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As ‘Brexit’ becomes a reality, legal uncertainties remain

On 31 January 2020 at 24:00 CET, the United Kingdom (hereinafter, UK) leaves the European Union, thereby becoming the first EU Member State to do so. The EU and the UK will enter into a transition period, which should end on 31 December 2020 and during which further preparations and negotiations for the post-‘Brexit’ relationship between the two parties are to take place. Most importantly, the EU and the UK intend to shortly commence negotiations for a free trade agreement, though it appears to be rather unlikely that an agreement could be in place by the end of the transition period. At the same time, the UK has already begun to define its own future domestic policies, for example in the agro-food sector. As ‘Brexit’ finally becomes a reality, many questions remain unanswered and legal uncertainty persists.

On 29 March 2017, the UK Government had officially notified the EU of its intention to withdraw from the EU and originally committed to leave the EU at 24:00 CET on 29 March 2019. ‘Brexit’ negotiations took place from June 2017 to November 2018, when the EU and the UK reached a ‘technical agreement’. From the beginning of 2018, negotiations also focused on the questions of a transition period and the future relationship between the EU and the UK. On 23 March 2018, both sides reached agreement on a transition period from 29 March 2019 to 31 December 2020 (see *Trade Perspectives*, [Issue No. 7 of 6 April 2018](#)). On 25 November 2018, the Withdrawal Agreement and the Declaration on the Framework for the Future Relationship were endorsed by EU Member States’ leaders. The Withdrawal Agreement was approved by the UK Cabinet, but initially rejected multiple times by the UK Parliament, leading to the postponement of ‘Brexit’. Following parliamentary elections in December 2019, on 23 January 2020, the Withdrawal Agreement was ratified by the UK Parliament. During its plenary meeting on 29 January 2020, the European Parliament voted in favour of the Withdrawal Agreement. After 47 years of membership, the UK becomes the first Member State to leave the EU.

The Withdrawal Agreement establishes the terms for the UK to leave the EU with the objective of providing an orderly withdrawal and legal certainty. The Withdrawal Agreement addresses the following areas: 1) Common provisions; 2) Citizens’ rights; 3) Separation issues; 4) Transition period; 5) Financial settlement; 6) Governance structure; 7) Legally operative solution to avoid a hard border between the Republic of Ireland and Northern Ireland; 8) Protocol on the Sovereign Base Areas in Cyprus; and 9) Protocol on Gibraltar. The most sensitive areas have been the transition period, the protocol on Ireland/Northern Ireland and citizens’ rights. On 17 October 2019, the European Commission (hereinafter, Commission) and the UK had reached an agreement on slight revisions to the [Protocol on Ireland / Northern](#)

Ireland and on the *Declaration on the Framework of the Future Relationship*, intended to address concerns by the UK Parliament.

For now, the transition period will avoid what has been referred to as a ‘*hard*’ ‘*Brexit*’. The Withdrawal Agreement provides that the transition period may be extended once by one or two years, which is to be jointly decided by the EU and the UK before 1 July 2020. During the transition period, the UK will remain part of the EU Customs Union and the EU Single Market. During this time, EU law will continue to apply in the UK. Therefore, trade in goods and services between the EU and the UK should remain largely unaffected in the coming months and at least until the end of the year. However, having left the EU, from 1 February 2020, the UK will no longer participate in EU meetings, no longer take part in the EU law making process, and the UK’s Members of the European Parliament will leave the European Parliament.

With respect to the UK’s rights, the Withdrawal Agreement states that, during the transition period, the UK would be able to negotiate, sign and ratify its own free trade agreements (hereinafter, FTAs). However, these agreements may not yet enter into force during the transition period. The *Declaration on the Framework of the Future Relationship* (hereinafter, Declaration) sets the framework for the future relationship between the EU and UK and both sides committed to negotiate an ambitious free trade agreement, covering goods, services and investment. The EU and the UK “*envisage having an ambitious trading relationship on goods on the basis of a Free Trade Agreement, with a view to facilitating the ease of legitimate trade*”. However, as in all FTA negotiations, certain areas will likely prove sensitive and difficult. The Declaration states that the future FTA should “*ensure no tariffs, fees, charges or quantitative restrictions across all sectors [shall apply] with appropriate and modern accompanying rules of origin, and with ambitious customs arrangements that are in line with the Parties’ objectives and principles*”.

The services sector is another area that the future EU-UK comprehensive agreement is supposed to cover, with the Declaration noting that the future FTA should “*aim to deliver a level of liberalisation in trade in services well beyond the Parties’ World Trade Organization (WTO) commitments and building on recent Union Free Trade Agreements*”. In case the EU and the UK were not to conclude an agreement before the end of the transition period and if no extension were to be agreed, the EU-UK trade relationship would be governed by WTO rules, eventually leading to the so-called ‘*hard Brexit*’. On 3 February 2020, the Commission is expected to agree on draft negotiating directives, which then need to be adopted by the Council of the EU. The transition period leaves the EU and the UK with 11 months to conclude (and arguably to ratify) a trade agreement, which European Commissioner for Trade *Phil Hogan* and the President of the European Commission *Ursula von der Leyen* already considered as close to “*impossible*”. The EU and the UK would be able to jointly decide to extend the transition period, but UK Prime Minister *Boris Johnson* already stated that he did not have any intention to do so.

On 17 October 2019, the EU and the UK agreed on a revision to the ‘*Protocol on Ireland/Northern Ireland*’, which amended the so-called *Northern Ireland backstop*. The ‘*backstop*’ is a measure that would be put in place in case the EU and the UK were not to find agreement to avoid a ‘*hard*’ border (*i.e.*, border checks) between the EU Member State Ireland and Northern Ireland, which is part of the UK. Different from its previous version, in which Northern Ireland would have remained part of the EU Customs Union and EU Single Market, the revised Protocol states that Northern Ireland would be part of the UK customs territory, but would remain aligned to a limited set of EU rules, notably in relation to goods, in order to avoid border checks. The UK would have its own customs tariffs, which would apply to all products originating from third countries entering the UK. However, if a product entering Northern Ireland were to be considered at risk of entering the EU market, EU customs duties would apply. In this regard, Article 5 of the revised Protocol states that “*no customs duties shall be payable for a good brought into Northern Ireland from another part of the United Kingdom by direct transport (...), unless that good is at risk of subsequently being moved into the Union, whether by itself or forming part of another good following processing*”. While the Protocol provides a number of the requirements for when a product is to be considered “*at risk of subsequently*

being moved into the Union", there is only limited understanding on how the risk of goods entering the EU Single Market would be determined and what measures the UK would take to apply EU tariffs in such cases. The *'Protocol on Ireland/Northern Ireland'* will apply after the transition period for a term of four years. If, during that time, the EU and the UK were to reach agreement on their future trade relation, they would have to indicate the parts of the Protocol "*superseded*" by the agreement. Additionally, Article 18 of the *'Protocol on Ireland/Northern Ireland'* on *'Democratic consent in Northern Ireland'* provides the elected representatives of Northern Ireland with the possibility to decide, by simple majority, whether to continue applying relevant EU rules in Northern Ireland.

With respect to citizens' rights, the Withdrawal Agreement grants rights and protection to those EU citizens residing in the UK, and to UK citizens residing in any of the 27 EU Member States and continuing to reside there at the end of the transition period. UK and EU citizens must be registered in the respective State. The right to reside must have been exercised "*in accordance with Union law before the end of the transition period*". The protection is extended to children, spouses, registered partners, parents, grandparents, and grandchildren if they fulfil the requirements set in Article 10 of the Withdrawal Agreement. The Withdrawal Agreement states that the host State cannot impose any limitations or conditions for obtaining, retaining or losing residence rights on EU and UK citizens, family members who are EU or UK citizens, and family members who are neither EU or UK citizens, but have the right to reside in the host State according to Article 21 of the Treaty of the Functioning of the European Union (TFEU) and *Directive 2004/38/EC on the right of citizens of the Union and their family members to move and reside freely within the territory of the Member States*.

With respect to trade, from 1 February 2020, the UK will be able to begin negotiating its own FTAs with third countries. On 22 January, UK Prime Minister *Boris Johnson* stated that, at the beginning of February 2020, he would travel to the US to initiate negotiations regarding a future US-UK FTA. Reportedly, the UK's negotiating mandate is currently undergoing the scrutiny process by Cabinet Ministers. It is expected that the mandate would prioritise financial services, defence, and government procurement. US President *Donald Trump* has already stated that agricultural products figured high on the US agenda. Additionally, in past months, the UK has already successfully negotiated the *'roll over'* of existing EU trade agreements. The *'roll over'* agreements aim at ensuring that the UK safeguards its preferential market access to these countries after the transition period. So far, the UK has *'rolled over'* 20 agreements, namely those with Andean countries, Caribbean countries, Central America, Chile, Eastern and Southern Africa, the Faroe Islands, Georgia, Iceland, Israel, Jordan, Kosovo, Lebanon, Liechtenstein, Morocco, Norway, Pacific Island countries, the Palestinian Authority, Southern African nations, South Korea, Switzerland, and Tunisia. However, the *'roll over'* of 20 further agreements is still missing, namely those with Albania, Algeria, Andorra, Bosnia & Herzegovina, Cameroon, Canada, Côte d'Ivoire, Egypt, Ghana, Japan, Kenya, Mexico, Moldova, Montenegro, North Macedonia, San Marino, Serbia, Singapore, Turkey, and Ukraine. In case no *'roll over'* agreement is concluded with any EU FTA partner by the end of the transition period, UK trade relations with that country or those countries would be governed by WTO rules and subject to most-favoured nation tariffs. In more general terms, UK Prime Minister *Johnson* stated, on 22 January 2020, that he would detail the UK's trade priorities at the beginning of February 2020 and that he expected to start negotiations with the EU as soon as possible. He also stated that the UK Government would publish a set of position papers outlining the Government's priorities for post-*'Brexit'* trade.

During the transition period, the free circulation of goods will still apply to products within the EU and the UK market. In order to avoid market disruptions, the two parties have agreed that goods placed on the market before the end of the transition period may continue to circulate between these two markets until they reach the final consumers, without having to comply with additional requirements. The agro-food sector is one of the most integrated areas in the EU. In 2017, the value of EU agro-food exports to the UK amounted to EUR 41 billion, while the value of UK agro-food exports to the EU amounted to EUR 17 billion, underlining the relevance of EU-UK trade in this area. The Withdrawal Agreement establishes that, from the end of the transition period, the applicable rules of both parties on imports and sanitary controls of live

animals and animal products at the border would apply regardless of whether they were placed on the market before or after the end of the transition period. This exception to the general rule is considered necessary in view of the high sanitary risks associated with such products. Based on the Protocol on Northern Ireland and with the aim of protecting the internal market, EU rules on veterinary controls and on the marketing of agricultural products, will remain applicable in Northern Ireland even after the end of the transition period.

According to the UK Food Standards Agency's (FSA) '[Advice on the new authorisation procedure for a regulated food or animal feed product or process requiring pre-market approval in the UK](#)', from 1 January 2021, UK competent authorities will take over all tasks previously carried out at EU level regarding pre-market approvals and authorisations for food and feed additives, enzymes, flavourings, genetically-modified food and feed, and novel foods. However, the alignment will, initially, be rather straightforward since the UK updated its legal framework reproducing the EU mechanisms and postponing the decision on the pivotal issue of whether it should remain aligned to the EU food safety standards or develop its own. The possible future divergence may be fuelled not only by the fact that EU procedures have been criticised for being too slow and burdensome, but also by the position that the UK Government might take on controversial dossiers such as GMOs and growth promoter hormones. The position of the UK on those sensitive dossiers is considered crucial by the US Government in view of the negotiation of a possible bilateral preferential trade agreement and also in its objective of establishing common standards in areas where EU policies are considered not to be based on science.

An additional sensitive area addressed by the Withdrawal Agreement is the protection of EU-approved Geographical Indications (hereinafter, GIs). The Withdrawal Agreement grants general protection to more than 3,400 EU-approved GIs. Their degree of protection in the UK will be the same as it currently is within the EU and until a new agreement in this area will be concluded in the context of a future trade partnership. Similarly, EU-approved GIs indicating UK origins will receive the same degree of protection within the EU. The protection will be granted with no need of re-examination and will be free of charges.

The EU and the UK will now enter into a new phase of the '*Brexit*' process. The Commission is expected to publish shortly its proposal for negotiating directives for the future EU-UK trade relationship and time is of the essence considering that the transition period may lapse at the end of the year. Interested stakeholders, businesses in the EU, UK and third countries should diligently follow the developments and engage early in the game, so that their interests can be duly considered in the negotiations.

As the EU and the UK move into the transition period after '*Brexit*', the reallocation of EU/UK tariff-rate quotas remains controversial and unresolved

On 31 January 2020 at 24:00 CET, the UK leaves the EU and regains its full competences. However, due to the transition period, currently agreed until the end of 2020, most effects of '*Brexit*' will not yet materialise, as the UK will remain part of the EU Customs Union and the EU Single Market. Following the transition period, the UK will leave the EU Customs Union and regain authority over its membership in the World Trade Organization (hereinafter, WTO). The UK will then have to put in place its own trade and customs policy. One of the key issues that still need to be resolved until then, is the allocation of current EU tariff-rate quotas (hereinafter, TRQs) to address specific market access concerns, which will be affected by '*Brexit*'. This reallocation has led to significant controversies within the relevant WTO *fora*, as other WTO Members negotiate with the EU and strongly criticise the EU's approach, as well as the data on which negotiations are based.

TRQs determine the quantities of goods that may be imported duty-free or at reduced tariffs (*i.e.*, in-quota rates). Once a quota is filled, the regular higher tariff (*i.e.*, the out-of-quota rate) applies. The out-of-quota tariff rate can be significantly higher than the in-quota tariff, having

important implications for trade. TRQs are particularly important with respect to sensitive sectors, such as agricultural and fishery products. In view of the often wide gap between the in-quota and the out-of-quota tariff rates, which results in lucrative quota rents, TRQ allocation is of key importance. With respect to 'Brexit', both the EU and the UK will have to determine their future TRQ policies. Currently, the UK, as part of the EU's Customs Union, does not maintain its own TRQs, but the EU-wide TRQs also apply to the UK. In view of 'Brexit', these TRQs will have to be recalculated and reallocated by both the EU and the UK. Therefore, trade negotiations are currently ongoing with other WTO Members on this issue.

Already back in October 2017, the EU and the UK had sent a letter to all Permanent Representatives to the WTO and informed other WTO Members of how they would address the consequences of 'Brexit' for the multilateral trading system under the WTO (see *Trade Perspectives, Issue No. 18 of 5 October 2018*). Most importantly, they noted that the EU's scheduled commitments for goods, services and public procurement would remain applicable to its territory, but that the EU's existing quantitative commitments in the area of goods, namely through TRQs, would require certain adjustments to reflect 'Brexit'. With respect to the quantitative commitments in the form of TRQs, the future quotas are supposed to be established through an apportionment of the EU's existing commitments and based on current trade flows under each TRQ.

Originally, the EU and the UK had considered the apportionment of the TRQs between the EU and the UK to be only an adaptation of the WTO Schedules of Concessions to the post-'Brexit' situation and started bilateral discussions in order to adjust their Schedules without engaging in renegotiations under Article XXVIII of the General Agreement on Tariffs and Trade (hereinafter, GATT) and with the intention of using the quicker procedure foreseen within the WTO for rectification. However, a number of WTO Members and major exporters of agricultural products to the EU responded in a joint letter to the EU and UK and noted their concerns with respect to the intended approach, considering that the intended changes were more than a rectification of the Schedules, would lead to decreased flexibility, and would affect market access for their exporters. They further noted that, if market access conditions were to change due to the proposed quota apportionment, additional concessions would be needed in order to compensate for the loss of market access. They concluded that modifications of the EU's and the UK's current WTO commitments should be adopted with their agreement. The EU then acknowledged that the apportionment of TRQs would occur in accordance with Article XXVIII of the GATT.

In view of the uncertainties surrounding 'Brexit' and the possibility of a 'no deal'-'Brexit' with no transition period, the EU had already decided on the general approach to the apportionment of TRQs included in the EU's WTO Schedule following 'Brexit'. On 8 February 2019, the EU published *Regulation (EU) 2019/216 of the European Parliament and of the Council of 30 January 2019 on the apportionment of tariff rate quotas included in the WTO schedule of the Union following the withdrawal of the United Kingdom from the Union, and amending Council Regulation (EC) No 32/2000*, which provides, in its Annex, the product-specific allocations. The relevant parts of the Regulation will only become effective when *Council Regulation (EC) No 32/2000 of 17 December 1999 opening and providing for the administration of Community tariff quotas bound in GATT and certain other Community tariff quotas and establishing detailed rules for adjusting the quotas* does not apply anymore to the UK (i.e., when the UK has left the EU Customs Union). Recital 5 of the Regulation provides that the EU would, "following completion of preliminary contacts, engage in negotiations with WTO Members having a principal or substantial supplying interest or holding an initial negotiating right in relation to each of these tariff rate quotas".

On 26 June 2018, the Council of the EU authorised the European Commission (hereinafter, Commission) to open formal negotiations within the WTO on how to apportion the existing EU's TRQs between the EU-27 (i.e., the remaining 27 EU Member States) and the UK. The Regulation goes on to state that "given the time limits imposed on this process by the negotiations on the United Kingdom's withdrawal from the Union, it is possible that agreements might not be concluded with all WTO Members concerned in relation to all of the tariff rate

quotas on the date the Union's WTO schedule of concessions and commitments on trade in goods ceases to apply to the United Kingdom". Notably, the EU states that, due to *"the need to ensure legal certainty and the continuous smooth operation of imports under the tariff rate quotas to the Union and to the United Kingdom, it is necessary for the Union to be able to proceed unilaterally to the apportionment of the tariff rate quotas"*. However, taking into account the ongoing negotiations with other WTO Members, the Regulation empowers the Commission to adopt delegated acts on the basis of Article 290 of the Treaty on the Functioning of the European Union (TFEU) *"to take account of any agreements concluded or of pertinent information that it might receive in the context of those negotiations which would indicate that specific factors that were not previously known require an adjustment to the apportionment of the tariff quotas"*. Therefore, the TRQs provided in the Annex to Regulation 2019/216 will likely only constitute 'transitional' TRQs until the negotiations with all relevant WTO Members are concluded.

Article XXVIII of the GATT on the Modification of Schedules provides that a WTO Member may *"by negotiation and agreement"* with: 1) Any WTO Member with which such concession was initially negotiated (*i.e.*, holding *"Initial Negotiating Rights"*); and 2) Any other contracting party determined to have a principal supplying interest, and subject to consultation with any other contracting party determined by to have a substantial interest in such concession, modify or withdraw a concession. Article XXVIII of the GATT further provides that, in *"such negotiations and agreement, which may include provision for compensatory adjustment with respect to other products, the contracting parties concerned shall endeavour to maintain a general level of reciprocal and mutually advantageous concessions not less favourable to trade than that provided for in this Agreement prior to such negotiations"*.

The EU's approach has led to important debates within the relevant WTO *fora* and other WTO Members are highly critical of the EU's approach, calling on the EU to reconsider it. The debate on the reallocation of the EU's TRQs has become a recurring issue on the agenda of the WTO's Council for Trade in Goods, where WTO Members have been raising the issue at every meeting in recent months. At the most recent meeting in November 2019, fifteen WTO Members again raised the issue, noting a multitude of important concerns.

A key concern relates to the fact that the current EU-28 TRQs are not being used by the UK, as the UK is part of the EU Customs Union and EU Single Market and has unrestricted access to the EU Single Market. As the EU and the UK have not yet made significant progress on defining their future trade relationship, WTO Members are concerned that, following the transition period, the UK would, in the absence of a preferential trade agreement with the EU, access the EU under WTO rules. For those TRQs that are available *erga omnes* (*i.e.*, to all WTO Members), the UK would then compete with all other WTO Members for market access under the TRQs. Given the significant amount of trade between the EU and the UK, WTO Members are very concerned that EU-UK trade would absorb an important share of the TRQs to the detriment of other WTO Members and, thereby, significantly affect global trade flows, reducing other WTO Members' market access to the EU.

Another key concern by WTO Members relates to the potential compensation for other WTO Members. At the July 2019 meeting of the WTO Council for Trade in Goods, Australia noted that it *"could not accept the EU's assertion that no compensation was required on the grounds that there had been no loss in value of the concessions in question"*. Australia underlined that the *"proposed TRQ modifications would lead to significant year-on-year economic loss by removing flexibility for exporters and by making some TRQ allocations too small to be commercially viable"* and that the *"EU and UK must proceed with compensatory adjustments that factored in the significant resulting commercial losses and maintained the general level of reciprocal and mutually advantageous concessions"*. In previous discussions, it appears that the EU had argued that the reduced EU-27 TRQs would be compensated for by TRQ market access to the UK. This idea has been rejected by WTO Members, as not being in line with the EU's obligations under Article XXVIII of the GATT, which requires the compensation to be provided by the WTO Member in question and not coming from a different WTO Member (*i.e.*, the UK).

Another concern of WTO Members relates to the proposed changes to the TRQs currently applied by the EU-28, namely the splitting of these TRQs between the future EU-27 and the UK. The Annex to *Regulation (EU) 2019/216* provides for the TRQs for certain products to entirely remain for the EU-27 (thus depriving WTO Members of preferential market access for these products into the UK), while other TRQs would be reduced to 0 for the EU-27, as they would be taken over in their entirety by the UK. According to statements by WTO Members, WTO Members “*would suffer a loss of market access for 55 products in the UK market and five products in the EU market*”. Therefore, according to the WTO’s [report](#) on the most recent meeting of the Council for Trade in Goods in November 2019, many WTO Members are concerned “*that EU and UK proposals to split up the current EU TRQs would reduce the flexibility to move products between the UK and the rest of the EU-27*”, referring to “*the elimination proposed for 60 of the current 142 TRQs, which cover around 400 tariff lines*”, that would amount to “*EUR 28 billion worth of EU imports in 2018*”. In this regard, Russia clearly noted in July 2019 that it considered this approach to be inconsistent with WTO rules, unless compensatory adjustments were provided by the EU.

In a statement for the July 2019 meeting of the WTO Council for Trade in Goods, New Zealand summarised its concerns with the EU’s approach, referring to: 1) “*a significant loss of access into the EU market, including complete elimination of a small number of current quotas and a large-scale reduction in many more*”; 2) “*the risk that much of what remained of the reduced MFN TRQ access would be absorbed by the significant level of bilateral EU-UK trade*”; and that there would be a 3) “*loss of flexibility referred to above constraining the ability of both exporters and markets to respond appropriately to fluctuations in demand in the current uncertain environment*”. Negotiations between the EU and relevant WTO Members are ongoing and will likely continue well into 2020. Considering that the future EU-UK trade relationship is an element that would bring important clarification to the negotiations, it appears likely that WTO Members will wait until there is more clarity before agreeing to the new allocations. It can, therefore, be expected that the renegotiated TRQs will significantly differ from the allocations proposed by the EU in *Regulation (EU) 2019/216*. An important sector in this regard will be the agro-food sector, particularly with respect to beef and poultry, where significant trade battles have been fought in the past through a number of WTO dispute settlement proceedings (on poultry, see [Trade Perspectives, Issue No. 18 of 5 October 2018](#), and, on beef, see [Issue No. 17 of 21 September 2018](#)).

TRQs and, thereby, market access for a large number of products into the EU, remain an area where uncertainty prevails and where a sustainable solution is yet to be reached. It can be expected that WTO Members will wait for the EU and the UK to make progress on their future trade framework before agreeing to future TRQs. Businesses within the EU and its trading partners should carefully assess the EU’s proposal and contribute to the debate before new TRQs are agreed among WTO Members.

The EFSA finds that the intake of *Delta-9-tetrahydrocannabinol (Delta-9-THC)* by adult high consumers of most of hemp-containing food products exceeds safety levels

On 7 January 2020, the European Food Safety Authority (hereinafter, EFSA) published a scientific report on the ‘*Acute human exposure assessment to tetrahydrocannabinol (Δ 9-THC)*’. In its report, the EFSA found that the intake of *Delta-9-tetrahydrocannabinol* (hereinafter, *Delta-9-THC*) of adult high consumers (which can be defined as aged above 18 and consuming regularly on several days a week or more) of most of hemp and hemp-containing products (in particular dietary supplements) considered in the assessment exceeds the acute reference dose (hereinafter, ARfD) of 1 microgram per kilogram bodyweight ($\mu\text{g/kg}$ bw). The ARfD of a chemical was defined in 1998 by the United Nations’ Food and Agriculture Organization (FAO) and by the World Health Organization (WHO) as “*an estimate of a substance in food or drinking water, expressed on body weight basis, that can be ingested*

over a short period of time, usually during one meal or one day, without appreciable health risk to the consumer on the basis of all known facts at the time of evaluation". The EFSA's new exposure assessment alerts about the effects on the central nervous and cardiovascular system, as a result of consuming large amounts of hemp products containing the psychoactive compound *Delta-9-THC*, including dietary supplements, teas and hemp oil.

Delta-9-THC is a psychoactive compound naturally occurring in the hemp and marijuana plant (*i.e.*, *Cannabis sativa* L.). Reference is often only made to *Tetrahydrocannabinol* (hereinafter, THC). THC, as well as cannabidiol (hereinafter, CBD), are some of at least 113 cannabinoids identified in the cannabis plant. Cannabinoids are the chemicals that give the cannabis plant its medical and recreational properties. THC is the most abundant cannabinoid in the cannabis plant before CBD. CBD, which in the EU is considered to be a novel food (see *Trade Perspectives*, Issue No. 6 of 22 March 2019) does not appear to have any psychoactive effects, such as those caused by THC, and is considered a safer and less controversial alternative to THC, while still offering significant health benefits, such as a downregulating impact on disordered thinking and anxiety. Potential uses of CBD are still the subject of ongoing research. Hemp, or industrial hemp, is a variety of the *Cannabis sativa* L. plant species, which is cultivated specifically for the industrial uses of its derived products. CBD products from the hemp plant are typically produced from high-CBD, low-THC hemp. This sets it apart from medical marijuana products, which are typically produced from cannabis plants with high concentrations of THC. Because hemp contains only trace amounts of THC, CBD products are non-psychoactive.

In 2015, the *EFSA Panel on Contaminants in the Food Chain* (hereinafter, CONTAM Panel) adopted a *Scientific Opinion on the risks for human health related to the presence of tetrahydrocannabinol (THC) in milk and other food of animal origin*. The EFSA noted that THC, more precisely *Delta-9-THC*, is the most relevant constituent of *Cannabis sativa*. Although the assessment focussed on *Delta-9-THC* and the risks to human health through dietary exposure, other cannabinoids such as *delta-8-tetrahydrocannabinol* (*Delta-8 THC*), cannabinol (CBN), CBD and *delta-9-tetrahydrocannabivarin* (*Delta-9-THCV*) were also considered in the case of potential interactions with *Delta-9-THC*. The EFSA considered the central nervous system effects and an increased heart rate, which were noted at low *Delta-9-THC* dose levels in humans, as relevant for the risk assessment. As these effects occurred within a short time after dose administration, an ARfD of 1 µg *Delta-9-THC*/kg bw was established.

The exposure estimates in the 2015 opinion indicated that the exposure related to the presence of *Delta-9-THC* in milk and dairy products was, at the most, 3% and 13% of the ARfD of 1 µg/kg bw in adults and toddlers, respectively. The CONTAM Panel concluded, therefore, that these estimates of dietary exposure to *Delta-9-THC* were unlikely to pose a health concern, but noted that only limited data on the presence of *Delta-9-THC* in food of animal origin was available and limited data was available from the transfer rate from feed to food of animal origin. In view of the limited data available for the 2015 exposure assessment, the Commission adopted *Commission Recommendation (EU) 2016/2115 of 1 December 2016 on the monitoring of the presence of Δ^9 -tetrahydrocannabinol, its precursors and other cannabinoids in food*, considering it necessary to have more data on the presence of *Delta-9-THC* in food of animal origin, of which evidence is available that it is produced by animals being fed with feed containing hemp or hemp-derived feed materials. Furthermore, the Recommendation urges to collect more occurrence data on the presence of *Delta-9-THC* in hemp-derived foods and foods containing hemp or hemp-derived ingredients. *Recommendation (EU) 2016/2115* notes that it is also appropriate to analyse the non-psychoactive precursors (*i.e.*, substances that generally do not have a psychoactive effect, but are contained in chemicals and mixtures/natural products and can be used for the illegal manufacture of narcotic drugs and psychotropic substances) of the hemp plant *Cannabis sativa*. *Recommendation (EU) 2016/2115* therefore recommends to EU Member States, with the active involvement of food business operators and other interested parties, the monitoring of the presence of *Delta-9-THC*, its precursors and other cannabinoids in food and to provide these data to the EFSA on a regular basis and, at the latest, by October 2018.

In October 2018, the European Commission (hereinafter, Commission) issued an official request asking the EFSA for an acute dietary exposure assessment regarding *Delta-9-THC*, taking into account the new occurrence data available in the EFSA database and the updated comprehensive food consumption database. In addition, the EFSA was requested to provide an overview of the available occurrence data on the precursors of *Delta-9-THC* and other cannabinoids in food, together with information on their co-occurrence with *Delta-9-THC*. The reasoning behind the Commission's request was that, given the levels found in these foods and the regulatory levels applicable to certain hemp-derived foods in certain EU Member States, combined with an increasing consumption of such food, it could be reasonably assumed that the human exposure to *Delta-9-THC* from these foods is higher than the exposure from milk and dairy products and, more general, from food of animal origin.

In Germany, for example, based on the fact that various hemp-containing foods are available on the market, in 2018, the German Federal Institute for Risk Assessment (BfR) assessed the risk of psychogenic and pharmacological effects for all population groups, including children, through the consumption of hemp-containing foods containing THC. The BfR concluded in *Opinion No 034/2018* that the consumption of hemp-containing foods could lead to an exceedance of the ARfD of 1 µg/kg bw established by the EFSA in 2015. In the view of the BfR, *"It is possible, that doses of Δ9-THC which lie within the range of medically used doses of ≥ 2.5 mg per person and day are ingested through the consumption of hemp-containing foods. Pharmacological effects must therefore be expected in cases of this kind"*. The BfR considers that restrictions in the ability to drive or operate a dangerous piece of machinery might result from the consumption of foods containing hemp, which concerns, in particular, high consumers of products of this kind.

The new report by the EFSA, which was adopted on 25 November 2019 and endorsed by the EFSA CONTAM Panel, is based on occurrence data provided to the EFSA on the basis of *Commission Recommendation (EU) 2016/2115*. By the end of December 2018, the EFSA database contained 1,866 analytical results on *Delta-9-THC* and other cannabinoids in food. Samples were collected between 2000 until 2018, with most of the samples collected from 2016 onwards. Data were provided on a variety of hemp and hemp-based products, although the amount of data on food of animal origin remained very limited. Most of the analytical results reported from governmental organisations were from samples collected in Germany, Italy and the Czech Republic, while the industry reported samples from Germany and Romania. The occurrence data used to assess acute exposure to *Total-Delta-9-THC* was finally composed of 588 samples (covering 13 hemp and hemp-derived products). Compared to the EFSA opinion published in 2015, there was an increase of the number of samples, as well as of the number of food categories that could be used for exposure assessment. Overall, the inclusion of occurrence data on the sum of *Delta-9-THC/Delta-9-THCA* reduced the exposure estimates and its uncertainty, since more samples were available for the assessment. However, the EFSA notes that exposure estimates presented in the report are expected to represent an overestimation of the acute exposure to *Delta-9-THC* in 'single food' scenarios on consuming days. The EFSA assessed the acute human exposure to *Delta-9-THC*. Twelve independent scenarios based on single food categories (*i.e.*, hemp seeds, hemp oil, tea, breakfast cereals, raw pasta, bread and rolls, bread and rolls from hemp flour, cereal bars, fine bakery wares, chocolate (cocoa) products, energy drinks, dietary supplements, and beer and beer-like beverages) were considered, and acute exposure was assessed for consumption days only for all age groups excluding infants. Occurrence data for *Total-Delta-9-THC* were used for this assessment up to the highest reliable percentile (*i.e.*, a statistical measurement) for each food category. The ARfD of 1 µg/kg bw was exceeded by adult high consumers of most considered hemp and hemp-containing products (in particular, dietary supplements, tea and hemp oil).

The EFSA states that further research is required in order to obtain sensitive, validated, and *Delta-9-THC*-specific methods, which can be developed into reliable official methods. The EFSA also states that studies should look at the stability of *Delta-9-THC*, as well as at its conversion during food processing, including cooking. The EFSA encourages data providers

and, in general, the scientific community working in the field, to avoid the misclassification and the submission to EFSA of data on '*Total-Delta-9-THC*' as '*Delta-9-THC*'. Investigating the carry-over of *Delta-9-THC* in the food chain, where animals are fed with hemp products, would also be beneficial, the EFSA added. Finally, consumption data on hemp-derived products is needed to refine the exposure scenarios.

Manufacturers of hemp-containing food products should exercise caution when selecting hemp plants for their production. In the EU, varieties of hemp that are cultivated and used for feed must be listed in the EU's *Common Catalogue of Varieties of Agricultural Plant Species*. According to Article 32(6) of *Regulation (EU) No 1307/2013 of the European Parliament and of the Council of 17 December 2013 establishing rules for direct payments to farmers under support schemes within the framework of the common agricultural policy*, the maximum content of THC in these varieties is limited to 0.2%. By granting payments only for areas sown with hemp varieties with a low THC content, the common agricultural policy rules, therefore, prevent any support for the recreational use of cannabis. In the conduct of official controls of hemp cultivars, 2,151 samples were collected in the EU between 2006 and 2008, showing a mean THC content of 0.075% and only 2.6% of the samples exceeding the maximum content.

It should also be recalled that THC is an illegal substance in food. According to Article 2(g) of *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 definition of '*food*' shall not include narcotic or psychotropic substances within the meaning of the *United Nations Single Convention on Narcotic Drugs* and the *United Nations Convention on Psychotropic Substances*. Schedule I of the *United Nations Single Convention on Narcotic Drugs* (listing drugs that are subject to all measures of control under the Convention) currently lists "*delta-9-tetrahydrocannabinol*" (*Delta-9-THC*), which is, therefore, not a '*food*' under the EU definition.

A useful benchmark related to unauthorised or illegal substances in food and dietary supplements can be drawn from the EU's Rapid Alert System for Food and Feed (hereinafter, RASFF). The RASFF was put in place to provide food and feed control authorities with an effective tool to exchange information about measures taken in response to serious risks detected in relation to food or feed. Since January 2019, there have been a total of 51 notifications by EU Member States (*i.e.*, from Austria, Croatia, Cyprus, Czech Republic, Italy, Germany and Spain) and Switzerland to the Commission under the RASFF concerning products, including food supplements, teas, snacks, hemp oils containing the '*unauthorised substance tetrahydrocannabinol (THC)*', often together with the '*unauthorised novel food CBD*'.

The marketing of food products derived from *Cannabis sativa L.* in the EU has been considerably restricted since cannabinoids, including food products containing CBD, were catalogued by the Commission as novel foods. Furthermore, cannabis varieties containing higher levels THC should be strictly avoided in food production. The EFSA's new exposure assessment alerts about effects on the central nervous and cardiovascular system, as a result of consuming large amounts of hemp products containing the psychoactive compound *Delta-9-THC*, including dietary supplements, teas and hemp oil. However, the EFSA notes that little is known about how many people are eating such hemp products, or in which quantities they are consumed. Therefore, further research is needed in order to refine the exposure assessment.

Recently Adopted EU Legislation

Customs Law

- *Commission Implementing Regulation (EU) 2020/94 of 22 January 2020 amending Implementing Regulation (EU) 2015/2078 as regards tariff quotas for*

poultrymeat originating in Ukraine and derogating from that Implementing Regulation for the quota year 2020

Trade Remedies

- *Commission Implementing Regulation (EU) 2020/45 of 20 January 2020 amending Implementing Regulation (EU) 2019/1379 as regards the extension of the anti-dumping duty imposed on imports of bicycles originating in the People's Republic of China to imports of certain bicycle parts originating in the People's Republic of China by Council Regulation (EC) No 71/97*

Food and Agricultural Law

- *Commission Implementing Regulation (EU) 2020/126 of 29 January 2020 fixing the maximum amount of aid for private storage of olive oil within the tendering procedure opened by Implementing Regulation (EU) 2019/1882*
- *Commission Implementing Decision (EU) 2020/122 of 16 January 2020 on the conclusion of an Agreement in the form of an Exchange of Letters between the European Union and the United Mexican States concerning amendments to Annexes I and II of the Agreement between the European Community and the United Mexican States on the mutual recognition and protection of designations for spirit drinks*
- *Agreement in the form of an exchange of letters between the European Union and the United Mexican States concerning the replacement of Annex I and II to the Agreement between the European Community and the United Mexican States on the mutual recognition and protection of designations for spirit drinks*

Other

- *Commission Implementing Regulation (EU) 2020/105 of 23 January 2020 making imports of certain hot rolled stainless steel sheets and coils originating in the People's Republic of China and Indonesia subject to registration*
- *Commission Implementing Regulation (EU) 2020/104 of 23 January 2020 making imports of certain hot rolled stainless steel sheets and coils originating in the People's Republic of China, Taiwan and Indonesia subject to registration*
- *Commission Implementing Regulation (EU) 2020/44 of 20 January 2020 making imports of certain woven and/or stitched glass fibre fabrics originating in the People's Republic of China and Egypt subject to registration*

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