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The European Commission has published its proposal for an '*Agreement on the mutual acceptance of results of conformity assessment for industrial goods*' with the US

On 22 November 2019, the European Commission (hereinafter, Commission) published its proposal for an agreement on the conformity assessment for industrial goods with the US. The text proposal, which covers most industrial sectors where third-party conformity assessment is required by either party, stems from the agreement between the EU and the US reached in July 2018, where both sides agreed to "*to launch a close dialogue on standards in order to ease trade, reduce bureaucratic obstacles, and slash costs*". While the EU appears inclined to make progress on this important tool of trade facilitation, it remains to be seen if the US will be ready to find a common understanding on certain questions that have already proven sensitive during previous trade negotiations. While the proposal covers a range of important industrial products, it notably excludes all motor vehicles and their components, as well as all agricultural goods.

Between 2013 and 2016, the EU and the US conducted negotiations for a comprehensive Transatlantic Trade and Investment Partnership (hereinafter, TTIP). However, negotiations were suspended prior to the US Presidential elections in 2016. During the time in office of the current US Administration, EU-US trade relations have been subject to tensions and threats, which have eased to a certain extent in recent times. As part of the current US Administration's approach to trade policy, on 8 March 2018, US President Trump exercised his authority under Section 232 of the US *Trade Expansion Act of 1962* and announced the imposition of an additional 25% tariff on steel imports and an additional 10% tariff on aluminium imports, allegedly in order to protect US national security (see *Trade Perspectives*, Issue No. 5 of 9 March 2018). This led to the introduction of countermeasures by various affected trading partners and, later in 2018, to an important number of requests by other WTO Members for consultations under the WTO Dispute Settlement Understanding (see *Trade Perspectives*, Issue No. 20 of 2 November 2018). In view of the US Administration's threats to similarly impose additional tariffs on imports of motor vehicles from the EU, US President Trump and the outgoing President of the European Commission Jean-Claude Juncker, on 25 July 2018, agreed to a number of initiatives (see *Trade Perspectives*, Issue No. 15 of 27 July 2018). During the meeting, the EU and the US decided to set up an *Executive Working Group* to continue the discussions. Both sides agreed in a joint statement that, while the work of the *Executive Working Group* was ongoing, they would not go against the spirit of the amicable outcome, unless either party were to terminate the discussions.

In relevant part, Presidents Juncker and Trump agreed "*to launch a close dialogue on standards in order to ease trade, reduce bureaucratic obstacles, and reduce costs*". In the Autumn of 2018, various meetings of the *Executive Working Group* were held, further detailing potential areas of agreement. In January 2019, the Commission then published draft '*Directives for the negotiations with the United States of America for an agreement on the elimination of tariffs for industrial goods*' and the draft '*Directives for the negotiations with the United States of America for an agreement on conformity assessment*' and submitted them to the Council of the EU. Similarly, the Office of the United States Trade Representative (hereinafter, USTR) published, on 11 January 2019, its *Summary of Specific Negotiating Objectives* regarding the trade negotiations with the EU (see *Trade Perspectives*, Issue No. 2 of 25 January 2019). On 15 April 2019, the Council of the EU (hereinafter, Council) adopted a *Council Decision authorising the opening of negotiations with the United States of America for an agreement on the elimination of tariffs for industrial goods*, in combination with the *Directives for the negotiations with the United States of America for an agreement on the elimination of tariffs for industrial goods*, and a *Council Decision authorising the opening of negotiations with the United States of America for an agreement on conformity assessment* in combination with the *Directives for the negotiations with the United States of America for an agreement on conformity assessment* (see *Trade Perspectives*, Issue No. 8 of 19 April 2019).

The negotiation directives adopted by the Council in April 2019 largely reflect the proposals submitted by the Commission earlier this year. The negotiation directives have been kept rather short, which can be attributed to their limited scope. The negotiation directives related to the envisaged agreement on conformity assessment note that the future agreement is supposed to develop "*streamlined processes to ease the recognition of conformity assessment results that confirm compliance of products with a party's technical regulations*". Importantly, the negotiation directives for an agreement on conformity assessment require the Commission to suspend negotiations in case the US were to adopt measures against the EU under Section 232 of the Trade Expansion Act of 1962 or trade restrictions under Section 301 of the 1974 Trade Act or under similar US law.

In July of this year, the Commission reported on the progress of EU-US trade relations and on the discussions entertained within the *Executive Working Group*. In general terms, the representative of the Commission noted that the EU was ready to begin negotiations, but that the Commission had not received any "*signal*" from the US. Regarding negotiations on conformity assessment, the Commission notes that, since the Council had agreed on the negotiating directives for the horizontal agreement on conformity assessment for industrial products in April, there had already been "*three rounds of constructive discussions on regulatory cooperation*". Interestingly, the report does not refer to discussions having taken place specifically on conformity assessment and it appears that the actual negotiations have not yet started. Additionally, at a Civil Society Dialogue in July, the Commission did not appear particularly optimistic regarding a prompt launch of the negotiations, neither for the agreement on trade in industrial goods, nor for the agreement on conformity assessment. Thus, the publication of the EU's text proposal might now serve as an important incentive to begin concrete negotiations on the issue of conformity assessment.

In simple terms, a manufacturer from a third country may only place a product on the EU market when it complies with all relevant EU requirements and standards. Through so-called conformity assessment, it is verified that a specific product does indeed comply with all legal and technical requirements and can be considered as safe to be placed on the EU market. The verification process can consist of, *inter alia*, testing, inspection and certification. Importantly, conformity assessment is typically undertaken by accredited organisations, for example laboratories, inspection or certification bodies. The accreditation requirement is intended to ensure that the conformity assessment bodies possess the relevant technical capacity and competence. As a secondary effect, conformity assessment also aims at reinforcing the EU consumers' and other users' trust.

The EU's draft *Agreement between the European Union and the United States of America on the mutual acceptance of results of conformity assessment* (hereinafter, Draft Agreement) already covers all elements, from a limited number of recitals, to institutional provisions, and the annexes listing the products covered.

As provided in Article 2 of the Draft Agreement, its overall objective is trade facilitation and, more specifically, the Draft Agreement "*specifies the conditions by which each Party will accept results of conformity assessment procedures, produced by the other Party's conformity assessment bodies, when assessing conformity to the importing Party's mandatory requirements*" in relation to the covered products. Article 3 of the Draft Agreement is particularly significant, as it relates to the scope of the future Agreement and, notably, the sectors not covered. As for the covered sectors, Article 3(1) refers to Annexes 1 and 2, which refer to, *inter alia*, electrical and electronic equipment, toys, machinery, construction products, pyrotechnic articles, lifts, and medical devices including accessories. While the coverage of industrial goods is broad, it does exclude the import sectors of motor vehicles and rail systems. Finally, by definition, all agricultural products are excluded from the scope.

Section 2, with its Articles 4 to 10, then provides the rules related to conformity assessment bodies. Article 4 of the Draft Agreement provides the commitment by both Parties "*to accord to conformity assessment bodies located in the territory of the other Party treatment no less favourable than that it accords to conformity assessment bodies located in its own territory*". In this regard, Article 4 of the Draft Agreement provides that a "*US conformity assessment body may apply to be accredited by an EU accreditation body*" or by a US accreditation body, when a US accreditation body has been recognised by the EU, which is linked to a number of conditions, including a reciprocal obligation by the US to accept "*the accreditation of EU conformity assessment bodies by EU accreditation bodies to assess conformity to US technical regulations for the same areas*". Article 6 of the Draft Agreement concerns the delicate issue of public oversight over third party conformity assessment bodies required for certain products by EU law. Article 6(1) provides that that the US public authorities would have to "*designate the US conformity assessment bodies that are duly accredited for a particular scope by an EU accreditation body or an US accreditation body recognised by the European Union*". Reportedly, such a role being played by US public authorities had been controversial during the TTIP negotiations.

With Article 13 of the Draft Agreement, the EU intends to address the US *Nationally Recognized Testing Laboratories* (hereinafter, NRTL) scheme by the US *Occupational Safety and Health Administration* (hereinafter, OSHA). The provision intends to ensure that, if a "*finished equipment*" as a single product is subject to NRTL certification, the individual components would not need to be certified by an NRTL. Additionally, on the basis of Article 13(3) of the Draft Agreement, the US would allow EU conformity assessment bodies to be recognised as NRTLs by the OSHA and that the certificates issued by them would be recognised. Finally, Article 14 of the Draft Agreement provides for mutual recognition of reports by conformity assessment bodies, recognised under the Medical Device Single Audit Programme (MDSAP), regarding medical devices.

In its press release on the issue, the Commission states that this "*is an area where we can achieve meaningful results quickly*" and that the EU was "*ready to conclude an agreement as early as next year*". However, considering the US Administration's apparent reluctance to launch actual trade negotiations, it appears uncertain if the EU's Draft Agreement will indeed be subject to such negotiations. Additionally, it must be taken into account that, in the US, more products require third party conformity assessment and testing by laboratories accredited by US agencies. The interest in the issue and the agreement might, therefore, be comparatively greater on the EU side.

Still, in addition to reducing tariffs, striving for greater trade facilitation, including on important issues such as conformity assessment, appears to be the right way forward and it can only be hoped that this approach would also be recognised and embraced by the US Administration. However, in view of overall trade, the focus on industrial goods falls short, as it entirely neglects

the agro-food sector, which accounts for almost EUR 40 billion of EU-US trade in 2018. Agro-food issues have been a very controversial issue in the context of the previous TTIP negotiations, with certain different approaches in regulation and practices having been widely used by non-governmental organisation to incite opposition to the negotiations. It is true that regulations and agro-food practices differ, causing significant obstacles for market actors. The sensitivity of food products, however, should not deter the EU and the US from addressing this important sector, which would greatly benefit from further trade facilitation. It must be noted in this regard, that, with regards to tariffs, it is the EU that currently opposes extending future negotiations to tariffs on agro-food products likely in view of the important sensitivities in that sector.

Even if negotiations were to be launched, the impending US election campaign and the Presidential and Congressional elections in November 2020 might not provide for a favourable negotiating environment. Still, considering the large trade volume, facilitating trade between the EU and the US should remain on top of the agenda on both sides of the Atlantic.

Striking a balance between transparency and the protection of commercial information – New EU food law rules for the authorisation process of regulated substances and products

Following the controversy surrounding the (re-)evaluation of disputed products, such as glyphosate, on 6 September 2019, the EU published *Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC*. *Regulation (EU) 2019/1381* entered into force on 26 September 2019, but will only apply from 27 March 2021 and, certain provisions, only from 1 July 2022. *Inter alia*, *Regulation (EU) 2019/1381* amends *Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety* (the Regulation on General Food Law, hereinafter, GFL), the EU's landmark piece of food legislation, which established the European Food Safety Authority (hereinafter, EFSA) and introduced the risk analysis principle into EU food law. Most notably, the amendments of the GFL provide for a general strategy for enhancing risk communication, increased transparency, and new rules on the protection of commercial information.

The Commission's so-called '*fitness check*' of the GFL had concluded that risk communication, which is a substantial part of the risk analysis principle, together with risk management and risk assessment, is not sufficiently effective, leading to a significant impact on consumers' confidence and overall impeding the effective functioning of the risk analysis process. Therefore, the Commission proposed increasing the transparency of the risk assessment process through a more participative and open dialogue between all interested parties and in close cooperation with the EFSA and the EU Member States concerning all areas of the food chain. On that basis, in June 2019, EU legislators adopted *Regulation (EU) 2019/1381*. According to the Commissioner for Health and Food Safety *Vytenis Andriukaitis*, the new rules would make EU risk assessment for food safety, which is already considered one of the most stringent worldwide, more transparent and sustainable.

Authorisation procedures in the EU for genetically modified food and feed, feed additives, smoke flavourings, food contact materials, food additives, enzymes and flavourings, plant protection products, and novel foods are based on the principle that it is for the applicant to prove that the subject of an application complies with the relevant EU requirements. The EU considers that human health, animal health, and the environment are better protected when the burden of proof is on the applicant, who has to prove, prior to its placing on the market, that the object of its application is safe. In accordance with that principle, for the support of

their applications, applicants are required to submit relevant studies to demonstrate the safety and, in some cases, the efficacy of a substance.

Regulation (EU) 2019/1381 modifies the GFL in relation to the notification of studies commissioned by the applicant, by introducing a phase for pre-submission advice, and by changing the rules governing the confidentiality of information contained in the scientific dossiers presented by manufacturers to the EFSA for assessment.

The amended GFL provides for the mandatory notification to the EFSA of any study commissioned by applicants to support a future application for an authorisation procedure. These studies will become part of a common European database of commissioned studies managed by the EFSA. The idea is that companies applying for a product authorisation submit all related information, which then allows the EFSA to cross-check information on the basis of the studies performed. By making the notification of studies mandatory, applicants will, as of 27 March 2021, no longer be able to hold back unfavourable studies. This mandatory requirement concerns not only the business operators, but also laboratories or other testing facilities carrying out studies aimed at supporting authorisation procedures. In addition to the confidentiality rules, existing intellectual property rights, and data exclusivity provisions for proprietary data, remain applicable.

The new Article 32(a) of the GFL provides for a pre-submission phase, during which applicants for authorisations may request the EFSA's advice on the relevant provisions and the required content of the application for authorisation. This possibility is a direct response to industry demand, especially from small and medium-sized enterprises, which is intended to further support them in the preparation of complete applications.

Furthermore, in the effort of strengthening the transparency of the risk assessment, the new Article 32(b) of the GFL introduces an obligation for the EFSA to make publicly available all studies submitted as part of an application process for all substances and products for which previous authorisation for the placing on the market is required. In order to protect confidential information, the new provisions also ensure that the public disclosure of data does not entail the possibility for further use or exploitation by third parties. When submitting an application supported by scientific data and other supplementary information, the applicant may request that certain parts of the information submitted be treated as confidential in accordance with the amended Article 39 of the GFL. The request must be supported by verifiable justification demonstrating that, for each one of the items required to be treated as confidential, the disclosure of the information concerned might significantly harm the commercial interests of the applicant.

The amended Article 39 of the GFL provides that the only items that, upon request from the applicant, may benefit from confidentiality are: 1) Information on the manufacturing or production process, including the possible method and innovative aspects, as well as other technical and industrial specifications inherent to that process or method, except for information which is relevant to the assessment of safety; 2) Commercial links between a producer or an importer and the applicant or the authorisation holder, where applicable; 3) Commercial information revealing sourcing, market shares or business strategy of the applicant; and 4) Information on quantitative composition of the subject matter of the request, except for information which is relevant to the assessment of safety.

Regulation (EU) 2019/1381 also amends all the legal instruments addressing the above-mentioned sectors of the food chain in the areas of confidentiality and public access to information, to make them consistent with the modifications of the GFL.

Regulation (EU) 2019/1381 further includes measures to ensure the quality and objectivity of the studies used by the EFSA for its risk assessment. In that respect, the Commission has the right to perform controls, including audits, to verify the compliance of testing facilities with relevant standards and may request the EFSA to commission verification studies. Such

verification studies may only be commissioned in exceptional circumstances, for instance in cases of a serious controversy or of conflicting results in existing scientific literature.

In parallel to the adoption of *Regulation (EU) 2019/1381* amending the GFL, the Court of Justice of the EU (hereinafter, CJEU) ruled on two cases and established higher standards for the disclosure of industry information when it comes to pesticides. In the judgements T-716/14 *Tweedale* v. *EFSA* and T-329/17 *Hautala* v. *EFSA* of 7 March 2019, the EU's General Court annulled two decisions of the EFSA, by which it refused "*access to the toxicity and carcinogenicity studies related to the active substance glyphosate*", citing business confidentiality. The EFSA based its decision on Article 4 of *Regulation (EC) 1049/2001 on public access to European Parliament, Council and Commission documents*, which establishes that the EU Institutions and bodies are to refuse access to documents in their possession where their "*disclosure would undermine commercial interests of a natural or legal person, including intellectual property, unless there is an overriding public interest in disclosure*". However, the *Aarhus Convention*, introduced into the EU legal regime by *Regulation (EC) 1367/2006 of the European Parliament and of the Council of 6 September 2006 on access to information in environmental matters*, lays down that, with the only exception of investigations concerning possible infringements of EU law, for all other exceptions listed in Article 4 of *Regulation (EC) 1049/2001* on access to documents, an overriding public interest would always exist where the information requested relates to emissions into the environment. In both cases, the General Court established that the requested studies had to be classified as information that relates to emissions into the environment and that, therefore, there was an overriding public interest in the disclosure of the requested studies. The General Court added that "*the public interest in having access to the information relating to emissions into the environment is specifically to know not only what is, or foreseeably will be released into the environment, but also to understand the way in which the environment could be affected by the emissions in question*".

With the new rules introduced by *Regulation (EU) 2019/1381*, the EU introduced more transparency regarding the studies on which EFSA relies for its assessment of substances that may be used for food production. The food industry reportedly welcomed the new rules, noting that the protection of confidential business information is vital to preserve the innovation in a sector that, in the EU, according to the EFSA, is worth almost EUR 4 trillion and that faces fierce competition from international competitors.

Therefore, the objective of more transparency must be balanced with the fact that companies spend large amounts of their yearly budgets on innovation and research and development, the protection of which is fundamental for the future of the agro-food industry. According to official figures from the European Crop Protection Association (ECPA), the pesticide sector alone invests more than EUR 5 billion each year in research and development, and it currently takes, on average, 11 years and a budget of EUR 250 million to successfully bring a new substance to the market. Therefore, being able to safeguard the interests of innovative companies is essential to guarantee continued scientific progress and investments in the EU.

The new provisions, which will only apply from 27 March 2021, seek to strike a balance between transparency and confidentiality. Business operators are advised to consider their commercial interests when submitting a dossier for the authorisation on the placing on the market of regulated substances and products, since confidentiality would only be granted on the basis of duly justified requests. Moreover, the public EU register for submitted studies will likely force business operators to carefully plan their studies at an early stage considering that also studies with less favourable outcomes would be scrutinised for inconsistencies with subsequent studies. At the same time, more guidance can be expected from the EFSA in the pre-submission phase, possibly speeding up the actual authorisation procedure. Given the fact that the new provisions will only apply from 2021, business operators are advised to consider speeding up, or delaying, their application for authorisation, depending on their needs and interests.

The debate on '*plant-based*' dairy products labelling in the EU and the US: What's in a name?

In the EU and the US, there is an ongoing debate on the legality of denominations of '*plant-based*' '*dairy*' products, such as almond milk, tofu butter, soymilk, oat milk and vegan mozzarella cheese. This article looks at the current regulatory situation in the EU, where the debate has been mostly settled, and in the US, where it appears that the current legal framework might soon change.

In the EU, the legal debate on '*plant-based*' '*dairy*' names was mostly settled on 14 June 2017, when the Court of Justice of the European Union (hereinafter, CJEU) handed down its judgment in Case C-422/16 *Verband Sozialer Wettbewerb* v *TofuTown* (hereinafter, TofuTown). The German company *TofuTown* promoted and distributed purely plant-based products under the designations '*Soyatoo Tofu butter*', '*Plant cheese*', '*Veggie Cheese*', '*Cream*' and other similar designations. The CJEU held that purely plant-based products, such as tofu or soya, cannot, in principle, be marketed with designations such as '*milk*', '*cream*', '*butter*', '*cheese*' or '*yoghurt*', which, under EU law, are reserved for animal-derived products. According to the CJEU, the same applies even if those designations are accompanied by clarifying or descriptive terms indicating the plant origin of the product concerned and/or that it does not contain animal products. In its judgment, the CJEU observed that, in principle, for the purposes of the marketing and advertising in question, the relevant legislation reserves the term '*milk*' only for milk of animal origin. In addition, except where expressly provided, such legislation reserves designations, such as '*cream*', '*butter*', '*cheese*' and '*yoghurt*', solely for products derived from milk. Thereby, the CJEU interpreted the term '*milk*' and the respective terms for milk products very narrowly.

Annex VII, Part III, point 1 of *Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products* (Single CMO Regulation) defines '*milk*' as "*exclusively the normal mammary secretion obtained from one or more milkings without either addition thereto or extraction therefrom*". Annex VII, Part III, point 2 second subparagraph (a) of *Regulation (EU) No 1308/2013*) then lists the following designations of milk products that may be used at all stages of marketing only for products derived from milk: whey, cream, butter, buttermilk, butteroil, caseins, anhydrous milk fat (AMF), cheese, yogurt, kephir, koumiss, viili/fil, smetana, fil; rjaženka, and rūgušpiens. A list of exceptions to the principle that the descriptions of milk and milk products may not be used for milk products other than those in Annex VII is contained in *Commission Decision 2010/791/EU of 20 December 2010 listing the products referred to in the second subparagraph of point III(1) of Annex XII to Council Regulation (EC) No 1234/2007* (the previous Single CMO Regulation). EU Member States had to notify to the Commission an indicative lists of products, which they deemed meeting, within their own territories, the criteria for the abovementioned exception. In its judgment, the CJEU mentioned, as an example of such products notified to the Commission, the product traditionally designated '*crème de riz*' (*i.e.*, rice porridge) in French. Other examples are peanut or cocoa butter, as well as almond milk in various languages, or the German *Leberkäse* (*i.e.*, a meatloaf) and the Italian *Fagiolini al burro* (*i.e.*, a type of beans). The number of such exceptions notified to the Commission varies significantly depending on the language: for example, there are 21 designations in German, only one in Spanish and none in Bulgarian or Czech.

The CJEU concluded in *TofuTown* that the designations used by the German company could not be legally used to designate a purely plant-based product, unless that product is mentioned on the list of exceptions, which is not the case for soya or tofu. The CJEU went on to state that the addition of descriptive or clarifying additions indicating the plant origin of the product concerned, such as those used by *TofuTown*, had no influence on that prohibition. The CJEU held that this interpretation of the relevant legislation does not conflict with the principle of proportionality or the principle of equal treatment. As far as the principle of proportionality is concerned, the CJEU observed that the addition of descriptive or explanatory terms cannot completely exclude the likelihood of confusion on the part of consumers. As regards the

principle of equal treatment, the CJEU found that *TofuTown* could not rely on the principle of unfair treatment by asserting that the producers of vegetarian or vegan substitutes for meat or fish are not subject to restrictions comparable to those to which producers of vegetarian or vegan substitutes for milk or milk products are subject. The CJEU held that each sector of the common organisation of markets for agricultural products, established by *Regulation (EU) No 1308/2013,* embodies features specific to it and, as a result, a comparison of the technical rules and procedures adopted in order to regulate the various sectors of the market cannot constitute a valid basis for the purpose of proving discrimination between dissimilar products, which are subject to different rules. In fact, for meat products, with a few exceptions, there are no legal names, similar to those for milk products. Part 1 of Annex VII to of *Regulation (EU) No. 1308/2013* contains only general sales descriptions for meat of bovine animals (like '*veal*' in English), but currently no different language versions of meat products like sausage, *prosciutto*, or *Schnitzel*.

In the US, the Food and Drug Administration (hereinafter, FDA) regulates the production and labelling of food, including of plant-based foods. Pursuant to the *Federal Food, Drug, and Cosmetic Act* (hereinafter, FFDCA), all labelling must not be false or misleading (21 U.S.C. § 343(a) of the FFDCA). US State laws reiterate this requirement. At the same time, an increasing number of US States has been adopting laws specifically targeting plant-based meat. In addition, both the FDA and the US Department of Agriculture (hereinafter, USDA) have adopted so-called '*standards of identity*' for a wide variety of foods. The USDA maintains '*standards of identity*' for a number of meat and poultry products and the FDA maintains '*standards of identity*' for a number of other foods, including dairy products.

For milk and cream, CFR (Code of Federal Regulations) Title 21 provides in § 131 for different '*standards of identity*' (*inter alia* on milk, acidified milk, cultured milk, concentrated milk, sweetened condensed milk, non-fat dry milk, non-fat dry milk fortified with vitamins A and D, evaporated milk, dry whole milk, dry cream, heavy cream, light cream, light whipping cream, sour cream, acidified sour cream, eggnog, half-and-half, yoghurt, low-fat yoghurt, and non-fat yogurt). A '*standard of identity*' essentially sets out what ingredients a product must contain, which ingredients it may contain, and any manufacturing specifications. Foods subject to a '*standard of identity*' must meet the regulatory definition for the food (for example, milk is defined, in relevant part, as "*lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows*"). Critics in the dairy industry, such as the US National Milk Producers Federation (NMPF) say that the FDA has not been properly enforcing '*standards of identity*' for products such as '*milk*'. When it comes to plant-derived '*milks*', for example, the FDA reportedly challenged the term '*soy milk*' in warning letters to manufacturers in 2008 and 2012 (claiming breaches of the '*standard of identity*' for milk), but did not follow up until early 2018, when then FDA Commissioner Scott Gottlieb said that he was actively looking at this issue and indicated that "*a new compliance policy*" might be established. Some stakeholders, such as producers of plant-based foods, believe that '*standards of identity*' are out of date and may impede innovation.

Between 28 September 2018 and 28 January 2019, the FDA had organised a public consultation on the use of and labelling of plant-based products with names that include the names of dairy foods, such as milk, yoghurt, and cheese, and received 13,077 comments. While most of the comments came from individual consumers, industry and non-governmental organisations also submitted their diverse opinions. The dairy industry, in particular, urged the FDA to enforce the '*standard of identity*' for milk. For instance, the Greek yogurt giant *Chobani*, after having introduced in the US its first non-dairy products earlier this year, submitted comments to the FDA that suggested that the improper and illegal use of dairy terms on plant-based alternatives "*poses a public health risk in that this terminology may confuse consumers and cause them to displace the nutrients that would otherwise be provided by dairy foods*". Chobani's view appears to go further than arguing that '*plant-based*' '*dairy*' names mislead consumers. But this position does not appear to reflect all dairy companies. *Danone North America*, a major player in the dairy market, which also owns a number of vegan brands, marketing dairy alternatives, such as soymilk, almond milk, coconut milk, cashew milk, dairy free yoghurt alternatives, and creamers, disagrees with Chobani and considers the way

companies label plant-based products to be "*consistent with regulations and case law*". *Danone* reportedly went on to say that "*the trend toward more consumption of plant-based foods should be embraced and not subverted by requiring confusing, unfamiliar labelling requirements*". *Danone* and others that spoke out against restrictive labelling argue that customers are not confused by the use of '*dairy*' terms. It must be noted that there would also be a major cost to change product labels, which have, so far, been '*tolerated*', which might even put some brands out of business. It appears that a majority of US consumers does not feel misled by dairy terms on plant-based products. Reportedly, 75% of responses in the FDA's public consultation were in favour of using dairy terms for plant-derived products. Recent US case law appears to confirm this. In the case *Painter V. Blue Diamond Growers*, ruled on 21 December 2018, the United States Court of Appeals for the Ninth Circuit held that using the term '*almond milk*' is not deceptive, noting that the complaint against it "*does not plausibly allege that a reasonable consumer would be deceived into believing that Blue Diamond almond milk products are nutritionally equivalent to dairy milk based on their package labels and advertising (…) Almond milk is not an 'imitation' of dairy milk within the meaning of 21 U.S.C. § 343(c) and 21 C.F.R. § 101.3(e)*".

In light of the many innovative food products, including plant-based products, placed on the market, the FDA is currently in the process of modernising food '*standards of identity*'. The FDA held a public meeting on 27 September 2019 to give interested parties an opportunity to discuss the FDA's efforts in this regard and to provide information about changes the FDA could make to existing '*standards of identity*'. More specifically, the FDA sought input about changes that "*may provide manufacturers with additional flexibility to use, for example, new technologies and new or novel ingredients without impacting the basic nature and essential characteristics of standardised foods*". The meeting was held as part of the FDA's comprehensive, multi-year nutrition innovation strategy. The FDA intends to modernise the '*standards of identity*' to: 1) Protect consumers against economic adulteration; 2) Maintain the basic nature, essential characteristics and nutritional integrity of food; and 3) Promote industry innovation and provide flexibility to encourage manufacturers to produce healthier foods.

With the debate on dairy terms being largely settled in the EU, discussions have moved on to the use of '*meaty*' names for plant-based products (see *Trade Perspectives*, Issue No. 9 of 4 May 2018 and Issue No. 21 of 16 November 2018). On 1 April 2019, Members of the European Parliament within the Committee on Agriculture and Rural Development (hereinafter, AGRI) voted by 29 votes to 7 against and 1 abstention in favour of new EU rules for the Common Market Organisation (CMO), the first of three-tranche legislation together forming the post-2020 Common Agricultural Policy (CAP). The compromise amendment number 41 reserved meat-related terms and names "*exclusively for edible parts of the animals*". However, the approved text did not reach the European Parliament's plenary stage in the legislative term that ended with the elections in May 2019. Following the European elections in May 2019, the European Parliament's plenary still has to close the first reading and, on 21 October 2019, the legislative file was referred to the AGRI Committee again.

In the US, the question is whether the FDA will ultimately require products like '*almond milk*' to be named and labelled '*almond drink*' or similar. In the EU, the debate on the use of '*meaty*' names for plant-based products will likely pick up again in view of the discussions of the post-2020 agricultural policy. Interested stakeholders are recommended to monitor the relevant developments, in particular related to the FDA's efforts to modernise food '*standards of identity*' and update the FDA's approach to food labelling enforcement in general.

Recently Adopted EU Legislation

Customs Law

- *Council Decision (EU) 2019/1955 of 21 November 2019 on the position to be taken on behalf of the European Union within the General Council of the World*

Trade Organization as regards the adoption of a decision on the review of the Understanding on Tariff Rate Quota Administration Provisions of Agricultural Products ('TRQ Understanding')

- *Commission Implementing Regulation (EU) 2019/1927 of 19 November 2019 on the derogations from the 'originating products' rules laid down in the Free Trade Agreement between the European Union and the Republic of Singapore that apply within the limits of annual quotas for certain products from Singapore*

Trade Remedies

- *Commission Implementing Regulation (EU) 2019/1948 of 25 November 2019 initiating an investigation concerning possible circumvention of anti-dumping measures imposed by Commission Implementing Regulation (EU) 2018/186 on imports of certain corrosion resistant steels originating in the People's Republic of China, and making such imports subject to registration*

Other

- *Council Decision (EU) 2019/1954 of 18 November 2019 establishing the position to be adopted, on behalf of the European Union, in the EPA Committee set up by the Interim Agreement with a view to an Economic Partnership Agreement between the European Community and its Member States, of the one part, and the Central Africa Party, of the other part, in connection with the adoption of the rules of procedure for mediation, the rules of procedure for arbitration and the code of conduct for arbitrators*

- *Council Decision (EU) 2019/1941 of 18 November 2019 establishing the position to be taken, on behalf of the European Union, in the EPA Committee set up by the Interim Agreement with a view to an Economic Partnership Agreement between the European Community and its Member States, of the one part, and the Central Africa Party, of the other part, in connection with the adoption of the list of arbitrators*

Ignacio Carreño, Fabrizio De Angelis, Tobias Dolle, Lourdes Medina Perez and Paolo R. Vergano contributed to this issue.

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