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### **European Commission launches the *Sustainable Cocoa Initiative* for more sustainable cocoa production**

On 22 September 2020, the European Commission (hereinafter, Commission) launched the *Sustainable Cocoa Initiative* for more sustainable cocoa production. The initiative intends to bring together the two main EU cocoa suppliers, namely Ghana and Côte d'Ivoire, representatives of the European Parliament, EU Member States, cocoa growers, and civil society with them aim of delivering “concrete recommendations to advance sustainability across the cocoa supply chain” and to enhance the EU private sector's role in the sustainability of cocoa supply chains. The initiative is aligned with the EU's broader political objectives laid out in the *European Green Deal* and the Commission's so-called “zero tolerance” approach towards child labour. The initiative is a step forward in a broader set of sustainability-related initiatives recently pursued by the Commission.

#### ***Cocoa and trade in sustainable cocoa***

According to a report by the *International Cocoa Organization* (ICCO), most cocoa beans worldwide are produced in Africa. Cocoa cultivation supports up to six million farmers' livelihoods in Ghana and Côte d'Ivoire alone. According to EU data, Ghana, and Côte d'Ivoire account for 70% of the global cocoa production. Both countries are major suppliers of cocoa to the EU, which is the world's largest importer of cocoa, with EU imports of cocoa accounting for 60% of world imports. In 2019, Ghana accounted for 43% of the EU's imports of cocoa and cocoa preparations, with a value of USD 3.48 billion, while Côte d'Ivoire accounted for 16.6% of the EU's imports of cocoa and cocoa preparations, with a value of USD 1.32 billion.

However, cocoa production in many producing countries is often linked to allegations of exploitative child labour, deforestation, and forest degradation, as well as low revenues for farmers. Therefore, a number of international initiatives have been launched over the years, such as the *Cocoa and Forest Initiative*, which was launched in 2017 under the public-private *Sustainability Trade Initiative* (IDH) and the *World Cocoa Foundation* and which, *inter alia*, aims at protecting national parks and forested land, as well as restoring forests that have been degraded by cocoa production. This initiative is currently being implemented by both Ghana and Côte d'Ivoire through their respective Frameworks for Action and it is being translated into national implementation plans.

At the international level, the *Roundtable for a Sustainable Cocoa Economy* (RSCE), a voluntary initiative for dialogue and sustainability amongst all stakeholders in the cocoa economy (*i.e.*, cocoa farmers and cooperatives, traders, exporters, processors, chocolate manufacturers, wholesalers, governmental and non-governmental organizations, financial

institutions, as well as donor agencies), was launched in 2007 and intends to “*build a consensus on defining a concept or model of criteria, indicators and ways to achieve a sustainable world cocoa economy through a participatory and comprehensive approach*”. However, it appears that no further meetings were held since the second meeting in 2009.

### ***Building on existing initiatives by EU Member States***

The initiative on more sustainable cocoa follows from the EU’s broader commitment to sustainability and from existing similar initiatives and policy measures. The EU has committed to implement the United Nations (UN) *Sustainable Development Goals* (hereinafter, *SDGs*), both in its internal and external policies, and has adopted the UN’s *2030 Agenda for Sustainable Development*. With respect to the implementation of the *SDGs*, the Commission claims that the EU has “*embarked a transition towards a low-carbon, climate neutral, resource efficient and circular economy that goes hand in hand with increased security, prosperity, equality and inclusion*”.

Certain EU Member States have already launched their own initiatives for sustainable cocoa. The Netherlands launched the public-private *Dutch Initiative on Sustainable Cocoa* (*DISCO*), which aims at ensuring proper livelihoods for farmers, fighting deforestation linked to the cocoa supply chain, and contributing to ending all forms of child labour by 2025. In December 2018, a wide group of stakeholders active in the Belgian chocolate and cocoa sector launched the ‘*Beyond Chocolate*’ initiative and committed to end deforestation related to cocoa cultivation and to pursue reasonable incomes for cocoa farmers.

Already in 2012, the multi-stakeholder *German Initiative on Sustainable Cocoa* (hereinafter, *GISCO*), a joint initiative of the Federal German Government, represented by the German Federal Ministry of Food and Agriculture and the Federal Ministry for Economic Cooperation and Development, the German sweets and confectionary industry, the German retail grocery trade, and civil society, was launched. This initiative aims at improving the livelihood of cocoa farmers and their families, and to increase the proportion of sustainably produced cocoa. Members of the *GISCO* intend to closely coordinate with the Governments of cocoa-producing countries. In 2019, Germany adopted a *10-Point Plan for Economic Cooperation and Development on Cocoa* with the objective of achieving a more sustainable cocoa sector, including a call for binding regulations for sustainably-produced cocoa (see *Trade Perspectives, Issue No. 4 of 22 February 2019*).

### ***The European Commission’s initiative for more sustainable cocoa production***

The Commission’s initiative for more sustainable cocoa production provides for the establishment of a multi-stakeholder dialogue that aims at delivering “*concrete recommendations to advance sustainability across the cocoa supply chain through collective action and partnerships*” and whose launch event was held on 22 September 2020. In the context of the launch event, the Commission’s Executive Vice-President and designated European Commissioner for Trade *Valdis Dombrovskis* stated that the EU is planning to “*develop concrete recommendations on sustainable cocoa as trade is not only about growth and profits, but also the social and environmental impact of our policies*”.

The Commission’s initiative builds on the 2019 joint initiative by Ghana and Côte d’Ivoire, which established a minimum price for cocoa on the world market and put in place a *Living Income Differential* with representatives of the cocoa and chocolate industry, to ensure decent revenues for local farmers, as well as the already existing initiatives of EU Member States, third countries, and international organisations. The initiative foresees further dialogues within thematic groups that are supposed to take place between October 2020 and July 2021.

The objective of the multi-stakeholder dialogues is to work towards a sustainable cocoa supply chain. To achieve this objective, the initiative reportedly intends to establish enhanced cooperation with Ghana and Côte d’Ivoire as the two main cocoa producing countries. The dialogues are also supposed to have an impact on EU policy, feeding into relevant Commission

initiatives, such as due diligence for sustainable supply chains and deforestation. Stakeholders' input is also supposed to feed into other relevant Commission initiatives, such as “*the implementation of trade and sustainable development aspects under the Economic Partnership Agreements*” concluded with the Africa, Caribbean, and Pacific (ACP) countries, as well as “*a planned legislative proposal to minimise the risk of deforestation associated to products placed on the EU market*”. Furthermore, stakeholders' input is supposed to feed into initiatives under the EU's Circular Economy Action Plan, such as the development of legislation on “*green claims*” and the transparency initiative under the Commission's ‘*Farm to Fork*’ Strategy.

### ***Feeding into broader initiatives***

The EU is already working on broader initiatives to address issues related to human rights, deforestation, and climate change. One of the key initiatives is the upcoming EU legislation on mandatory due diligence for companies with respect to human rights and the environmental impact. The objective of this policy initiative is to regulate the human rights and environmental impact linked to corporate operations, both within and outside of the territory where the business operations take place. Another related initiative is the Commission's ‘*Farm to Fork*’ (F2F) strategy “*for a fair, healthy and environmentally-friendly food system*”, which combines both regulatory and non-regulatory initiatives to attain its objectives of making the entire food chain from production to consumption more sustainable and neutral in its impact on the environment.

### ***Cooperation instead of unilateral rules is the key***

The Commission's *Sustainable Cocoa Initiative* underscores the need for enhanced consultations and cooperation. While the Commission's multi-stakeholder dialogues will not have any direct impact on businesses, potential changes in policies in producing countries, as well as the various policy initiatives within the EU will likely have significant impacts on businesses involved in cocoa production, related supply chains and trade around the world. Given the increased focus on sustainability, it can be expected that this will not remain the Commission's last commodity to be subject to increased scrutiny and engagement, but that others will follow.

The focus on cooperation is key and should always be given preference over unilateral rules imposed by the EU, which inevitably lead to certain EU trading partners suffering setbacks when accessing the EU market, without necessarily leading to improvements on the ground, especially if alternative export destinations exist. A bilateral, plurilateral or multilateral approach would also avoid a flurry of likely WTO litigation, when unilateral measures by the EU may be seen as pursuing also or only a trade protectionist agenda, as it is unfortunately happening vis-à-vis other commodities. Avoiding unilateral actions does not only mean engaging with consultations and providing affected countries and industries with a voice during the legislative process, but also ensuring that the sustainability standards, related technical regulations, conformity assessment procedures, certification schemes, traceability mechanisms and, if need be, incentives or disincentives, are negotiated between the EU and producing countries.

Further dialogues between representatives from the EU Institutions, industry representatives and traders, interested EU Member States, civil society, international organisations, and institutional representatives from Ghana and Côte d'Ivoire are scheduled to take place between October 2020 and July 2021. A plenary session of the multi-stakeholder dialogues is then scheduled for the autumn of 2021 and a report with the recommendations and suggestions on the way forward is supposed to be published thereafter. Commodity traders and affected industries around the world should diligently follow the developments, get involved and participate in the various *fora*, before new rules are set or agreed between producing and importing countries.

## ASEAN Member States officially implement the ASEAN-Wide Self-Certification Scheme

On 20 September 2020, the ASEAN Member States (*i.e.*, Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, the Philippines, Singapore, Thailand, and Viet Nam, hereinafter AMSs) formally began implementing the *ASEAN-Wide Self-Certification* scheme (hereinafter, AWSC), a unified self-certification scheme for a good's origin under the *ASEAN Trade in Goods Agreement* (hereinafter, ATIGA), which follows the EU's self-certification model of '*Certified Exporters*'. The AWSC, which was introduced within ASEAN with the signing of the *First Protocol to Amend the ATIGA* on 22 January 2019, is in line with the objective of the *ASEAN Economic Community (AEC) Blueprint 2025* to simplify the ASEAN rules of origin requirements.

The AWSC intends to make compliance with rules of origin more business-friendly, so as to enable the participation of small businesses in intra-ASEAN trade. In essence, the AWSC scheme is an alternative that businesses can utilise when declaring the originating status of their goods, without the requirement to obtain a *Certification of Origin (Form D)* for every shipment.

### ***The AWSC facilitates intra-ASEAN trade by simplifying the certification of origin***

The AWSC is a trade facilitation initiative that allows certified exporters (hereinafter, CEs) in all AMSs to self-declare the origin status of their goods in order to benefit from the tariff preferences provided under the ATIGA. In particular, the system aims at reducing the compliance costs (by exporters) and administrative costs (by issuing authorities) associated with the application for a *Certificate of Origin (Form D)*, which will remain available to businesses. Additionally, the AWSC intends to facilitate intra-ASEAN trade by reducing the delays that often result from the rejection of origin certificates by the competent authorities of importing AMSs.

The AWSC is the negotiated outcome of two pilot projects. The First Pilot Project was implemented in 2010 by Brunei Darussalam, Malaysia, and Singapore, with, Thailand, Cambodia and Myanmar subsequently joining. In 2014, Indonesia, Lao PDR, and the Philippines launched the Second Pilot Project, which Thailand and Viet Nam subsequently joined. The pilot projects served as a testing ground for relevant authorities in AMSs, who did not yet have the legal basis and prior experience to adopt a self-certification scheme, to gradually introduce the system in their respective countries (both legally and institutionally), determine a suitable design for all AMSs considering the different levels of their preparedness, as well as to build confidence and competence of both Government authorities and businesses in implementing a self-certification scheme. In the case of the Philippines, for instance, the Second Pilot Project provided the legal basis that paved the way for the adoption and implementation of the self-certification scheme by the Philippines' Customs authorities.

The AWSC finally merged the two pilot projects to provide a harmonised system and a holistic application within the ASEAN region. In particular, the AWSC addressed key differences in the two pilot projects, namely the definition of a '*Certified Exporter*' and the commercial documents allowed for origin declaration. Under the AWSC, all ASEAN exporters (*i.e.*, manufacturers and traders) are eligible to apply as CEs under the AWSC, as long as they can prove that their products adhere to the ATIGA origin criteria. Moreover, the AWSC allows CEs to make an origin declaration not only on the commercial invoice, but also on other commercial documents, such as the bill of lading or the delivery order or packing list.

### ***How can ASEAN exporters participate in the AWSC scheme?***

Under the unified self-certification scheme, CEs that have demonstrated their competence to comply with the origin criteria under the ATIGA, are now allowed to issue an origin declaration on certain commercial documents (*e.g.*, commercial invoices, billing statements, delivery

orders, or packing lists) vis-à-vis all AMSs, instead of requesting a *Certificate of Origin (Form D)* from the Issuing Authority of the exporting AMS. The minimum eligibility criteria to become a CE are provided in Rule 12A of the Operational Certification Procedures of the ATIGA and additional requirements may be applied by individual AMSs. In particular, in order to be granted CE status, the exporter must meet these criteria: 1) Be registered in the exporting AMS; 2) Apply correctly the ATIGA rules of origin; 3) Be an experienced exporter; 4) Have no record of rules of origin fraud; 5) Have shown good compliance as measured by risk management rules; 6) Have a “*manufacturer’s declaration*” and be ready for a retroactive audit; and 7) Have a sound bookkeeping system.

CEs should benefit from greater convenience due to the elimination of the requirement to submit a *Certificate of Origin (Form D)* for every shipment, incur cost savings in relation to administrative charges for *Certificate of Origin (Form D)* applications, and enjoy smoother clearance of goods at the port of importation.

### ***Ratification of the AWSC scheme in Indonesia***

On 27 July 2020, the Government of Indonesia ratified the First Protocol to Amend the ATIGA through the entry into force of *Presidential Regulation No. 84 Year 2020*. To further implement the regulation, Indonesia’s Ministry of Finance issued *Regulation No. 131/PMK.04/2020 concerning Procedures for Imposing Import Duty Tariffs on Imported Goods Based on the ATIGA*. The Government also issued *Minister of Trade Regulation No. 71 Year 2020 concerning Rules of Origin of Indonesia and Provisions for the Issuance of Document of Origin for Indonesian Goods under the ATIGA* to implement the AWSC scheme. Under the Regulation, Indonesian exporters now have the option to choose between the following instruments: 1) An origin declaration/self-certification via the [e-ska.kemendag.go.id](http://e-ska.kemendag.go.id) website; or 2) The issuance of a certificate of origin, either in paper (Form D) or electronically (e-Form D) by the Certificate of Origin Issuing Agency.

The information contained in the origin declaration will be entered into the *Indonesia National Single Window* (hereinafter, INSW) system and shall be automatically linked to the *ASEAN Single Window* (hereinafter, ASW). The Director General of Foreign Trade of Indonesia’s Ministry of Trade *Didi Sumedi* affirmed that self-certification is expected to have positive effects and lead to increasing exports from Indonesia to other AMSs.

### ***Legal basis and guidelines for the implementation of the ASWC in the Philippines***

The *Philippine Bureau of Customs* (BoC) issued the *Customs Memorandum Order (CMO) No. 24-2020* (hereinafter, CMO 24-2020) to implement the ASWC from 20 September 2020. The new CMO repeals *CMO 18-2015*, which had been issued to implement the Second Pilot Project and sets out the guidelines and operational procedures for the BoC to enforce the AWSC for originating goods of CEs traded within the ASEAN region.

Under the *CMO 24-2020*, interested Filipino exporters can now submit their applications to obtain CE status from the BoC in both hard copy and electronic format. *CMO 24-2020* also lays out the required information and guidance on how to issue the origin declarations in the commercial invoice or other commercial documents. All qualified Filipino exporters that have been granted the CE status are to be immediately included in the *AWSC Database* for at least three years from the date of granting the status. This is to ensure that Filipino CEs will enjoy the benefits, such as convenience and cost savings, offered under the AWSC scheme.

### ***Criteria and procedures on the implementation of the AWSC in Singapore***

Singapore is one of the AMSs that already implements self-certification schemes outside ASEAN and more strongly advocated for the adoption of the AWSC. However, many Singapore-based companies are still not confident with respect to self-certification. To prepare businesses for the implementation of the AWSC in Singapore, *Singapore Customs* provides, on its website, the specific criteria and procedures for obtaining a CE status under the AWSC.

This also includes the application form to become a CE under the AWSC, the indicative format of origin declaration for goods originating in Singapore, and the indicative format of back-to-back origin declaration.

### ***The AWSC as one of many ASEAN trade facilitation initiatives***

The AWSC is the latest of a number of trade facilitation instruments that ASEAN has launched in recent years in order to fulfil the promises of the ATIGA and of the ASEAN Economic Community, which came to fruition in 2015. Intra-ASEAN trade, despite the preferential tariff conditions offered under the ATIGA, remains low at roughly 25% of total trade by AMSs. This share is very low if compared to intra-EU trade, which is over 60% of total EU Member States' trade. What is also worrying is that, while intra-EU trade has continued to grow during the last 10 years, intra-ASEAN trade has actually decreased during the same period. Particularly at a time of global turbulence and economic downturn triggered by the *Covid-19* pandemic, ASEAN needs the contribution of greater intra-ASEAN trade, stronger regional economic integration and increased trade facilitation for its businesses.

To this end, three other ASEAN trade facilitation initiatives are worth mentioning and stand a chance to significantly support the process of regional economic integration: 1) the ASEAN Customs Transit System (ACTS); 2) the ASEAN Trade Repository (ATR); and the system of ASEAN Solutions for Investments, Services and Trade (ASSIST).

The ACTS (<https://acts.asean.org>) is a computerised Customs transit management system available to operators that move goods across borders without paying the required duties and taxes otherwise due when the goods enter (or leave) the country, thus requiring only one (final) Customs formality. It offers an administratively simple and cost advantageous procedure to carry goods across Customs territories outside the normal import and export Customs regimes. Within ASEAN, the ACTS would be a game-changer and progressively help to create the single market and production base characterized by free flow of goods that is the ultimate objective of the AEC.

The ATR (<https://atr.asean.org>) is meant to enhance the all-important legislative and regulatory transparency and the degree of legal predictability that businesses and traders so desperately need in order to trade within and across ASEAN. In particular, when fully operationalized, the ATR intends to become the single point of access to all the trade-related information of all ASEAN Member States. In essence, it is an ASEAN-level IT interface that links a series of interoperable National Trade Repositories (NTRs), which provide and maintain national-level trade related information that is collected, classified, summarized and provided to users on the basis of a standardized approach and a single search engine.

Finally, ASSIST (<https://assist.asean.org>) is a non-binding and consultative mechanism for the expedited and effective solution of operational problems encountered by ASEAN enterprises, especially small and medium-sized ones, on cross-border intra-ASEAN trade issues related to the implementation of ASEAN economic agreements and within the framework of the ASEAN Economic Community (AEC). ASSIST is very simple to use, based on streamlined and rapid procedures, fully internet-based and free of charge.

It is worth noting that the ACTS, the ATR and ASSIST are just three of the flagship trade facilitation instruments that ASEAN has developed in recent years with assistance from the European Union's ARISE and ARISE Plus Programmes of regional integration support (<https://ariseplus.asean.org>). The ACTS is about to be piloted across several AMSs, the ATR is progressively being operationalized and to date contains over 3,500 properly classified and summarized non-tariff measures (NTMs) of the 10 AMSs (with the category of sanitary and phytosanitary NTMs being complete), and ASSIST is already providing a non-judicial and efficient venue for ASEAN enterprises to address their practical problems at the border.

## ***The way forward***

The implementation of the AWSC is supposed to deliver greater trade facilitation for businesses by simplifying administrative compliance, decrease transaction costs related to certification of origin procedures, as well as allow ASEAN-originating goods to move more easily within the region. Companies, traders, businesses, and other relevant stakeholders are encouraged to review the newly applicable rules, so as to take greater advantage of the preferential treatment provided under the ATIGA. CEs and ASEAN exporters that are not (yet) comfortable and confident to use the AWSC, can still use both the paper-based *Certificate of Origin (Form D)* or the *e-Form D* to claim ATIGA tariff preferences, which remain available. ASEAN traders should also become acquainted with the ACTS, the ATR and ASSIST. These trade facilitation tools are available: now is the time to use them and grow intra-ASEAN trade to the benefit of the region's socio-economic development.

## **First steps outside of the EU: The UK's Food Standards Agency issues a Guidance on cannabidiol (CBD) as a novel food**

On 24 September 2020, the UK's *Food Standards Agency* (hereinafter, FSA) issued a new *Business guidance on cannabidiol (CBD) as a novel food* (hereinafter, Guidance), which confirms the status of cannabidiol (hereinafter, CBD) products as novel foods. In recent times, the EU market for CBD products has been characterised by legal uncertainty and frequent changes in the regulatory environment. Although the UK rules on the marketing of CBD products might, in the future, be different from the rules applied in the EU, the recently issued guidance clarifies a number of aspects related to the EU-UK transition period, which will lapse on 31 December 2021.

### ***Hemp and CBD***

CBD is one of the 113 cannabinoids, which give the cannabis plant its characteristic medical and recreational effects. CBD accounts for up to 40% of the plant's extract and does not appear to have any psychoactive effects, such as those caused by *tetrahydrocannabinol* (hereinafter, THC), another cannabinoid identified in the cannabis plant. Industrial hemp is a variety of the *Cannabis sativa L.* plant species, which is cultivated specifically for industrial uses, and its derived products typically contain high CBD and low THC levels. CBD, which is abundant in industrial hemp products, is considered a less controversial alternative to THC because, while it does not have any psychoactive effects, it is considered to provide significant health benefits, such as analgesic and anti-inflammatory effects.

### ***The EU regulatory environment***

Since January 2019, the European Commission (hereinafter, Commission) considers all extracts of hemp and derived products containing cannabinoids as novel foods, thus falling under *Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods* (hereinafter, Novel Foods Regulation). The Novel Food Regulation requires, *inter alia*, that for a new novel food to be placed on the EU market, its safety for human health must be demonstrated on the basis of the available scientific evidence. For this reason, the quality and reliability of the scientific data aimed at substantiating the product's safety are considered a crucial part of the authorisation dossier.

With the aim of further facilitating the process for food business operators, in September 2016, the *European Food Safety Authority* (hereinafter, EFSA) adopted a *Guidance on the preparation and presentation of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283*. The guidance provides detailed information on the scientific evidence that food business operators should provide to the EFSA in order to demonstrate that the novel food is not harmful for human health.

As reported on 27 July 2020 by the *European Industrial Hemp Association*, the Commission is currently evaluating the possibility of considering “*extracts from industrial hemp varieties of Cannabis sativa L., and thus not-synthetic CBD, as a ‘drug’.*” This preliminary conclusion, if confirmed, would oblige the Commission to reject novel food applications submitted under Article 10 of the Novel Food Regulation for products made from hemp flowers, for the fact that they do not fall into the definition of food established by Article 2 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* (see *Trade Perspectives, Issue No. 15 of 31 July 2020*). Article 2 of Regulation (EC) No 178/2002 defines “*food*” as “*any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans*”. Food includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. Under the third sentence of Article 2, point (g) of Regulation (EC) No 178/2002 food does, however, not include any “*narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic Drugs, 1961, and the United Nations Convention on Psychotropic Substances, 1971*”.

### ***The UK approach to CBD products***

On 31 January 2020, the UK officially left the EU and became a third country. A transitional period has been agreed until 31 December 2020, during which the *EU Novel Food Regulation* continues to apply to the UK. From 1 January 2021, the UK will manage its own novel food authorisation process (unless the transition period were to be extended, which currently looks improbable) and the UK’s FSA will start accepting applications under its novel food approval regime.

As regards CBD products, the UK authorities officially declared that they would not follow EU determinations and would keep considering extracts from hemp flowers as food. Applications for the authorisation of CBD products already placed on the UK market must be submitted to the FSA for approval and must be fully validated by 31 March 2021. After this date, “*only products for which the FSA has received a valid application will be allowed to remain on the market*” and no new CBD extracts may be sold until the necessary authorisation has been granted. The FSA has further established that “*businesses can continue to sell their existing CBD products during this time, provided they are not incorrectly labelled, are not unsafe and do not contain substances that fall under drugs legislation*”.

Importantly, also for EU-based food business operators, the requirements on the content of new novel food applications submitted to the UK’s FSA will remain the same and the FSA underlines that it would continue to rely on the EFSA’s guidance on the preparation and presentation of an application for authorisation of a novel food.

Once a CBD product is authorised, that authorisation, although not proprietary as it may happen in the case of feed additives, applies only to that specific product. This means that, for the product to be placed on the market under the granted authorisation, it must meet the following criteria: 1) Be produced on the basis of the declared manufacturing process; 2) Respect the conditions of use detailed in the authorisation; and 3) Use the same safety evidence base.

### ***Challenges to keep CBD products on the UK market***

The FSA’s *Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment* (hereinafter, CoT), on the basis of a [scoping paper on the potential adverse effects of CBD products](#) presented on July 2019, concluded that, as regards safety for human health, there was a “*lack of toxicological information especially in the areas of reproduction and immunology*” and that the “*information is of limited quality and it is unclear to what extent it is applicable to the CBD products currently on the market given their heterogeneity*”. It appears that, for this reason, the FSA, in its Guidance of 24 September 2020, established that

*“applicants will need to include details of the toxicological studies they have undertaken or propose to undertake with clear details of the reasoning for these particular tests”*. This means that already existing data in the scientific literature will most likely not be sufficient and the gaps identified by the CoT will need to be filled-in with new scientific data to be generated by novel food applicants. The FSA underlines that, without such information, it was unlikely to validate any novel food application. The FSA further notes that, *“with so little publicly available information on the safety of CBD, we anticipate that directly relevant studies will be needed”* and that only *“by including this directly relevant safety information will applications be able to progress and potentially be authorised”*.

The EFSA’s guidance requires that scientific studies be conducted in accordance with international guidelines. With respect to toxicological information, the *OECD 408 Repeated Dose 90-Day Oral Toxicity Study in Rodents* (hereinafter, OECD 408 standard) is an international standard providing information on the design and duration of toxicological studies aimed at *“defining health hazards likely to arise from exposure to test substance via oral administration”*. The OECD 408 standard provides for a detailed study procedure, which requires the collection of extensive appropriate background information to ensure that the toxicological study is valid and fit for the specific purpose.

The provision of such detailed studies appears to be challenging for food business operators, which already have CBD products on the UK market, and which are required to submit applications for validation before the deadline of 31 March 2021. In this context, the UK *Association for the Cannabinoid Industry* (ACI) estimates that the financial investment required to produce this type of data would amount to hundreds of thousands of pounds. With such significant investments at stake, individual businesses planning to remain in or enter the CBD market in the UK will likely be very cautious and may be hesitant to take further steps. To mitigate this requirement, the ACI recently announced *“the launch of a landmark study with a consortium of CBD companies who are together committed to building a sustainable, safe and fully compliant industry in the UK”*.

### ***An uncertain future?***

It is the responsibility of food business operators to demonstrate the safety of the novel foods that they wish to place on the market, in the EU, as well as in the UK. The FSA requirements for granting authorisation to (continue to) place CBD products on the UK market appear to be very challenging and the deadline of 31 March 2021 for the validation of applications is relatively close. For this reason, manufacturers and suppliers, wishing to continue to market their CBD products in the UK, are advised to seek guidance in order to prepare applications that fit the quality requirements indicated by the UK authorities and to avoid unnecessary costs.

## **Recently Adopted EU Legislation**

### **Food and Agricultural Law**

- *Commission Implementing Regulation (EU) 2020/1371 of 1 October 2020 concerning the authorisation of a preparation of endo-1,4-beta-xylanase and endo-1,4-beta-glucanase as a feed additive for lactating sows (holder of the authorisation BASF SE) ( 1 )*
- *Commission Implementing Regulation (EU) 2020/1373 of 1 October 2020 concerning the authorisation of zinc chelate of lysine and glutamic acid as a feed additive for all animal species ( 1 )*
- *Commission Implementing Decision (EU) 2020/1360 of 28 September 2020 authorising the placing on the market of products containing, consisting of or produced from genetically modified soybean MON 87708 × MON 89788 × A5547-*

127, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (notified under document C(2020) 6435) ( 1 )

## Environment

- *Decision No 2/2019 of the Joint Committee established by the Agreement between the European Union and the Swiss Confederation on the linking of their greenhouse gas emissions trading systems of 5 December 2019 amending Annexes I and II to the Agreement between the European Union and the Swiss Confederation on the linking of their greenhouse gas emissions trading systems [2020/1359]*

## Trade-Related Intellectual Property Rights

- *Commission Implementing Regulation (EU) 2020/1340 of 22 September 2020 entering a name in the register of protected designations of origin and protected geographical indications [‘Brački varenik’ (PGI)]*

## Other

- *Commission notice concerning the application of the Regional Convention on pan-Euro-Mediterranean preferential rules of origin or the protocols on rules of origin providing for diagonal cumulation between the Contracting Parties to this Convention*

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