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As part of its *Farm to Fork Strategy*, the EU is working towards a harmonised animal welfare label

Over the past years, concerns over animal welfare increased in the EU. As part of its *Farm to Fork Strategy,* the EU committed to "*consider options for animal welfare labelling to better transmit value through the food chain*". On 31 March 2021, the European Commission (hereinafter, Commission) published its *Evaluation of the European Union Strategy for the Protection and Welfare of Animals 2012-2015*, which actually covers the period from 2012 to 2018. The findings of the evaluation will now be taken into account by the Commission for its forthcoming proposal for an EU-wide animal welfare label. Such labelling requirement would likely have an important impact on international trade and its compatibility with World Trade Organization (hereinafter, WTO) rules will have to be determined.

Current EU legislation on animal welfare

Currently, EU legislation on animal welfare covers animal welfare on farms, during transport, and at the time of killing. *Council Directive 98/58/EC of 20 July 1998 concerning the protection of animals kept for farming purposes* is the main legal instrument for "*food producing animals*". The Directive is complemented by additional Directives on certain species, namely laying hens, broilers, pigs, and calves, setting minimum standards for the protection of such species. Additionally, in 2005, the EU adopted *Regulation (EC) No 1/2005 of 22 December 2004 on the protection of animals during transport and related operations* and, in 2009, *Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of killing*.

In 2012, the Commission adopted the *EU Strategy for the Protection and Welfare of Animals 2012-2015*, with the objective "*to ensure uniform application and enforcement of the legislation in all Member States*" and to "*consider the feasibility of introducing a simplified EU legislative framework with animal welfare principles for all animals*". On 20 May 2020, the Commission announced, in its '*A Farm to Fork Strategy - for a fair, healthy and environmentally-friendly food system*', that it would consider options for animal welfare labelling to better transmit value through the food chain (on the *Farm to Fork Strategy*, see *Trade Perspectives*, Issue No. 10 of 22 May 2020). In its Conclusions on the *Farm to Fork* Strategy, the Council of the EU (hereinafter, Council), gathering all EU Member States, invited the Commission to assess the

impact of an EU regulatory framework with criteria for an EU-wide animal welfare labelling scheme. The welfare of animals is an issue of increasing importance for European citizens and has been recognised as such by general EU law, in particular by Article 13 of the Treaty on the Functioning of the European Union (hereinafter, TFEU), which notes that "*In formulating and implementing the Union's agriculture, fisheries, transport, internal market, research and technological development and space policies, the Union and the Member States shall, since animals are sentient beings, pay full regard to the welfare requirements of animals*".

Setting the criteria for an EU-wide animal welfare label

On 7 December 2020, the Council adopted its *Conclusions on an EU-wide animal welfare label*, which were endorsed by the EU Member States' Ministers of Agriculture on 15 December 2020.

In the Council conclusions, EU Member States' Ministers called for specific criteria to be taken into account when the Commission develops an EU-wide animal welfare label. Notably, the Commission was invited to consider the following aspects before submitting a proposal: 1) To develop a tiered transparent labelling scheme allowing for sufficient incentives for producers to improve animal welfare; 2) To establish EU-wide harmonised, measurable and verifiable criteria that go beyond current EU legal requirements on animal welfare; 3) To gradually include all livestock species in the label covering their entire lifetime (including transport and slaughter); 4) To create a standardised EU logo and to determine easily understandable protected terms; and 5) To ensure a smooth interplay with existing national schemes and the new EU-wide animal welfare labels. Additionally, the Council conclusions note that the new EU-wide labelling scheme should incorporate the animal welfare provisions of *Regulation (EU) 2018/848 on organic production and labelling of organic products* and the provisions of *Regulation (EU) No 1308/2013 establishing a common organisation of the markets in agricultural products*.

On 31 March 2021, the Commission published the final evaluation of the *EU Strategy for the Protection and Welfare of Animals 2012-2015* (hereinafter, Evaluation). The Evaluation notes six objective that remain relevant. One of those six objectives is to "*provide consumers and the public with appropriate information*". Regarding this objective, the Evaluation states that, in order to achieve improvements in consumer knowledge, the establishment of labelling schemes would be necessary. The Evaluation points out that the increased interest by consumers to receive better information on animal welfare had increased the number of animal welfare claims among existing labels on foodstuffs. The Evaluation notes that, due to the lack of a common methodology, "*the proliferation of claims increases the difficulty for consumers to really assess their reliability*". The Evaluation reiterates that the Commission had committed, as part of the *Farm to Fork Strategy*, to explore the options for an EU-wide animal welfare label. Furthermore, the Evaluation states that "*actions in this area will elaborate on the findings of this evaluation in terms of consumers' awareness and demand for information*".

Towards voluntary animal welfare labelling

In December 2020, Germany's Federal Minister of Food and Agriculture *Julia Klöckner*, who, at that time, presided the EU's Agriculture and Fisheries Council during the German Council Presidency, emphasised that animal welfare had become "*an EU priority for more ambitious and higher standards*" and stated that "*a common EU label on animal welfare would increase credibility and transparency in our markets and would enable consumers to make more informed choices. It would also help reward producers who respect those standards*".

Importantly, the European Commissioner for Agriculture *Janusz Wojciechowski* stated that "*the animal welfare label scheme the EU executive is set to propose will only be voluntary*". In December 2020, many campaigners for increased animal welfare in the EU welcomed the news that a decision had been reached on animal welfare labelling by the Council and stated that a label that covers the entire lifetime of animals, including factors such as transport, slaughter, and all aspects of the living conditions of the animals, is needed. However, other

campaigners criticised the failure to already specify clear requirements for the label, warning that this called into question whether the future label would indeed be effective in increasing animal welfare standards.

The Council conclusions do not explicitly call for a voluntary or mandatory system. However, in Recital 4, they "*draw attention to existing initiatives in the Member States, in particular to the already successfully established voluntary animal welfare labels in some of them*", which can be seen as a preference for a voluntary system.

Some EU Member States already adopted national animal welfare labelling schemes for certain animals, such as chickens and pigs, namely France, Germany, and Italy.

Towards a WTO-compatible measure?

At this point, the details of the EU's future animal welfare label, its application towards imports of food of animal origin, and how it would be implemented, remain uncertain. However, any such EU measure would have to comply with relevant international disciplines. An EU-wide animal welfare label might be considered incompatible with WTO disciplines by other WTO Members, which may see in the animal welfare label a "*disguised*" restriction on trade. If the verification linked to the animal welfare label were to be onerous and disproportionate vis-à-vis the information provided on the label, third countries could argue that the measure constitutes a "*disguised*" restriction on trade. If this were to be the case, such import restriction could be considered as a violation of the national treatment requirement under the General Agreement on Tariffs and Trade (GATT). Additionally, an EU-wide animal welfare labelling scheme could also come into conflict with the EU's commitments under the WTO Agreement on Technical Barriers to Trade (hereinafter, TBT) if the label were to be considered a technical regulation that is "*more trade restrictive than necessary*" to achieve a legitimate objective.

The way forward

The review by the Commission of the EU's existing animal welfare legislation is expected to be completed by 2023. However, the proposal for an EU-wide animal welfare label is already expected between 2021 and 2022. All relevant stakeholders should closely monitor the related developments and ensure that regulators are aware of the various factors and the potential implications of the future label.

The growth of electronic commerce in ASEAN and the regional efforts to regulate the e-commerce market

Electronic commerce (hereinafter, e-commerce), or the sale or purchase of goods or services conducted electronically, has become omnipresent in the global market. The growing e-commerce market provides big opportunities for businesses to participate in international trade, as it opens up access to larger markets and has the potential to reduce production costs by avoiding the need for manufacturing facilities in various countries. Globally, revenue from e-commerce had reached USD 1.6 trillion in 2018 and is expected to increase to approximately USD 2.7 trillion by 2023.

The Association of Southeast Asian Nations (hereinafter, ASEAN), grouping Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, the Philippines, Singapore, Thailand, and Viet Nam, is the world's largest and fastest-growing online market with an existing internet user base of over 350 million users and an overall market size of USD 72 billion in 2018. As the internet and technological advancements have transformed the way in which trade and business are conducted, there has been a growing demand for a more digital-friendly framework to facilitate the digital transformation in the ASEAN region. Therefore, in the past few years, ASEAN Member States have undertaken significant efforts, individually and collectively, in the area of e-commerce and digital trade regulation.

ASEAN Agreement on Electronic Commerce and other related ASEAN instruments

Within the regional framework, ASEAN Member States jointly developed various instruments in an effort to enhance and facilitate cross-border e-commerce transactions. The *ASEAN Economic Community Blueprint 2025* refers to the importance of global e-commerce, noting that ASEAN should intensify cooperation in this area. In line with this mandate, the *ASEAN Agreement on Electronic Commerce* was signed on 12 November 2018 and adopted on 22 January 2019, making ASEAN the first region to have concluded a regional agreement on e-commerce. This agreement is part of the implementation of the *ASEAN Work Programme on Electronic Commerce 2017*-2025, which contains eight elements related to e-commerce, such as infrastructure, education and technology competency, as well as consumer protection.

The *ASEAN Agreement on Electronic Commerce* applies to measures adopted and/or maintained by ASEAN Member States that affect e-commerce. It addresses, *inter alia,* the basic legal principles and ASEAN's cooperation on e-commerce, as well as the role of cybersecurity and electronic payments. In essence, the Agreement can be seen as a first attempt to pave the way to improved e-commerce cooperation within the ASEAN region, underlining the ASEAN Member States' commitment to cooperate and collaborate in areas that might be of interest to the private sector, namely related to information and communications technology (ICT) infrastructure, online consumer protection, interoperable e-payment systems, intellectual property rights, cybersecurity, legal and regulatory frameworks, logistics facilitating e-commerce, and competition policy. With regard to facilitating cross-border e-commerce, Article 7 of the *ASEAN Agreement on Electronic Commerce* provides various mechanisms that should be implemented by ASEAN Member States, such as paperless trading between businesses and authorities, the adoption of consumer protection measures, and the acknowledgment of the legal validity of electronic authentication and electronic signatures.

It is important to note that, in order to attain the Agreement's objectives, each ASEAN Member States will need to undertake efforts to support the development of regional e-commerce. The *ASEAN Agreement on E-Commerce* merely provides a starting point for a common framework guiding the enactment of domestic laws and regulations in the respective ASEAN Member States. Therefore, enacting the necessary laws and regulations is undoubtedly critical in enhancing the implementation of e-commerce within ASEAN.

At the same time, other ASEAN instruments complement the *ASEAN Agreement on Electronic Commerce*, namely the *ASEAN Digital Integration Framework Action Plan,* the *ASEAN Guideline on Accountabilities and Responsibilities of E-Marketplace Providers,* and the *ASEAN Digital Integration Framework Action Plan (DIFAP) 2019-2025.*

E-commerce in preferential trade agreements involving ASEAN Member States

In 1992, ASEAN Member States established the ASEAN Free Trade Area, which aimed at eliminating tariff barriers among its Member States. Between 2004 to 2010, ASEAN Member States concluded preferential trade agreements with China, Japan, Korea, India and Australia/New Zealand, known as the *"ASEAN+1"* PTAs. Of these agreements, the *ASEAN-Australia-New Zealand FTA* (hereinafter, AANZAFTA), which entered into force in January 2010, is the only ASEAN+1 PTA that contains a dedicated chapter on e-commerce with obligations relating to transparency, domestic regulatory frameworks, transparency, electronic authentication, and digital certificates. Under Article 3 of the AANZAFTA, for instance, the Parties commit to publish and make publicly available all measures relating to e-commerce, while, under Article 4 thereof, the Parties commit to maintain or adopt domestic laws and regulations governing electronic transactions by taking into account the *UNCITRAL Model Law on Electronic Commerce 1996.*

On 15 November 2020, ASEAN Member States signed the *Regional Comprehensive Economic Partnership Agreement* (hereinafter, RCEP), grouping the ten ASEAN Member

States with the six regional countries under the *ASEAN+1 PTAs* minus India (see *Trade Perspectives*, Issue No. 22 of 27 November 2020). The RCEP goes beyond the existing ASEAN+1 PTAs and includes new commitments, including on e-commerce. In general terms, the agreement encourages the Parties to improve trade administration and processes with electronic means. On the basis of Article 12.11 of the RCEP, the Parties commit to refrain from imposing customs duties on electronic transmissions, in line with the WTO's *moratorium on e-commerce*, under which WTO Members committed to abstain from imposing customs duties on electronic transmissions. Article 14.14 of the RCEP prohibits data localisation requirements, unless they are necessary to achieve a Party's public policy objectives or to protect its security interests. Once the RCEP enters into force, all ASEAN Member States, as well as China, Japan, Korea, Australia, and New Zealand will be subject to the new commitments on e-commerce.

Singapore launches national guidelines for e-commerce transactions to develop customer-centric e-commerce policies

Despite its small geographical footprint and population, Singapore can be considered as the economic *'powerhouse'* of the Southeast Asian region, including its e-commerce market. The 2019 e-Conomy report by *Google*, *Temasek* and *Bain & Company* determined that Singapore's e-commerce industry is set to reach a value of USD 22 billion by 2025, a significant increase from its current estimated value of USD 9 billion. In line with the aim to transform the country into a regional and global e-commerce hub, Singapore has been assisting businesses and other relevant market operators to accelerate the digital transformation.

On 12 June 2020, *Enterprise Singapore* (ESG), Singapore's "*government agency championing enterprise development*", and the *Singapore Standards Council* (SSC) launched the country's first national standard on e-commerce, namely the *Technical Reference 76 concerning guidelines for e-commerce transactions*. The Technical Reference provides a reference guide for online retailers detailing information on the entire e-commerce transaction process, from pre-purchasing activities to payment procedures and customer support. It complements the Government of Singapore's efforts to support the presence of small and medium sized enterprises in the e-commerce market.

Essentially, the new Technical Reference offers a checklist for retailers to develop their e-commerce policies, as well as to ensure that comprehensive information is available to consumers. Some of the general guidelines include: 1) E-marketplaces and merchants should develop mechanisms to handle customers' enquiries, complaints, and dispute resolution; 2) E-marketplaces must ensure that the information for the products and/or services offered is clearly provided; 3) E-marketplaces working with third-party logistics providers must ensure that they adhere to the applicable handling protocols; and 4) Prices should be displayed with the applicable currency and product reviews, comparisons, and ratings.

The framework governing e-commerce in Indonesia

Aside from Singapore, Indonesia has been amongst the world's top markets with the highest online shopping penetration rate. According to the e-Conomy report, e-commerce transactions in Indonesia are expected to quadruple in the next six years with the gross merchandise value projected to amount to USD 82 billion in 2025, compared to USD 21 billion in 2019. In November 2019, Indonesia issued its first legal framework governing e-commerce activities, *Government Regulation No. 80 Year 2019* (*GR No. 80/2019*), as further clarified by the *Minister of Trade Regulation No. 50 Year 2020* (*MOT Regulation No. 50/2020)*, which aim at improving governance in relation to the rapid development of internet- and electronic-based trading activities. In general terms, the regulations define, *inter alia*, the types of businesses involved in e-commerce, set out specific requirements for business activities, and provide a framework for consumer protection.

Key provisions include, somewhat controversially, the requirement to prioritise the trade of domestic goods or services and for online marketplaces to promote such goods or services in

dedicated sections of their platforms. In addition, the rules regulate foreign e-commerce entities, establishing that those that have a significant economic presence in Indonesia will be considered as having a permanent establishment in the country, and are, therefore, considered as Indonesian tax subjects.

With regard to consumer protection, *GR No. 80 Year 2019* states that e-commerce businesses must respect consumer protection and rights, as stated in Indonesia's *Law No. 8 Year 1999*. They must also provide, *inter alia*, for a complaint service for consumers, which must include at the very least: 1) Proper procedures that set out the process on how consumers can complain; 2) An address and contact number to file complaints; 3) Follow-up procedures for complaints; and 4) A time period for resolving complaints.

What's next?

Taking into account the various initiatives and frameworks in ASEAN and individual ASEAN Member States, regulations surrounding e-commerce and its operation appear to be a positive development that could enhance international and intra-ASEAN trade, benefitting market operators, as well as consumers. Undoubtedly, the continued growth of e-commerce, further fuelled by restrictions during the *Covid-19* pandemic, will play a valuable role in developing ASEAN's digital economy.

To take advantage of these developments, businesses and consumers should closely monitor the opportunities and challenges, as well as the regulatory developments in order to understand and use to their benefit the applicable rules and requirements. ASEAN should also further integrate the regulation and implementation of the trade facilitation rules under the ASEAN Trade in Goods Agreement (ATIGA) with the regulatory frameworks of the *ASEAN Agreement on Electronic Commerce* and related ASEAN instruments, as well as with the relevant disciplines under the RCEP, with respect to goods traded across borders through e-commerce platforms. The convergence and synergy of those parallel regulatory frameworks looks poised to become a powerful engine of regional economic integration within ASEAN and beyond.

The European Commission incorporates botanical species containing *hydroxyanthracene* derivatives (HADs) in the EU list of '*forbidden foods*': An uncertain future of *aloe* extracts and other botanicals in food supplements

On 7 April 2021, *Commission Regulation (EU) 2021/468 of 18 March 2021 amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards botanical species containing hydroxyanthracene derivatives* entered into force. This Regulation incorporates botanical species containing *hydroxyanthracene* derivatives (hereinafter, HADs), which are certain chemical compounds naturally occurring in different botanical species, into an EU list of '*forbidden food*'. The article looks at which substances are now prohibited, restricted and under scrutiny in EU law, and at the impact on food supplements containing, *inter alia*, *aloe* extracts.

The EU list of prohibited foods

According to Article 8(2) of *Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods* (also known as the Food Fortification Regulation), on its own initiative or on the basis of information provided by EU Member States, the European Commission (hereinafter, Commission) may initiate a procedure to include a substance or an ingredient containing a substance other than a vitamin or a mineral in Annex III to *Regulation (EC) No 1925/2006* listing the substances whose use in foods is prohibited (in Part A), restricted (in Part B), or under EU scrutiny (in Part C). Annex III to *Regulation (EC) No 1925/2006* had remained empty from the adoption of the Regulation in 2006 until 2015, when the first

substances were included in Annex III at an initiative of Germany. *Commission Regulation (EU) 2015/403 of 11 March 2015 amending Annex III to Regulation (EC) No 1925/2006* added two substances used in food supplements to Annex III, namely the *Ephedra* herb and its preparations originating from *Ephedra* species, which were listed in Part A, and *Yohimbe* bark and its preparations originating from *Yohimbe* (*Pausinystalia yohimbe (K. Schum) Pierre ex Beille*), which were listed as substances under scrutiny in Part C.

More recently, *Commission Regulation (EU) 2019/649 of 24 April 2019 amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards trans fat, other than trans fat naturally occurring in fat of animal origin* established the condition that "*Maximum 2 grams per 100 grams of fat in food intended for the final consumer and food intended for supply to retail*" may be present in food and included *trans* fats in Part B of Annex III as a restricted substance. These restrictions apply since 1 April 2021.

Interestingly, in January 2003, in a preliminary draft proposal for a Regulation on the addition of vitamins and minerals and of certain other substances to foods, the Commission initially listed some substances in Annex III, including substances under EU scrutiny (*i.e.*, *glucoronolactone*, *taurine* and *guarana*), restricted substances (*i.e.*, *caffeine* and *quinine*, where the content in soft drinks might not exceed a limit to be established in mg/l), and prohibited substances and ingredients containing them (*i.e.*, *ephedrine* and its *alkaloids*, *hormones*, *kava-kava*, *nicotine*, *aristolochic acid* and *St John's wort*). When the proposal was finally adopted on 10 November 2003, and the legislative procedure began, the Commission withdrew the originally foreseen list of substances for Annex III, after consultations with the European Parliament, the Council of the EU, EU Member States, and relevant stakeholders. In the last years, it appears that the Commission is using the possibility to prohibit, restrict or put under scrutiny substances other than vitamins and minerals, listing them in Annex III on a case-by-case basis.

The prohibition of aloe-emodin, emodin, danthron and aloe preparations containing HADs in food

The listing in Annex III of *Regulation (EC) No 1925/2006* of substances, whose use in foods is prohibited, restricted, or under EU scrutiny, concerns substances associated with a risk to consumers as defined by Article 8(1) of *Regulation (EC) No 1925/2006* as the case "*where a substance other than vitamins or minerals, or an ingredient containing a substance other than vitamins or minerals, is added to foods or used in the manufacture of foods under conditions that would result in the ingestion of amounts of this substance greatly exceeding those reasonably expected to be ingested under normal conditions of consumption of a balanced and varied diet and/or would otherwise represent a potential risk to consumers*".

Hydroxyanthracene derivatives (HADs) are a class of chemical compounds naturally occurring in different botanical species and used in food supplements to improve bowel function. In its *Scientific Opinion of 9 October 2013 on the scientific substantiation of a health claim related to hydroxyanthracene derivatives and improvement of bowel function*, the European Food Safety Authority (hereinafter, EFSA) concluded that HADs in food can improve the bowel function, but advised against long-term use and consumption at high doses due to potential safety concerns, such as the danger of electrolyte imbalance, impaired function of the intestines and dependence on laxatives. On 22 November 2017, following a request by the Commission, the EFSA adopted a *Scientific Opinion on the evaluation of the safety of hydroxyanthracene derivatives for use in food*. The HADs considered by the EFSA in the context of this risk assessment were those found in the root and rhizome of *Rheum palmatum L.* and/or *Rheum officinale Baillon* and/or their hybrids, leaves or fruits of *Cassia senna L.*, bark of *Rhamnus frangula L.*, bark of *Rhamnus purshiana DC.,* and in leaves of *Aloe barbadensis Miller* and/or various *Aloe* species, mainly *Aloe ferox Miller* and its hybrids.

In its opinion of 22 November 2017, the EFSA found that the HADs *aloe-emodin* and *emodin,* and the structurally related organic substance *danthron,* have been shown to be genotoxic *in vitro* (*i.e.*, in lab ware). According to the EFSA, *aloe* extracts have also been shown to be

genotoxic *in vitro,* most likely due to the HADs present in the extract. Furthermore, *aloe-emodin* was shown to be genotoxic *in vivo* (*i.e.*, in a living organism) and the whole leaf *aloe* extract and the structural analogue *danthron* were shown to be carcinogenic. Given that *aloe-emodin* and *emodin* may be present in the extracts, the EFSA concluded that HADs should be regarded as genotoxic and carcinogenic, unless there are specific data to the contrary, and that there is a safety concern for extracts containing HADs, although uncertainty persists. The EFSA was unable to provide advice on a daily intake of HADs that does not give rise to concerns for human health.

In *Regulation (EU) 2021/468*, the Commission states that, considering the severe harmful effects on health associated with the use of *aloe-emodin*, *emodin*, *danthron* and *aloe* extracts containing HADs in food, and that no daily intake of HADs that does not give rise to concerns for human health could be set by the EFSA, such substances should be prohibited and, therefore, should be included in Part A of Annex III to *Regulation (EC) No 1925/2006*.

Finally, as there is a possibility of harmful effects on health associated with the use of *Rheum*, *Cassia* and *Rhamnus* and their preparations in food, and while scientific uncertainty persists about whether such preparations contain the substances listed in Part A of Annex III to *Regulation (EC) No 1925/2006*, such substances should be placed under EU scrutiny and, therefore, should be included in Part C of Annex III to *Regulation (EC) No 1925/2006*.

Enforcement, maximum levels of HADs and mitigation measures

It appears currently unclear how *Regulation (EU) 2021/468* will be enforced. Stakeholders in the food chain, from growers to food business operators marketing products derived from plants that contain HADs, and especially *Aloe*, will need to test the raw material or final products in order to verify that it complies with *Regulation (EU) 2021/468*. Recital 13 of *Regulation (EU) 2021/468* states that the measures provided for in this Regulation are in accordance with the opinion of the EU's Standing Committee on Plants, Animals, Food and Feed (PAFF Committee). In the meeting of the PAFF Committee of 5 October 2020, in which EU Member States' delegates adopted a positive opinion of the draft Regulation, the Commission "*reminded the Committee that the EU Reference Laboratory on mycotoxins and plant toxins (EURL) had been asked for assistance in determining validated analytical methods and limits of quantification (LOQs) for hydroxyanthracene derivatives (HADs) in the different botanical preparations*". The LOQ is the lowest analyte concentration that can be quantitatively detected with a stated accuracy and precision. The Commission also indicated "*that the level of 1 ppm for aloe-emodin/emodin and the level of 1 ppm for the sum of aloin A and aloin B are for the time being the lowest levels that can be reliably quantified in laboratories across the EU and can therefore be put forward as limits of quantification in an EU harmonised risk management approach*". However, these considerations can only be found in the minutes of the PAFF meeting and are not provided in *Regulation (EU) 2021/468*.

As regards possible mitigation measures, in Recital 10 of *Regulation (EU) 2021/468*, the Commission notes that, "*during manufacture, hydroxyanthracene derivatives can be removed from the botanical preparations through a series of filtering processes resulting in products that contain those substances only at trace levels as impurities*". However, there is no guidance on what these filtering processes are and how they would need to be applied to remove HADs.

Industry reactions

Regulation (EU) 2021/468 has been criticised by the *European Federation of Associations of Health Product Manufacturers* (hereinafter, EHPM), which argues that, by removing the substances that improve intestinal function, the benefits linked to *Aloe* and similar plants like Rhubarb would also be eliminated in food supplements for alleged safety reasons. The EHPM appears to fear that an entire category of food supplements beneficial for proper bowel function would be concerned.

In addition, according to the EHPM, the Commission failed to give the EFSA sufficient time to consider new scientific studies, including clinical studies by the Italian Society of Toxicology, which reportedly confirm the safety of *Aloe* and other affected plants in food supplements. In addition, the EFSA's assessment was reportedly carried out on individual substances obtained by chemical synthesis, some of which are already known to be cancerogenic.

Outlook

Considering the severe harmful effects on health associated with the use of *aloe-emodin*, *emodin*, *danthron* and *aloe* extracts containing HADs in food, and that no daily intake of HADs that does not give rise to concerns for human health could be set, the Commission has prohibited such substances in *Regulation (EU) 2021/468*. Arguably, levels of 1 ppm for aloe-emodin/emodin and for the sum of aloin A and aloin B can, for the time being, be considered as LOQs. As to mitigation measures resulting in products that contain HAQS only at trace levels as impurities, further instructions or guidelines might be expected at the national level. Stakeholders in the nutrition industry should analyse their ingredients and review their supply chains in order to comply with *Regulation (EU) 2021/468* and monitor further developments. The future of *Aloe* and other botanicals in food supplements has indeed become uncertain.

Recently Adopted EU Legislation

Trade Law

- *Commission Delegated Regulation (EU) 2021/576 of 30 November 2020 amending Annex III to Regulation (EU) No 978/2012 to include the Republic of Uzbekistan among the countries benefiting from tariff preferences under the GSP+*

Customs Law

- *Commission Delegated Regulation (EU) 2021/573 of 1 February 2021 amending Delegated Regulation (EU) 2019/625 as regards import conditions for live snails, for composite products and for casings placed on the market for human consumption ([1])*

- *Commission Implementing Regulation (EU) 2021/575 of 30 March 2021 concerning the classification of certain goods in the Combined Nomenclature*

Food Law

- *Commission Delegated Regulation (EU) 2021/571 of 20 January 2021 amending the Annex to Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the list of substances that may be added to infant and follow-on formula, baby food and processed cereal-based food ([1])*

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