

**Issue No. 3 of 10 February 2017**

- **Burdensome, but partly ineffective – Illegal seafood circumventing the EU's IUU fishing rules underlines the need for stronger plurilateral and multilateral engagement**
- **The US Food and Drug Administration issues its guidance on the non-proprietary naming of biological products**
- **European Parliament's ENVI Committee votes for restrictions of advertisements for HFSS foods aimed at children, including in social networks**
- **Recently Adopted EU Legislation**

**Burdensome, but partly ineffective – Illegal seafood circumventing the EU's IUU fishing rules underlines the need for stronger plurilateral and multilateral engagement**

At the end of January 2017, a coalition of environmental non-governmental organisations (hereinafter, NGOs), namely the Environmental Justice Foundation (EJF), Oceana, the Pew Charitable Trusts and the World Wildlife Fund (WWF), published two case studies and repeated recommendations that relate to the implementation of the EU's framework on illegal, unreported and unregulated (hereinafter, IUU) fishing. The case studies and related recommendations suggest that, due to shortcomings of the current application of the EU's IUU framework, illegal seafood is still easily entering the EU. The recommendations, already included in position papers published by those NGOs in July 2016, call for an EU-wide electronic database and stronger harmonisation between EU Member States. In a broader perspective, efforts should not stop there and should take advantage of the ongoing trade negotiations, which offer a unique opportunity to connect trade and sustainability in future trade agreements.

IUU fishing refers to fishing that: (1) lacks authorisation, does not comply with conservation and management measures developed by regional fishery management organisations, or violates national laws or international obligations (*i.e.*, is illegal); (2) is not properly reported under international, regional or national laws and regulations (*i.e.*, is unreported); and (3) is performed by vessels with no national flag or that jeopardise fish stocks (*i.e.*, is unregulated). *Council Regulation (EC) No 1005/2008 of 29 September 2008 establishing a Community system to prevent, deter and eliminate illegal, unreported and unregulated fishing* (hereinafter, the EU's IUU fishing Regulation), which entered into force in 2010, and the additional instruments adopted in November 2013 (see *Trade Perspectives*, Issue No. 23 of 13 December 2013) require the flag state to certify the origin and legality of fishery products in order to trace the fishery products on the EU market. It is exactly this catch certification scheme and its management by EU Member States' authorities that has now come under scrutiny by this coalition of NGOs. More specifically, the EU's IUU fishing Regulation introduced a system of catch certification for consignments of fishery products for human consumption traded with the EU (exports and imports). Since 1 January 2010, all marine

fishery products (except aquaculture products and certain species), consigned by EU vessels and by third countries to the EU market, must be accompanied by a certificate signed by the master of the originating fishing vessel stating that the products were caught legally. The catch certificate must be validated by a competent authority of the flag state of the vessel. The catch certification scheme is designed to ensure full traceability of all marine fishery products traded with the EU, so that no product derived from IUU fishing appears on the EU market.

However, the catch certificate scheme is currently paper-based and no central EU database exists. Currently, about 275,000 paper-based catch certificates have to be checked by EU Member States' authorities each year. One of the case studies presented by the coalition of NGOs focussed on an exemplary case that took place in an unnamed EU Member State. In this case, the same paper-based catch certificate was again used in the same EU Member State, was rejected, but then submitted and accepted in another EU-Member State. The coalition of NGOs further notes that processed fishery products present a particular challenge. This is attributed to the characteristics of the supply chain that may include several countries (a country where the fish is caught and another or more where it is processed), product conversions and the breaking up of consignments. For such split consignments, Article 14(2)(c)(ii) of the EU's IUU fishing Regulation expressly allows the photocopying of paper-based catch certificates, which further complicates the matter. The paper-based system also means that EU Member States' authorities, responsible for the verification of the catch certificates upon importation, are currently unable to cross-check catch certificates with the documents received in other EU Member States. Consequently, paper copies of a catch certificate can easily be used in multiple EU Member States to import multiple consignments into different entry points and in excess of the total weight certified, without being noticed.

Additionally, a lack of harmonisation with respect to the controls by EU Member States' authorities appears to persist. Article 17 of the EU's IUU fishing Regulation provides the framework for the risk assessment as the basis for verification to be initiated by EU Member States' authorities. Furthermore, Article 31 of *Commission Regulation (EC) No 1010/2009 of 22 October 2009 laying down detailed rules for the implementation of Council Regulation (EC) No 1005/2008 establishing a Community system to prevent, deter and eliminate illegal, unreported and unregulated fishing* sets out the criteria for the risk assessment. However, a second case study presented by the coalition of NGOs appears to show that there is lack of harmonisation of the risk assessment and the application of the risk criteria, as well as of the verification procedures. Such variable implementation, paired with the paper-based catch certificates that do not allow immediate cross-checks across EU Member States, has led to a situation in which a generally lauded anti-IUU framework actually allows very porous EU borders with respect to the import of illegal seafood.

Therefore, the coalition of NGOs is advocating two recommendations: The first recommendation relates to the implementation of an EU-wide electronic database to process catch certificates. The second recommendation relates to a harmonisation of the application by EU Member States' authorities of the processes for risk assessment and verification. The position papers and the report of the case studies provide very detailed recommendations that the EU can take into account when modernising the implementation of the EU's IUU fishing Regulation. The modernisation and improvement of the application appear particularly important in order to reward those countries that have made significant efforts (and incurred significant costs) to comply with the EU's IUU fishing Regulation, but that see illegal seafood still entering the EU undetected and in potentially large quantities from countries that have not complied and that are distorting competition. In fact, the EU is currently in the process of

modernising the application of its IUU fishing Regulation as set out in a [communication](#) published in October 2015. This communication specifically notes the transition from a paper-based system to an electronic system during 2015-2016, a deadline that was apparently not met.

As noted, the reports also highlight the need for the harmonisation of IUU fishing measures and implementation across all EU Member States and in accordance with a risk-based approach. However, a harmonised approach should not be the only objective to be sought. The EU's IUU fishing framework is deemed to be the most advanced instrument against IUU fishing worldwide. It has also considerably contributed to global improvements in this area and has led to important reforms in third countries. This includes the enhanced cooperation that the EU has achieved in relation to fisheries with several trading partners (see *TradePerspectives*, [Issue No. 9 of 6 May 2016](#)), as well as the coordination with other important seafood markets, such as the US, that are establishing their own frameworks (see *TradePerspectives*, [Issue No. 3 of 12 February 2016](#)). These positive and successful developments should now be taken further and '*institutionalised*' within a framework of international trade and sustainability commitments. The high number of ongoing trade negotiations conducted by the EU, as well as by other countries or regions, provide a unique opportunity to deal with the issue of trade in fishery products and the fight against IUU fishing within such commercial and economic context.

Preferential trade agreements (hereinafter, PTAs) generally cover the '*classic*' areas of trade agreements such as, *inter alia*, market access, sanitary and phytosanitary measures, and technical barriers to trade. However, their scope is being progressively expanded to cover further areas linked to trade. The EU typically covers the issue of IUU fishing and further social and environmental issues in a dedicated Chapter on Trade and Sustainable Development (hereinafter, TSD Chapter) of its PTAs. However, such agreements are still mostly bilateral in nature, binding the EU and one single trading partner. The problems caused by the lack of harmonisation in the application of the IUU fishing rules, and the high costs for seafood exporting countries to comply with the piecemeal of IUU fishing frameworks that are now being implemented around the world, have become obvious. The only sustainable answer appears to be a concerted plurilateral or multilateral approach.

As the difficulties of a global and multilateral approach have also become obvious (see *TradePerspectives*, [Issue No. 18 of 7 October 2016](#)), the starting point could and should be plurilateral or regional agreements that can then be expanded further later on. For example, trade negotiations between the EU and ASEAN (still envisaged by the EU) and between the EU and MERCOSUR (currently ongoing) provide the appropriate context for such negotiations between regional blocks. Obviously, negotiations and future TSD Chapters should not be limited to enhanced provisions addressing IUU fishing. Those chapters provide participating parties with the unique opportunity to tackle a number of important issues related to trade and sustainability. Further areas include the issues of timber (building on forest law enforcement schemes such as the EU's FLEGT system) and vegetable oils (in particular the issue of soy and oil palm cultivation). The inclusion of all these issues in trade agreements offers the important advantage of combining key policy commitments with economic benefits for all participating parties. On the contrary, the current unilateral piecemeal approach that sees major economies such as the EU and the US impose their frameworks on third countries, including important trading partners, is in no way sustainable.

The fight against IUU fishing and the broader goal of making production and trade of goods more sustainable must be continued by all available and appropriate means. However, countries should not resort to unilateral action and impose their diverse frameworks, thereby

increasing compliance costs, but rather cooperate and strive to achieve plurilateral or multilateral solutions. As the example of the implementation of the EU's IUU fishing Regulation shows, the current approach often benefits those trying to undermine and circumvent the regulations, occasionally placing compliant countries at a comparative disadvantage. There are innovative ways forward and the high number of ongoing trade negotiations is a strong sign that enhanced future cooperation is possible. These opportunities should be seized, with a view to future approaches that more significantly facilitate trade than current unilateral undertakings do. In the meantime, stakeholders and Governments should be aware of the current shortcomings and work together to improve the existing frameworks. As the EU is expected to roll out its new EU-wide electronic database for IUU catch certificates within this year, interested stakeholders in the EU and fishery exporting countries, as well as partner countries' Governments, should closely monitor the developments and contribute to these developments.

### **The US Food and Drug Administration issues its guidance on the non-proprietary naming of biological products**

In January 2017, the United States Food and Drug Administration (hereinafter, FDA) issued a definitive non-binding guidance on the non-proprietary naming of biological products, intended to set the industry standard in the area. The guidance builds on the previous draft, which was released in August 2015 and that attracted a number of comments from the biological medicines industry and patient advocacy groups.

Today, biological medicines account for around a quarter of all drug sales globally. Unlike chemically-derived drugs, biological medicines are obtained from living organisms, which produce active substances usually consisting of large molecules with complex structures. Examples include, *inter alia*, hormones (e.g., insulin), proteins, blood components and vaccines. The biological origin and complex structure of such medicines prevents their exact copying. Manufacturers other than the original manufacturer may, therefore, only produce a drug, which is highly similar, yet not identical, to the *reference* product (*i.e.*, a product which has been approved for marketing by a relevant authority). This is what differentiates biosimilar medicines from chemically synthesised generics - the active substance of the latter may be identical to that of their respective brand-name drug.

Pursuant to Section 351(i)(2) of the US Public Health Service Act (hereinafter, PHS Act), in order to receive authorisation for the marketing of a *biosimilar* product, an applicant is required to demonstrate to the FDA that: (1) the proposed product is highly similar to the reference product notwithstanding minor differences in clinically inactive components; and (2) there are no clinically meaningful differences between the biological product and the reference product in terms of their safety, purity, and potency (for comparison, the European Medicine Agency's (hereinafter, EMA) guideline on similar biological medicinal products uses safety, quality and efficacy as the criteria). A biosimilar product is additionally *interchangeable* with a reference product (Section 351(k)(4) of the PHS Act) when it has been shown to the FDA's satisfaction that: (1) the product can be expected to produce the same clinical result as the reference product in any given patient; and (2) alternating or switching between the use of the reference product and the biosimilar product does not increase the risk to patients in terms of safety or efficacy *vis-à-vis* the risk without such alternation or switch. In the EU, interchangeability falls within the competence of national authorities and is, therefore, not addressed in the EMA guidance. These characteristics of interchangeable products mean that they can be substituted for their respective reference product without the intervention of the prescribing doctor. Finally, *related* biological products are, simply put, biological products filed for approval, for which an approved product with the same drug substance name ("*core*" name, see below) already exists.



Like chemically derived drugs, biological medicines can be referred to by their proprietary (trademark) name or by their non-proprietary (proper) name, which identifies the product's active substance. As a biosimilar and/or related medicine is not identical to its respective originator (*i.e.*, originally approved) drug, the question arises as to whether, and how, the naming should ensure differentiation between originator, related, and biosimilar products. This is an issue distinct from biosimilar product labelling (see [TradePerspectives, Issue No. 7 of 8 April 2016](#)).

In essence, the FDA guidance provides for complementing the non-proprietary name of each biological medicinal product with a product-specific identifier in the form of a four-letter suffix separated from the “core” name (*i.e.*, the name identifying the active substance) with a hyphen. The suffix is an additional element intended to distinguish between an originator product, its related products, and its biosimilar products. The FDA puts forward four considerations that led it to adopt this particular approach. Firstly, this manufacturer-specific identifier facilitates pharmacovigilance (*i.e.*, measures to ensure drug safety, particularly after it has been released into the market) by helping to track “adverse events” (*i.e.*, adverse effects of the drug) to a specific manufacturer, manufacturing site, or lot. This, in turn, allows more targeted remedial action. Addressing some industry groups’ scepticism about the need for a distinctive element in the non-proprietary name, the FDA notes that alternative identifiers (such as national drug codes or proprietary names) would not routinely be recorded and could not, therefore, always be effectively used for the tracking purpose. Secondly, the additional suffix would contribute to safer use of the drugs by preventing their inadvertent substitution. An originator (reference) biological medicine and its related and biosimilar medicines would not necessarily be interchangeable among each other (in particular, there may be differences in indications or routes of administration), but a common non-proprietary name without an additional distinguishing identifier might create a false impression that they are, thereby resulting in confusion and dosing errors. This FDA guidance does not address identification of interchangeable products. Thirdly, the FDA believes that this format of an additional identifier, in particular its inclusion in a medicine’s non-proprietary name, would promote the routine use of the identifier in ordering, prescribing, dispensing, record-keeping and pharmacovigilance, thus contributing to the accomplishment of the first two objectives. Last but not least, the application of the suffix to originator, as well as to related and biosimilar products, would also avoid biased perceptions as to the safety and effectiveness of related and biosimilar products.

While reactions to adding a distinctive suffix to a non-proprietary name were mixed, what appears to have attracted universal opposition from the industry, since the time of the FDA’s draft guidance of 2015, is the FDA’s decision to adopt suffixes that are devoid of meaning, essentially constituting a random set of letters. While the FDA now offers applicants an opportunity to propose ten variants of suffixes of their choice, it specifically recommends that, *inter alia*, the suffixes not look similar to, or otherwise connote, the name of the license holder. While generally welcoming the framework proposed by the FDA, the Alliance for Safe Biologic Medicines (hereinafter, ASBM), for example, already back in 2015 opined that a “*meaningful, intuitive suffix applied consistently to all products by a single manufacturer would be more memorable and thus easier for healthcare providers to use, limit proliferation of suffixes, and reduce the likelihood of juxtaposition or confusion*”. The Chairman of the Biosimilars Council, a division of the Generic Pharmaceutical Association (a US trade association of pharmaceutical industry companies), in turn, has questioned the whole idea of adding a distinctive identifier to non-proprietary names of biological medicines, saying that the FDA’s proposed framework “*confers no additional safety benefit, and in fact would require the healthcare professional to be armed at all times with a code-breaking reference*”, while proper names “*without suffixes are [...] safely and effectively utilised in [the] EU, Canada, Australia and Japan*”.

Indeed, [Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use](#) does not set out any special naming conventions for biological medicinal products. It provides, in Article 1(20)

thereof, read in combination with Article 1(21), that the name of a medicinal product may be: (1) either an invented name not liable to confusion with the international non-proprietary name (hereinafter, INN) recommended by the World Health Organisation (hereinafter, WHO) or, if such name does not exist, with the usual common name; or (2) an INN/common name or scientific name accompanied by a trade mark or the name of the marketing authorisation holder. Article 54(a) further provides that the outer packaging of medicinal products must contain the name of a medicinal product and, separately, its INN. The European Biosimilars Group (hereinafter, EBG), a sector group of '*Medicines for Europe*', an association representing the generic and biosimilars industry in Europe, believes this approach is "*highly reliable and the model for the world*". According to EBG, the European approach would allow reliable identification and traceability of medicines using already existing identifiers (e.g., the brand name), and there would be no need in the EU for biosimilar products (whose comparability to reference product in terms of quality, safety and efficacy is guaranteed) to be distinguished with additional signs.

This opinion is shared by the EMA, which believes that, in particular, the biological qualifier scheme recently developed by the WHO would not add value to the EU's existing identification system. The WHO's proposal, which seeks "*to provide a uniform global means of identification to avoid the proliferation of differing national schemes*", was released in January 2016 and lays down a framework similar to that put forward by the FDA. In particular, it provides for the introduction of a "*Biological Qualifier*" (hereinafter, BQ), which is a unique identification code distinct from the respective medicine's INN and consists of four consonant letters and, optionally, a two-digit checksum to be located immediately after the letters or between two groups of two letters each. Like the FDA's suffix, the BQ will ensure traceability back to the manufacturer. In contrast to the FDA's scheme, however, the BQ is not attached to the INN, the letters in the BQ are assigned automatically by an online system, and it is up to the individual regulatory authority to decide whether it wants to adopt the BQ system with or without the two-digit checksum.

While the FDA's guidance remains silent on why the authority did not heed to the industry's calls to use meaningful suffixes, the WHO explained that it eventually decided not to link BQs to applicants' names because: (1) this would effectively make the BQ code a proprietary item; (2) over the years, mergers and acquisitions would result in a BQ code which represents one marketing authorisation holder being used by another; (3) national regulatory authorities, when consulted, preferred a meaningless random code.

Inconsistency in the naming conventions for biological and biosimilar medicinal products may prove to be a significant barrier to international trade, especially while the number of approved biosimilar products remains low. As the WHO itself recognises, its efforts to establish uniform rules "*will only be as useful as the breadth with which [they are] taken up globally*". While the FDA's rules appear generally compatible with the WHO's proposal, some important jurisdictions, such as the EU, may be unwilling – perhaps, for a lack of objective need – to adopt a similar system for their market and their producers. Therefore, it is for the relevant authorities to ensure that the requirements they set in this area are proportionate to the objectives pursued and do not create unnecessary impediments for patients' access to advanced medicines.

### **European Parliament's ENVI Committee votes for restrictions of advertisements for HFSS foods aimed at children, including in social networks**

On 31 January 2017, the European Parliament's Committee on Environment, Public Health and Food Safety (hereinafter, ENVI) has voted for restrictions of advertisements for food and drinks that are high in fat, sugar and salt (hereinafter, HFSS foods), not only during peak viewing times, but more generally during children's programmes and in content aiming at a children's audience, including social networks. In particular, the ENVI Committee voted (with

29 votes in favour, 7 against and 30 abstentions) on an opinion requested by the European Parliament's Committee on Culture and Education (hereinafter, CULT Committee) on the proposal for a *Directive of the European Parliament and of the Council amending Directive 2010/13/EU on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the provision of audiovisual media services in view of changing market realities* (hereinafter, AVMSD).

On 25 May 2016, the European Commission (hereinafter, Commission) published its proposal for an amended AVMSD, which seeks to respond to the market, consumption and technological changes in the audiovisual media landscape, due to ever-increasing convergence between television and services distributed via the Internet. Traditional broadcasting in the EU remains strong in terms of viewership, advertising revenues and investment in content (around 30% of revenues). However, broadcasters are extending their activities online and new players offering audiovisual content via the internet (e.g., video-on-demand providers and video-sharing platforms) are getting stronger and competing for the same audiences, although they are subject to different rules and varying levels of consumer protection. The general objectives of the AVMSD proposal are to: (1) enhance the protection of minors and consumers in general through, where possible, harmonised EU audiovisual standards; (2) ensure a level playing field between traditional broadcasters, on-demand audiovisual media services and video-sharing platforms; and (3) simplify the legislative framework, in particular as regards commercial communication.

As regards commercial communications, the AVMSD proposal aims at reducing the burden of TV broadcasters while maintaining, and even reinforcing those rules seeking to protect the most vulnerable. For example, the revised AVMSD maintains the strict 20% limit on advertising time, but gives broadcasters more flexibility as to when advertisements can be shown. It also allows more flexibility regarding product placement and sponsorship and it encourages the adoption of '*self- and co-regulation*' for the existing rules, seeking to protect the most vulnerable as regards advertising for alcoholic beverages and HFSS foods. Article 9(2) of the current AVMSD only requests EU Member States and the Commission to encourage media service providers to develop codes of conduct regarding inappropriate audiovisual commercial communications, accompanying or included in children's programmes, of foods and beverages containing nutrients and substances with a nutritional or physiological effect, in particular those such as fat, trans-fatty acids, salt/sodium and sugars, excessive intakes of which in the overall diet are not recommended.

The ENVI opinion demands that the limitation of inappropriate commercial communications for minors and children, as well as the prohibition of product placement, should cover all children's programmes and content aiming at a children's audience, rather than only programmes with a significant children's audience. The opinion explicitly adds '*social networks*' to the well-established new players (including providers of video-on-demand services and video-sharing platforms), which according to the proposal increasingly generate new types of content, such as short videos or user-generated content. In so far as social networks constitute a major source of information for consumers and depend increasingly on audiovisual content generated or made available by their users, such networks should be included in the scope of the AVMSD when they fall within the definition of a video-sharing platform. In essence, the ENVI Committee's opinion is in favour of restricting unhealthy food marketing during children's peak viewing times, such as during family programmes, not just adverts broadcast around programmes specifically aimed at children. It also extends restrictions to video-sharing platforms, such as YouTube.

However, neither the proposal nor the ENVI Committee's opinion defines what exactly is meant by '*unhealthy*' or HFSS foods under the AVMSD. The proposal states that "*certain widely recognised nutritional guidelines exist at national and international level, such as the World Health Organisation (WHO) Regional Office for Europe's nutrient profile model, in order to differentiate foods on the basis of their nutritional composition in the context of foods television advertising to children.*" Furthermore, EU Member States should be encouraged to

ensure that self-and co-regulatory codes of conduct are used to effectively reduce the exposure of children and minors to audiovisual commercial communications regarding foods and beverages that are high in salt, sugars or fat or that otherwise do not fit these national or international nutritional guidelines. On the other hand, the ENVI Committee's opinion does not mention the WHO's nutrient profile model, but encourages EU Member States to ensure that self-and co-regulatory codes of conduct, such as the *EU Pledge* initiative and others developed in the framework of the Commission's Platform for Action on Diet, Physical Activity and Health, are used to effectively reduce the exposure of children to audiovisual commercial communications regarding HFSS foods.

The *EU Pledge* is an ongoing (2008-2020) voluntary commitment of the World Federation of Advertisers to the EU Platform for Action on Diet, Physical Activity and Health. Through it, major food companies, including *Coca Cola*, *Mars*, *Mondelez*, *Nestlé* and *Unilever*, have agreed not to advertise to children under 12, except for products fulfilling certain nutritional criteria. The Commission has not yet conducted an official evaluation of the EU Pledge. It was, however, subject to an external evaluation financed by the *EU Pledge* Secretariat, which concluded that it had contributed to a reduction in children's exposure to advertising for products that do not meet the chosen nutritional criteria. However, there is criticism that the food industry's voluntary efforts to market their products more responsibly are inadequate and that self-regulation is not delivering. Consumer protection organisations had called to use nutrient profiles established by the WHO and not industry-led criteria. For example, according to the nutrient profiles set by the *EU Pledge*, breakfast cereals containing up to 30g of sugar per 100g may be marketed to children, while the WHO's nutrient thresholds set the limit at 15g.

The establishment of nutrient profiles under the EU Nutrition and Health Claims Regulation (NHCR) has proven to be difficult, if not, impossible. Under the Commission's Regulatory Fitness and Performance programme (REFIT), the concept of nutrient profiles may even be abandoned (see *TradePerspectives*, [Issue No. 8 of 22 April 2016](#), [Issue No. 12 of 17 June 2016](#) and [Issue No. 13 of 26 June 2015](#)). The amendment of the AVMSD is part of a worldwide trend of public policies aimed at restricting advertisements addressed to children, such as through Chile's Consumer Protection Law, Nutritional Composition of Food Labelling and Advertising Law and Food Health Regulation (see *TradePerspectives*, [Issue No. 22 of 2 December 2016](#)). Under Chilean law, advertising may be banned if directed to children under 14 years of age if it uses, *inter alia*, children's characters and figures, animations, cartoons, toys, children's music, if it contemplates the presence of people or animals that attract the interest of children of this age group, or if it contains statements or fantastic arguments about the product or its effects, children's voices, language or expressions of children, or situations that represent their daily lives, such as school, playground or children's games.

Before the Proposal for an amended AVMSD is submitted for a vote in the European Parliament's plenary, a vote is scheduled in the CULT Committee on 22 March 2017. Developments in the EU on the AVMSD proposal and, in particular, on the development of nutrient profiles, should be closely monitored and operators should be prepared to participate in shaping potentially upcoming EU legislation by interacting with EU Institutions, Governments, relevant trade associations and affected stakeholders.

## Recently Adopted EU Legislation

### Trade Remedies

- [Commission Implementing Regulation \(EU\) 2017/220 of 8 February 2017 amending Council Implementing Regulation \(EU\) No 1106/2013 imposing a definitive anti-dumping duty on imports of certain stainless steel wires originating](#)



*in India following a partial interim review under Article 11(3) of Regulation (EU) 2016/1036 of the European Parliament and of the Council*

- *Commission Decision (EU) 2017/206 of 6 February 2017 terminating an expiry review of the anti-dumping measures applicable to imports of certain polyethylene terephthalate originating in the People's Republic of China*

## **Customs Law**

- *Commission Delegated Regulation (EU) 2017/217 of 5 December 2016 amending Annex II to Regulation (EU) No 978/2012 of the European Parliament and of the Council applying a scheme of generalised tariff preferences*

## **Food and Agricultural Law**

- *Commission Implementing Regulation (EU) 2017/211 of 7 February 2017 concerning the authorisation of a preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Bacillus subtilis* (LMG-S 15136) as a feed additive for poultry, weaned piglets and pigs for fattening, and amending Regulations (EC) No 1259/2004, (EC) No 1206/2005, and (EC) No 322/2009 and repealing Regulation (EC) No 516/2007*
- *Commission Implementing Decision (EU) 2017/205 of 3 February 2017 amending the Annex to Implementing Decision 2014/709/EU concerning animal health control measures relating to African swine fever in certain Member States*
- *Commission Implementing Regulation (EU) 2017/187 of 2 February 2017 concerning the authorisation of a preparation of *Bacillus subtilis* (DSM 28343) as a feed additive for chickens for fattening*

## **Other**

- *Commission Regulation (EU) 2017/172 of 1 February 2017 amending Regulation (EU) No 142/2011 as regards parameters for the transformation of animal by-products into biogas or compost, conditions for imports of petfood and for the export of processed manure*
- *Commission Decision (EU) 2017/176 of 25 January 2017 on establishing EU Ecolabel criteria for wood-, cork- and bamboo-based floor coverings*

*Laura Boschi, Ignacio Carreño, Tobias Dolle, Yury Rovnov, Bruno G. Simões and Paolo R. Vergano contributed to this issue.*

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

**FRATINI VERGANO**  
EUROPEAN LAWYERS

Rue de Haerne 42, B-1040 Brussels, Belgium Tel.: +32 2 648 21 61 - Fax: +32 2 646 02 70  
[www.FratiniVergano.eu](http://www.FratiniVergano.eu)

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

To stop receiving Trade Perspectives® or for new recipients to be added to our circulation list, please contact us at:

[TradePerspectives@FratiniVergano.eu](mailto:TradePerspectives@FratiniVergano.eu)