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The EU sets its new legislative framework for all things digital: The *Digital Services Act* and the *Digital Markets Act* have been finalised

On 27 October 2022, the EU published in its Official Journal *Regulation (EU) 2022/2065 of the European Parliament and of the Council of 19 October 2022 on a Single Market For Digital Services and amending Directive 2000/31/EC* (hereinafter, *Digital Services Act*). A few weeks earlier, on 12 October 2022, the EU had published in its Official Journal *Regulation (EU) 2022/1925 of the European Parliament and of the Council of 14 September 2022 on contestable and fair markets in the digital sector and amending Directives (EU) 2019/1937 and (EU) 2020/1828* (hereinafter, *Digital Markets Act*). According to the European Commission (hereinafter, Commission), the two Regulations aim at creating "*a safer digital space where the fundamental rights of users are protected and to establish a level playing field for businesses*". The *Digital Services Act* and the *Digital Markets Act* pave the way for new harmonised digital rules in the EU that will inevitably have an impact on businesses operating in the EU and on (digital) trade with third countries.

Establishing a harmonised legislative framework for the digital space

In December 2020, the Commission had tabled two legislative proposals with the objective to upgrade existing rules governing digital services in the EU, namely the *Digital Services Act* and the *Digital Markets Act*. On 25 March 2022, the European Parliament, the Council of the EU (hereinafter, Council), and the Commission reached political agreement on the *Digital Markets Act*, and on 23 April 2022, agreed on the *Digital Services Act*. These two regulations establish a new set of rules that will be applicable across the EU. The two main objectives are: 1) "*To create a safer digital space in which the fundamental rights of all users of digital services are protected*"; and 2) "*To establish a level playing field to foster innovation, growth, and competitiveness, both in the European Single Market and globally*".

The Digital Markets Act

The *Digital Markets Act* entered into force on 1 November 2022 and introduces new rules for platforms that act as so-called '*gatekeepers*' in the digital sector, complementing the enforcement of competition law at the EU and at national EU Member States' level. The *Digital Markets Act* defines '*Gatekeeper*' as "*an undertaking providing core platform services, designated pursuant to Article 3*". Article 3 of the *Digital Markets Act* establishes the criteria

that must be taken into account to designate a company as '*gatekeeper*', namely that a company: *"(a) has a significant impact on the internal market; (b) provides a core platform service which is an important gateway for business users to reach end users; and (c) enjoys an entrenched and durable position, in its operations, or it is foreseeable that it will enjoy such a position in the near future*". Core platform services are listed in the *Digital Services Act* and include, *inter alia*, online intermediation services, online search engines, online social networking services, and video-sharing platform services. In simple terms, the *Digital Markets Act* applies to all core services of digital service provides such as *Amazon*, *Apple*, *Alphabet*, *Microsoft*, and *Meta*, *inter alia*.

The *Digital Markets Act* aims at preventing '*gatekeepers*' from imposing unfair conditions on businesses and end users and at ensuring the openness of important digital services, referring to "*a large category of online services, from simple websites to internet infrastructure services and online platforms*". Under the *Digital Markets Act*, '*gatekeepers*' will have to, *inter alia*: 1) Ensure that unsubscribing from core platform services is as easy as subscribing; 2) Ensure that the basic functionalities of instant messaging services are interoperable, namely by enabling users to exchange messages, send voice messages or files across messaging applications; 3) Provide business users access to their marketing or advertising performance data on the platform; and 4) Inform the Commission of their acquisitions and mergers. Additionally, '*gatekeepers*' will be prohibited to, *inter alia,* rank their own products or services higher than those of others (*i.e.*, self-preferencing), pre-install certain apps or software, or prevent users from easily un-installing these apps or software or require the most important software such as web browsers to be installed by default when installing an operating system. The *Digital Markets Act* foresees the application of sanctions in the event that companies designated as '*gatekeepers*' do not comply with the obligations established in the *Digital Markets Act*.

The *Digital Markets Act* brings significant changes and introduces a series of new rules that '*gatekeepers*' will need to comply with in order to continue providing their services in the EU. The *Digital Markets Act* would significantly change how some systems, such as *Apple*'s iOS operating system, work. For instance, *Apple* would need to allow users to install third-parties apps and app stores, which would allow third parties to interoperate with its services. Additionally, the *Digital Markets Act* states that the burden of proof will lay on the '*gatekeeper*', who will be responsible to demonstrate that they are providing a fair and open platform.

The *Digital Markets Act* will become applicable on 2 May 2023, providing affected businesses some time to prepare for the new rules.

The Digital Services Act

The *Digital Services Act* entered into force on 27 October 2022 and concerns covers intermediary services, such as social media, online marketplaces, and online platforms "*offered to recipients of the service that have their place of establishment or are located in the Union, irrespective of where the providers of those intermediary services have their place of establishment*". Providers of such services will be subject to certain responsibilities and accountabilities and will need to comply with certain transparency obligations. The *Digital Services Act* provides for EU-wide due diligence obligations that will apply to all digital services that connect consumers to goods, services, or content, including new procedures for faster removal of illegal content, as well as comprehensive protection for users' fundamental rights online.

The *Digital Services Act*, establishes a new set of rules for digital services providers that include, *inter alia*: 1) Special obligations for online marketplaces to combat the online sale of illegal products and services; 2) Measures to "*counter illegal content online and obligations for platforms to react quickly, while respecting fundamental rights*"; 3) Measures to protect minors online by prohibiting platforms from using *"targeted advertising based on the use of minors' personal data as defined in EU law"*; 4) Specific rules to limit the presentation of advertising and the use of sensitive personal data for targeted advertising, including "*gender, race, and*

religion"; and 5) The prohibition of misleading interfaces known as '*dark patterns*', as well as practices aimed at misleading.

Additionally, the *Digital Services Act* introduces stricter rules for very large platforms and search engines (*i.e.*, which have, on average, monthly active recipients of the service equal to or above 45 million users in the EU), which will be required to, *inter alia,* assess the systemic risks that they create (*i.e.*, risks related to the dissemination of illegal content, negative effects on fundamental rights, on electoral processes and on gender-based violence or mental health). It is important to note that such obligations would only apply to very large online platforms, as small and medium enterprises would be exempt from these provisions. Enforcement will be key to address illegal activities, such as the sale of products or services prohibited by the EU or EU Member States. In this regard, the *Digital Services Act* states that EU Member States must appoint an authority that will act as the *Digital Services Coordinator* that will oversee the enforcement of the Regulation. The *Digital Services Coordinator* itself will designate '*trusted flaggers*', referring to entities that are to identify illegal content and inform online platforms through "*notice and action*" mechanisms. Such mechanisms must be established by providers of hosting services to allow entities or individuals to notify information that they consider to be illegal. '*Trusted flaggers*' must have "*particular expertise and competence for the purposes of detecting, identifying and notifying illegal content*", be "*independent from any provider of online platforms*"*;* and carry out their "*activities for the purposes of submitting notices diligently, accurately and objectively*".

The *Digital Services Act* will only apply from 17 February 2024, providing affected businesses time to prepare for the application of the new rules.

Regulating digital services and digital trade

Developments in digital technology have revolutionised economies around the world by providing innovative ways to produce, market, distribute, communicate, and consume goods and services. In the past few years, the growing importance of digital trade has found its way into regional and international trade initiatives, notably with several countries attempting to include dedicated chapters on digital trade or on e-commerce (or both) in their preferential trade agreements.

For instance, a more digital-friendly legal framework has been developed within the Association of Southeast Asian Nations (hereinafter, ASEAN), which groups Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, the Philippines, Singapore, Thailand, and Viet Nam (see *Trade Perspectives*, Issue No. 7 of 9 April 2021).

At the same time, the EU has been refining the chapter on '*Digital Trade*' in its EU Preferential Trade Agreements (hereinafter, PTAs). As opposed to merely focusing on certain aspects of e-commerce, as was the case in earlier agreements, the EU's approach to digital trade has been broadened and now includes, *inter alia,* the prohibition of Customs duties on electronic transmissions, cross-border data flows, the regulation of data localisation, privacy issues, and data protection, as well as the protection of software codes. Additionally, the EU has been negotiating with certain trading partners, notably Japan and Singapore, to establish *Digital Partnerships*, which cover additional areas, such as the facilitation of digital trade, secured international connectivity, green data infrastructures and digital rules, as well as the resilience of global supply chains (on the *EU-Japan Digital Partnership*, see *Trade Perspectives*, Issue No. 11 of 6 June 2022).

The *Digital Services Act* and the *Digital Markets Acts* will regulate digital services and digital service providers in the EU, automatically affecting trade in services. A few of the underlying principles, such as the protection of consumers from illegal activities online, and the fight against traders that abuse platforms by selling unsafe or counterfeit goods, are already finding their way into the trade negotiations led by the EU. Some of these principles have also already been reflected in the EU's Chapter on Digital Trade of its PTAs, or are under discussion within the *Digital Partnerships* that the EU is currently negotiating with some of its trading partners.

While some elements of the *Digital Services Act* and *Digital Markets Acts* are already addressed in PTAs or the *Digital Partnerships*, both Regulations will likely provide further issues that must be addressed bilaterally or plurilaterally in order to facilitate trade in services.

Prepare and take action

The *Digital Services Act* and the *Digital Markets Act* are important pieces of legislation for businesses operating in the digital space. All relevant stakeholders should undertake efforts to understand the new rules, ensure compliance, and take action with respect to any potential issues or trade concerns.

Australia and Singapore sign a landmark *Green Economy Agreement* to advance '*green*' trade and investment

On 18 October 2022, Australia and Singapore signed the *Australia-Singapore Green Economy Agreement* (hereinafter, *Australia-Singapore GEA*), the first instrument of its kind, to accelerate both Parties' respective green transitions and support green economy cooperation.

The *Australia-Singapore GEA* builds on the Parties' existing bilateral relationship and cooperation, notably under the *Singapore-Australia Free Trade Agreement*, the *Memorandum of Understanding of Low Emissions Solutions*, and the *2021 Cooperation on Low-Carbon Hydrogen*. Australia's Department of Foreign Affairs and Trade highlights that, through the *Australia-Singapore GEA*, both Parties were *"laying the foundations necessary for cross-border economy activities that drive growth and reduce emissions"*, which includes facilitating trade flows of environmental goods and services, green and transition finance, and clean energy. This article discusses the action plans provided under the *Australia-Singapore GEA* in an effort to enhance cooperation in the green economy between the two Parties, notably by removing trade barriers affecting environmental goods and services.

The road to the Australia-Singapore Green Economy Agreement

In June 2021, Australia and Singapore agreed to develop a *Green Economy Agreement* to increase trade and investment in environmental goods and services, while addressing environmental concerns. A *Joint Vision* was published on 21 October 2021, highlighting Australia's and Singapore's vision of an agreement that is *"practical, ambitious, and innovative to achieve our ambition of net zero emissions as soon as possible"*. The *Joint Vision* marked the launch of the negotiations for the *Australia-Singapore GEA*, which, after 13 negotiating rounds, was signed on 18 October 2022. On the same day, the Government of Australia announced an initial investment of USD 19.6 million over the course of four years of cooperation under the *Green Economy Agreement* to: 1) Facilitate trade and investment in green goods and services; 2) Promote collaboration between businesses to build capability in new green growth sectors; and 3) Foster harmonisation and collaboration on standards, technical regulations, and conformity assessment procedures to improve the interoperability of markets.

Areas of cooperation and 17 joint initiatives

According to Australia and Singapore, the *Australia-Singapore GEA* is the *"first-of-its-kind agreement",* blending the Parties' trade, economic, and environmental objectives and aimed at supporting economic growth, creating jobs in green sectors, promoting the decarbonisation of economic activities, and promoting sustainability. Australia and Singapore believe that the *Green Economy Agreement* would *"serve as a model for cooperation with other partners to support the regional transition to net zero emissions".* The *Australia-Singapore GEA* also recognises the need for the Parties to uphold their obligations under the *United Nations Framework Convention on Climate Change* and, more specifically, under the *Paris Agreement*.

The *Australia-Singapore GEA* first defines the Parties' *Vision and Objectives*, then enumerates the agreed *Principles of Green Economy Cooperation*, and then spells out in greater detail the *Areas of Cooperation*. The *Australia-Singapore GEA* identifies seven priority areas of cooperation, which *"may be expanded in the future",* namely: 1) Trade and investment; 2) Standards and conformance; 3) Green and transition finance; 4) Carbon markets; 5) Clean energy, decarbonisation and technology; 6) Skills and capabilities for green growth; and 7) Engagement and partnerships. In order to deliver tangible outcomes for the benefit of consumers and businesses, Australia and Singapore agreed to jointly implement 17 initiatives across these seven areas, as listed in Annex A of the A*ustralia-Singapore GEA.* Some of the initiatives within the areas of trade and investment have already been completed, such as the establishment of lists of environmental goods and services.

Environmental goods and services

As elaborated in the section on the *Areas of Cooperation* of the *Australia-Singapore GEA*, Australia and Singapore commit to expanding their existing commitments on trade liberalisation by, *inter alia*: 1) Identifying a comprehensive list of environmental goods and services; 2) Improving the Parties' access to environmental goods and services by addressing the existing tariff and non-tariff barriers; 3) Identifying green economy-related trade facilitation initiatives through digitalisation; and 4) Fostering trade and investment in sustainable food systems "*by recognising the merits of nationally-appropriate production practices and outcome-focused sustainability metrics*".

Under Annexes B 1.1 and B 1.2 of the *Australia-Singapore GE*A, the Parties established a list of 372 environmental goods (*e.g.*, solar window film, bicycle tyres and clean hydrogen) and a list of 155 environmental services (*e.g.*, hazardous waste treatment services and general construction services of irrigation and flood control waterworks), which are considered to contribute towards the attainment of environmental objectives, such as the protection of natural resources and biodiversity and the mitigation of greenhouse gas emissions. The non-exhaustive lists are subject to a periodic review within two years after the conclusion of the Green Economy Agreement in order to enable *"further industry consultations and to account for technical and technological advances"*.

Removing tariff and non-tariff barriers for trade in environmental goods and services

The lists of environmental goods and services are intended to be used to "*promote and facilitate trade in environmental goods and services, providing opportunities for businesses and more choice for consumers*". To reduce costs for exporters and increase the deployment of and access to green and low-emissions technology, Australia and Singapore have identified and will work together to address tariff and non-tariff barriers to trade in those environmental goods and services, as listed under Annexes B 1.1 and B 1.2. The reduction and removal of trade barriers in environmental goods is to be achieved through government-to-government cooperation and by means of engagement with related stakeholders.

The *'Mechanism to Identify and Address Non-Tariff Barriers'* under Annex B.1.3 of the *Australia-Singapore GEA* states that Singapore would conduct regular consultations with local stakeholders to identify the trade challenges and barriers faced by businesses, while Australia commits to utilising its existing *Trade Barriers* reporting portal to look at potential non-tariff barriers reported by stakeholders. On the basis of the identified barriers, Singapore and Australia intend to conduct a dialogue with a view to addressing the identified trade barriers. Both Parties also commit to engage in a dialogue to discuss non-tariff barriers imposed by other trading partners under regional, plurilateral, and multilateral agreements, for instance, within the World Trade Organization's (hereinafter, WTO) Committee on Technical Barriers to Trade and within the Joint Committee under the Regional Comprehensive Economic Partnership (RCEP).

Implications for trade and businesses

The facilitation of the flow of environmental goods and services between Australia and Singapore is expected to reduce costs for exporters and to "*increase the deployment of and access to zero and low-emissions technologies, goods and services*". The *Australia-Singapore GEA* emphasises the importance of engagement with the private sector and relevant organisations throughout the implementation of the Agreement, which should help reduce regulatory burdens for businesses. Point 9(f) of the *Australia-Singapore GEA* also reiterates the Parties' commitment to facilitate business-to-business engagements through business missions, joint webinars and seminars, and joint promotion of green economy events.

Ongoing discussions in international fora

Liberalising the trade of environmental goods and services is an important trade policy initiative contributing to climate change mitigation and is an issue that has already been discussed within the WTO in the past. On 8 July 2014, 18 participants representing 46 WTO Members including Australia, Singapore, and the EU, had launched plurilateral negotiations for the establishment of the WTO Environmental Goods Agreement, in order to reduce tariff and non-tariff barriers affecting trade in environmental goods. Despite the potential benefits for trade and the environment, the negotiations on environmental goods and services have been on hold since 2016, as WTO Members struggled to agree on the scope and definition of environmental goods. The low number of WTO Members participating in the negotiations was also identified as a concern, particularly given that the discussions mainly involved high-income countries.

In addition to the WTO level, bilateral and regional trade agreements increasingly include dedicated chapters on trade, the environment, and sustainable development. For instance, Chapter 24 on *'Environment'* of the *United States–Mexico–Canada Agreement* contains the Parties' commitment to facilitate trade in environmental goods and services by identifying existing trade barriers and developing "*cooperative projects on environmental goods and services to address current and future global environmental challenges*". The *United States–Mexico–Canada Agreement* does not identify specific environmental goods and services, nor any concrete action plans to reduce trade barriers affecting trade in environmental goods and services.

The EU's approach to trade and the green economy

In recent years, the EU has been advocating a stronger fight against climate change and the protection of the environment through trade. Concretely, the EU has been pursuing the inclusion of increasingly detailed Chapters on Trade and Sustainable Development in its preferential trade agreements. For instance, Article 12.10(b) of the *EU-Singapore Free Trade Agreement* states that the Parties commit to "*cooperate in international fora addressing environmental aspects of trade and sustainable development, including in particular at the WTO, under the United Nations Environment Programme and under multilateral environmental agreements*". Article 12.11 of the *EU-Singapore Free Trade Agreement* provides for commitments to facilitate trade in environmental goods, including in addressing non-tariff barriers affecting such goods.

A positive signal for other countries to follow?

The conclusion of the *Australia-Singapore GEA* represents an ambitious action on trade and the environment, in view of climate change mitigation objectives, which could help accelerate the pursuit of the Parties' climate goals. Taking into account the advanced areas of cooperation and the various initiatives, the *Australia-Singapore GEA* sets a positive benchmark for developing cross-border policy initiatives and frameworks to catalyse green investment and green trade. Meanwhile, from a business perspective, relevant stakeholders in Australia and Singapore should be prepared to take advantage of *Australia-Singapore GEA's* economic development and new investment opportunities.

The European Commission addresses widespread "*tuna fraud*" and sets maximum limits for additives

On 10 October 2022, the European Commission (hereinafter, Commission) adopted *Commission Regulation (EU) 2022/1923 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of ascorbic acid (E 300), sodium ascorbate (E 301) and calcium ascorbate (E 302) in tuna,* which aims at combating fraud and at protecting consumers from the risk of histamine or scombroid poisoning. The Commission notes that "*the use of high amounts of food additives in tuna to artificially restore the colour of fresh tuna flesh provides an opportunity to deceptively market that tuna as fresh tuna, selling it at a higher price, misleading the consumers about the product and exposing them to the risk of histamine poisoning*". The limits will apply with respect to the use of *ascorbic acid, sodium ascorbate*, and *calcium ascorbate* as antioxidants in tuna. This article reviews the regulation, its objectives, and the impact on businesses.

The EU list of food additives approved for use in food and their conditions of use

Annex II to *Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives* lays down an EU list of food additives approved for use in food and their conditions of use. According to Article 10(3) of *Regulation (EC) No 1333/2008*, that list may be updated in accordance with the common procedure referred to in Article 3(1) of *Regulation (EC) No 1331/2008 of the European Parliament and of the Council of establishing a common authorisation procedure for food additives, food enzymes and food flavourings*, either on the initiative of the Commission or following an application by an EU Member State or by an interested party.

Annex II to *Regulation (EC) No 1333/2008* lists the food additives *ascorbic acid* (with the E-number E300), *sodium ascorbate* (E301), and *calcium ascorbate* (E302), which have, so far, been authorised as food additives in, among other categories, category 09.1.1 '*Unprocessed fish*' and category 09.2 '*Processed fish and fishery products including molluscs and crustaceans*', at "*quantum satis*" (Latin for "*sufficient quantity*") and, according to Article 3(2)(h) of *Regulation (EC) No 1333/2008* "'*quantum satis' shall mean that no maximum numerical level is specified and substances shall be used in accordance with good manufacturing practice, at a level not higher than is necessary to achieve the intended purpose and provided the consumer is not misled*".

'*Antioxidants*' is a functional class of food additives defined in Annex I to *Regulation (EC) No 1333/2008* as "*substances which prolong the shelf-life of foods by protecting them against deterioration caused by oxidation, such as fat rancidity and colour changes*". They differ from the functional class of '*preservatives*', which refers to substances acting against microorganisms. Antioxidants are used in unprocessed fish to slow down the discoloration of fish flesh and the rancidity development. In unprocessed tuna, consumers link freshness to the naturally red colour of fresh tuna flesh.

The European Food Safety Authority (hereinafter, EFSA), in its *Scientific Opinion on the re-evaluation of ascorbic acid (E 300), sodium ascorbate (E 301) and calcium ascorbate (E 302) as food additives of 14 April 2015*, confirmed the Scientific Committee on Food's (the EFSA's predecessor) assessment that the use of *ascorbic acid, sodium ascorbate*, and *calcium ascorbate* as antioxidants is acceptable, that there is no safety concern for their use as food additives at the reported uses and use levels, and that there is no need for the setting of a numerical acceptable daily intake. According to the Commission, "*such a conclusion means that the substance is of a very low safety concern, there is reliable information for exposure and toxicity and there is a low probability of adverse health effects in humans at doses that do not induce nutritional imbalance in animals"*. So far, no maximum numerical level is, therefore, laid down for those food additives and they are to be used at *quantum satis*.

Avoiding poisoning from adulterated tuna

An article by Italian food lawyer *Dario Dongo* describes the current situation: "*Thawed* [i.e., defrosted] *tuna with added additives is the subject of a gigantic and systemic food fraud - still unpunished in the EU, with rare exceptions - that has lasted for at least 5 years. Member States (Italy, Spain, France and Sweden in particular) have reported hundreds of foodborne illnesses associated with the consumption of sophisticated fish fillets containing nitrites and other additives. However, the European Commission abandoned work to tackle this type of food fraud in 2017, although they are well known and still ongoing*". The poisoning that occurs after the ingestion of tuna adulterated with additives is the *scombroid* syndrome, which is a reaction to high histamine intake, similar to an allergy in some respects, manifested with symptoms such as redness and itching of the skin, dizziness and headache, nausea, vomiting and diarrhea.

With the adoption of *Regulation (EU) 2022/1923*, the Commission appears to take action to address this matter. Recital 5 of *Commission Regulation (EU) 2022/1923* provides that thawed tuna loins marketed as '*fresh*' tuna are to be obtained from tuna frozen below –18°C after fishing ('*fresh tuna*'), whereas other thawed tuna loins are to be used only for canning ('*tuna for canning*'), in accordance with *Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin*. The Commission further notes that "*the use of the food additives in tuna for canning in high amounts to artificially restore the colour of fresh tuna flesh gives an opportunity to deceptively market that tuna for canning as fresh tuna, selling it at a higher price, misleading the consumers about the product and exposing them to the risk of histamine poisoning*". Such use of the food additives at issue, however, does not comply with the general conditions for inclusion and use of food additives in the EU lists and with the *quantum satis* principle.

Over the past few months, in addition to numerous alerts notified on the EU's Rapid Alert System for Food and Feed (RASFF) because of additives used in quantities significantly higher than the permitted limits, there have been notifications for serious poisoning risks in thawed tuna with histamine from India, Maldives, Sri Lanka, Thailand and Viet Nam.

Following food fraud investigations under *Regulation (EU) 2017/625 of the European Parliament and of the Council on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products*, competent authorities in the EU Member States regularly report cases where tuna loins sold as fresh are found to contain the food additives in amounts higher than those considered by those competent authorities as necessary to achieve the typical antioxidant effect on fresh tuna. In this regard, the Commission notes that "*the competent authorities suspect that the food additives are being used on tuna for canning to restore their colour and place them on the market as fresh*". The Commission is referring here to the international OPSON initiative, coordinated by Europol and Interpol, which aims at encouraging control authorities to cooperate in the fight against food fraud. In 2018, authorities in 11 European countries (France, Germany, Hungary, Italy, Liechtenstein, the Netherlands, Norway, Portugal, Spain, Switzerland, and the United Kingdom) participated in Operation Opson VII, which led to the seizure of 45 metric tonnes of illegally thawed tuna in Spain alone.

The setting of maximum level for the use of the antioxidants in tuna to combat fraud

As it is for national EU Member States' competent authorities to establish that the *quantum satis* principle has not been complied with, EU Member States, in particular Spain, requested the Commission to lay down an appropriate maximum level for the use of the food additives as antioxidants in thawed tuna sold as fresh tuna (unprocessed) or marinated tuna (processed).

Recital 9 of Commission *Regulation (EU) 2022/1923* notes that "*in the interest of legal certainty, and to ensure a high level of consumer protection and fair practices in food trade, it*

is therefore appropriate to set a maximum level of use in tuna of the additives in food categories 09.1.1 and 09.2 in Part E of Annex II to Regulation (EC) No 1333/2008".

On the basis of the information provided by the industry to the EFSA in view of the re-evaluation of the safety of the food additives at issue, a maximum level of 300 mg/kg is considered appropriate by the Commission. This level is the highest use level reported by the industry, as listed in the EFSA's scientific opinion and should, therefore, allow to maintain the current levels of legitimate use following good manufacturing practices. The Commission states that setting a maximum level for the use of *ascorbic acid* (E 300), *sodium ascorbate* (E 301), and *calcium ascorbate* (E 302) as antioxidants in tuna is not liable to have an effect on human health. Therefore, under Article 3(2), second subparagraph, of *Regulation (EC) No 1331/2008*, it is not necessary to seek the opinion of the EFSA.

The industry and an EU Member State do not agree with the new maximum level

The Commission reports that it had been "*made aware of studies carried out by the fish industry and the opinion of one competent authority of an EU Member State which concluded that the use of 900 mg/kg of the food additives is necessary to control oxidation in tuna loins maintained below 4 °C for 10 days*". However, in light of the information available, and in particular of the fact that official controls carried out by some other EU Member States' competent authorities showed that a shelf-life of 10 days may be achieved for thawed tuna with a treatment at 300 mg/kg without it changing the initial colour, the Commission concluded that the level of 300 mg/kg appears to be sufficient to achieve the desired antioxidant effect. The dissenting opinion of one competent authority of an EU Member State is most likely coming from Spain, as, in the preparation of *Commission Regulation (EU) 2022/1923*, the Commission had noted that "*the arguments of Spain/industry are not convincing*".

Conclusion and outlook

Commission Regulation (EU) 2022/1923 entered into force on 31 October 2022 and is binding in its entirety and directly applicable in all EU Member States. The Commission has finally taken action to address the widespread tuna fraud and the matter of histamine intoxication by setting maximum limits for the antioxidants *ascorbic acid* (E 300), *sodium ascorbate* (E 301), and *calcium ascorbate* (E 302). The maximum levels of 300 mg/kg in tuna are already applicable and the fish industry must be ready to avoid costly product withdrawals and recalls.

Recently adopted EU legislation

Trade Remedies

- *Commission Implementing Regulation (EU) 2022/2189 of 9 November 2022 amending Implementing Regulation (EU) 2021/1784 imposing a definitive anti-dumping duty on imports of aluminium flat-rolled products originating in the People's Republic of China*

- *Council Implementing Regulation (EU) 2022/2180 of 8 November 2022 implementing Regulation (EU) 2017/1509 concerning restrictive measures against the Democratic People's Republic of Korea*

- *Council Implementing Decision (CFSP) 2022/2188 of 8 November 2022 implementing Decision (CFSP) 2016/849 concerning restrictive measures against the Democratic People's Republic of Korea*

Customs Law

- *Commission Implementing Regulation (EU) 2022/2183 of 8 November 2022 amending Annexes V and XIV to Implementing Regulation (EU) 2021/404 as regards the entries for Canada, the United Kingdom and the United States in the lists of third countries authorised for the entry into the Union of consignments of poultry, germinal products of poultry and fresh meat of poultry and game birds (Text with EEA relevance)*

Food Law

- *Commission Implementing Regulation (EU) 2022/2127 of 4 November 2022 granting a Union authorisation for the biocidal product family 'Ecolab UA BPF 1-Propanol' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (Text with EEA relevance)*

- *Corrigendum to Commission Delegated Regulation (EU) 2021/1189 of 7 May 2021 supplementing Regulation (EU) 2018/848 of the European Parliament and of the Council as regards the production and marketing of plant reproductive material of organic heterogeneous material of particular genera or species (Official Journal of the European Union L 258 of 20 July 2021)*

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