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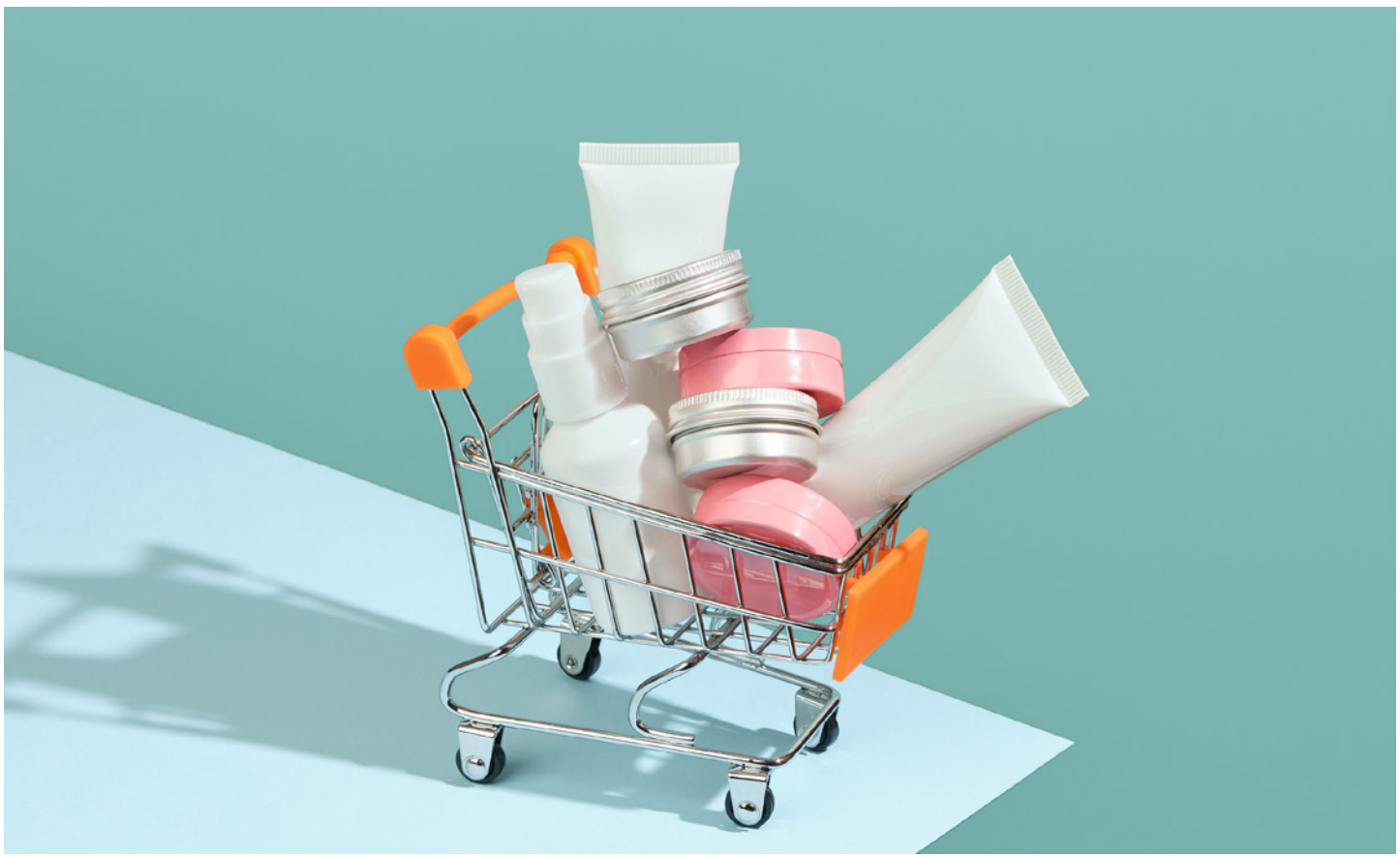
Cosmetics regulation and risk management

FW discusses cosmetics regulation and risk management with Samantha Silver, Sarah-Jane Dobson, Miran Bahra and Katherine Ciclitira at Kennedys.

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FW: Could you provide an overview of recent regulatory trends and developments impacting the cosmetics sector, particularly for manufacturers across the European Union (EU) and UK?

Dobson: The EU Cosmetics Products Regulation 2009, and its predecessor legislation, have governed the cosmetics industry in the EU and UK for over 40 years. From a product safety perspective, the industry is one of the most highly regulated in Europe in recognition of the fact that cosmetic products, given their use and nature, have a greater propensity to impact consumer health more than other consumer products. Since the inception of the regime, there has been a considerable shift in consumer behaviour in light of new entities entering the market as well as scientific and innovative advancements. Substantial wider regulatory reform of the mainstay EU product safety regimes, including to account for software and modern sales modes such as online marketplaces, is also applicable to the cosmetics sector. Chemicals harmful to health or the environment are being targeted, with their restriction or prohibition dominating the legislative agenda. This trend is reflected in the proposed targeted revision of the EU cosmetics regime and the UK calls for data to consider various hazardous substances widely used in cosmetics, such as endocrine disruptors, nanomaterials, and other chemical substances, including per and polyfluoroalkyl substances (PFAS). Environmental, social and

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governance (ESG)-focused initiatives are also a priority for regulators and industry. There has been increased enforcement by safety and advertising regulators in respect of 'greenwashing' claims made about cosmetics, namely claims about a product that can mislead consumers based on exaggerated environmentally friendly characteristics. The UK's competition regulator, the Competition and Markets Authority (CMA), is empowered to enforce against these types of unsubstantiated greenwashing claims, suggesting an escalation of the issue as a market-wide problem. Post-Brexit, regulatory divergence between the EU and UK has also been at the forefront of developments. The UK continues to create UK-specific mechanisms, albeit largely based on EU regimes given the reliance on the retained law. Nevertheless, it is also moving away from the EU's position in some respects. For example, it has specifically opted to no longer grant licences for animal testing of chemicals that are intended only to be used as ingredients in cosmetics products under the EU Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regime for proof of safety from a health and safety perspective, namely the safety of workers, or environmental perspective.

FW: Drilling down, what is the nature of the EU's involvement in the cosmetics industry? How does the EU enable information exchange and ensure implementation of EU requirements in the sector? What is the equivalent process in the UK post-Brexit?

Bahra: Europe is widely recognised as a world leader in the cosmetics industry, being a prominent exporter of cosmetic products. The EU's contribution to the industry is in the form of the development of its regulatory framework for market access, which is modelled internationally, and its international trade relations. It also plays a significant role in relation to ESG-related issues, including in relation to animal testing and the prohibition of chemicals unsafe for human health or the environment. The European Commission is further tasked with cooperating with its partners at EU and international level to enable the exchange of information and ensure the efficient implementation of EU legal and regulatory requirements in the industry. The EU and UK also have respective mandatory notification systems in place in which manufacturers, importers and distributors must report to regulators prior to placing or making a cosmetic product available on the market. The EU's Cosmetics Products Notification Portal (CPNP) allows information on a cosmetic product to be shared electronically between national competent authorities for market surveillance, market analysis and evaluation, and to poison centres established by EU countries for the provision of medical treatment. In tandem, the UK has introduced its own Cosmetics Product Notification (CPN) portal in which a new cosmetic product that has not been notified on the EU's CPNP by 31 December 2020 will need to be notified on the CPN before being placed on the Great Britain market. The EU and UK also have active industry-led bodies which lobby and create guidance in the field of cosmetics. This is, in particular, due to a continued focus on empowering consumers to enable them to make informed decisions on the products they are purchasing. For example, Cosmetics Europe, a prominent European industry association, has created a public database for cosmetic ingredients to better inform consumers of the ingredients, health and environmental impacts of their cosmetics.

> THE ISSUE OF QUALIFICATION HAS BEEN HOTLY DEBATED POST-BREXIT WITH QUALIFICATIONS WITHIN AND OUTSIDE OF THE EU BEING TREATED DIFFERENTLY GENERALLY BY THE EU AND UK REGIMES.
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> MIRAN BAHRA
> Kennedys

FW: In what ways has the introduction of the EU Cosmetics Products Regulation 2009 shaken up the sector? How does the regulation aim to protect public health and the functioning of the internal market?

Bahra: The predecessor to today's cosmetics regulatory regime, the Cosmetics Directive 76/768/EEC, was intended to harmonise the legal principles and requirements for cosmetic products across the EU. However, national transposition of the Directive into local laws resulted in divergence across EU member states. Frequent subsequent amendments also

led to a complicated and incoherent framework for businesses to follow. The revision of the Directive via the EU Cosmetic Products Regulation 2009 aimed to establish simplified rules for cosmetic products available in the EU to ensure the functioning of the internal market and a high level of protection to human health. Due to its 'regulation' status, the 2009 Regulation has been uniformly applied in EU member states after its entry into force without the need to be transposed into national laws. The main changes from the earlier regime, among others, included simplifying procedures and streamlining terminology to reduce the administrative burden on businesses, the requirement for a 'responsible person' to be designated within the EU before placing a cosmetic product on the market to ensure that there is an entity to undertake compliance activities and be answerable to EU regulators, a centralised notification system for all cosmetic products placed on the EU market via the CPNP, new rules on nanomaterials, and the obligation to notify serious undesirable effects to national authorities which are to be shared with other EU countries. The current regime is, at an international level, considered an exemplar and modelled by many other countries and regions for this reason.

FW: How would you characterise the extent of the regulatory risk and burden on companies that sell cosmetic products in the EU and UK markets?

Dobson: The EU and UK regimes are known to be some of the most sophisticated and complex cosmetics regulatory regimes in the world. Those wishing to sell cosmetic products in these markets are required to achieve a high level of product safety to supply in these jurisdictions. The requirement for pre-market notification to regulators, which is a key feature of pre-market access in these jurisdictions, further acts as a deterrent or obstacle for those not engaged with the rigorous requirements of the regime. Post-market obligations also require significant ongoing resource for those marketing in the EU and UK to monitor their sales. The UK, although still largely mirroring the EU position, has UK-specific features, such as the CPN and labelling requirements. If the UK takes further advantage of its legislative sovereignty in respect of cosmetics, as it has done in product safety generally to date, companies operating in both markets may find themselves subject to two sets of distinct requirements in the EU and UK. The UK's approach in general, however, has been to simplify and streamline obligations and deregulate where possible, such that the additional regulatory burden may be less significant at first glance. A failure to adhere to the complex and onerous requirements of the EU and UK product safety regimes carries considerable risk for companies. These include reputational harm, particularly pertaining to ESG-type issues such as animal testing or 'greenwashing', operational risks with prohibition on operations, and potential civil and criminal liability risks.

FW: What are the potential liability exposures for manufacturers and suppliers of cosmetics products? Can retailers be held accountable if a product causes injury?

Silver: The potential liability exposures faced by manufacturers and suppliers of cosmetic products are increasing. This is mostly due to the rapid expansion of the global cosmetics market and greater consumer awareness of the possible adverse effects that such products might have on their health, as well as environmental and sustainability impacts. Civil liability may attach when a consumer has suffered injury or loss as a result of using a cosmetic product. In the UK, these claims are typically brought under the Consumer Protection Act 1987 (CPA), the legislation that transposed the EU Product Liability Directive into UK law, although consumers may also pursue claims in negligence or contract. As the CPA imposes strict liability on manufacturers, suppliers and importers of defective products, it tends to be the preferred route of redress for consumers because it does not require them to prove fault on the part of the manufacturer or supplier. Retailers, as well as other actors

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> SARAH-JANE DOBSON
> Kennedys

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>
> SAMANTHA SILVER
> Kennedys

across the supply chain, including importers into the UK, wholesalers and distributors, can all be held accountable under the CPA. Manufacturers and suppliers are also at risk of being held criminally liable for unsafe or non-compliant cosmetic products that breach product safety requirements. As responsible consumerism becomes increasingly prevalent, manufacturers and suppliers may also be exposed to civil actions brought in response to greenwashing, the practice of making unsubstantiated or misleading claims about a product's environmental, social or sustainability credentials. These types of greenwashing actions could also be brought in respect of an alleged breach of implied terms owed under the Consumer Rights Act 2015 which, for example, requires the product to comply with the description given at the time of sale.

FW: Are there any emerging liability trends that the cosmetics industry should be aware of?

Ciclitira: Growing concerns by consumers, environmental activists and regulators over the presence of PFAS in a vast array of consumer goods is giving rise to a heightened litigation risk in the UK and EU. The risk is particularly prevalent in the EU in light of new laws enabling cross-border collective actions, combined with the increasing availability of litigation funding in Europe. PFAS, often described as 'forever chemicals' due to their environmental persistence, are used by producers of cosmetics and personal care products because of their water and oil resistant properties. Earlier this year, the EU looked set to ban the use of around 10,000 PFAS, in line with the aims of the European Green Deal. However, recent media reports indicate that it is expected to backtrack on its promise following political and industry pressure. In April 2023, the UK's Health and Safety Executive, as the Agency for UK REACH, published its 'Analysis of the most appropriate regulatory management options (RMOA)' for PFAS which makes recommendations, including potentially limiting the use of PFAS in certain products including firefighting foams, textiles, furniture and cleaning products. Although there is no explicit recommendation to limit PFAS use in cosmetics, the report cautions that restrictions could, in the future, be proposed in relation to other consumer articles if other gaps are identified in consultation with other legislative regimes. While PFAS claims, including class action lawsuits, are a dominant feature of the US litigation landscape, they have only reached European shores recently. In the Netherlands, a class action was commenced in September against a US chemical company, and its former parent company, alleging that it had been deliberately and illegally contaminating the environment with PFAS for decades, causing environmental damage and injury to human health. Notably, a Dutch court recently found that US company liable for environmental damage in related proceedings that had been commenced by four local municipalities several years ago. Similar group action proceedings have also been brought in France against a chemical company by local residents. While claims in Europe have to date focused on alleged environmental contamination by PFAS, we expect to see allegations of misrepresentation or misinformation in relation to PFAS in the future, particularly in light of the developing regulatory framework around greenwashing. This may be in connection with a particular product's safety or environmental credentials, or the product's ingredients or formulation, as stated on the packaging label. Such allegations have already featured in some of the PFAS litigation brought in the US; for example, a class action lawsuit brought against a global cosmetics company in April 2022 concerned allegations that it had misleadingly marketed its products, which contained PFAS, as clean and natural.

FW: How important is for manufacturers of cosmetics products to conduct rigorous risk-based safety evaluations? What are the key aspects of this process?

Bahra: Before placing a cosmetic product on the UK and EU markets, a Cosmetic Product Safety Report (CPSR) must be undertaken to demonstrate that a cosmetic product is safe for human health when used under normal or reasonably foreseeable conditions, among other requirements. The safety assessments of cosmetic ingredients and products are based on an evaluation of certain key characteristics of the product including the composition, characteristics and stability of chemicals, microbiological quality, impurities and traces, and foreseeable use and exposure of consumers to the cosmetics. As a minimum, the CPSR must include sections containing cosmetic product safety information and a cosmetic product safety assessment. The latter should be performed by a person in possession of a diploma or other evidence of formal qualifications awarded on completion of a university course of theoretical and practical study in pharmacy, toxicology, medicine or a similar discipline. The issue of qualification has been hotly debated post-Brexit with qualifications within and outside of the EU being treated differently generally by the EU and UK regimes.

FW: What steps do manufacturers need to take to ensure the chemical properties of their cosmetic products are compliant with the requirements of the EU Cosmetics Products Regulation 2009?

Dobson: The EU and UK's chemical regimes, known to be particularly onerous, attach to the supply of chemicals themselves, and have wide reaching impact by placing obligations all the way down the supply chain to raw material suppliers. For example, chemical-specific regimes such as REACH, Regulation (EC) No 1272/2008, which sets out classification, labelling and packaging requirements (CLP), and the Persistent Organic Pollutants (POP) Regulation to restrict use of POPs are applicable to chemicals supply and use in the EU and UK. Furthermore, the UK and EU cosmetics product regimes explicitly contain a list of substances which are prohibited from inclusion or are restricted in use as a chemical within a finished cosmetic product. The provisions within the 2009 Regulation that relate to chemicals are not always immediately apparent, and

this confusion has been the source of much criticism from the cosmetic industry over the years. In particular, the position on animal testing, being expressly banned in the 2009 Regulation, but being required or allowed in some instances under REACH for purposes other than consumer safety, such as worker safety or environmental matters, for example, has been a particular source of contention. Decisions made by the chemicals regulators and agencies have simultaneously required animal testing in the chemicals regime. This is directly at odds with the ban in the cosmetics regimes. The UK's departure from the acceptance of animal testing under the chemicals regime is therefore a significant development, and could be a turning point for the UK's increased attractiveness for cosmetics businesses going forward.

FW: What advice would you offer to cosmetics manufacturers on effectively managing the regulatory burden in the years ahead?

Dobson: Cosmetic companies wishing to future-proof their businesses in the EU and UK can take numerous proactive steps to do so. First, companies should ensure they keep abreast of the direction of travel of regulatory trends. The focus on the prohibition or restriction of specific ingredients or chemicals is often foreshadowed by long, industry-wide debates and a protracted legislative process. There are often opportunities for companies to partake in the direction of travel of such legislative developments in this way, including by way of participating in ingredient consortia, designated under the Cosmetics Regulation, of 'higher risk' ingredients. Horizon scanning should not be limited to cosmetic products, particularly in the knowledge that the cosmetics industry regularly borrows concepts from other industries, for example the use of food contact material principles in packaging for cosmetics in the EU and UK. Companies should also engage in proactive market-surveillance activities to continually monitor the performance of their products in the field and take steps to mitigate or avoid product safety risks to avoid adverse incidents, and related reporting obligations, or fully-fledged consumer-facing recalls, which can have long-lasting negative impact on brands. Sophisticated traceability tools are also recommended, given the frequent need in modern times to trace and at times recall products in the hands of consumers. Companies should consider the use of novel methods of communication with consumers, including via new technologies if relevant. Global companies should be mindful of keeping their distribution models under review, ensuring geographical reach is only as intended and where products are fully compliant, with geo-blocking or other active practices being undertaken to prevent sales taking place where that is not the case. ■