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A '*softer*' '*Brexit*'? The UK publishes its proposal for the post-'*Brexit*' relationship with the EU

On 12 July 2018, the Government of the UK published its *White Paper* entitled '*The future relationship between the United Kingdom and the European Union*', detailing the UK's revised approach to its future relationship with the EU. On 6 July 2018, the UK's Cabinet, in the so-called '*Chequers Agreement*', had agreed to the general terms of the approach for the future relationship with the EU after '*Brexit*' and published a statement with the main conclusions. The UK envisages the establishment of a free trade area with the EU for trade in goods, including agricultural goods, and special rules for trade in services. In view of this revised and '*softer*' approach, key members of the UK Government resigned in recent days. In particular, on 8 July 2018, David Davis, Secretary of State for Exiting the European Union, the UK's chief negotiator, resigned, followed by the resignation of Boris Johnson, Secretary of State for Foreign and Commonwealth Affairs. '*Brexit*' negotiations have been on hold since the beginning of June and it remains to be seen if the new proposal, as well as the new Government officials in charge of the negotiations, can now achieve swifter progress.

On 29 March 2017, the UK Government had officially notified the EU of its intention to withdraw from the EU. Article 50 of the Treaty on the Functioning of the EU (TFEU) provides for a two-year period to negotiate the exit and, in its '*Brexit*' Bill, the UK formally committed to leave the EU at 23:00 GMT on 29 March 2019. On 23 March 2018, the European Council confirmed the agreement reached on a transition period, which would last from 29 March 2019 until 31 December 2020 (see *Trade Perspectives*, Issue No. 7 of 6 April 2018). However, this transition period is conditional to the broader *Withdrawal Agreement* being concluded between the EU and the UK. On 29 June 2018, the European Council, in an EU 27 format without the UK, adopted conclusions on the progress made, and EU Member States expressed their concerns on a certain number of issues that still need to be agreed. A key remaining issue is the EU's interest of avoiding a '*hard*' border (*i.e.*, the reintroduction of border controls and customs checkpoints) between Northern Ireland, which is part of the UK, and the Republic of Ireland, an EU Member State (see *Trade Perspectives*, Issue No. 12 of 15 June 2018).

In January 2017, UK Prime Minister Theresa May had set the UK's general objectives for '*Brexit*' negotiations. Since then, the UK Government has published several position papers, detailing its approach regarding '*Brexit*' and the future relationship with the EU (see *Trade Perspectives*, Issue No. 6 of 24 March 2017 and Issue No. 19 of 20 October 2017). More specifically, the UK intends to no longer allow the free movement of people, does not intend to continue contributing to the EU budget, does not intend to subject itself to the jurisdiction

of the Court of Justice of the EU (hereinafter, CJEU), and, finally, intends to follow its own external trade policy. As noted above, a key aspect of the EU's approach is to avoid a '*hard*' border between Northern Ireland and the Republic of Ireland. The debate on the terms of the UK's departure from the EU has often been simplified to two terms, namely '*hard Brexit*' and '*soft Brexit*'. The first refers to the UK entirely leaving the EU's Customs Union and Single Market and the latter refers to UK remaining closely aligned with EU rules and for example, remaining in the EU Single Market.

The *White Paper* now details the UK's revised approach for a future relationship with the EU after '*Brexit*'. A key element is the proposal for the establishment of a free trade area for goods, including agricultural goods, by the UK and the EU. The free trade area aims at avoiding friction at the borders and tries to find a solution for the need to uphold the commitments to Northern Ireland and Ireland. The UK's new approach appears to be shifting the UK's position further towards a '*softer*' '*Brexit*', away from a complete separation of policies and rules. The UK aims at ensuring close and frictionless trade relations with the EU, but at the same time safeguarding some '*flexibility*' in order to establish and manage its own policies. To this end, the renewed position of the UK details four key elements.

Firstly, the UK notes that "*the UK and the EU would maintain a common rulebook for all goods including agri-food*". This is a complete and significant turnaround vis-à-vis the previous underlying approach of the UK negotiators and likely the reason for the resignations by Ministers Davis and Johnson, fervent supporters of a '*hard*' '*Brexit*'. Now, the UK intends to commit to an "*ongoing harmonisation with the EU rules on goods*". However, this is only supposed to cover those rules that are necessary to provide frictionless trade at the border. How this will be decided and operationalised remains unclear. The UK further specifies that the UK's Parliament *"would have oversight of the incorporation of these rules into the UK's legal order, with the ability to choose not to do so, recognising that this would have consequences*". Again, it is not clear how this would work in practice. It appears unlikely at best that such approach would provide any legal certainty to businesses in the EU or the UK, insofar as regulatory changes might or might not be incorporated into the UK's legal order. The UK's recognition that this "*would have consequences*" cannot arguably satisfy businesses in the UK, as well as around the EU and the world, trading with the UK.

Secondly, the UK and the EU would incorporate "*strong and reciprocal commitments related to open and fair trade into the legal agreements*", which would define the future relationship. Most importantly, the UK is proposing reciprocal commitments beyond those usually made in trade agreements. More specifically, the UK is proposing to: 1) Commit to a common rulebook on State aid, enforced and supervised in the UK by the Competition and Markets Authority (CMA); and 2) Maintain current antitrust prohibitions and the merger control system with rigorous UK enforcement of competition law alongside strong cooperation with EU authorities.

Thirdly, the UK envisages the establishment of "*a joint institutional framework to provide for the consistent interpretation and application of UK-EU agreements by both parties*". However, the UK notes that this would mean that the interpretation and application of such agreements in the UK would be done by UK courts and in the EU by EU courts. The UK suggests that, when courts in the EU or the UK interpret provisions of national legislation intended to give effect to the future EU-UK agreements, they could take relevant case law of the courts of the other party into account. In the area of trade in goods, where the UK intends to retain a common rulebook with the EU, the UK would commit that its courts pay due regard to CJEU case law. Additionally, the UK proposes that the future framework also include "*robust and appropriate means for the resolution of disputes*". This would be done through: 1) A Joint Committee; and 2) Binding independent arbitration panels, accommodating, through a joint reference procedure, the role of CJEU as the interpreter of EU rules, but founded on the principle that the court of one party cannot resolve disputes between the two. Negotiations will have to show if this could indeed be a feasible approach to the future intra EU-UK legal order.

Fourthly, the UK proposes that the EU and UK negotiate a phased introduction of "*a new Facilitated Customs Arrangement that would remove the need for customs checks and controls between the UK and the EU as if combined a customs territory*". This would entail that the UK set and apply its own tariffs and trade policy for goods intended for the UK and the EU's tariffs and trade policy for goods intended for the EU. The UK's proposal states that "*mirroring the EU's customs approach at its external border*" would guarantee that the goods entering the EU through the UK would have complied with the applicable EU customs rules. Officials in the UK and the EU already voiced their concerns and described the new customs arrangement proposal by the UK as "*unworkable*", as the practical implementation remains unclear.

Another relevant aspect is the UK's intention to establish separate and different trade regimes for goods and services, respectively. With respect to services, the *White Paper* states that a new arrangement for services would not entail a common market for services, thereby allowing the UK to regain regulatory flexibility. This means that the UK and the EU would "*not have current levels of access to each other's markets*". Still the UK notes that, according to the WTO General Agreement on Trade in Services (GATS) free trade agreements must cover all modes of services supply and to have substantial sectoral coverage, and underlines that the UK proposes arrangements with broad coverage. In any case, the future EU-UK agreements have to be compatible with the rules of the World Trade Organization (WTO) and, in particular, with Article XXIV of the General Agreement on Trade and Tariffs (GATT) and Article V of the General Agreement on Trade in Services (GATS) requiring free trade areas to liberalise "*substantially all the trade*". Considering that in 2017, services accounted for 32% of the UK's exports to the EU, it is clear that services must, in one form or the other, be part the future trade liberalisation.

So far, EU and EU Member States officials have been cautious in their reactions to the UK's new approach. Senior officials stated that the proposal opened a new phase for '*Brexit*' negotiations, now requiring the EU to show some flexibility. Irish Prime Minister Leo Varadkar went as far as suggesting that "*the EU might consider relaxing its red lines in the Brexit negotiations*". The details of the proposed customs arrangement and the proposed regime for services, however, appear to be key concerns. Supporters of a '*hard Brexit*' immediately criticised the move towards a '*softer*' '*Brexit*', in particular as it concerns trade in goods and the continued harmonisation with EU rules. The UK's National Farmers' Union (NFU) and the UK's National Pharmacy Association (NPA) welcomed the new approach, noting, however, that the lack of details impeded them to determine whether the final agreement would provide them with the certainty that their respective industries need.

Despite the many remaining questions and the rather '*creative*' approach for many areas of negotiation, the UK's proposal for the future relationship with the EU after '*Brexit*' is an important step forward. The *White Paper* provides the basis for further discussions between the EU and the UK, which are expected to recommence shortly. The UK's negotiating team will engage with the EU's negotiators with a view to concluding the Article 50 TFEU negotiations this autumn, reaching agreement on both the *Withdrawal Agreement* and the framework for the future trade relationship. In the UK, the agreement will then be debated in both Houses of the UK Parliament, while in the EU the European Parliament will have to give its consent. Both sides still work towards reaching a political agreement by the EU Summit to be held on 18 and 19 October 2018. This would then provide the EU and the UK with the necessary time for ratification ahead of the UK's 29 March 2019 formal exit from the EU. With the UK's *White Paper* on the future relationship with the EU, '*Brexit*' negotiations can resume and will have to progress swiftly, or the entire schedule will be put in jeopardy. The UK's turn towards a '*softer*' '*Brexit*' is a first indication of the way forward, but a multitude of open questions remain.

The CJEU will have to assess questions related to France's COOL for milk and milk used as an ingredient – French *Conseil d'État* refers preliminary questions

On 27 June 2018, the French *Conseil d'État* (the Council of State, an institution of the French Government that acts both as legal adviser of the executive branch and as the supreme court for administrative justice) referred preliminary questions relating to the mandatory country of origin labelling (hereinafter, COOL) for milk and milk used as ingredient of food under French law to the Court of Justice of the EU (hereinafter, CJEU). The French COOL measures for milk and milk used as an ingredient were strongly criticised across the EU and, in the absence of clear action by the European Commission (hereinafter, Commission), the controversial aspects will now have to be assessed by the courts.

Decree no. 2016-1137 of 19 August 2016 relating to the indication of the origin of milk and milk and meat used as ingredient (*i.e.*, *Décret n° 2016-1137 du 19 août 2016 relatif à l'indication de l'origine du lait et du lait et des viandes utilisés en tant qu'ingrédient*, hereinafter, *Decree 2016-1137*) governs the arrangements for labelling the origin or provenance of milk, as well as milk and meat used as an ingredient, specifies the geographical and material scope of this obligation, and provides for control measures and sanctions in case of violations of the rules. *Decree 2016-1137* made compulsory, for a trial period from 1 January 2017 to 31 December 2018, the indication of origin of milk, as well as milk and meat used as an ingredient in pre-packaged foods, (see *Trade Perspectives*, Issue No. 1 of 16 January 2017). By application of 24 October 2016, the *Lactalis Group*, a multinational dairy group based in France and biggest dairy and cheese group, as well as the biggest milk collector in Europe, requested the *Conseil d'État* to annul for excess of power the *Decree 2016-1137*. The *Lactalis Group* questions the utility of COOL for milk and milk used as an ingredient and considers the scheme too complex and costly. The *Conseil d'État* considered the application by the *Lactalis Group* to be admissible insofar as it sought the annulment of Decree 2016-1137 related to milk, as well as milk used as an ingredient.

First, the *Conseil d'État* addressed a number of procedural questions concerning the introduction of *Decree 2016-1137*. The *Lactalis Group* had submitted that the notification of the Decree to the Commission, required under Article 45(1) of *Regulation (EU) No 1169/2011 on the provision of food information to consumers* (hereinafter, FIR), and the consultation of the Standing Committee on the Food Chain and Animal Health under Article 45(2) of the FIR, concerned a draft decree that did not correspond to the provisions finally adopted by the French Government, so that the Commission was not in a position to give its opinion on this exact text. The *Conseil d'État* held that the modifications made after the favourable opinion of the Commission on the submitted draft decree did not raise any new questions and, consequently, dismissed the allegation by the *Lactalis Group* that the contested decree was taken following an "*irregular procedure*".

The *Conseil d'État* then underlined that international trade rules, namely Article 2.9 and Article 13 of the Agreement on Technical Barriers to Trade (hereinafter, TBT) relating to the notification requirement and the World Trade Organization's (hereinafter, WTO) TBT Committee, had no direct effect and that the applicant could not refer to and/or invoke these rules. These provisions do not confer rights or obligations to individuals and only bind the Member States of the WTO. Therefore, the *Conseil d'État* held that the *Lactalis Group* could not base its claims on the fact that France had not notified *Decree 2016-1137* to the WTO and dismissed the plea to that effect. Most importantly, the *Conseil d'État* discusses four substantive questions related to *Decree 2016-1137* and the FIR, which were raised by the *Lactalis Group*.

The first question concerns the issue of harmonisation. Under the FIR, Article 38(1) provides that, with respect to "*matters specifically harmonised by this Regulation, Member States may not adopt nor maintain national measures unless authorised by Union law*". Additionally, as regards COOL, Article 26(5) of the FIR provides that "*the Commission shall submit reports to the European Parliament and the Council regarding the mandatory indication of the country*

of origin or place of provenance for the following foods: (…) (b) milk; (c) milk used as an ingredient in dairy products". As the *Lactalis Group* alleged that on the basis of Articles 26 and 38 of the FIR, France had not been allowed to regulate the issue of COOL for milk and milk used as an ingredient, the *Conseil d'État* asks the CJEU 1) Whether Article 26 of the FIR should be regarded as having expressly harmonised that question within the meaning of Article 38(1) of the FIR; and 2) If this then constituted an obstacle for EU Member States to adopt measures requiring additional mandatory labelling requirements on the basis of Article 39 of the FIR, which allows additional national measures under certain conditions.

The second question concerns Article 39(2) of the FIR, which provides that "*By means of paragraph 1, Member States may introduce measures concerning the mandatory indication of the country of origin or place of provenance of foods only where there is a proven link between certain qualities of the food and its origin or provenance. When notifying such measures to the Commission, Member States shall provide evidence that the majority of consumers attach significant value to the provision of that information*". With respect to these two conditions (*i.e.*, the existence of a proven link between certain qualities of the food and its origin or provenance, and that the majority of consumers attach significant value to the provision of that information), the *Conseil d'État* raised the question if the two criteria must be read together and, in particular, if the assessment of the established link can only be based on subjective elements with respect to the importance of the link that consumers make between the qualities of the food and its origin or provenance.

The third question also concerns the interpretation of Article 39(2) of the FIR. The *Conseil d'État* raises the question if, insofar as the qualities of the food can be understood as all the elements that contribute to the quality of the food, considerations related to the transport of the food and its ability to withstand the risk of deterioration during transport could be used as a basis to establish the link between certain qualities of the food and its origin or provenance.

Fourthly, the *Conseil d'État* raises the question if the assessment of the conditions set out in Article 39 of the FIR presupposes that the qualities of a food are considered to be unique because of their origin or provenance or that the qualities are being guaranteed on the basis of the origin or provenance. In the latter case, the *Conseil d'État* raises the question, notwithstanding the harmonisation of health and environmental standards applicable within the EU, if the reference to the origin or provenance could actually be more precise than noting '*EU*' or '*Outside EU*', as the origin.

With respect to these four issues, the *Conseil d'État* held that they were decisive for the resolution of the case and, therefore, on the basis of Article 267 of the Treaty on the Functioning of the EU (TFEU), they must be referred to the CJEU. Until a decision of the CJEU is delivered, which will take months, the proceedings will be stayed.

Most questions referred to the CJEU by the *Conseil d'État* point at Article 39(2) of the FIR, under which EU Member States may introduce additional measures concerning mandatory COOL only where there is a proven link between certain qualities of the food and its origin or provenance. EU Member States must notify such measures and provide credible evidence to the Commission that the majority of consumers attaches significant value to the provision of that information. Apart from the claimed wish of the consumer to know the origin or provenance of a product, a link must be established between the respective EU Member State of origin and a particular quality attribute. Such link must be established and corroborated by the respective EU Member State with respect to every single COOL scheme.

The question related to harmonisation points at national COOL requirements, which may already restrict the free movement of goods if they discriminate against businesses based in other EU Member States and, thereby, possibly violate Article 34 of the Treaty of the Functioning of the EU (hereinafter, TFEU). The effect of mandatory origin labelling on all operators that are subject to the COOL requirements is an added cost for processors, which has consequences at all levels of the dairy supply chain, from farmers to consumers. More

importantly, national COOL measures, such as the French *Decree 2016-1137,* appear to encourage local sourcing without regard to the detrimental impact that it may have on established supply chains, which transcend national, and sometimes even EU, borders (see *Trade Perspectives*, Issue No. 15 of 28 July 2018). Although national COOL requirements, including the French *Decree 2016-1137,* typically do not apply to products lawfully produced or marketed in another EU Member State on the basis of a '*mutual recognition clause*', they may still have a detrimental effect on the internal market. For example, a Belgian cheese made with Belgian milk does not need to state '*Origin: Belgium*', when marketed in France. However, it can be easily identified as a foreign product because it does not state '*Origin: France*' or it might not even reach the French retail stage at all because retailers no longer buy it, leading to *de facto* discrimination (in form of a potential *de facto* '*boycott*' by retailers in France). Another example is the decline of liquid milk imports by France since French processors, due to pressure from retailers, appear to prefer milk of French origin in order to be able to indicate such origin on the product label according to the COOL scheme (see *Trade Perspectives*, Issue No. 15 of 28 July 2017).

At the meeting of the EU's Agriculture & Fisheries Council in July 2017, EU Ministers were strongly divided on the issue of COOL. The Government of Belgium highlighted the development of the trade flows from Belgium to France during the preceding year: the French COOL for scheme milk had been announced in the summer of 2016 and, as many contracts in the retail sector are fixed-term contracts, some were already abandoned or not renewed, at that time, in order to prepare for the national rules establishing COOL. According to Belgium, it appeared that some major multinational retail companies, with big acquisition power, had increased the pressure on the other partners of the food supply chain to adapt to these national rules. Especially fresh milk producing dairy companies immediately felt an impact. The monitoring of the meat and dairy product volumes exported to France, which were closely checked by the sector, and the figures of the Belgian National Bank, also show decreasing exports. Belgium stated that the first '*hint of trouble*' had already come with the announcement of the sector in the spring of 2016 that there had been a decline of 17% for milk exports, compared to the same period in 2015. A further decline was attributed to the actual start of the measure at the end of 2016.

According to Belgium, these sectoral figures show that the internal market is under pressure because of the French *Decree 2016-1137*. By comparison, the export of dairy from Belgium to other EU markets without COOL schemes in force (*e.g.*, Germany, the Netherlands) had remained stable over the same period. It is, therefore, not surprising that the French *Decree 2016-1137* is now the subject of judicial proceedings.

Considering the importance of the interpretation of the EU's FIR, it is only pertinent that the key questions are assessed at the EU level by the CJEU. The effects of the piecemeal of national EU Member State COOL measures on the internal market are obvious. During 2016 and 2017, a number of these measures were introduced for trial periods, some of which, such as the trial period established by *Decree 2016-1137*, will conclude at the end of 2018. France has promised to provide the Commission, after the trial period, a report that would allow it to review consumer patterns and the potential impact on the internal market. It is due time that a more uniform approach be taken at EU level, which would benefit food business operators across the EU and EU consumers alike. All interested stakeholders should closely follow the proceedings of the CJEU case, as the outcome will likely have important consequences for COOL measures across the EU.

EFSA publishes new guidance on nanotechnologies in food and feed

On 4 July 2018, the European Food Safety Authority (hereinafter, EFSA) published its "*Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain: Part 1, human and animal health*" (hereinafter, Guidance). The EFSA stated in a press release on the same day that the Guidance gives practical suggestions on the types of testing that are needed and the methods that can be applied in order to evaluate

the safety of nanotechnology applications. The EFSA also stated that the Guidance was "*very timely because it gives applicants the tools they need to prepare complete nanotechnology applications and equips risk assessors such as EFSA with the appropriate tools to evaluate their safety*". As nanomaterials become more commercialised, guidance on their safe use in food and feed is needed.

The Guidance addresses the complex matter of establishing a definition of '*nanomaterials*'. The Guidance states that, although a definition of '*engineered nanomaterial*' currently exists, as established by Article 3(2)(f) of *Regulation (EU) 2015/2283 on novel foods* (which is also referred to in *Regulation (EU) No 1169/2011 on the provision of food information to consumers*), a possible revision of the existing definition in the light of European *Commission Recommendation of 18 October 2011 on the definition of nanomaterial*, which is currently under review, may provide more clarity on the type of materials to be covered. According to that recommended definition, '*nanomaterial*' means a natural, incidental or manufactured material containing particles in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number-size distribution, one or more external dimensions is in the size range 1-100 nm. In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number-size distribution threshold of 50% may be replaced by a threshold between 1 and 50%. The provisions of the recommended definition include a requirement for review in the light of experience and of future scientific and technological developments.

The European Commission (hereinafter, Commission) is expected to conclude this review during the course of this year. The Guidance notes that, if this recommended definition (or any update of it) were to be embedded in EU food law, it would provide further information on whether or not a material should be regarded as a nanomaterial in the context of any of the food regulations. Nanomaterials are used in a variety of manufacturing processes, products and healthcare (*e.g.*, paints, filters, insulation and lubricant additives), but also by the food and feed industry, for example in packaging materials. In terms of nutrition, it may be easier for the body to absorb nutrients, vitamins or enzymes contained inside a nanoparticle, which could also help mask undesirable flavours.

The Guidance, which focuses on the safety assessment for human and animal health, underwent a three-month public consultation from January to March 2018 (see *Trade Perspectives*, Issue No. 3 of 9 February 2018) and, according to the EFSA, takes into account all comments received. It covers areas such as novel foods, food contact materials (hereinafter, FCMs), food and feed additives, and pesticides, and is intended for all interested parties, in particular risk assessors, risk managers and applicants.

The EFSA's Scientific Committee has undertaken a revision of the previous Guidance on risk assessment of nanoscience and nanotechnology applications in the food and feed chain, published in 2011. Part 1 of the updated Guidance relates to human and animal health aspects of nanomaterial applications in the areas within EFSA's remit. Part 2 of the Guidance will separately address those aspects that relate to environmental risk assessment. The revision takes into account the relevant applications areas, including novel foods, FCMs, food/feed additives and pesticides, as well as physicochemical characterisation and the data needed for safety assessment of nanomaterials in food/feed. The Guidance, therefore, provides an overview on information requirements and how to perform risk assessment of nanomaterials in the food and feed area. For example, under *Regulation (EU) No. 2015/2283*, a food consisting of engineered nanomaterials will be considered a novel food and, as such, it will require authorisation. *Regulation No. 2015/2283* establishes that risk assessment of novel foods shall be carried out by the EFSA, which is also responsible for verifying that the most up-to-date test methods have been used to assess safety.

The Guidance aims at providing a structured pathway for carrying out safety assessments of nanomaterials in the food and feed area. The Guidance applies to: 1) A material that meets the criteria for an engineered nanomaterial as outlined in *Regulation (EU) No 2015/2283* and *Regulation (EU) No 1169/2011* (*i.e.,* nanomaterials that, amongst other criteria, have particle

sizes in the defined nanoscale of 1–100 nm); 2) 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 or different toxicokinetic behaviour *(i.e.*, significant changes in absorption, distribution and/or metabolism) as compared with its non-nanomaterial. This may be the case for materials resulting from production processes that are aimed at reducing the average diameter of materials' particles (*e.g.*, micronisation). 3) A material that is not engineered as nanomaterial, but that contains a fraction of particles, less than 50% in the number-size distribution (as per the recommended Commission definition), with one or more external dimensions in the size range 1-100 nm (this is expected to be the case of manufacturing processes for powdered or particulate food chemicals that typically result in materials with a range of sizes); 4) 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 5) 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). Although the Commission's *Recommendation on a definition for a nanomaterial* is currently still under review, and has not yet been adopted under the relevant regulatory frameworks, the EFSA's Scientific Committee advises to take this and any future reviews into consideration when assessing the safety of materials consisting of nanomaterials.

The Guidance also presents a decision flow scheme in order to facilitate ascertaining whether or not a material is a nanomaterial according to the Commission's recommended definition, and to identify relevant methods and tools for its characterisation. The Guidance states that, in principle, the current risk assessment paradigm for chemicals, which is based on hazard identification/characterisation, together with exposure assessment and risk characterisation, also applies to nanomaterials. However, as highlighted in the Guidance, reducing the size of particulate materials to the nanoscale can impart certain changes in properties and biokinetics behaviour, which may also lead to altered toxicological effects compared with corresponding non-nanomaterial. Therefore, the safety of a nanomaterial should not be automatically assumed to be similar/comparable to its corresponding non-nanomaterial or another nanomaterial. This also means that, for a specific nanomaterial, data and information would need to be provided on certain nano-specific properties, in addition to the data and information generally required according to the relevant conventional regulation. Some of the currently available testing methods may also need adaptation in order to take account of the specific properties of nanomaterials. Therefore, safety assessment of nanomaterials must be carried out in accordance with the provisions of the Guidance. The Guidance proposes a structured pathway for carrying out safety assessment of nanomaterial in food/feed and related applications, and provides practical suggestions for the types of testing needed and the methods that can be used for this purpose.

As a general principle, the test requirements stipulated in the current EFSA guidance documents for conventional materials and EU legislation for various food and feed areas should be applied to a nanomaterial, according to its intended use. However, the risk assessment of nanomaterials, in terms of testing requirements and procedures, requires additional considerations that are indicated in the new Guidance. This Guidance also covers the additional information needed for physicochemical characterisation owing to the specific characteristics and properties of nanomaterial. The specific information related to the characteristics and properties of the nanomaterial, along with the information stipulated in the relevant EFSA Guidance documents for the specific intended use of the nanomaterial (*e.g.*, novel foods, FCMs, food/feed additives and pesticides), is used for a case-by-case risk assessment. There are substantial ongoing developments alternative to *in vivo* testing approaches, but validated *in vitro* (*i.e.*, in a living organism) / *in silico* (*i.e.*, performed on computer or via computer simulation) methods for specific endpoints are still limited, which necessitates that information from *in vivo* testing be used for risk assessment purposes. The use of animals for risk assessment should be considered thoroughly during the design of experimental studies and applicants are advised to consult the EFSA's Scientific Committee opinion in the document '*Existing approaches incorporating replacement, reduction and*

refinement of animal testing: applicability in food and feed risk assessment'. It is also recommended that any existing data generated for other relevant regulations (*e.g.,* REACH) be used to minimise/avoid animal testing. The Guidance also identifies circumstances under which some data requirements for the risk assessment could be waived, for example where there is no migration or transfer of a nanomaterial from a FCM into the food).

The Guidance describes how to carry out and present the analysis of uncertainty relating to physicochemical characterisation, exposure assessment, and hazard identification and characterisation for nanomaterials. In Appendix E, the Guidance discusses specific aspects relating to nanomaterial applications for food/feed additives, pesticides, nano-carriers, novel foods, contaminants and FCMs. For example, the novel food legislation establishes that vitamins, minerals or other substances that contain or consist of engineered nanomaterial be considered as novel foods. Here, the Guidance states that it remains to be clarified whether the wording '*contains or consists*' would also warrant an assessment of these nutrients or other substances if they are encapsulated or in other forms of carrier nanomaterials, as mentioned in the Guidance. Another example is the reference to nano(plastic) contaminants. There is a possibility that certain nanomaterials enter the food and feed chain as contaminants from anthropogenic (*i.e.*, originating in human activity) or natural sources through traditional processes of waste disposal. In this respect, the Guidance states that, in principle, the data resulting from toxicity testing of nanomaterials, as recommended in the Guidance, can also be used for assessing the human health risk from nanomaterials as contaminants of food/feed.

In its conclusions and recommendations, the Guidance highlights certain gaps where further research is needed in order to facilitate adequate safety assessment of materials that consist of small-sized particles. Currently, for example, there is no agreed definition of the term '*nanopesticides*'. The EFSA's Scientific Committee strongly suggests that regulatory authorities take note of the recommended Guidance. It also proposes that, during the next update of the legal data requirements, consideration be given to Appendix E.2 of the Guidance (Recommended guidance for nanomaterial pesticides). Applicants for novel foods, FCMs, food/feed additives containing nanomaterial will need to use the tools mentioned in the Guidance to prepare complete nanotechnology applications.

The Guidance will now be subject to a pilot phase and is foreseen to be finalised by the end of 2019. The second part of the Guidance on "*environmental risk assessment of nanoscience and nanotechnology applications in the food and feed chain*" will also be developed in 2019. As regards the review of the definition, the Commission states that it was not considering any major alterations or changes in scope, but rather minor clarifications in the text and ways to facilitate its implementation. The main elements (*i.e.*, the definition only related to size and particle number size distribution) are intended to remain the same. Developments on nanomaterials, in particular regarding their definition and safety, should be carefully monitored.

Recently Adopted EU Legislation

Market Access

- *Commission Implementing Regulation (EU) 2018/981 of 11 July 2018 amending the list of Brazilian establishments from which imports into the Union of fishery products intended for human consumption are permitted*

Trade Remedies

- *Commission Implementing Regulation (EU) 2018/931 of 28 June 2018 imposing a definitive anti-dumping duty on imports of oxalic acid originating in India and*

the People's Republic of China following an expiry review pursuant to Article 11(2) of Regulation (EU) 2016/1036 of the European Parliament and of the Council

Food and Agricultural Law

- *Commission Implementing Regulation (EU) 2018/949 of 3 July 2018 amending Regulation (EC) No 1235/2008 laying down detailed rules for implementation of Council Regulation (EC) No 834/2007 as regards the arrangements for imports of organic products from third countries*

- *Commission Implementing Regulation (EU) 2018/941 of 2 July 2018 amending Regulation (EC) No 669/2009 implementing Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin and Commission Implementing Regulation (EU) No 885/2014*

Other

- *Council Decision (EU) 2018/966 of 6 July 2018 on the signing, on behalf of the European Union, of the Agreement between the European Union and Japan for an Economic Partnership*

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