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## The scope of '*patent linkage*' in the US-South Korea Free Trade Agreement and the potential effects on international trade agreements

The implementation of the provisions relating to patent linkage in the US-Korea Free Trade Agreement (hereinafter, KORUS FTA) has recently triggered a controversy between the two trading partners. At the heart of the exchange between the two administrations is whether the patent linkage requirement included in Chapter 18 of the agreement (on Intellectual Property Rights, hereinafter, IPRs) covers biopharmaceutical products (also referred to as "*biological*" or "*biologics*"). Patent linkage requirements, which some jurisdictions maintain as an incentive to stimulate innovation and attract investments in the pharmaceutical sector, have an impact on the marketing and trade of generic pharmaceutical products and, where applicable, on biosimilars (*i.e.*, non-originator biologic pharmaceutical products). As a consequence, they affect the accessibility and availability of medicines and competition in the pharmaceutical products sector.

'*Patent linkage*' refers to the requirements linking regulatory approval of pharmaceutical products to the patent status of the products. Patents on pharmaceutical inventions and regulatory approval for pharmaceutical products are normally granted by separate agencies (patent offices and health regulators, respectively). However, certain jurisdictions' domestic laws link regulatory approval (which is based on an evaluation of safety and efficacy of the pharmaceutical product) to the patent status of the pharmaceutical product. Therefore, under a patent linkage mechanism, the marketing authorisation will not be granted to a generic medicinal product until the patent has expired or is found to be invalid. This has the consequence of considerably delaying market entry of generic products. In countries where patent linkage is recognised, the regulatory authority effectively acts as a patent enforcement agency, as patent linkage prevents that authority from granting marketing authorisation to a generic medicine where it appears that there is a valid patent still in existence.

Patent linkage requirements are present, in relevant part, in Canada, the US and Japan, as well as in few other jurisdictions as a result of the conclusion of FTAs, notwithstanding the fact that patent linkage is not a requirement of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (*i.e.*, the TRIPs Agreement). The US incorporated patent linkage into the *Drug Price Competition and Patent Term Restoration Act of 1984* (which is usually, and hereinafter, referred to as the "*Hatch-Waxman Act*").

In relevant part, under the *Hatch-Waxman Act*, a manufacturer that is seeking marketing approval for a generic pharmaceutical product must inform the holder of the relevant patent. If

the holder of the relevant patent objects, such as when it believes that its patent is still valid, the US Food and Drug Administration grants an automatic stay of 30 months to allow for legal challenges. To encourage patents' challenges, the act also provides that the first company that files a generic application containing a patent challenge certification may be rewarded with 180 days of generic market exclusivity. The *Hatch-Waxman Act* does not apply to biologics. Instead, relevant requirements for manufacturers of biosimilars are found in the *Biologics Price Competition and Innovation Act*, which does not foresee patent linkage.

On the other hand, patent linkage requirements are not allowed in the EU. As recognised by the EU Commission in its Pharmaceutical Sector Inquiry of 2008, the EU's regulatory framework for approval of pharmaceutical products does not allow authorities to take the patent status of the originator medicine into account when deciding on marketing authorisations of generic medicines. Therefore, patent linkage is considered by the EU Commission an anti-competitive instrument to delay generic and biosimilar medicines entry into the market and, as such, subject to EU competition rules. As result, EU trade agreements do not contain patent linkage requirements.

As it is common for international trade agreements to which the US is a party, the KORUS FTA provides a patent linkage obligation. Under Article 18.9.5 thereof, when a non-originator manufacturer of a "*pharmaceutical product*" applies for marketing approval, the relevant patent owner must be notified of the identity of the person making such request, and the government must have measures implemented "*to prevent such other persons from marketing a product without the consent or acquiescence of the patent owner during the term of a patent notified to the approving authority as covering that product or its approved method of use*". Chapter 18 of the KORUS FTA does not define "*pharmaceutical product*". The concept of "*new pharmaceutical product*" is found in other provisions (*i.e.*, Article 18.8.6) as "*a product that at least contains a new chemical entity that has not been previously approved as a pharmaceutical product in the territory of the Party*". A definition of "*pharmaceutical product*" which explicitly covers biologics (*i.e.*, "*pharmaceutical product or medical device means a pharmaceutical, biologic, medical device, or diagnostic product*") is included in Chapter 5 of the KORUS FTA, which pertains to pharmaceuticals and medical devices. However, as clarified by Article 5.8 thereof, this definition is valid only for the purposes of Chapter 5, and is therefore not applicable to the provisions contained in Chapter 18, including the patent linkage requirement. The wording employed in the two definitions, and the fact that the latter distinguishes clearly between "*pharmaceutical*" and "*biologic*" arguably suggests that patent linkage for biologics is not a requirement under the KORUS FTA.

This apparent ambiguity of the KORUS FTA has fuelled a debate between South Korea and the US on whether patent linkage under the KORUS FTA covers biologics.

Under the terms of the KORUS FTA, South Korea was required to fully implement patent linkage by 15 March 2015 (*i.e.*, at least three years from entry into force of the agreement). In order to do so, South Korea had to amend its patent laws and introduce patent linkage requirements. In response to proposals in South Korea's National Assembly aimed at carving out biologics from the government's draft, the US Ambassador to South Korea issued a letter in which he sought to "*assure …that KORUS patent linkage obligations cover all pharmaceutical products, including biologics, as set forth in the agreement*". The Ambassador also stated that the US "*meets its obligation through the Hatch Waxman Act and the Biologics Price Competition and Innovation Act*". South Korea's implementing act, an amendment of the *Pharmaceutical Affairs Act*, ultimately introduced a "*Hatch-Waxman*" style patent linkage requirement for both generic and biosimilar medicines.

Therefore, while South Korea applies the same notification requirements to manufacturers of generics and biosimilars, the US framework distinguishes between generics and biosimilars, insofar as patent linkage is concerned. In the US, under the *Biologics Price Competition and*

*Innovation Act* (hereinafter, BPCIA), a non-originator applying for marketing approval of a biologic must simply "*provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing*" of the biosimilar. This obligation is a requirement to notify the marketing of the product, not the kind of notification requirement that exists under the "*Hatch-Waxman Act*" for generics, where the applicant for authorisation of a generic medicine must notify of its intent to seek approval for a generic version of the reference product, and which may ultimately trigger the authority to grant an automatic stay in case of objections from the patent holder. In addition, the "*reference product sponsor*", which is the addressee of the notification requirement, is not necessarily the patent holder. The sponsor, who would receive such notice, can be different from the patent holder. In simple terms, marketing authorisation for biosimilars under the BPCIA is not linked to the status of the patent.

As a result of the apparent ambiguity of the language in the KORUS FTA and the related exchange between the two administrations, South Korea has effectively implemented more burdensome requirements on manufacturers of South Korean biosimilars than those that would arguably be required under the agreement and that apply to manufacturers of biosimilars in the US. The US Ambassador indicated that the US is advocating for similar provisions to be included in the Trans-Pacific Partnership (hereinafter, TPP), which is currently being negotiated by 12 countries (*i.e.*, Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, the US and Vietnam). To avoid the type of ambiguity that has affected South Korea's implementation of the KORUS FTA, future trade agreements should at least clarify that patent linkage does not apply to biologics.

In fact, the inclusion of patent linkage requirements in trade agreements should be avoided altogether. Inasmuch as it prevents the registration and authorisation of generic medicines until after a finding of invalidity or expiry of a patent pending marketing approval, patent linkage has the effect of delaying generic market entry and affecting competition in pharmaceutical products. The degree of investment and innovation that patent linkage requirements are supposed to stimulate is outweighed by the burdens caused by the implementation of such requirements, which often result in onerous procedures and instances of patent abuse, especially where appropriate safeguards to prevent this are not put in place.

Patent linkage requirements stand to be particularly problematic in a context such as the TPP negotiating framework, which involves countries with little IPR enforcement '*experience*' and no patent linkage requirements in place. Inasmuch as the functioning of the patent linkage mechanism relies on the ability of domestic systems to quickly assess the existence or the validity of a patent, pending the grant of regulatory approval, patent linkage requirements imposed on countries whose systems do not currently meet such standard are likely to pose significant challenges and to result in additional burdens and further delays and impediments on trade in pharmaceutical products. In the context of these negotiations, certain countries are reportedly accepting the inclusion of patent linkage requirements in exchange for concessions in other sectors or areas of the agreement, without properly considering the impact that patent linkage requirements stand to have on their domestic framework. With respect to biologics, the further consideration to be made is that, given the early stage of competition in the biologic industry and the constantly evolving scientific and regulatory landscape surrounding biologics, the establishment of complex and layered IP protection for biologics (including patent linkage requirements) is largely premature. Instead, proposals tabled in the various stages of the TPP negotiations included suggestions to broaden the scope of patent linkage, while avoiding the '*check and balances*' that such systems should include (such as requirements to provide for incentives to encourage patent challenge).

Therefore, it is important that all factors be appropriately considered and reflected in the negotiation of IPR Chapters of trade agreements. Negotiators and affected constituencies must ensure that the appropriate balance, between encouraging investment and ensuring

competition and technology transfer in the pharmaceutical sector, is achieved. Where present, patent linkage requirements add to a number of other, WTO "*TRIPs-plus*", protections (*e.g.*, data exclusivity requirements and patent term extensions) that are routinely included in bilateral or plurilateral trade agreements by the US and other countries or blocks, such as the EU, EFTA (*i.e.*, Iceland, Liechtenstein, Norway and Switzerland) and Switzerland, all of which result in delayed generic and biosimilar entry, less competition, higher costs for medicines and loss of significant savings for national healthcare systems and the economy.

With respect to patent linkage requirements, the simplest way of achieving such balance is to avoid including such requirements, just as the EU does. Where included in the negotiations, it must be clear that patent linkage must not apply to biologics, and, with respect to generics, that such requirements be limited as to the scope of the patents that are covered and be balanced by appropriate '*safeguards*' to prevent abuse. On the other hand, stakeholders must also ensure that domestic implementation of such requirements does not in itself result in unnecessary and unwarranted stricter frameworks.

## The China - Australia FTA is set to include a most-favoured nation provision on services and investment

In November 2014, China and Australia announced the conclusion of the free trade agreement (hereinafter, FTA) that the two countries had been negotiating since 2005. Pending translation and legal review, it is expected that the text of the ChAFTA (*i.e.*, China - Australia FTA) will be published later in 2015. When fully implemented, the ChAFTA will provide, in relevant part, for the removal of tariffs applying to approximately 95% of goods from both trading partners, enhanced market access in a number of services sectors and promote investment. The ChAFTA contains a number of additional commitments, including a framework for electronic commerce, provisions on cooperation in competition policy and a commitment to facilitate customs procedures.

In particular, the ChAFTA foresees tariff reductions (that will apply gradually) covering key goods for Australia (such as dairy products, beef and wine) and for China (*e.g.*, clothing, footwear, household appliances and cars). In addition, it embodies a periodic review mechanism allowing for the trading partners to commit to further liberalisation, which will apply three years after the entry into force of the agreement and every five years thereafter. It is expected that this mechanism will allow Australia and China to agree on additional market access commitments and to settle a number of specific issues, including non-tariff barriers in place in China affecting, *inter alia*, rice, sugar, cotton and canola from Australia.

In March 2015, the two trading partners announced that the ChAFTA is set to include a most-favoured nation (*i.e.*, MFN) provision applying to the services and investment chapters. According to this clause, any more favourable services or investment treatment, that one party agrees to in future agreements with other trading partners, will need to be extended to the other party. As applied to the services chapter, the MFN clause stands to further deepen the commitments agreed to by the parties, which already cover, *inter alia*, the legal, financial, educational and telecommunications sectors. Considering that the relevant provisions have not yet been released, the extent to which such liberalisation will be effective (including the exact modes of supply that are to be covered), remains to be confirmed.

With regards to investment, the MFN provision will also extend to the bilateral relations between China and Australia any more favourable treatment granted to investors from third parties. That would be the case if, for instance, better treatment were to be agreed between China and the US in the framework of their ongoing negotiations for a bilateral investment treaty. In particular, if such negotiations were to deliver the results that the US reportedly expects, Australian investors could gain majority ownership rights in Chinese firms, up from

the 49% ceiling envisaged in ChAFTA. As for the procedural aspects, it is noted that ChAFTA provides for investors to have recourse to an investor-to-state dispute settlement (*i.e.*, ISDS) mechanism. If ISDS is not excluded from the MFN treatment obligation, investors will also be able to invoke the MFN provision to receive any more favourable treatment on ISDS that China or Australia will grant to third parties. This would be in line with the outcome of the *Maffezini* case (decided in the context of the World Bank's International Centre for Settlement of Investment Disputes), where it was established, *inter alia*, that the MFN clause in investment treaties applies to dispute settlement provisions, including the ISDS mechanism.

Apart from the immediate benefits for Australian and Chinese companies, the MFN provisions in ChAFTA also stand to have important systemic implications in the wider context. Although the relevant clauses have not yet been disclosed, it appears that they may be similar to other MFN provisions on services and investment included in a number of existing FTAs. In particular, the FTAs negotiated by the EU and the US with, *inter alia*, Canada and South Korea, and with Panama, Peru and South Korea, respectively, include, albeit through different language and subject to varying conditions, MFN clauses on services and/or investment.

Arguably, the inclusion of a MFN provision in preferential trade agreements adds to the long-standing debate on the appropriateness of a network of overlapping FTAs (*i.e.*, the so-called '*spaghetti bowl*') *vis-à-vis* the rules of the WTO multilateral trading system. The proliferation of FTAs, which operate as an exception to the WTO regime, may respond (at least, partly) to the stagnation of the WTO Doha Development round of multilateral trade talks. Detractors argue, *inter alia*, that the network of FTAs may hamper trade by increasing transaction costs and imposing variable tariffs and complicated rules of origin; whereas advocates maintain that it responds to practical circumstances and the actual needs of countries and regions. In any event, the important trade negotiations that are currently taking place (including those between the EU and the US for a Transatlantic Trade and Investment Partnership; and between Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, the US and Vietnam, for a Trans-Pacific Partnership), arguably illustrate a tendency to commit to deeper trade liberalisation away from multilateral *fora* (*i.e.*, WTO). From a theoretical viewpoint, it may be argued that the inclusion of MFN provisions contributes to strengthen the liberalisation process through the proliferation of FTAs. However, this trend also raises a number of questions, including on the value of FTAs (concluded, for instance, by countries with limited bargaining power) that do not envisage similar MFN provisions.

The publication of the ChAFTA will shed light on the expectations that private operators involved in trade between China and Australia can reasonably have. It remains to be seen, once it is fully operative, to what extent the ChAFTA (in combination with other FTAs) will increase trade, as well as whether and to what extent the MFN provision will effectively contribute to services and investment liberalisation. It will also be interesting to see whether (and how) the existence of the MFN clause affects ongoing and future trade negotiations. Thus far, China appears to have purposefully conducted its trade negotiations with South Korea entirely at the margin of the negotiations with Australia. Sources reported that the China - South Korea FTA was concluded in November 2014 (*i.e.*, only a few days prior to the announcement of the conclusion of the ChAFTA, and months before the existence of the MFN provision was disclosed).

Businesses concerned with transnational trade are advised to assess the impact of the provisions of the ChAFTA and of other relevant FTAs, possibly seeking expert advice on how to fully exploit the opportunities granted by these agreements, with the aim of enhancing their international trade performance. After all, the commercial objectives of the industry are a fundamental drive of government-to-government relations and negotiations.

## Calls for measures on *trans* fats in the EU

On 21 April 2015, the European Consumer Organisation (hereinafter, BEUC) sent an open letter to the EU Commission, urging it to publish, without further delay, the report on the presence of *trans* fatty acids (hereinafter, TFAs) in foods and in the overall diet of the EU population, as required by *Regulation (EU) No. 1169/2011 of the European Parliament and of the Council* (*i.e.*, the *Food Information Regulation* or FIR). The European Society of Cardiology (hereinafter, ESC) has also called for measures on TFAs. In addition, in March 2015, the World Health Organisation (hereinafter, WHO) released an Interim Report through its Commission on Ending Childhood Obesity, which calls for taxation and restricted marketing of '*unhealthy'* foods and drinks to children, in order to help cut childhood obesity. The purview of '*unhealthy'* foods normally includes foods that are high in saturated fats, TFAs and salt, as well as sugar-sweetened non-alcoholic beverages and energy-dense, nutrient-poor foods (see Trade Perspectives, Issue No. 7 of 2 April 2015).

TFAs are fats that have been processed to make them artificially hard through hydrogenation (or fat hardening), which turns liquid oil into solid fat. Industrially produced TFAs (hereinafter, IP-TFAs) were invented in the 1890s, but it was only in the 1970s and 1980s that they started to be used at a larger scale as cheap stabilising agents in processed foods. Their use was also favoured by the industry, which benefited from TFAs' ability to withstand repeated heating. However, TFAs are known to increase levels of '*bad'* low-density lipoprotein (LDL) cholesterol and to reduce levels of '*good'* high-density lipoprotein (HDL) cholesterol. Although some TFAs occur naturally in the digestive system of ruminant animals (such as cows, sheep and goats) and end up in their derived products, IP-TFAs may only be obtained through the process of partial hydrogenation. Partial hydrogenation of vegetable oils impacts on the physiochemical and functional properties of the unsaturated fatty acids, thereby leading to a high content of TFAs (depending on the type of fat and method). Conversely, the process of complete hydrogenation (which is more costly), does not lead to TFAs. The majority of TFAs can be found in industrial food products, such as ready meals, biscuits, potato chips, ready-made sauces or margarines, but also in take-away food. Scientists associate the consumption of TFAs with the increase of obesity, diabetes and cardiovascular diseases. According to the ESC, it is a fact that TFAs have a negative influence on coronary heart diseases.

Article 30(7) of the FIR called on the EU Commission to prepare, by 13 December 2014, a report on the presence of TFAs in foods and in the overall diet of the population. This report could provide for legislative proposals, but has not yet been published. The question is what policy options the EU Commission may propose (if any) with the report.

First, it could propose that the placing on the market of food products, in which the amount of TFAs exceeds a certain threshold for every 100g of the total fat content, be prohibited. On request of the EU Commission, the European Food Safety Authority (hereinafter, EFSA) published on 25 March 2010 a scientific opinion, which dealt, *inter alia*, with TFAs. The *Scientific Opinion on Dietary Reference Values for fats, including saturated fatty acids, polyunsaturated fatty acids, monounsaturated fatty acids, TFAs, and cholesterol*, adopted by the EFSA Panel on Dietetic Products, Nutrition and Allergies, states that TFA intakes should be "*as low as possible*". However, it does not establish a specific maximum level. Rather, it states that "*[d]ietary trans fatty acids are provided by several fats and oils that are also important sources of essential fatty acids and other nutrients. Thus, there is a limit to which the intake of TFAs can be lowered without compromising adequacy of intake of essential nutrients. Therefore, the Panel concludes that TFAs intake should be as low as is possible within the context of a nutritionally adequate diet. Limiting the intake of TFAs should be considered when establishing nutrient goals and recommendations*" (see Trade Perspectives, Issue No. 15 of 26 July 2013).

The WHO has suggested that TFA consumption be limited at 1% of the total energetic intake. This has been interpreted by several countries as a limit of 2g of TFAs per 100g of fat, and appears to have become the standard in the legislation of some countries. A number of EU Member States (*i.e.*, Austria, Denmark and Hungary) and other European countries (*i.e.*, Iceland and Switzerland) have already adopted limitations on TFAs in food. In particular, the Danish *Executive Order No. 160 of 11 March 2003 on the Content of Trans Fatty Acids in Oils and Fats,* the Austrian *Ministerial Decree No. 267 of 20 August 2009 on trans fat content in food* and the Hungarian *Decree 71/2013 (XI. 20.) on the highest permitted amount of trans fats in food products*, all provide that the content of TFAs in oils and fats shall not exceed 2g per 100g of oil or fat.

In its open letter to the EU Commission, BEUC supports EU-wide legal limits on the use of IP-TFAs in foodstuffs and argues, in particular, the following: (i) even though the food industry has removed IP-TFAs from many food products, some foods still contain these harmful fats; (ii) according to recent consumer research, IP-TFAs are found in popular foods such as waffles, biscuits and margarine spreads, sometimes at very high levels; (iii) lower socioeconomic groups are particularly exposed to IP-TFAs, which contributes to health inequalities; (iv) there is unanimous scientific evidence on the harmful effects of IP-TFAs, particularly on heart health; (v) EU-wide legal limits will help food businesses operate across the EU, as they will have to comply with a single standard; and (vi) it would also create a level playing field, therefore reassuring companies that have already made efforts to reformulate products, that they will not be at a competitive disadvantage. This is all the more relevant knowing that several countries have already put in place restrictions on the use of IP-TFAs. BEUC stresses that legal limits are the only option to offer legal certainty to businesses and equal protection to all consumers. By contrast, BEUC maintains that labelling schemes would not equally protect consumers, while food industry bodies have criticised this option arguing that it would be overly burdensome.

An additional important aspect must be considered. In 2005, the EU Commission initiated infringement proceedings against Denmark contending that the Danish legislation on TFAs imposed barriers to trade for other EU Member States. The Danish Government maintained that, from a health point of view, the legislation was legitimate and forwarded extensive scientific documentation to confirm this. In March 2007, the EU Commission decided to withdraw its case against Denmark. The prohibition of placing on the market food products in which the amount of TFAs exceeds 2g for every 100g of the total fat content appears to be scientifically justified.

Is such measure effective? 10 years after its entry into force, the Danish Ministry for Agriculture, Food and Fisheries claimed that the legislation limiting TFAs has not resulted in significant adjustment problems for the industry and that no important concerns have been reported when it comes to substituting TFAs with other types of fats. In addition, the substitution has apparently not caused any significant rise in the price of the involved commodities of food. Comparisons of the fatty acid profiles have shown that, in 68% of the concerned products, IP-TFAs have mainly been substituted with saturated fatty acids (mostly originating from either coconut fat or palm oil, which in most cases do not need to go through the process of partial hydrogenation, while providing the same industrial stability). It was also reported that the national law restricting the use of IP-TFAs to no more than 2g of IP-TFAs per 100g of fat did not lead to price increases in Denmark.

In conclusion, it appears that, in relation the first policy option, a careful analysis is needed to fully understand the impact of restrictions on TFAs at the EU level. Reportedly, the food industry in Eastern Europe would be more strongly affected by similar measures, inasmuch as TFAs are more widely used in that geographical area. It would also need to be assessed whether 2g TFAs for every 100g of fats and oils is, according to the latest available science, the correct margin.

A second policy option could relate to the adoption of labelling requirements for TFAs. EU legislation, in its rules on nutrition labelling laid down in the FIR, puts an emphasis on saturated fats. Article 30 of the FIR, which establishes the mandatory content of the nutrition labelling declaration as of 13 December 2016 (currently, the nutrition declaration is provided on a voluntary basis), requires that the nutrition labelling declaration includes: (a) energy value; and (b) the amounts of fat, saturates, carbohydrate, sugars, protein and salt. No indication of TFAs is required. However, the content of the mandatory nutrition declaration may be supplemented with an indication of the amounts of, *inter alia*, monounsaturates and polyunsaturates. The FIR's predecessor on nutrition labelling, *Council Directive 90/496/EEC of 24 September 1990 on nutrition labelling for foodstuffs*, already singled-out saturated fats.

In the list of ingredients, EU legislation does not require a specific reference to TFAs, neither does it regulate the content of TFAs in foodstuffs. The FIR requires, in No. 8 of Part A of Annex VII, that the expression "*fully hydrogenated*" or "*partly hydrogenated*", as appropriate, accompany the indication of hydrogenated fats and oils in the lists of ingredients. Therefore, a knowledgeable consumer aware that partly hydrogenated vegetable fats contain TFAs can already identify, by carefully reading the list of ingredients, whether a product contains TFAs (although not in what amount). BEUC believes that labelling options should not even be considered by regulators, on grounds that they require consumers' knowledge and can be misleading. A possible solution could be to amend No. 8 of Part A of Annex VII of the FIR, so that the expression "*partly hydrogenated vegetable oil (contains trans fats)*" be required. Arguably, that would add clarity to the list of ingredients, although a certain degree of consumer education about TFAs would still be necessary. In turn, this could be achieved through information campaigns.

A third policy option could be a tax on TFAs. The WHO calls for taxation and restricted marketing of '*unhealthy'* foods and drinks to children, in order to help cut childhood obesity. However, '*fat taxes*' are a complex matter. In order to justify specific taxation of certain foods for purposes of health protection, regulators should collect credible scientific evidence that additional taxes on food products effectively encourage consumers to follow a more balanced diet and lead a healthy lifestyle. Against this background, the food industry has been calling for such a (scientific) link between taxes and health, as it believes that no such justification exists (see Trade Perspectives, Issue No. 1 of 13 January 2012). Before considering the adoption of a harmonised EU '*fat tax*' on TFAs, the EU should therefore carry out a thorough and critical legal review of its envisaged measures, to ensure that they are in compliance with its obligations, including those stemming from the WTO. In particular, the EU would need to ensure that such measures are consistent with the requirements of the General Agreement on Tariffs and Trade (*i.e.*, the GATT), including that they do not give cause to discrimination *vis-à-vis* imported products (see Trade Perspectives, Issue No. 8 of 20 April 2012). Interestingly, between October 2011 and January 2013, Denmark applied a tax on meat, dairy products, oils and other foods containing more than 2.3% of saturated fat (see Trade Perspectives, Issue No. 18 of 7 October 2011). The market distortive effects of such measures were so controversial on the internal market that the EU Commission went as far as, once the Danish tax had already been withdrawn, opening a state aid investigation against it (see Trade Perspectives, Issue No. 4 of 20 February 2015).

Lastly, the EU Commission could propose voluntary reformulations by food manufacturers. Voluntary reformulation relies on the concerned companies' willingness to reformulate their products' composition and, as such, it cannot lead to a homogeneous decrease of IP-TFAs in food, nor to a harmonised level of consumer protection. According to BEUC, a voluntary approach has been favoured in the past fifteen years, which has led to the current situation where the food industry can decide what TFA levels are tolerable and achievable. As a result, according to BEUC, IP-TFAs are still present in some foods and put consumers' health at risk. Given that the majority of food businesses claim that they do no longer use IP-TFAs, having

the current voluntary restrictions enshrined in EU legislation should, according to BEUC, not be problematic. However, the policy option of voluntary reformulation may fail to protect consumers.

Reportedly, the EU Commission's report on TFAs is likely to be released in June 2015. The next steps taken in the EU on TFAs and other '*unhealthy'* foods should also be monitored and operators should be prepared to participate in shaping upcoming EU legislation by interacting with EU Institutions, third country Governments, relevant trade associations and affected stakeholders.

## Recently Adopted EU Legislation

### Market Access

- *Commission Implementing Regulation (EU) 2015/736 of 7 May 2015 prohibiting the introduction into the Union of specimens of certain species of wild fauna and flora*

### Trade Remedies

- *Commission Implementing Regulation (EU) 2015/763 of 12 May 2015 imposing a provisional anti-dumping duty on imports of certain grain-oriented flat-rolled products of silicon-electrical steel originating in the People's Republic of China, Japan, the Republic of Korea, the Russian Federation and the United States of America*

- *Commission Implementing Regulation (EU) 2015/706 of 30 April 2015 initiating an investigation concerning the possible circumvention of anti-dumping measures imposed by Commission Implementing Regulation (EU) 2015/82 on imports of citric acid originating in the People's Republic of China by imports of citric acid consigned from Malaysia, whether declared as originating in Malaysia or not, and making such imports subject to registration*

### Customs Law

- *Commission Implementing Decision (EU) 2015/714 of 24 April 2015 concerning the validity of certain binding tariff information (notified under document C(2015) 2888)*

### Food and Agricultural Law

- *Commission Regulation (EU) 2015/705 of 30 April 2015 laying down methods of sampling and performance criteria for the methods of analysis for the official control of the levels of erucic acid in foodstuffs and repealing Commission Directive 80/891/EEC*

## Other

- *Directive (EU) 2015/720 of the European Parliament and of the Council of 29 April 2015 amending Directive 94/62/EC as regards reducing the consumption of lightweight plastic carrier bags*

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