presidential Directive No. 6 Year 2016*. Relevant stakeholders should closely monitor the implementation of *MOI Regulation No. 16/2020,* as well as related developments, and seek legal advice to navigate the evolving regulatory landscape.

Swedish '*Keyhole*' labelling system: Front-of-pack nutrition labelling or a nutrition claim '*on the overall nutritional quality of foods*'?

On 26 June 2020, the Swedish National Food Agency notified to the European Commission (hereinafter, Commission) *draft Regulations amending the Swedish National Food Agency's Regulations (LIVSFS 2005:9) on the use of a particular symbol*. The notified draft Regulations concern amendments to the current Regulations on the so-called '*Keyhole*' symbol, a voluntary label for prepacked and non-packed foods, which is supposed to enable consumers to make better dietary choices. In the context of the Commission's Report to the European Parliament and the Council regarding the use of additional forms of expression and presentation of the nutrition declaration (hereinafter, '*front-of-pack*' or FoP Report) of 20 May 2020 (see *Trade Perspectives*, Issue No. 11 of 5 June 2020), the Swedish notification clarifies whether the '*Keyhole*' labelling system and the corresponding symbol is a front-of-pack (FoP) nutrition labelling or rather a nutrition claim on the overall nutritional quality of foods.

The voluntary 'Keyhole' labelling system and symbol

'*Keyhole*' labelling is a voluntary labelling system in the area of food and health that was introduced in Sweden in 1989. The '*Keyhole*' symbol has also been used in Denmark and Norway since 2009, and in Iceland since 2013. Lithuania in 2013, and Northern Macedonia in 2015, announced the intention to use the '*Keyhole*' as well. The '*Keyhole*' is a voluntary label for foods, which is supposed to enable customers to make better choices on the basis of the fat, sugar, salt and fibre content of 33 defined food categories (*e.g.*, bread, cheese, ready meals) provided in Annex 2 to the Swedish National Food Agency's Regulations on the use of a particular symbol, the '*Keyhole*'.

Under the '*Keyhole*' system, only conditions that have been considered relevant for the respective foods are determined. For example, for milk, there are only criteria regarding the fat content. The Swedish authorities state that '*Keyhole*' labelling indicates that a complete assessment of the nutritional quality of the product has been made. The symbol may not be used on products that have a low nutritional value, such as salted snacks or soft drinks. Food manufacturers may use the '*Keyhole*' in the presentation and labelling of foods that are included in the food groups in Annex 2 to the Regulation if they meet all the nutritional conditions laid down for the respective food. Food manufacturers that use the '*Keyhole*' must ensure compliance with the Regulations, which is monitored by the inspection authorities.

The revision of the Regulations of the 'Keyhole' labelling

The Swedish National Food Agency continuously revises the Regulations of the '*Keyhole*' labelling with regard to food categories and conditions, partly because of the ongoing product development in the market. The draft Regulations notified in June concern amendments to the current Regulations (LIVSFS 2005:9), which were last notified in 2014. Norway, Denmark and Iceland are making corresponding amendments to their Regulations. The amendments mainly concern the conditions in Annex 2 of food categories 26-31 on ready meals and food category 25 on vegetable products. Most of the amendments are being made in order to expand the food categories to include more products, especially products with more whole grains and a larger proportion of vegetables. The proposed amendments are based on the Nordic Nutrition Recommendations 2012 (NNR 2012), which highlights, *inter alia*, eating habits that can reduce the risk of the most important lifestyle diseases, especially cardiovascular diseases, type 2 diabetes and osteoporosis. In preparation of the revision of the '*Keyhole*' labelling, in 2019, a working group with participants from Denmark, Iceland, Norway, and Sweden discussed the conditions for the '*Keyhole*' to promote healthy eating by consumers and for companies that develop healthy foods. The work has mainly focused on products suitable for vegetarians and ready meals.

Additional forms of expression and/or presentation of the nutrition declaration or nutrition claim?

According to Article 35(1) of *Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers* (hereinafter, FIR), the mandatory nutrition declaration may be complemented by a voluntary repetition of the energy value and the amount of nutrients in the principal field of vision (known as the '*front-of-pack*' or FoP), in order to help consumers see at a glance the essential nutrition information when purchasing foods. Additional forms of expression and/or presentation of the nutrition declaration may be used by food business operators or recommended by EU Member States, but must be notified to the Commission.

The Swedish Government, however, has not notified this measure under the procedure foreseen in the FIR. Rather, Sweden notified the draft measure to the Commission under the Technical Regulation Information Service (TRIS) procedure, set up under *Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services* and noted under "*Notification Under Another Act*" that the notification was made in accordance with Article 23 of *Regulation (EC) No 1924/2006 on nutrition and health claims made on foods* (hereinafter, NHCR). Article 23 of the NHCR provides that, if an EU Member State considers it necessary to adopt new legislation on nutrition and health claims, it is obliged to notify the Commission and the other EU Member States of the envisaged measures and give the reasons justifying them. The Commission then consults the Standing Committee on Plants, Animals, Food and Feed, if it deems such consultation to be useful or if an EU Member State so requests, and will give an opinion on the envisaged measures. The EU Member State concerned may take the envisaged measures six months after the notification, provided that the Commission's opinion is not negative.

Schemes providing information on the FOP on the overall nutritional quality of foods

In the FoP Report, the Commission noted that, considering the limited experience in this area in the past years and some recent developments at national level, it postponed the adoption of the FoP Report with a view to include the experience with recently introduced schemes. Most importantly, the FoP Report goes beyond the scope of Article 35 of the FIR, which refers only to additional forms of expression and/or presentation, repeating the information provided in the nutrition declaration, and "*includes also schemes that are providing information on the FoP on the overall nutritional quality of foods, since such a differentiation would not be pertinent from a consumer's perspective*".

In the FoP Report, the Commission notes that "*some FoP schemes developed by Member States or food business operators do not fall under Article 35 of the FIR since they do not repeat information provided in the nutrition declaration as such but provide information on the overall nutritional quality of the food (e.g. through a symbol or letter)*". The Commission considers such schemes "*as 'voluntary information' under Article 36 of the FIR which shall not mislead the consumer, not be ambiguous or confusing for the consumer and shall, where appropriate, be based on the relevant scientific data*".

Importantly, the Commission notes that, when a scheme attributes an overall positive message (for example through a green colour), it also fulfils the legal definition of a '*nutrition claim*' as it provides information on the beneficial nutritional quality of a food as defined in the NHCR. According to the NHCR, claims are to be based on scientific evidence, are not to be misleading, and are only permitted if the average consumer can be expected to understand the beneficial effects expressed by the claim. These requirements also apply to overall positive messages, such as green colours.

This explains why the Swedish authorities did not notify the amendments to the '*Keyhole*' scheme as an additional form of expression and/or presentation of the nutrition declaration under Article 35 of the FIR, but as a voluntary scheme (according to Article 36 of the FIR),

which needs to be notified under the NHCR, as the '*Keyhole*' attributes an overall positive message, fulfilling the legal definition of a nutrition claim and as it provides information on the beneficial nutritional quality of a food as defined in the NHCR.

Nutri-Score as scheme on the overall nutritional quality of foods with positive and negative nutrition claims?

In the part of the FoP Report on FoP schemes endorsed or under consideration by EU Member States, the Commission also addressed the *Nutri-Score* scheme as a scheme providing information on the FoP on the overall nutritional quality of foods and not as an additional form of the nutritional declaration on the FoP established in Article 35(1) of the FIR. In the FoP Report, the Commission simply states that "*Nutri-Score, based on the UK Food Standards Agency nutrient profiling model, indicates the overall nutritional quality of a given food item. The label is represented by a scale of five colours, from dark green indicating food products with the highest nutritional quality to dark orange for products with lower nutritional quality, associated with letters from A to E. The algorithm to calculate the nutritional score considers both negative (sugars, saturated fats, salt and calories) and positive elements (protein, fibre, fruits, vegetables, legumes and nuts)*".

In comparison with the '*Keyhole*' symbol, it must be said that the *Nutri-Score* symbol also appears to be a nutrition claim (beneficial if green and non-beneficial if dark orange). Typically, nutrition claims are '*beneficial*' claims since the operator, who uses them on its products, intends to highlight something nutritionally '*positive*'. This is the reason why '*non-beneficial*' nutrition claims (like '*rich in fat*') do not fall under the scope of the NHCR, which states in recital 6 that "*[n]on-beneficial nutrition claims are not covered by the scope of this Regulation; Member States intending to introduce national schemes relating to non-beneficial nutrition claims should notify such schemes to the Commission and to other Member States in accordance with (…) (the TRIS procedure)*". In any event, as for the Swedish '*Keyhole*', schemes like the *Nutri-Score* need to be notified to the Commission under the NHCR.

Mandatory FoP nutrition labelling scheme to be proposed by the end of 2022

With respect to the Swedish amendments, starting from the date of notification of the draft Swedish Regulations, a three-month standstill period until 28 September 2020 applies, during which Sweden may not adopt the technical regulation in question, enabling the Commission and the other EU Member States to examine the notified text and to respond.

The FoP Report concludes that it seems appropriate to introduce an EU legislative proposal on a harmonised mandatory FoP nutrition labelling scheme in line with the objectives of the European Commission's *Farm to Fork* (F2F) *Strategy*, in which the Commission announced that, by the fourth quarter of 2022, after launching an impact assessment on the different types of FoP schemes, it intended to announce such legislative proposal. No specific FoP scheme has been recommended in the FoP Report, and it also appears that FoP schemes providing information on the overall nutritional quality of foods, such as the '*Keyhole*' or the *Nutri-Score*, do not appear to be appropriate for a harmonised mandatory FoP nutrition labelling scheme under the current legal framework of the FIR.

On 15 July 2020, the German Minister of Food and Agriculture *Julia Klöckner* laid out the German EU presidency's agrifood priorities and highlighted, *inter alia*, an EU-wide nutritional label as a key focus. "*Food policy issues are going to be high on the agenda in the next few months, for example, having extended nutritional labelling to better guide consumers in their purchasing*", Minister *Klöckner* said, adding that, in view of ongoing contention among EU Member States, "*harmonisation of law labelling is, of course, the best possible scenario if we can get that*", but warned that waiting until there was agreement across the board might not necessarily be the best option. She concluded that the EU may need to review the available labelling scheme options or do a "*general evaluation of certain products, covering different criteria*".

Recently Adopted EU Legislation

Trade and Customs Law

- *Commission Implementing Regulation (EU) 2020/1024 of 14 July 2020 opening and providing for the management of Union tariff quotas for certain products originating in the Socialist Republic of Viet Nam*

- *Commission Implementing Regulation (EU) 2020/991 of 13 May 2020 opening and providing for the administration of import tariff quotas for rice originating in the Socialist Republic of Vietnam*

Food and Agricultural Law

- *Commission Implementing Regulation (EU) 2020/1029 of 15 July 2020 fixing the closing date for the submission of applications for private storage aid for sheepmeat and goatmeat under Implementing Regulation (EU) 2020/595*

- *Commission Implementing Regulation (EU) 2020/1028 of 15 July 2020 fixing the closing date for the submission of applications for private storage aid for fresh or chilled meat of bovine animals aged eight months or more under Implementing Regulation (EU) 2020/596*

- *Commission Implementing Regulation (EU) 2020/1027 of 14 July 2020 on amending Implementing Regulations (EU) No 771/2014, (EU) No 1242/2014 and (EU) No 1243/2014 as regards the implementation and monitoring of specific measures to mitigate the impact of the COVID-19 outbreak in the fishery and aquaculture sector*

- *Commission Delegated Regulation (EU) 2020/990 of 28 April 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council, as regards animal health and certification requirements for movements within the Union of aquatic animals and products of animal origin from aquatic animals*

- *Commission Implementing Regulation (EU) 2020/975 of 6 July 2020 authorising agreements and decisions on market stabilisation measures in the wine sector*

Trade Remedies

- *Commission Implementing Decision (EU) 2020/1051 of 16 July 2020 terminating the absorption reinvestigation concerning imports of certain cast iron articles originating in the People's Republic of China*

- *Commission Implementing Regulation (EU) 2020/966 of 1 July 2020 terminating a 'new exporter' review of Implementing Regulation (EU) 2019/1379 imposing a definitive anti-dumping duty on imports of bicycles originating in the People's Republic of China for one Chinese exporting producer, imposing the duty with regard to that producer's imports and terminating the registration of these imports*

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