2022 product liability and product safety forecast: trends and future risks

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Kennedys

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Foreword

There can be no doubt that product innovation made its mark in 2021. Whilst COVID-19 vaccines may have taken centre stage, the development of emerging technologies continued to gather pace, penetrating every industry sector as businesses sought to recover and rebuild following the mammoth disruption caused by the pandemic. In 2022, we expect to see an acceleration of this drive to innovate.

In the midst of one of the most turbulent periods for global supply chains, product manufacturers are turning to new and alternative methods to strengthen their networks and mitigate risk, including the use of e-commerce and artificial intelligence (AI).

We have seen the beginnings of an evolution of the regulatory and civil liability landscape in the wake of Brexit, with UK and EU governments and regulators seeking to modernise the existing laws and regulations that underpin product liability and safety so that they are fit for the future.

This drive for change has revived and strengthened corporate awareness of corporate social responsibility (CSR), environmental issues and sustainability, with significantly increased focus on these concepts in the context of product compliance and safety.

The approval of the EU Representative Actions Directive in December 2020 has the potential to change the product liability litigation landscape, paving the way for future large scale domestic and cross-border consumer group actions against manufacturers and suppliers of allegedly defective or non-compliant goods.

The UK continues to follow the same direction of travel, having seen a surge in large scale group actions, particularly in the context of competition law and data breach. The increased use of remote and data driven products and technologies, and consequential complex risks and liabilities, provides fertile ground for future product related group actions.

Against this backdrop, we highlight recent legal and regulatory developments in the product safety and product liability sphere, and provide an overview of the key topics and trends that are likely to impact upon corporates and their insurers in the months ahead.

Legislative developments

Product safety and product liability reform

The proposed reform and modernisation of existing product safety and liability frameworks in the EU and the UK is expected to develop further over the course of 2022.

This will build upon a series of expert discussions and public consultations regarding how, and the extent to which, existing regimes need to be updated to ensure consumers are adequately protected against the risks posed by new technologies and modern supply mechanisms.

Product safety

The EU

The EU has led the charge for reform, showing a commitment to developing legislation that balances the promotion of innovation with consumer protection. Over the last year, there has been a raft of actual and proposed general product safety legislation.

The General Product Safety Regulation

In June 2021, the European Commission (EC) proposed revisions to the 20 year old General Product Safety Directive (GPSD) by virtue of the General Product Safety Regulation (GPSR).

The GPSR identifies various areas of improvement including market surveillance, product recalls, cybersecurity, online marketplaces and new technologies such as connected products and artificial intelligence (AI), most of which are subject to separate pieces of draft EU legislation which are currently being considered in parallel to the GPSR.

The GPSR remains under review by EU institutions following the European Parliament's proposed amendments published in December 2021 and a vote on whether to enshrine the GPSR in law is expected to take place in May 2022.

Implementation of the GPSR would significantly increase compliance obligations on businesses involved in all aspects of the product supply chain. The GPSR remains under review by EU institutions following the European Parliament's proposed amendments published in December 2021.

The Market Surveillance Regulation (MSR) (Regulation (EU) 2019/1020)

In July 2021, the MSR came into force to bring online platforms (OPs), including online marketplaces, within the remit of the EU's product safety framework, establishing more robust processes for market surveillance, compliance controls and promoting closer cross-border cooperation among enforcement authorities.

> "The EU's expansion in mainstay product safety regimes of the concept of what is a 'safe' product, to include cybersecurity threats, coupled with the parallel development of increased regulation of overseas-based manufacturers and online selling practices, has increased legal exposure for all those involved in the manufacture and supply of these products. The UK is likely to follow suit in its approach."
>
> ***Sarah-Jane Dobson, Partner, London***

Proposals to regulate AI

The safety and liability implications of AI has been one of the most debated topics in recent years. In April 2021, the EC published a landmark proposal for a regulation laying down harmonised rules on AI designed to complement existing EU legislation, such as the GDPR.

The EC's proposals were followed by the publication of a draft report by the European Parliament's Special Committee on Artificial Intelligence in a Digital Age (AIDA), which highlights that the EU should focus on fostering the enormous potential of AI. The report was adopted following a vote by the Special Committee on 22 March 2022 and there will be a plenary debate and vote in May 2022.

The UK

In a post Brexit era, the UK will not be directly impacted by reform of the EU's regime and it looks poised to depart further from the EU by seeking to modify retained EU laws and creating its own legal framework.

Reform of the UK product safety regulatory framework

The outcome of the Call for Evidence initiated by the Office for Product Safety and Standards (OPSS) in March 2021 makes clear that, although aspects of the existing product safety framework functions well, it is likely to be subject to extensive reform.

Although the UK Government is yet to publish draft legislation, reform is expected to simplify and strengthen the current framework, particularly in relation to new technologies, online and marketplace sales, enforcements, and sustainability and net zero targets.

> **Increased regulatory focus on product safety more generally could mean that any regulatory breach or regulatory non-compliance becomes a more central focus in a court's assessment of defect in future product liability claims.**

Product liability

The EU

The Product Liability Directive 85/374/EEC (PLD)

In tandem with the proposed reform of AI, the EC is also moving forward with its proposals to reform the PLD, the EU legislation on liability for defective products, so that it is suitable for the digital age and the circular economy.

A public consultation launched by the EC which concluded on 10 January 2022, sought views from interested stakeholders, including consumers, businesses and their insurers, to consider to what extent the PLD needs to be adapted to account for the digital age, including AI. Although the consultation outcome is awaited, draft legislation could be available by Q3 2022.

Areas of reform have the potential to be significant:

- Alleviation or reversal of the burden of proof for technically complex products, including AI.
- Expanding the scope of the PLD to cover intangible items such as digital content, software and data.
- Addressing defects resulting from changes to products after they have been put into circulation, e.g. software updates or product refurbishments.
- Removal of the 'development risk defence' for AI products, which was designed to shield producers from defects which arose in the course of innovation.

The UK

Consumer Protection Act 1987

The potential review and reform of the Consumer Protection Act 1987 (CPA), the implementing legislation which transposed the PLD into UK law, is being reviewed by the Law Commission of England and Wales as part of its 14th Programme of Law Reform, having recently invited views as to whether the CPA should be extended to cover all software and take account of tech developments.

The Law Commission's final programme of reform is expected to be published in the coming months, having recently invited views as to whether the CPA should be extended to cover all software and to take account of tech developments.

> "Some of the proposed areas of reform of the PLD are far-reaching and have the potential to completely revolutionise the EU product liability landscape. However, insurers in the EU have already cautioned against dramatic changes to the PLD that could make it difficult to insure certain risks, particularly in respect of AI technologies.
>
> The UK Law Commission's review of the CPA 1987 remains in its infancy which may give it the advantage of waiting to see whether the EC's draft proposals to amend the PLD are revolutionary, or merely revisionary."
>
> ***Samantha Silver, Partner, London***

Sector specific legislative reform

The proposed modernisation of the EU and UK product safety and liability regimes is complemented by the introduction of sector-specific legislation and regulation to ensure industry adapts and responds to innovation and new technologies.

The timing of Brexit, together with parallel legislative developments at EU and UK level, has meant the immediate divergence of UK law from EU law in some sectors, for example medical devices. This divergence is only at regulatory level and, at present, the liability regimes in respect of defective products remains aligned.

Life sciences

The EU

In May 2021, the Medical Device Regulations (MDR) (2017/745) came into a force following a one year delay owing to the COVID-19 pandemic. The MDR brought EU legislation into line with new technological advances in medical devices and changes in medical science.

Against the backdrop of perceived historical issues with medical device safety in Europe generally, the new laws aim to create a more robust, transparent, and sustainable regulatory framework, to improve clinical safety and to create fair market access for manufacturers and healthcare professionals.

The In Vitro Diagnostic Regulations (IVDR), which introduce a new mandatory regulatory framework for IVD medical devices (e.g. pregnancy tests, SARS-COV-2 tests) are due to take effect from 26 May 2022. They will be subject to a progressive roll out following long standing concerns raised by industry stakeholders that the implementation of these regulations would be extremely challenging in light of a shortage of notified bodies and the deployment of resources due to the COVID-19 pandemic.

The Regulation on Health Technology Assessment was adopted by the European Parliament in December 2021. It aims to assist EU Member States determine the effectiveness and value of new technologies, strengthen cooperation between Member States and quality of services, and improve the availability of healthcare technologies, including medical devices.

> “The timing of Brexit, coupled with the delayed implementation of the revised EU legislative suite on medical devices as a result of the COVID-19 pandemic, has meant the UK has maintained its existing medical device regime until a new, modern framework is put in place.
>
> This puts the UK in a particularly challenging position, resulting in medical device manufacturers being forced to incur additional costs in order to comply with both regimes when producing and selling products on the UK and EU markets.”
>
> ***Nathalie Smyth, Legal Director, London***

The UK

As the above EU regulations were made following the UK’s withdrawal from the EU, they do not apply in the UK. The Medicines and Medical Devices Act 2021 (MMD), which came into force in February 2021, seeks to address this regulatory gap. The MMD introduces targeted delegated powers in fields, including medical devices, to enable the existing regulatory frameworks to be updated post-Brexit and ensure that the UK remains at the forefront of the global life sciences industry.

The MMD aims to provide the UK with an easier regulatory route to move away from EU laws and to regulate these medical products via amendments to the existing laws in Great Britain. It also aims to enhance patient safety whilst encouraging innovation.

The focus on innovation was recently reflected in a report by the UK's independent Regulatory Horizons Council which heralds new technology as being a significant area of development for the UK medical devices industry.

From 1 July 2023 all medical devices placed on the market in Great Britain will be subject to new UK Conformity Assessed (UKCA) mark requirements. However, CE marked medical devices will continue to be accepted until 30 June 2023.

In September 2021, the MHRA published its Software and AI as a Medical Device Change Programme as part of an ambitious programme of reform. This included a consultation on the future regulation of medical devices in the UK with a view to updating the Medical Devices Regulations 2002.

The consultation closed on 25 November 2021 and the outcome is awaited. In line with other areas of proposed reform, the MHRA announced that it intended to address regulations applying to software and AI as a medical device in the form of an extensive work programme.

Automotives

The automotive industry continues to develop its regulatory and legislative framework in response to fast technological advancements and ever growing environmental considerations.

Autonomous vehicles

With autonomous technology advancing at pace, the EU and UK have taken steps to introducing a regulatory framework to facilitate the safe deployment and commercialisation of driverless vehicles.

In the EU, against a backdrop of policy and legislative developments at national level, the EC is working on a draft regulation, first published in March 2021, to establish EU wide rules for the type-approval of fully automated vehicles with regard to the automated driving system (ADS).

The legislative process includes a public consultation which opened in November 2021. Developments are expected later this year.

In the UK, the Law Commission of England & Wales and the Scottish Law Commission (the Law Commissions) published their joint report on Automated Vehicles on 26 January 2022 following a three-year review.

The 75 recommendations in the report include the introduction of a new Automated Vehicles Act to provide a new regulatory and legal framework for automated vehicles, building upon the Autonomous and Electric Vehicles Act 2018 which imposes liability on an insurer for damage caused by an insured automated vehicle.

Whilst insurers may bring a claim against the vehicle producer under the CPA, the Law Commissions recognise that there are difficulties as to how the CPA applies to new technologies and urges the UK Government to review the way in which product liability laws apply to new technologies generally, not just automated vehicles.

Electric vehicles (EV)

With governments aiming for net-zero carbon emissions, the EV market is expected to continue growing at a rapid pace ahead of the 2030 ban on new petrol and diesel vehicle sales.

Sophisticated connected and automated technologies and software incorporated within EV systems could give rise to increased potential for cyber risks, including malicious cyber-attacks on EVs and their charging stations, with potential safety implications for EV users. Segmentation technology has been proposed and the Electric Vehicles (Smart Charge Points) Regulations 2021 should help to reduce this associated risk.

> “Although product liability insurance is likely to be the main focus for EV related losses, other types of liability insurance (such as employers’, public, cyber, motor, property and environmental) could also be affected.”
>
> ***Karishma Paroha, Legal Director, London***

For more details on autonomous and electric vehicles, please see our 2022 motor transport forecast: trends and future risks report.

Chemicals

UK REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals), the UK’s parallel regulatory framework to EU REACH for the management of chemicals in Great Britain post Brexit, is expected to be subject to further reform this year following concerns raised by stakeholders in relation to its operation. In particular, the registration process has resulted in importers and distributors of chemicals having difficulty in assessing and fulfilling their obligations under the regulation.

The Department for Environment, Food & Rural Affairs (DEFRA) will consult this year on extending the first UK REACH registration deadline from 2023 to 2025 and will explore alternative information requirements.

In the EU, on 20 January 2022, the EC launched a public consultation seeking views on the proposed revision of EU REACH aiming to align the EU chemical rules with the EC’s ambition for safe and sustainable chemicals and a high level of protection of health and the environment, while preserving the internal market.

The consultation is wide in scope and covers a range of topics including the revision of registration requirements, such as establishing the obligation to register polymers, simplification of communication in supply chains and the revision of provisions for control and enforcement.

Construction

The Building Safety Bill

In July 2021, the then Housing Secretary Robert Jenrick unveiled further plans to reform building safety with the publication of an updated version of the Building Safety Bill 2021 (the Bill), who described the Bill as "the biggest improvement to building safety in 40 years". The Bill is a crucial part of the UK Government's building safety reform programme and represents a significant overhaul of the regulatory regime, making wide-ranging changes to building regulation, management and law.

A key part of the Bill is the creation of a new Building Safety Regulator – being the Office for Product Safety and Standards (OPSS) - within the Health and Safety Executive (HSE).

The Bill continues to be subject to new amendments, including in relation to limitation periods for building safety claims and cladding.

> "The UK has historically led the way in terms of specialist regulators and hierarchy amongst its product safety regulators, notably by introducing the first overseeing generalist product safety regulator in Europe in 2018 and the first US-like (CPSC) regulatory body. The introduction of a new product-specific regulator for construction products, alongside a revised product-specific safety regime, heralds a new age for the construction sector, and adds further strength to the UK's world-renowned product safety regulatory regime."
>
> ***Sarah-Jane Dobson, Partner, London***

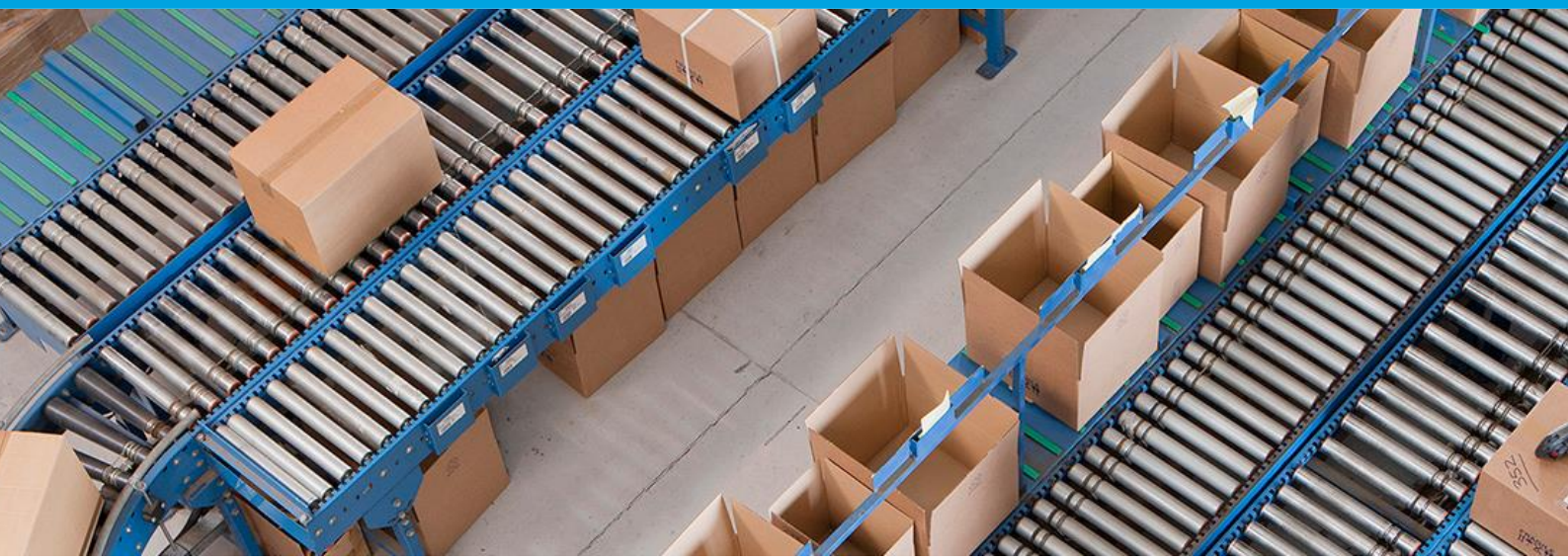
Construction Products Regulations 2022

With a view to improving the safety of products used in the construction industry are the proposed new Construction Products Regulations (the Regulations), published in October 2021, will complement the Building Safety Bill.

The Regulations provide that manufacturers, importers and distributors must not market construction products in the UK unless they are safe products. The term 'safe product' will be defined in the Regulations as a "construction product which, under normal or reasonably foreseeable conditions of use does not present any risk to the health and safety of persons; or if it does, the risk is as low as it can be compatibly with using the product".

> **The Regulations seek to strengthen the existing market surveillance and enforcement regime for construction products, so that compliance can be monitored and enforcement can be taken by the Regulator, the OPSS, where necessary.**

For more detail on construction developments, please see our 2022 construction forecast: trends and future risks report.



Key topics to watch in 2022

CSR, environmental issues and sustainability

Against a backdrop of green and sustainable initiatives such as the EU Green Deal 2019 and the Circular Economy Action Plan 2020, in which the UK partook prior to Brexit, and the recent 2021 United Nations Climate Change Conference (COP 2026), CSR, environmental and sustainability considerations are increasingly becoming the backbone of company policy and strategy and are integral to core business activity across all sectors.

The shift in the way these concepts are viewed and adopted are in line with the general direction of travel towards sustainability being embedded into the corporate governance framework.

This is reflected in the UK's proposed amendments to the Modern Slavery Act 2015 which seek to tackle modern slavery risks across supply chains and also in the European Commission's (EC) recently proposed Directive on corporate sustainability due diligence which seeks to address the human rights and environmental impacts of global value chains by placing onerous obligations on EU and non-EU companies and improving access to remedies for those impacted as a result of corporate behaviour.

"The conceptualisation of ESG issues as core product compliance and safety matters has been developing slowly over a long period of time. Perhaps because of this organic growth, obligations applicable to manufacturers and supply chain operators alike are not always obvious, even for the best-intentioned and most well-heeled companies, because they are contained within discrete pieces of legislation.

Whilst growing subject-matter specific legislation continues to develop to address this topic, therefore, the next phase of legislative development is to have these issues properly reflected in the mainstay product compliance and safety laws. The joining up of related pieces of subject-matter legislation, such as the EU Corporate Due Diligence Regulations, with existing and overarching obligations in respect of product safety, will also need to be undertaken to ensure important ESG initiatives are not at the expense of innovation."

Sarah-Jane Dobson, Partner, London

Packaging and waste

In the products sphere, there has been a broadening of compliance obligations to incorporate concepts of CSR, environment and sustainability, with a particular focus on reducing plastic packaging and waste.

- The Environment Act 2021 described by the UK government as "world-leading legislation" empowers the government to make targets, plans and policies for improving the national environment including addressing waste and resource efficiency, air and water quality, and nature and biodiversity with cross-sector impact. National authorities will be empowered to introduce regulation which aims to eliminate avoidable waste by 2050 by introducing robust measures such as making producers responsible for the disposal of waste products and charges.
- Plastic Packaging Tax (PPT) - As of 1 April 2022, manufacturers or importers of plastic packaging products into the UK may be liable under Part 2 of the Finance Act 2021 to pay a tax on those products, known as PPT. The introduction of PPT follows the EU's introduction of a levy on non-recycled plastic packaging waste in July 2020 and reflects the growing trend toward sustainable practices across industries and the demand for greater corporate responsibility by large scale manufacturers, importers and their insurers. It aims to incentivise manufacturers and importers to incorporate more recycled plastic into its packaging with the ultimate goal of reducing plastic waste.

Stakeholders across the supply chain must become fully aware of their duties and obligations under this new legislation. Failure to comply could leave companies and their insurers exposed to civil and criminal penalties and consequential reputational damage.

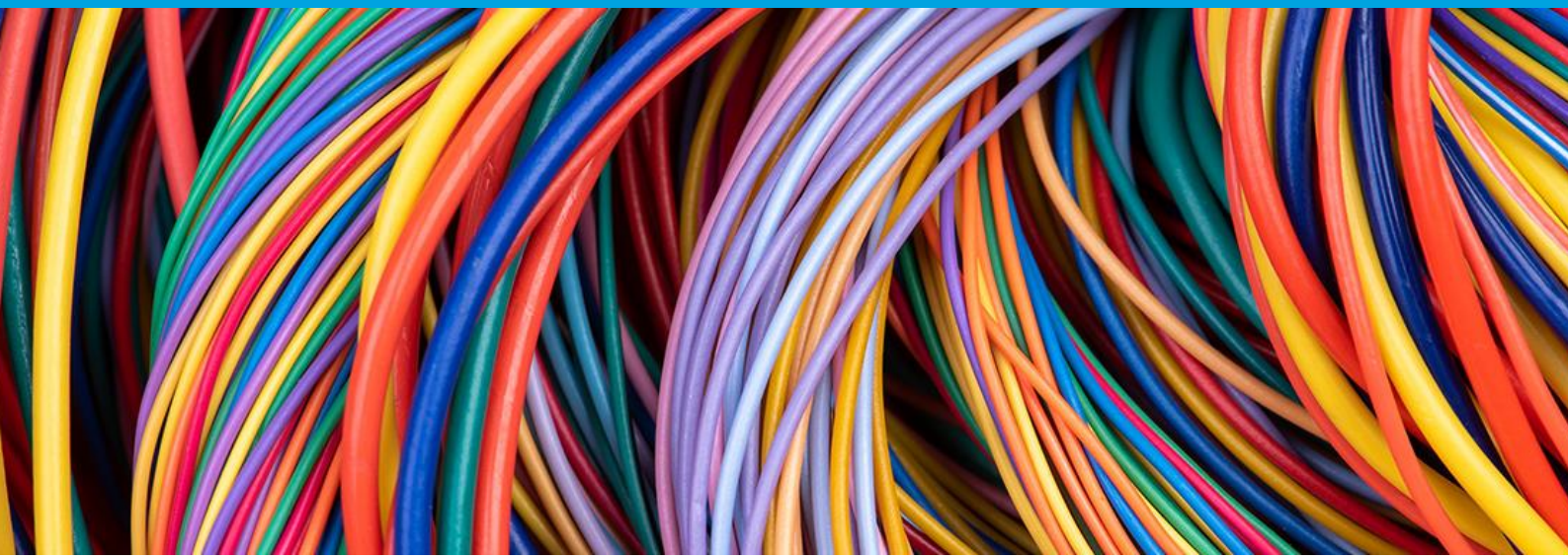
Further regulation in this area can be expected in the coming years following the passing of a Resolution on 2 March 2022 for the creation of the United Nations Plastics Treaty, a legally binding treaty designed to address plastic pollution on a global scale.

Cybersecurity and data risks

As industries operate in an increasingly digitised and interconnected world, the cybersecurity risks that product manufacturers and suppliers face continue to grow. Products encompassing new technologies, from smart medical devices to virtual reality gaming headsets and many others, are at risk of unauthorised access to data or malicious interference by third parties.

- In the UK, the introduction of the Product Security and Telecommunications Infrastructure Bill aims to protect connected consumer devices from cyber-attacks and introduces substantial penalties for non-compliance.
- In the EU, the EC's proposed Data Governance Act (DGA) encourages the safe sharing of data between businesses and making public sector data available for re-use, with a view to ensuring Europe is at the forefront of pioneering the innovative development of products and services in Europe.
- The DGA will be complemented by the Data Act, as proposed by the EC on 23 February 2022, which sets out new rules on who can use and access data generated in the EU across all economic sectors. The Data Act aims to ensure fairness in the digital environment, stimulate a competitive data market and open opportunities for data-driven innovation. In particular, it includes measures to allow users of connected devices to gain access to data generated by them, which is often exclusively harvested by manufacturers, and to share data with third parties. It also provides for safeguards against unlawful data transfer.

> "Where emerging, data-driven technologies are widely used by consumers, any vulnerabilities those technologies have to data breaches or third party interference will bring with them an exposure to the potential for group litigation.
>
> The data privacy action of *Lloyd v Google* saw the UK Supreme Court effectively put a



stop to the use of the opt-out representative actions procedure to bring class actions arising from alleged breaches of the Data Protection Act 1998, at least where an assessment of damages was required for each claimant. However, the decision left the position uncertain in relation to breaches of the UK GDPR and does not prevent such claims where a class can show uniform damage or distress.

With growing calls for a generic opt-out regime in the UK and the potential for interconnected products to give rise to large numbers of claim even on an 'opt in' basis, group litigation in the products/data privacy space remains a real and possibly growing risk for businesses and their insurers. ”

Barnaby Winckler, Partner, London

Diversity and inclusion (D&I)

With D&I continuing to be a priority for businesses, manufacturers and industry stakeholders are becoming increasingly mindful of the importance of diversity in innovation. Product design and development is naturally strengthened by the employment of a diverse workforce comprising individuals from a variety of backgrounds, who bring differing life experiences, views and perspectives to the table.

Not only does the underrepresentation of gender, ethnic minority groups and race in innovation risk a product being used by a significantly reduced consumer cohort, there can be significant safety implications for users as a consequence of such bias. For example, vehicle test crash protocols involving dummies modelled on the average male risks a car not being properly designed to ensure the safety of women and children.

In the life sciences arena, bias in product design, testing and clinical trials may result in some devices and medicines not being as effective on certain patient groups.

> **In the context of new technologies, such as AI, companies are at risk of discriminating against certain groups if data sets are narrow or algorithms are biased.**

This has been recognised by the UK's Information Commissioner's Office (ICO) which is developing an AI Auditing Framework to mitigate discrimination risk in AI models.

In the UK, the Equality Act 2010, the Human Rights Act 1998 and sector specific anti-discriminatory laws offer individuals protection from discrimination, whether generated by a human or automated decision-making system. All UK agencies have a non-delegable duty to document anticipated and potential algorithmic discrimination prior to use. The GDPR also allows people to opt out of fully automated decisions.

In the EU, the EC's proposal for a regulation on AI recognises that technical inaccuracies of AI systems can lead to bias and discriminatory

effects, particularly in respect of age, ethnicity, sex or disabilities.

> “A failure by companies to take these issues into account when developing products could lead to future claims and reputational damage. Seeking to minimise and mitigate human prejudicial bias within their AI models should be a priority going forward.”
>
> ***Karishma Paroha, Legal Director, London***

Perfluoroalkyl and Polyfluoroalkyl substances (PFAS)

PFAS, often referred to as 'forever chemicals', are a complex and expanding group of man-made chemicals found in a variety of products used by consumers and industry, including cosmetics, clothing, food packaging, cookware, cleaning products and fire-fighting foams. The chemicals have recently been under the scrutiny of various stakeholders across the globe, culminating in a series of international noteworthy legal and regulatory developments, because of their alleged impact on health and the environment.

In the EU, PFAS are subject to stringent regulation, including REACH restrictions, the Classification, Labelling and Packaging Regulation and the Drinking Water Directive. The EC has also pledged to phase out all PFAS, allowing their use only where they are proven to be irreplaceable and essential to society.

It remains to be seen whether the UK will take a similar approach although the Health and Safety Executive (HSE) opened a call for evidence on PFAS to support a regulatory management options analysis conducted under the UK REACH regime, seeking views on all aspects of the manufacture, import, hazard profile, use and exposure to PFAS. DEFRA has also identified PFAS as a priority group for action.

> “PFAS have been identified as one of the top emerging litigation risks. There have been rising concerns amongst businesses and the insurance market that PFAS contamination claims could expose companies and their insurers to unprecedented numbers of claims, including large scale class actions, similar to the asbestos-related claims pursued at the turn of the millennium.”
>
> ***Samantha Silver, Partner, London***

Fashion and textiles

Sustainable goods

ESG is currently at the forefront of the retail sector, including the fashion industry. In the US, the fashion industry’s commitment to sustainability has recently been encompassed into proposed legislation in New York State through the Fashion Sustainability and Social Accountability Act, introduced on 7 January 2022. The Act seeks to hold fashion’s biggest stakeholders to account for their environmental and social impact and will be world leading legislation, if passed.

Although the EU and UK are yet to introduce fashion-specific legislation, they are following a similar direction of travel to the US. As part of a broader package of ESG focussed initiatives relevant to the retail sector, the EC held a public consultation on the development of an EU Strategy for Sustainable Textiles to facilitate a shift towards a climate-neutral, circular economy, where products are designed to be more durable, reusable, repairable, recyclable and energy-efficient.

The EU’s strategy document is expected to be published in the coming months. Similar initiatives have also been launched in the UK, including Textiles 2030, an ambitious programme for sustainability in clothing and textiles.

> “While we wait and see what the EU’s proposals will be, future legislation is likely to be complex and will require greater transparency that will necessitate quick and expensive changes. Companies falling foul of any future legislation could potentially see large penalties if found in breach.
>
> Until then, companies have the opportunity to develop robust reporting processes that demonstrate their claims of sustainability are truthful and avoid accusations of greenwashing.”
>
> ***Elaine Barker, Senior Associate, London***

Smart clothing

Smart clothing is also starting to become more mainstream, with garments interacting with the user to track their heart rate, health data and movements as well as providing the ability to interact with music and other apps without requiring the user to reach for their phone. The collation and processing of health data is classed as sensitive data under EU’s mainstay data privacy legislation, the GDPR, which was implemented into UK law prior to Brexit.

As with any smart device, cybersecurity, data breaches and privacy are risks arising from the use of smart clothing.

Manufacturers, importers and distributors of smart clothing and/or smart technologies incorporated into clothing may have liability exposure if steps are not taken to ensure that the devices are properly safeguarded against such risks.

Food

Lab-grown meat

The food and beverage industry has been no exception to the use of new technology in its mission to develop more sustainable food products. With consumers showing an increased interest in the environmental impacts of their food choices, the industry is looking at new ways to replicate the animal based products that consumers have enjoyed eating for most of their lifetime.

Lab-grown meat, also known as cultured meat, has been in development over a number of years and involves the harvesting of cells extracted from living animals to produce meat, poultry and fish, without necessitating the death of an animal.

Recent research by the UK’s Food Standards Agency suggests that up to a third of UK consumers are willing to try lab-grown meat. The Good Food

Institute's 2020 State of the Industry report on Cultivated Meat also states that investment in lab grown meat was in the region of £257 million ($350 million).

Whilst lab-grown meat has real potential to revolutionise the agricultural and food industries, it also presents risks:

- The industry will be highly regulated. Manufacturers, suppliers and their insurers will need to be aware of the evolving regulatory landscape in this area. In the UK and EU, lab grown meat will be considered a novel food and will need to be registered and approved by the UK's Food Standards Agency (FSA) and the European Food Safety Authority, unless Genetically Modified Organisms are used in the production process which is subject to a separate regulatory regime.
- Lab-grown meat products will need to be advertised in accordance with the Advertising Standards Authorities' guidance and will need to ensure that any claims about the product are not misleading to consumers.
- Product recall and consequential liability risks may also arise in the future if a product is found to cause illness.

Allergens and food labelling

As of 1 October 2021, labelling requirements for 'prepacked for direct sale food' (PPDS) changed in England, Wales and Northern Ireland, following a campaign by the family of a teenager who died after suffering from an allergic reaction to a sandwich.

The objective behind the legislative change was to increase the level of information on allergens and strengthen protection for consumers, bearing in mind the severity of some allergies which can be potentially life threatening. Prior to October 2021, allergen information for PPDS food was arguably less stringent and could be provided by any means – including orally – to consumers.

On 6 December 2021, the FSA launched a consultation on precautionary allergen labelling and information. This covers the wording "may contain" which can be found on the label of a lot of food in England, Wales and Northern Ireland.

The consultation, which was primarily directed to food businesses, consumers, etc. closed on 14 March 2022. The outcome is expected to lead to a proposal for a more stringent set of requirements, such as more systematic and explicit wording and a single set of rules that apply across the board in the future.

The framework may also move away from the current voluntary basis and make it more prescriptive for food businesses, leading to increased costs and potential claims in respect of non-compliance.

Genetic technologies and Genetically Modified Organisms (GMOs)

Following a public consultation last year on the regulation of gene edited (GE) organisms, the UK looks set to diverge from the EU following the introduction of draft legislation, the Genetically Modified Organisms (Deliberate Release) (Amendments) (England) Regulations 2022, due to come into force in the coming weeks.

Current EU legislation controlling the use of GMOs, which was retained in the UK at the end of the Brexit transition period, requires all GE organisms to be classified as GMOs, irrespective of whether they can be produced by traditional breeding methods.

The UK Government's view is that where genetic alterations and combinations are of the type that are selected for in traditional breeding, the environmental release of those plants should not be regulated in the same way. This is because it is the environmental release of GMOs as the characteristics of the end-product that determine

its risk to human health and the environment, not how they were made.

This will enable products containing genetically modified organisms that could have occurred naturally or through traditional methods to be released for non-marketing purposes, i.e. not for consumer sale or food, enabling the UK's bioscience sector to further test the benefits and safety of the new products, without unnecessary regulatory red tape.

The degree of regulation of these products globally is growing increasingly disparate, with countries often adopting more or less stringent approaches dictated by the general consumer views of GMOs. The requirement for labelling to note the existence of GMOs, and the nature of such labelling (as a 'warning' in some countries in Latin America for example), often reflects these consumer sentiments also. The legal landscape for regulatory or litigation in respect of GMOs is no doubt equally tied the country-specific views of these novel food technologies.

> "GMOs have historically been treated with caution by consumers, including partly due to negative media coverage of the topic. The requirement to allow consumers to make informed decisions, based on clear labelling, is therefore paramount to the more widespread introduction of GMOs globally.
>
> Whilst it remains to be seen whether consumers would accept the same, it is clear that countries that are seeking to reduce regulation of GMOs in certain circumstances (like the UK), intend to rely more and not less on these novel technologies as food supply chains continue to be pressured post-global pandemic."
>
> ***Emilie Civatte, Senior Associate, London***

Cannabis

Cannabis-containing food has also been the subject of specific judicial focus and a particularly disparate approach from food regulators across Europe. Since January 2019, it has been listed as a 'novel food' under EU Regulation 2015/2283 and therefore subject to safety assessments and market authorisation before entering the EU market.

In cases where CBD products have been sold from 1 April 2021 in UK without the requisite approval, local authorities will be responsible for enforcement of the novel food regulations and will make specific enforcement decisions based on the facts of individual cases and circumstances. These may include a fine and/or in rare instances imprisonment.

As the ever-changing regulatory landscape for cannabis products continues to evolve, there is scope for disputes and corrective actions such as product recalls.

Key contacts | get in touch

If you would like to discuss any of the issues raised in this report in more detail, please reach out to your Kennedys client relationship partner or get in touch with any of the contacts listed below.

To find out more about our services, expertise and key contacts, visit our website.

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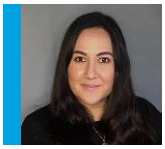

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