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Modernising trade ties between Latin American countries and the EU

From 30 January to 2 February 2018, the EU and Mercosur (*i.e.*, Argentina, Brazil, Paraguay and Uruguay) resumed negotiations to finally conclude a free trade agreement (hereinafter, FTA) before March 2018 and, on 6 February 2018, the EU and Mexico commenced their most recent negotiating round on the modernisation of the existing trade agreement in Brussels. On the same day, the European Commission (hereinafter, Commission) published its initial textual proposals setting out the EU's position in specific areas of the negotiations for a modernised FTA between the EU and Chile. The increased efforts clearly indicate the negotiating parties' commitment to conclude negotiations ahead of election seasons in Brazil and Mexico, which would most likely impede further negotiations. Still, important diverging interests, mainly in the agricultural sector, need to be overcome.

In 1997, Mexico was the first country in Latin America to sign an Economic Partnership, Political Coordination and Cooperation Agreement (*i.e.*, the Global Agreement) with the EU, which entered into force in 2000. Already in 1999, the Commission had received a mandate to negotiate an FTA with Mercosur, but negotiations were suspended in 2004 and again in 2012, until they were resumed in 2016. In 2002, the EU and Chile concluded an Association Agreement, which includes a comprehensive FTA that entered into force in 2003. The EU now aims at finally concluding the FTA with Mercosur and at upgrading the existing agreements with Chile and Mexico. Negotiations with Mercosur and Mexico are in their final stages and, in November 2017, the EU and Chile held their first negotiating round.

In 2000, the EU and Mercosur began negotiations for an FTA as part of the bi-regional Association Agreement. Due to substantial differences between the parties, mainly in the areas of trade in agriculture, services and the opening-up of public procurement markets, negotiations were put on hold twice. The negotiations re-started in 2016 and are now nearing conclusion. The most recent round of negotiations took place from 30 January to 2 February 2018. According to the Commission's Vice-President Jyrki Katainen, talks were "*constructive*" and negotiations had entered the "*end game*" stage. The EU and Mercosur already attempted to reach political agreement on the side-lines of the World Trade Organisation's Eleventh Ministerial Conference in December 2017. However, remaining sensitive issues, in particular tariff rate quotas (hereinafter, TRQs) for beef, prevented the conclusion. Trade in beef has been a controversial issue for both parties. In October 2017, the EU proposed to grant Mercosur beef access for 70,000 metric tonnes per year. However, the EU proposal

was not well received by Mercosur, having initially requested a beef quota of 400,000 metric tonnes per year. At the end of 2017, the Commission raised its proposal to 99,000 metric tonnes per year, while it remained unclear whether this amount would enter the EU duty-free. The EU's increased proposal on market access for beef raised concerns among a number of EU Member States, in particular Ireland and France. The European trade association of farmers and cooperatives, Copa-Cogeca, stated that the Commission's most recent offer was unacceptable and that the sector was also facing uncertainty over '*Brexit*'. Additionally, some Central European countries, such as Poland and Slovakia, are concerned about the impact that the EU-Mercosur agreement could have on ethanol production. Copa-Cogeca pointed out that the sugar and ethanol sectors were heavily subsidised in Mercosur Member States, mainly in Brazil and Argentina. In October 2017, the EU had offered a quota of 600,000 metric tonnes of ethanol, including 200,000 metric tonnes for use in transport fuel. Despite the remaining issues, the EU and Mercosur expect to conclude negotiations at the next meeting on 26 February 2018.

Similar to the EU-Mercosur negotiations, the EU and Mexico aimed at concluding negotiations in December 2017. However, agreement on sensitive areas, such as market access for meat and dairy, rules of origin and geographical indications (hereinafter, GIs), was not reached and negotiations were extended to 2018. The current Global Agreement covers political dialogue, trade relations and cooperation. The trade provisions were later developed into an FTA, which covers trade in goods and trade in services. The Global Agreement had already eliminated and reduced tariffs in the automobile sector and eliminated 62% of tariffs on total agricultural trade. However, with respect to agriculture, the Global Agreement includes a list of sensitive products (*i.e.*, cereals, sugar, meat products and dairy), that was not considered for the elimination of tariffs. Under the Global Agreement, both Parties agreed to liberalise trade of these products no later than three years after the agreement entered into force. However, since 2003, the EU and Mexico were not able to agree on the liberalisation and instead agreed on preferential TRQs. In May 2016, Mexico and the EU began negotiations to modernise the Agreement. The updated agreement seeks to include an investment chapter, increased market access for agricultural products and public procurement, an improved chapter on intellectual property rights (including GIs), chapters on rules of origin (the current agreement only covers an annex on originating products), sustainable development, and a novel chapter on anti-corruption.

On 25 January 2018, the Commission reported important progress after the seventh round of negotiations that took place from 12 to 22 December 2017. Reportedly, agreement was reached on eight chapters, including trade in goods. Diverging approaches still remained regarding investment, the protection of GIs, and public procurement (namely market access on the sub-federal level in Mexico). The protection of GIs is one of the main issues that prevents the conclusion. Final discussions are focussed on the EU's proposal to protect 57 cheese names originating in the EU, cheeses that Mexico also produces under the same name. Most notably, Spain has been insisting on this issue, noting the incorrect use of '*manchego*' cheese. Spanish '*manchego*' is a sheep milk cheese produced in Spain's La Mancha region, while Mexican '*manchego*' is a very popular cow milk cheese that is exported to the US. Spanish '*manchego*' producers expressed that confusion over the cheese's name and origin had led to significant monetary loss for Spanish producers, particularly in the US market, where Mexican *'manchego*' is sold at a lower price than Spanish '*manchego*'. According to the Mexican National Chamber of the Dairy Industry, Mexico is already respecting 30 of the 57 European-origin cheeses. Reportedly, while European and Mexican negotiators had reached an agreement on allowing, *inter alia*, sales of Mexican brie, camembert, gouda, and mozzarella, among other European cheese varieties, the issue of '*manchego*' remained unresolved. Additionally, trade in meat and sugar are still contentious issues in the negotiations. Mexico is seeking improved market access for these two sectors, as they are currently *de facto* excluded from liberalisation. Mexico is a top cane sugar producer, mainly exporting to the US. Achieving better EU market access for sugar would be an important success for Mexico. The most recent negotiation round between the EU and Mexico, which is already the second meeting in 2018, took place from 5 to 9 February 2018.

Both Parties are committed to conclude the negotiations at the end of February and the tenth negotiation round is scheduled to take place from 12 to 16 February 2018 in Mexico.

The EU-Chile Association Agreement was signed on 18 November 2002, including sections on political dialogue, cooperation and on trade. The trade pillar of the EU-Chile Association Agreement entered into force on a provisional basis on 1 February 2003 and the full agreement on 1 March 2005. The current agreement covers all areas of EU-Chile trade relations, eliminating barriers to trade, establishing rules for exporters, importers and investors, creating a free trade area in goods, services and government procurement, liberalising investment and capital flows, and strengthening the protection of intellectual property rights. Already in 2015, both Parties discussed options to modernise their current agreement, but the first negotiation round was only held in November 2017. The second round of negotiations took place from 15 to 19 January 2018.

On 6 February 2018, the Commission published the EU's 18 initial textual proposals, setting out the EU's specific positions in the negotiations. On the same day, the Commission published its report on the second negotiating round. The report notes that, although negotiations were still at an early stage, the negotiating teams were able to make good progress in most areas. Currently, 90% of trade between the EU and Chile is already liberalised. However, both Parties seek to improve different areas, such as intellectual property and opportunities for small and medium-sized enterprises, and to include a chapter on trade and sustainable development, as well as a novel chapter on gender equality. Furthermore, the EU would like to improve mutual market access in the field of government procurement, covering tenders at all government levels, and bringing the existing government procurement rules in line with the revised WTO Government Procurement Agreement (see *Trade Perspectives*, Issue No. 6 of 21 March 2014). Additionally, the EU aims at expanding the protection of GIs, while Chile aims at improving access to services and investment, as well as market access for agricultural products, such as dairy, cereals, rice and olive oil. Negotiators agreed to meet again soon and seek to finalise negotiations by the end of 2018.

The EU-Mexico Global Agreement and the EU-Chile Association Agreement had been concluded as mixed agreements and their ratification process required the ratification by the relevant institutions in all EU Member States. In the case of mixed agreements, an agreement only enters into force when the trading partner, the EU and all EU Member States have exchanged the respective ratification instruments. Since the modernisation of the EU-Mexico Global Agreement and the EU-Chile Association Agreement does not change the existing structure of the agreements, the ratification of the modernised agreements will arguably require the ratification by all relevant institutions of all EU Member States. On the other hand, for the EU-Mercosur FTA, the EU has taken the 2017 opinion by the Court of Justice of the European Union (hereinafter, CJEU) on the division of competences between the EU and its Member States with respect to the EU-Singapore FTA into account (see *Trade Perspectives*, Issue No. 10 of 19 May 2017). Most notably, the EU-Mercosur FTA will not include an investment chapter and will likely only have to be ratified by the EU and not by its Member States. Considering the strong opposition against the agreement's potential impact on meat trade, difficult discussions with EU Member States can be expected, though.

EU negotiations with Mexico and Mercosur are in their final stages and it appears possible that they will be concluded soon. Overcoming the remaining differences and finding agreeable compromises can still prove difficult. Once negotiations are concluded, the looming ratification process might also prove difficult, in particular concerning the EU-only nature of the EU-Mercosur FTA. While the EU-Chile negotiations are still at an early stage, both sides appear to pursue an ambitious timeline. All interested stakeholders should get involved now and engage with their respective interlocutors in the EU and the various Latin American countries before negotiations come to a close.

The provision of the indication of origin or place of provenance of the primary ingredient of a food – the delicate question of how to inform EU consumers

On 1 February 2018, the public consultation for the EU's *Draft Commission Implementing Regulation laying down rules for the application of Article 26(3) of Regulation (EU) No 1169/2011 on the provision of food information to consumers, as regards the rules for indicating the country of origin or place of provenance of the primary ingredient of a food where different to that given for that food* (hereinafter, the Draft Implementing Regulation) was concluded. In view of the increasing piecemeal nature of EU Member States' measures on country of origin labelling (hereinafter, COOL), the Draft Implementing Regulation could be an important step towards harmonising rules across the EU. Stakeholder feedback shows clearly diverging interests that the Commission will now have to evaluate, while there also appears to be a need to make the Draft Implementing Regulation less ambiguous.

Article 26 of *Regulation (EU) No 1169/2011 on the provision of food information to consumers* (hereinafter, FIR) already provides for general rules and requirements with respect to the indication of the country of origin or place of provenance of food. Article 26(2)(a) of the FIR requires the indication of the country of origin or place of provenance where its omission could mislead the consumer as to the true country of origin or place of provenance of the final food in question, in particular if the information accompanying the food or the label as a whole would otherwise imply that the food has a different country of origin or place of provenance. Article 26(3) of the FIR provides that *"[w]here the country of origin or the place of provenance of a food is given and where it is not the same as that of its primary ingredient: (a) the country of origin or place of provenance of the primary ingredient in question shall also be given; or (b) the country of origin or place of provenance of the primary ingredient shall be indicated as being different to that of the food"*. The Commission had to adopt an implementing act on the application of this paragraph by 13 December 2013, following impact assessments. That date has clearly passed, but the Commission is now preparing said implementing act. The Draft Implementing Regulation and the public consultation has incited strong reactions from stakeholders, in particular in Italy. The Commission received 143 comments from stakeholders, including public authorities such as the Government of Canada, EU and EU Member States' trade associations, as well as 50 comments from Italian citizens. The latter often remained anonymous and generally spoke out in favour of mandatory COOL and the consumers' right to know the origin of everything they are consuming.

Article 26(3) of the FIR addresses cases where the country of origin or place of provenance is given mandatorily, including in accordance with Article 26(2)(a) of the FIR, or voluntarily by food business operators through any indication, such as statements, terms, pictorial presentation or symbols. Article 26(3) of the FIR requires mandatory labelling, but leaves it to food business operators to decide whether to indicate the origin of the primary ingredient or only saying that it is different than the food. Article 26(3) of the FIR only applies to processed food products. Therefore, the Implementing Regulation will make most recently introduced COOL measures in EU Member States, often concerning products containing meat or dairy, obsolete insofar as they relate to processed food. This is important because a number of those EU Member States' COOL measures are arguably illegal under EU law (see *Trade Perspectives*, Issue No. 23 of 15 December 2017). In view of the new harmonised labelling rules being introduced by the Implementing Regulation at the EU level, the European Association of Dairy Trade (EUCOLAIT) and other trade associations, as well as the consumer association BEUC, called, in the context of the consultation, on the EU to ensure that the EU Member States' COOL measures be discontinued. As EUCOLAIT pointed out, the Italian measure on mandatory COOL for milk and dairy products expressly notes that it applies only until the adoption at EU level of implementing acts on the basis of Article 26 of the FIR.

A key issue that is being put forth with respect to the Draft Implementing Regulation is the ambiguity of a number of terms used, which are not defined and are open for interpretation. First, the definition of '*origin*' appears to be unclear. The European association of farmers and cooperatives Copa-Cogeca underlines that the origin of an agricultural product refers to the place of farming, while, in trade law, country of origin refers to the place where the product underwent its last substantial modification (in this context, see *Trade Perspectives*, Issue No. 20 of 5 November 2010). Copa-Cogeca further notes that only for certain agricultural products, such as meat, '*origin*' is specifically defined in mandatory EU COOL rules. Second, stakeholders raised the question of what '*primary ingredient*' meant in the context of the Draft Implementing Regulation. Third, the reference to generic and customary names in Recital 8 is not further defined. Finally, the actual rules on how to indicate the origin or place of provenance of the primary ingredient, provided in Article 2, have been strongly criticised.

Article 2 of the Draft Implementing Regulation states that: "*The country of origin or the place of provenance of a primary ingredient which is not the same as the given country of origin or the given place of provenance of the food shall be given: (a) with reference to one of the following geographical areas: (i) "*EU*", "*non-EU*" or "*EU and non-EU*"; or (ii) Region, or any other geographical area either within several Member States or within third countries, if defined as such under public international law or well understood by normally informed average consumers; or (iii) FAO Fishing area, sea or freshwater body, if defined as such under international law or well understood by normally informed average consumers; or (iv) Member State(s) or third country(ies); or (v) Region, or any other geographical area within a Member State or within a third country, which is well understood by normally informed average consumers; or (vi) The country of origin or place of provenance in accordance with specific Union provisions applicable for the primary ingredient(s) as such; (b) or by means of a statement as follows: "*(name of the primary ingredient) do/does not originate from (the country of origin or the place of provenance of the food)*" or any similar wording likely to have the same meaning for the consumer*". This long list of vague options leaves a large scope of interpretation to food business operators, as well as to EU Member States' authorities that will have to enforce the rules. Most notably, noting the origin based on the determination of whether a region is "*well understood by normally informed average consumers*" might pose a challenge.

Despite the already existing ambiguities, FoodDrinkEurope (hereinafter, FDE), the trade association representing the European food and drink manufacturing sector, requests more flexibility for the indication to take sophisticated supply chains into account. More specifically, FDE proposes to allow statements such as "*[primary ingredient] may be of a different origin*". The added value of this information for the consumer, however, appears to be very limited and even arguable. While at various instances, the Draft Implementing Regulation underlines the importance of providing precise, meaningful and comprehensible information to the consumer, the European Consumer Organisation BEUC highlights the provided information as an important shortcoming. According to BEUC, the option to indicate that the primary ingredient does not originate from the country of origin or the place of provenance of the food, as well as the indication of "*non-EU*" or "*EU and non-EU*" would not provide meaningful information to EU consumers. Rather, the specific country should be provided. The Italian agricultural organisation Coldiretti notes that the "*extreme flexibility*" of the Draft Implementing Regulation could actually be used as an unfair trade practice to mislead consumers. This is supported by the Copa-Cogeca, which notes that the draft text is too flexible and vague.

Italian food manufacturers are particularly concerned by the potential consequences on food "*Made in Italy*". Concerns mainly revolve around Recital 8 of the Draft Implementing Regulation. Recital 8 notes that customary and generic names including geographic terms that literally indicate origin, but whose common understanding is not an indication of origin or place of provenance of the food, should not be covered by the Implementing Regulation. The exemption appears to be a particular issue for Italian manufacturers, where a food product

often references a specific region (*e.g.*, Risotto alla milanese or pasta bolognese) or has become a '*generic*' name, such as mozzarella. Italian manufacturers are concerned that the Implementing Regulation would make product names and design less reliable by allowing any food business operator to use those names on its products, even when the primary ingredient does not originate in the specific region or country. The impact on so-called '*Italian sounding products*' will likely increase in the EU and potentially lead to negative effects for the manufacturers of genuine Italian specialties. Outside of the EU, the volume of products with generic names (*e.g.*, parmesan or mozzarella) is significant, remains unresolved in EU trade negotiations and is increasingly costly, in terms of lost opportunities or unfair competition, for EU food business operators (see *Trade Perspectives*, Issue No. 4 of 26 February 2016).

Another exemption from the scope relates to geographical indications (hereinafter, GIs) and trademarks. Article 1(2) of the Draft Implementing Regulation limits the scope of application and states that the rules shall not apply to protected geographical indications and trademarks registered *"pending the adoption of specific rules concerning the application of Article 26(3) to foods bearing such indications*". This appears to be a controversial issue with respect to both GIs and trademarks. With respect to trademarks, the consumer organisation BEUC notes concerns that food business operators might circumvent the labelling requirements by registering a trademark. While a majority of trade associations considers that the Draft Implementing Regulation should not apply to GIs and trademarks, due to the existing specific EU rules, agricultural associations are requesting to extend the scope to GIs. The Commission appears to be aware of the issue, noting in Recitals 6 and 7 that it would be necessary to further examine how the origin of the primary ingredient should be indicated for products bearing GIs or trademarks. Finally, an additional exemption was requested by the Association of Chocolate, Biscuit and Confectionery Industries of Europe (CAOBISCO) in the context of the consultation. CAOBISCO argued that "*ingredients that generally do not originate in any territory of the EU*" should be exempt from the scope of the Draft Implementing Regulation because the absence of such information would not mislead the average consumer.

In addition to industry and consumer concerns, the EU will have to take its international trade obligations into account. In its comments on the Draft Implementing Regulation, the Government of Canada focuses on the international trade dimension of the issue and notes that international standards on COOL did not require the labelling of primary ingredients and that any such EU rule should, therefore, be voluntary. Even if voluntary, however, the labelling might become *de facto* mandatory for food business operators due to retail and consumer demand. Another relevant aspect, in light of relevant WTO case law, is the extent to which the labelling regime provides added-value to consumers. As noted above, the foreseen range of options to indicate the origin or place of provenance might lead to more confusion than better information. On 12 January 2018, the EU formally notified the Draft Implementing Regulation to the WTO and Canada indicated that it would raise certain issues within the Committee on Technical Barriers to Trade (TBT).

The Draft Implementing Act currently provides that it shall apply from 1 April 2019, but allows foods placed on the market or labelled prior to that date to be marketed until stocks are exhausted. A number of stakeholders called on the Commission to develop additional guidelines well before the implementation of the Regulation and to postpone the entry into effect at least until 2020. The Draft Implementing Regulation is an important step to begin harmonising the country of origin labelling for food products in the EU. It could improve the situation for consumers, as well as for food business operators, but the ambiguities of the current draft do not appear to be going in the right direction. All interested stakeholders should continue to monitor the developments related to the Draft Implementing Regulation. While the EU consultation for stakeholders closed on 1 February 2018, WTO Members have until 13 March 2018 to comment on the notified draft. At the same time, food business operators should prepare for the new rules to become effective as early as in April 2019.

Nano-developments: EFSA opens public consultation on nanoscience and nanotechnology applications, while food manufacturers are accused of undeclared nanoparticles

On 12 January 2018, the European Food Safety Authority (hereinafter, EFSA) opened a public consultation on a draft guidance document for the risk assessment of nanoscience and nanotechnology applications in the food and feed chain. The guidance document covers the relevant areas within EFSA's remit, such as novel foods, food contact materials, food and feed additives, and plant protection products. Regarding nanomaterials, it has been reported that the French consumer organisation *UFC Que Choisir* recently filed a legal complaint to the High Court of Paris' prosecutor (*i.e.*, the *Procureur auprès le Tribunal de Grande Instance de Paris*) against four food manufacturers over undeclared nanoparticles.

The actual definition of nanomaterials is of great interest, in the EFSA's draft guidance, as well as in EU food labelling and novel food law. According to Article 3(2)(f) of *Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001* "'*engineered nanomaterial' means any intentionally produced material that has one or more dimensions of the order of 100 nm or less or that is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic of the nanoscale. Properties that are characteristic of the nanoscale include: (i) those related to the large specific surface area of the materials considered; and/or (ii) specific physico-chemical properties that are different from those of the non-nanoform of the same material*".

In terms of food labelling law, *Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers* (hereinafter, FIR) requires in Article 18 that the list of ingredients of foods shall be headed or preceded by a suitable heading, which consists of or includes the word '*ingredients*' and shall include all the ingredients of the food, in descending order of weight, as recorded at the time of their use in the manufacture of the food. Paragraph 3 of Article 18 adds that all ingredients present in the form of '*engineered nanomaterials*' shall be clearly indicated in the list of ingredients and that the names of such ingredients shall be followed by the word '*nano*' in brackets. Article 18(5) of the FIR obliged the European Commission (hereinafter, Commission) to adjust and adapt the definition of engineered nanomaterials, which was originally laid down in point (t) of Article 2(2) of the FIR, to technical or scientific progress or to definitions agreed at international level. On this basis, the Commission adopted on 12 December 2013 a Commission Delegated Regulation amending the FIR and notified it to the European Parliament and to the Council of the EU. On 12 March 2014, the European Parliament adopted a Resolution objecting to the Delegated Regulation considering that the Commission, by excluding certain food additives from the scope of the definition, had exceeded its delegated powers (see *Trade Perspectives*, Issue No. 6 of 21 March 2014). *Regulation (EU) 2015/2283 on novel foods*, which became applicable on 1 January 2018, takes up the definition of '*engineered nanomaterials'* as laid down in the FIR. Therefore, the definition of engineered nanomaterial, along with the related conferral of delegated powers to the Commission, is to be deleted from the FIR and replaced by a reference to the definition in *Regulation (EU) 2015/2283 on novel foods*.

The definition of engineered nanomaterials is crucial when it comes to labelling obligations under the FIR, as can be observed in the legal complaint to the High Court of Paris (*i.e.*, the *Tribunal de Grande Instance de Paris*) that the French consumer group *UFC Que Choisir* has filed against food businesses *Mars Chocolat France*, *McCormick*, the French retailer *Groupe Casino* and the coffee maker *Jacobs Douwe Egberts,* due to the "*significant*

proportion" of undeclared nanoparticles in certain products despite the legal labelling requirement. *UFC Que Choisir* tested 20 consumer goods (seven food products, nine cosmetics and four medicines) and reportedly also filed complaints over *Sanex* deodorant, *AquaFresh* toothpaste, *Avene* lip balm and *Lavera* sun cream. *UFC Que Choisir's* tests revealed that the silicon dioxide additive (E551) used in *McCormick*'s Ducros *Mélange Malin Italien* spice mix, *Jacobs Douwe Egberts*' *Maxwell House* instant cappuccino and *Casino Group*'s dehydrated chicken soup was nano-sized. Also, over one third of the titanium dioxide additive (E171) used in *Mars*' peanut *M&Ms* was nano-sized. The complete results will be published in the February edition of *UFC Que Choisir*'s magazine. Titanium dioxide is used to give a white colour or shiny, iridescent appearance, while silicon dioxide is an anti-caking agent that prevents clumping. *UFC Que Choisir* states that, although legal, use of nano-sized particles in everyday food, cosmetics and drugs is worrying because the change from normal size to nanometric size affects the particles' behaviour and properties. The small particle size has led to concerns that they could pass through biological barriers, such as human tissue. In 2017, researchers at the French National Institute for Agronomic Research (INRA) claimed to show for the first time in an in vivo setting (*i.e.*, in a living organism) that titanium dioxide crosses the intestinal barrier and passes into the bloodstream, reaching other parts of the body. The research reportedly showed that nano-sized particles could be detected in the animals' livers, which could be linked to immune system disorders.

UFC Que Choisir reportedly expects that the complaints would make the companies respect the regulations so that consumers can choose their products knowingly and be aware of the presence of nanoparticles in the products they buy. However, it must be noted that the FIR states that only '*engineered nanomaterials*' need to be labelled, referring only to any intentionally produced material of nano size. A spokesperson for McCormick reportedly stated that the *Ducros* spice mix complies with the FIR as it does not contain '*intentionally produced nanomaterials*' as defined in EU legislation and nothing is used in this product with the functional properties of nanoparticles.

In another development in France, on 16 January 2018, the French Government's General Directorate for Competition Policy, Consumer Affairs and Fraud Control (*DGCCRF* in its French acronym) presented the findings of its analysis on titanium dioxide nanoparticles in food and cosmetics to the Ministry of Economy and Finance. One third of the food products that *DGCCRF* tested contained nano-sized materials and the legal labelling requirements were arguably insufficiently respected. The *DGCCRF* is calling for harmonised control measures at EU level and is due to present its findings to the Commission.

The EFSA is currently developing a *guidance for the risk assessment of nanoscience and nanotechnology applications in the food and feed chain (Part 1, human and animal health)*. The draft guidance highlights the scientific complexity of this field, already when it discusses the different definitions of nanomaterials, a matter of great importance considering, *inter alia*, the complaints filed in France because of undeclared nanoparticles. The draft guidance, developed by the EFSA's Scientific Committee upon request by EFSA, provides an overview of information requirements and how to perform risk assessment of nanomaterial in the food and feed area (*e.g.*, novel food, food contact materials, food/feed additives and plant protection products). For example, under the new *Regulation (EU) 2015/2283 on novel foods*, a food consisting of engineered nanomaterials will be considered a novel food and, as such, will require authorisation. The novel foods regulation provides that risk assessment of novel foods shall be carried out by the EFSA, which shall also be responsible for verifying that the most up-to-date test methods have been used in order to assess their safety.

The draft guidance takes into account scientific developments that have taken place since publication of the previous guidance in 2011, particularly studies that provide more insights to physicochemical properties, exposure assessment, and hazard characterisation of nanomaterials. It specifically elaborates on the physicochemical characterisation of nanomaterials in terms of how to establish whether a material is a nanomaterial, the key parameters that should be measured, the methods and techniques that can be used for

characterisation of nanomaterials and their determination in complex matrices. The draft guidance also details the aspects relating to exposure assessment and hazard identification and characterisation. In particular, nano-specific considerations relating to in vivo (*i.e.*, in a living organism) / in vitro (*i.e.*, in lab ware) toxicological studies are discussed and a tiered framework for toxicological testing is outlined. The draft guidance also proposes ways to carry out risk characterisation and uncertainty analysis. Part 2 of the guidance will separately address those aspects that relate to environmental risk assessment.

Regarding definitions, the EFSA's draft guidance applies to any material that meets the criteria for an '*engineered nanomaterial*' as outlined in *Regulation (EU) 2015/2283 on novel foods* and in the FIR (*i.e.*, nanomaterials that have particle sizes in the defined nanoscale of 1–100 nm). But, it also applies to other types of nanomaterials, as follows: 1) A material that contains particles having a size above 100 nm, which could retain properties that are characteristic of the nanoscale, for example, related to the large specific surface area of the materials; 2) A material that is not engineered as nanomaterial, but which contains a fraction of particles, less than 50% in the number-size distribution with one or more external dimensions in the size range 1–100 nm (*e.g.*, in the case of manufacturing processes for powdered food chemicals that typically result in materials with a range of sizes); 3) A nanomaterial having the same elemental composition, but that occurs in different morphological shapes, sizes, crystalline forms and/or surface properties as, for example, a consequence of different production processes; and 4) A nanoscale entity made of natural materials that has been deliberately produced to have nano-enabled properties, or that has been modified for use in the development of other nanoscale materials (*e.g.*, for encapsulating (bioactive) compounds). Arguably, the draft guidance discusses a variety of nanomaterials, of which only the '*engineered*' ones require labelling under the FIR.

Developments on nanomaterials, in particular regarding their definition and safety, should be carefully monitored. The court proceedings initiated in Paris appear important regarding the labelling obligations of food manufacturers. As regards the EFSA draft guidance, interested parties are invited to submit written comments by 4 March 2018.

Recently Adopted EU Legislation

Market Access

- *Commission Delegated Regulation (EU) 2018/172 of 28 November 2017 amending Annexes I and V to Regulation (EU) No 649/2012 of the European Parliament and of the Council concerning the export and import of hazardous chemicals*

- *Commission Implementing Regulation (EU) 2018/163 of 1 February 2018 making imports of new and retreaded tyres for buses or lorries originating in the People's Republic of China subject to registration*

Customs Law

- *Commission Delegated Regulation (EU) 2018/148 of 27 September 2017 amending Annexes II, III and IV to Regulation (EU) No 978/2012 of the European Parliament and of the Council applying a scheme of generalised tariff preferences*

Trade Remedies

- *Commission Implementing Regulation (EU) 2018/186 of 7 February 2018 imposing a definitive anti-dumping duty and collecting definitively the provisional duty imposed on imports of certain corrosion resistant steels originating in the People's Republic of China*

- *Commission Implementing Regulation (EU) 2018/140 of 29 January 2018 imposing a definitive anti-dumping duty and collecting definitively the provisional duty imposed on imports of certain cast iron articles originating in the People's Republic of China and terminating the investigation on imports of certain cast iron articles originating in India*

Food and Agricultural Law

- *Commission Implementing Regulation (EU) 2018/183 of 7 February 2018 concerning the denial of authorisation of formaldehyde as a feed additive belonging to the functional groups of preservatives and hygiene condition enhancers*

- *Commission Regulation (EU) 2018/175 of 2 February 2018 amending Annex II to Regulation (EC) No 110/2008 of the European Parliament and of the Council on the definition, description, presentation, labelling and the protection of geographical indications of spirit drinks*

- *Commission Implementing Regulation (EU) 2018/154 of 30 January 2018 opening a tendering procedure for buying-in skimmed milk powder during the public intervention period from 1 March to 30 September 2018*

- *Commission Implementing Regulation (EU) 2018/150 of 30 January 2018 amending Implementing Regulation (EU) 2016/1240 as regards methods for the analysis and quality evaluation of milk and milk products eligible for public intervention and aid for private storage*

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