Regulatory Outlook

Welcome to the Regulatory Outlook, providing you with high-level summaries of important forthcoming regulatory developments to help you navigate the fast-moving business compliance landscape in the UK.

Developments to keep an eye out for include:

- The UK Equality and Human Rights Commission has published guidance on menopause in the workplace, setting out an employer's legal obligations under the Equality Act 2010
- The UK government's response to its AI regulation white paper consultation confirms it will not introduce new legislation and will continue with its decentralised approach.
- The three European Supervisory Authorities (EBA, EIOPA and ESMA) have published the first set of draft technical standards under the Digital Operational Resilience Act (DORA).

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Advertising and marketing

EU Parliament and Council formally adopt their positions on directive to empower consumers for the green transition

The European Parliament has formally adopted a legislative resolution for a directive "empowering consumers for the green transition" at first reading. Following this, the Council of the EU has given its final approval for the directive. It will then be published in the Official Journal of the EU and will be subject to a transposition period of 24 months after it comes into force, to allow Member States to implement the changes.

The new directive will amend the Unfair Commercial Practices Directive and the Consumer Rights Directive to add new blacklisted offences related to greenwashing and the early obsolescence of goods and impose new information requirements regarding their sustainability (see more in the Products section).

It is designed to work together with the green claims directive which has recently been adopted by the Parliament's Internal Market and Environment committees and awaits the Parliament's vote at first reading.

EU Commission publishes the outcome of its influencer marketing 'sweep'

The EU Commission has published the results of its screening of social media posts from influencers. This "sweep" of influencer marketing content was conducted in cooperation with the Consumer Protection Cooperation (CPC) Network. See this Regulatory Outlook for background.

The sweep has found that non-compliance with existing advertising and consumer protection rules was rife. In particular, it concluded 80 per cent of influencers did not consistently communicate the content was advertising when they published commercial content. Even when such disclosures were present, they were often not visible during the entire communication and the influencers did not make use of existing platform labels, preferring to use more ambiguous disclosures such as "collaboration" or similar.

The sweep also concluded that influencers routinely acted as traders who advertised and sold their own products. However they were often not compliant with mandatory rules in this area. For example, 60 per cent did not consistently disclose that this material was advertising nor did they provide mandatory information, such as their contact details, in the event there was an issue with the product.

The results of the sweep will feed into the Commission's ongoing digital fairness fitness check of EU consumer law. In the interim, it has also set up a influencer legal hub to inform influencers of their obligations under the legislation.

ASA designated as regulator of online advertising of less healthy food and drink products

Using its powers under the Communications Act 2003, Ofcom has designated the Advertising Standards Authority (ASA) as a co-regulator for the online advertising of less healthy food and drink products until 31 October 2034. Under Ofcom's designation, the ASA will assess and determine whether an advertiser is in breach of the requirements in the 2003 Act in the first instance and publish guidance setting out how it intends to do this.

See this Insight for more HFSS updates.

CAP issues enforcement notice to non-UK based cosmetic surgery providers

The Committee for Advertising Practice (CAP) has issued an enforcement notice to non-UK based cosmetic surgery providers that advertise their services to UK consumers. This follows a number of enforcement actions by the ASA against ads which breached the UK advertising rules by: (i) failing to make potential risks of cosmetic surgery clear; (ii) trivialising the decision to undergo surgery; (iii) making misleading claims around safety; and (iv) making misleading claims about the credentials of doctors.

In its enforcement notice, CAP provides guidance on how marketers can ensure that their ads for cosmetic surgery abroad comply with the CAP Code. CAP has also set a deadline of 29 February 2024 for advertisers to ensure that their ads are compliant. After this, CAP intends to take targeted enforcement action to ensure consistent standards across the industry. CAP has also begun enhanced monitoring to identify and tackle irresponsible ads for cosmetic surgery procedures, using its Active Ad Monitoring system.

UK government's response to report on risks to sport and culture of NFTs and blockchain

Advertising and marketing

See Consumer law.

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Artificial Intelligence

Artificial Intelligence

UK updates

Government's response to AI white paper

The UK government has published its much-anticipated consultation response to its March 2023 white paper on pro-innovation approach to AI regulation.

The response reasserts that there will be no new AI legislation for the UK. Its approach to regulating AI remains softly-softly, with the emphasis on creating an innovation-friendly regulatory landscape. Existing regulators will apply their existing powers to matters involving AI falling within their jurisdictions.

The UK government has published a series of letters addressed to a number of regulators requesting them to update their strategic approach to AI and inform about the steps they are taking in line with the expectations in the AI white paper. The regulators must report by 30 April 2024.

A significant number of further government consultations and calls for evidence that businesses may wish to engage in are planned in specific areas. See more in our Insight, which also picks up on relevant comments from the House of Lords Communications and Digital Committee's report on large language models (LLMs) and generative AI, published a few days earlier.

UK AI and copyright voluntary code of practice dropped

In its consultation response on the AI white paper, the government has confirmed that it has not been possible to agree an effective voluntary code of practice to provide clarity on the relationship between intellectual property law and AI.

It has promised that it will soon set out further proposals on the way forward and flagged that it intends to explore mechanisms for providing greater transparency so that rightsholders can better understand whether content they produce is used as an input into AI models. Our Insight explores this topic in more detail.

Guidance on AI assurance

The UK Department for Science, Innovation and Technology has published guidance on AI assurance to assist organisations with understanding of the techniques they can use to ensure the safe and responsible development and deployment of AI systems.

The guidance explains the meaning of "assurance" in the context of AI: "*assurance measures, evaluates and communicates the trustworthiness of AI systems*." It also explains the role of AI assurance in the current UK regulatory framework in line with the AI white paper and states that it will play a crucial role in the implementation of the five core principles outlined in the white paper. The guide outlines some of the AI assurance mechanisms at introductory level.

ICO consults on generative AI and data protection

The UK Information Commissioner's Office (ICO) has announced a series of consultations on how UK data protection law should apply in relation to generative AI. It notes that it has listened to feedback that generative AI raises distinct questions to traditional models, such as:

- what is the appropriate lawful basis for training generative AI models?
- how does the purpose limitation principle play out in the context of generative AI development and deployment?
- what are the expectations around complying with the accuracy principle?
- what are the expectations in terms of complying with data subject rights?

The first consultation looks at "The lawful basis for web scraping to train generative AI models" and is open until 1 March 2024 with an online response form.

NCSC report on impact of AI on cyber security

Please see Cyber security.

Artificial Intelligence

EU updates

AI Act progress

On 2 February 2024, Member State representatives at the Committee of the Permanent Representatives of the Governments of the Member States to the EU (COREPER) voted to accept the final draft of the AI Act. On 13 February 2024, the EU Parliament committees accepted the near-final text. The text will now undergo the process of legal and linguistic amendments (including sorting out numbering).

These votes at technical level mean that formal adoption of the AI Act text by the Council and Parliament will be uncontroversial, with further challenges now very unlikely. The Parliament vote is likely to be on 10 or 11 April; the date of the Council vote is not yet known.

Overall it appears that the AI Act is on track to be enacted in the coming months – our prediction is that it will become law in early summer, with the first provisions coming into force (prohibitions on some categories of AI) near the end of the year.

Commission creates AI Office

The European Commission has issued its formal decision establishing the AI Office, as part of preparations for the AI Act. It will sit within the Directorate-General for Communications Networks, Content and Technology (DG CNECT), which leads on EU digital policy.

Under the AI Act, it will have a number of functions in relation to monitoring general purpose AI models for compliance and unforeseen safety risks. It will support the Commission in developing guidance, standards, codes of practice, codes of conduct, and decisions. It will also play a key role in governance across the national AI regulatory bodies appointed in Member States, as well as convening new fora (including for AI developers and the open source community) to ensure collaboration around best practice.

The decision to establish the AI Office entered into force on 21 February 2024.

Commission consults on competition in generative AI markets

The Commission has announced a consultation gathering evidence on the state of competition in generative AI (in tandem with a consultation on virtual worlds, or the metaverse).

It has invited "*all interested stakeholders*" to share their views by 11 March 2024. The call for contributions explains that it is undertaking "*a forward-looking analysis of technology and market trends to identify potential competition issues that may arise in these fields on how competition is working*".

International updates

Guidelines on responsible implementation of AI in journalism

The Council of Europe has adopted and published guidelines on the responsible implementation of AI systems at all stages of the production of news and journalism.

The guidelines aim to assist media organisations and media professionals implementing journalistic AI systems, AI technology providers and platform companies as well as member states and national regulatory authorities on how to create conditions for the responsible implementation of AI in journalism.

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Bribery, fraud and anti-money laundering

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Environment Agency launches new Economic Crime Unit

The Environment Agency has established a new Economic Crime Unit to combat money laundering and conduct financial investigations in the waste sector, made up of accredited financial investigators and financial intelligence officers and financial crime analysts.

The unit comprises two teams: the Asset Denial Team, focusing on account freezing orders, cash seizures, pre-charge restraints and confiscations; and the Money Laundering Investigations team, responsible for conducting money laundering investigations targeting environmental offences.

Businesses within the waste sector should ensure they are adhering to proper financial practices and reporting any suspicious activities. It is crucial that should the Economic Crime Unit launch an investigation into a business, that businesses cooperate with this and provide necessary information. We have a team of Osborne Clarke experts who can assist with investigations from an early stage, so please get in touch should you need assistance.

Progress of the Criminal Justice Bill

As previously reported, the Criminal Justice Bill, among other things, proposes to further expand the "*identification doctrine*" to allow companies to be held criminally liable for criminal acts committed by senior managers of the company, to apply to all criminal offences. The bill is now due to have its report stage and third reading on a date to be announced.

See the current version of the bill. Find out more about the expansion of the corporate criminal liability regime in our Insight.

Government response to Law Commission review of SARs regime

The government published its response to the Law Commission's 2019 report on anti-money laundering and the suspicious activity reports (SARs) regime, accepting or partially accepting 13 of the 19 recommendations made, including that the following should be retained:

- the consent regime;
- the "all-crimes" approach to reporting suspicious activity; and
- the current approach to authorised disclosures on international criminality.

The government intends to issue guidance on the operation of the mixed-funds clause within the Economic Crime and Corporate Transparency Act 2023.

Changes to Money Laundering Regulations

The Money Laundering and Terrorist Financing (Amendment) Regulations 2023 came into force on 10 January 2024, amending the Money Laundering, Terrorist Financing and Transfer of Funds (Information on the Payer) Regulations 2017(MLRs) by:

- changing the starting point for the assessment where a customer or potential customer is a domestic politically exposed person (PEP); and
- inserting definitions for "domestic PEP", "non-domestic PEP", and "enhanced risk factors".

See the explanatory memorandum.

The Money Laundering and Terrorist Financing (High-Risk Countries) (Amendment) Regulations 2024 came into force on 23 January 2024, also amending the MLRs by:

- redefining "high-risk third countries" as those countries identified by the Financial Action Task Force; and
- removing Schedule 3ZA, which contains a list of high-risk third countries for which enhanced customer due diligence measures were required under the MLRs.

See the explanatory memorandumhttps://www.legislation.gov.uk/uksi/2024/69/pdfs/uksiem_20240069_en_001.pdf.

Bribery, fraud and anti-money laundering

Guidance on money laundering reporting obligations introduced by ECCTA 2023

The Home Office published guidance setting out the government position on the additional defence against money laundering provisions, introduced by the Economic Crime and Corporate Transparency Act with the aim of helping reporters to optimise the reporting process.

FCA update on reducing and preventing financial crime

The Financial Conduct Authority (FCA) published an update on its work over the last 18 months in reducing and preventing financial crime, which it identified as a priority in its 2022 to 2025 strategy.

The update highlights data and technology, collaboration, consumer awareness and metrics as areas where further cooperation will help mitigate the threats from fraud and money laundering.

Among other things, the FCA's in 2024 work will focus on:

- supporting government proposals to reform the anti-money laundering supervisory scheme; and
- working with the Payment Systems Regulator to support the mandatory reimbursement of Authorised Push Payment (APP) fraud (which is expected to enter into force in 2024). See our Insight for more on the new rules.

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Competition

Competition

Competition beyond borders

In a recent speech, Sarah Cardell, chief executive of the UK's Competition and Markets Authority (CMA), highlighted the importance of international cooperation and communication in the field of competition law. She emphasised that, while competition authorities remain independent and sovereign in their decisions, maintaining positive relationships and sharing knowledge with fellow enforcement agencies is crucial.

This is an important reminder for businesses both of the extent of information sharing between competition authorities and the possibility of divergent decisions. These factors mean that it is often necessary to take a multijurisdictional approach to competition law advice, expanding the compliance burden.

For example, the CMA, European Commission, US and other national competition authorities have all been involved in reviewing several recent high-profile mergers, including Adobe/Figma, Amazon/iRobot and Illumina/Grail. Ms Cardell highlighted the potential for divergence between the decisions of competition authorities in these types of cases, where one authority may permit a merger that another blocks or requires substantial remedies before it is permitted. While noting the efficiencies in coordination between authorities, Ms Cardell emphasised that instances of divergence are inevitable and "*entirely proper*" given that each authority reviews the merger under a different set of regulations and with a view to assessing the anti-competitive effects in its own jurisdiction.

International cooperation extends beyond merger control. The CMA recently has collaborated with other authorities in investigating anti-competitive conduct – such as its investigation into the fragrances sector (including anti-competitive employment agreements). This investigation led to the CMA cooperating with the US Department of Justice and the Swiss Competition Commission. Ms Cardell noted that such cooperation is particularly important in digital markets as competition issues may arise across multiple jurisdictions and be addressed differently in each. The Digital Markets Act in the EU and the anticipated UK Digital Markets, Competition and Consumers Bill (DMCCB) in the UK are prime examples of this.

The DMCCB will grant the CMA significant powers to address extraterritorial agreements that have an anti-competitive effect on the UK market as well as compel relevant information to be provided by overseas companies.

Businesses need to be aware of the extent of information-sharing between competition authorities as well as the possibility of divergent decisions being reached. It follows that, for companies engaging in international M&A activity or facing investigations in more than one jurisdiction, it will be necessary to seek competition law advice in all directly-impacted jurisdictions.

Revised Market Definition Notice

On 8 February 2024, the European Commission adopted a Revised Market Definition Notice. The notice provides helpful guidance on how the European Commission defines markets, which will influence whether and how the Commission intervenes in investigations and mergers.

This is the first revision of the Market Definition Notice since its adoption in 1997. It reflects the significant developments in competition law enforcement as well as in market innovation over the intervening years, in particular the increased digitalisation and the new ways of offering goods and services, as well as the interconnected nature of trading platforms and commercial exchanges.

The revised notice now provides guidance on market definition in multi-sided platforms, an area where market definition is particularly difficult. Multisided platforms are where demand from one group of users has an influence on demand from another group of users (the notice suggests examples such as payment card systems and advertising sponsored platforms, although this could also include price comparison websites for insurance, flights or hotels). It introduces the concept of defining a multi-sided platform as being part of one market encompassing all its user groups or separate interrelated markets for products offered on each side of the platform depending on how it is used, which the Commission hopes will simplify cases.

Another area addressed by the notice is market definition in the presence of after-markets, bundles and digital ecosystems. These typically occur where the consumption of one product leads to the consumption of another connected product, especially where technological links (such as interoperability) exist between the two products.

The notice also permits markets to be defined in a more forward-facing manner. For example, it allows market definition to take account of expected transitions in the market structure. This suggests a more dynamic evaluation of a market, rather than focusing solely on market structure at the time of the assessment. Market definition may take into account short-term and medium-term changes in market structure. This includes situations where there is a reasonable probability of new product types emerging or changes in the definition of the relevant geographic market. These changes could be driven by upcoming technological advancements or regulatory changes.

Market definition plays a key role in the enforcement of competition law. It is the primary tool for determining and assessing market power, market concentration and dominance, and remains central to the assessment of merger activity and the analysis of competitive interaction generally. However, digitalisation and more complex markets and technologies are increasingly challenging a rigid approach to market definition and we are seeing regulators seek a more flexible methodology.

The principal changes and additions in the Revised Notice codify existing Commission and judicial practice and consequently do not represent a fundamental shift in approach. Nevertheless, the additional clarity in how the Commission intends to approach novel markets is welcome given the importance of market definition in competition law.

Although the CMA is not bound to follow the notice (or any post-Brexit judgments of the European courts), it is also likely to prove informative for market definition in the UK – particularly as there is no current indication that the CMA is working on its own update.

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Consumer law

Consumer law

UK government publishes response to its consultation on proposed changes to consumer law

The UK government has published its response to the Department of Business and Trade consultation on "Improving Consumer Price Transparency and Product Information for Consumers". See our Insight for background.

Based on the outcome of the consultation, the government announced that it will:

- Add fake reviews to the list of blacklisted commercial practices (civil liability only).
- Make platforms accountable for performing "reasonable and proportionate" steps to ensure reviews published on their pages are genuine. The government will work with the Competition and Markets Authority (CMA) on guidance setting out what "reasonable and proportionate" steps traders would be expected to take to remove, and prevent consumers from seeing, fake reviews. The CMA intends to consult on this guidance before it is finalised and published.
- Clarify the law on drip pricing by requiring that unavoidable ("mandatory") fees be included in the headline price or indicated at the start of the purchasing process. Variable mandatory fees will have to be included alongside the headline price together with information on how they will be calculated. The government has said that, at present, it does not intend to legislate for similar measures on optional fees.
- Undertake further stakeholder engagement on what consumer law obligations platforms should have to comply with, and how that should be publicly set out.
- Amend the Price Marking Order 2004 (PMO) and associated guidance. The proposed changes to the PMO include: (i) making mandatory the consistent use of unit pricing measures (which means eliminating current exemptions, so for example, all products sold by weight would have a price per kilogram); (ii) in light of the Deposit Return Scheme, to exclude the deposit from the selling price displayed, and make the deposit clearly displayed separately; the unit price would be calculated excluding the deposit. The government also aims to work with industry and enforcement bodies to improve legibility of price labels, for example, by setting out minimum font sizes for prices.
- Extend the power to make applications to the court for online interface and interim online orders to all public designated enforcers as listed in Part 3 of the UK Digital Markets, Competition and Consumers Bill (DMCC Bill). Such regulators include. among others. the Financial Conduct Authority, the Information Commissioner, Ofcom and the Secretary of State.

Additionally, the government confirmed that it will not be adding misleading environmental practices (greenwashing) to the list of banned practices as such actions are already against the law. However, it intends to work further with the CMA on this.

The DMCC Bill completed the committee stage in the House of Lords on 7 February 2024. Following a third reading in the House of Lords, the bill will return to the House of Commons where the Lords' amendments will be considered.

Provisional agreement reached on the right to repair

The European Parliament and the Council of the European Union have reached a provisional agreement on the right to repair directive. See this Regulatory Outlook for background.

Key consumer-related aspects in the directive include:

- Consumers would be provided with an opportunity to borrow a product while their own one is being repaired, or have an option to choose a refurbished unit as an alternative.
- The legal guarantee would be extended to an additional one-year for repaired goods.
- Each Member State would need to introduce at least one measure to promote repair.
- Consumers will have free online access to repair services at EU level as well as in each Member State.
- Consumers should be informed about a manufacturer's duty to repair.

These changes are in addition to the (already agreed in principle) proposals to amend consumers' statutory rights, such as that repair be prioritised over replacement. For the products angle of the directive proposal, which includes manufacturer obligations and spare part requirements, please see the Products section.

EU DSA applicable to all online intermediaries in the EU

Since 17 February 2024, the EU Digital Services Act (DSA) became applicable to all online intermediaries in the EU. See our Insight covering what the DSA is, to whom it applies, and what affected companies can expect.

UK government's response to report on risks to sport and culture of NFTs and blockchain

The Culture, Media and Sport Committee has published the UK government's response to the committee's report on the risks to sport and culture of non-fungible tokens (NFTs) and the blockchain. See this Regulatory Outlook for more information about the report.

In its response, the government rejects the committee's recommendation for a code of conduct for online marketplaces, including NFT marketplaces, to protect copyright owners and consumers. In the government's view, the law which regulates the liability of online marketplaces and other intermediaries (the "safe harbour" provisions) already provides sufficient protection against IP infringement, although it says it will *"monitor developments"*.

As for protecting consumers from harm in respect of the advertising and marketing of NFTs, and the committee's recommendation that any advertising regime should compel the whole of the advertising supply chain to take steps to mitigate those risks, the government emphasises that the Online Advertising Programme will have a targeted focus on tackling illegal advertising. It intends to introduce a new regulatory framework to address scam and fraudulent advertising, including in relation to NFTs. The government also notes the work of the Online Advertising Taskforce in relation to illegal advertising, the role of the Online Safety Act 2023 in addressing fraudulent ads and the introduction of new legislation bringing financial promotions of qualifying cryptoassets into the existing regulatory regime for financial promotions administered by the Financial Conduct Authority.

CMA announces review of loyalty pricing in supermarkets

The CMA has announced the launch of its review of loyalty pricing by supermarkets, which complements the CMA's work on tackling cost of living pressures in the groceries sector.

The CMA aims to assess whether:

- loyalty pricing is able to mislead consumers, such as whether loyalty pricing is a genuine promotion or as good a deal as presented;
- any groups of consumers are at a disadvantage as a result of loyalty pricing;
- loyalty pricing has any impact on consumer behaviour and competition among supermarkets.

The CMA expects to provide an update on its work in July 2024, and to complete the review by the end of the year.

Directive to empower consumers for the green transition: EU Parliament and Council formally adopt their positions

See Advertising and Marketing

EU Commission publishes the outcome of its influencer marketing "sweep"

See Advertising and Marketing.

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Cyber-security

Cyber-security

LockBit operations disrupted by international law enforcement

On 20 February 2024, Europol announced that a joint international operation between ten countries successfully disrupted the operations of the LockBit ransomware group "*at every level*" to reduce the ransomware threat to organisations worldwide. Last year, the National Cyber Security Centre (NCSC) warned that LockBit presented the greatest ransomware threat to businesses in the UK.

Law enforcement agencies have also released free decryption tools to help organisations recover files encrypted by the LockBit ransomware. See the NCSC statement.

To find out about how to respond effectively to a ransomware attack, register to attend an in-person cyber "tabletop exercise" where Osborne Clarke's cyber team will take you through incident response best practice.

Joint advisory about state-sponsored cyber attackers compromising critical infrastructure

On 7 February 2024, the UK and its allies issued a warning to critical infrastructure operators about the threat from cyber criminals "living off the land" (LOTL) – a cyber attack technique where criminals compromise the IT environments of organisations by using legitimate IT administration tools to avoid detection.

The advisory updates the warning sent in May 2023 on China state-sponsored activity against critical infrastructure networks.

UK critical infrastructure operators are urged to follow the recommendations in the new identifying and mitigating living off the land guidance to help mitigate, detect and prevent LOTL activity.

To stay up to date with the latest cyber security obligations, register for our Dipping into Data webinar on "Cybersecurity: navigating the developing legal landscape".

Potential delay to Cyber Resilience Act

The European Council and Parliament reached a provisional agreement on the Cyber Resilience Act (CRA) in November 2023. The CRA will introduce cybersecurity requirements for products with digital elements, requiring manufacturers to ensure products conform with minimum technical requirements and disclose certain cybersecurity aspects to consumers.

As previously reported, work will continue to agree the full text of the CRA. However, there was recent speculation that the CRA will be delayed until September or October 2024. We will provide further updates once more official news has been published.

New international initiative to tackle commercial cyber intrusion sector

On 6 February 2024, the deputy prime minister, Oliver Dowden, hosted a conference attended by 35 nations on the proliferation and use of commercial cyber intrusion tools and services such as hackers-for-hire.

In response to the cyber threat, the government launched the Pall Mall Process declaration, a new international agreement signed by a number of countries, industries and members of civil society and academia pledging to take joint action to tackle commercial cyber intrusion capabilities.

Government response to call for views on software resilience and security for businesses

The government published its response to the Department for Science, Innovation and Technology (DSIT)'s call for views on software resilience and security for businesses and organisations. Three key themes identified were:

- **setting clear expectations for software vendors** – the government plans to address this through the introduction of a voluntary code of practice for software vendors;
- **strengthening accountability in the software supply chain** – the government will address this by developing cybersecurity training aimed at UK procurement professionals, creating standardised procurement clauses for organisations to insert into contracts, working with the NCSC to publish content on the use of a Software Bill of Materials; and

- **protecting high risk users and addressing systemic risks** – by exploring the creation of minimum security requirements for organisations supplying software to the government and a government initiative to improve the resilience of free and open source software, working with the industry on incorporating best practice into government.

NCSC report on impact of AI on cyber security

The NCSC published a report assessing the future impact of AI on the cyber threat over the next two years and on how AI will affect cyber operations. The NCSC takes view that AI "*will almost certainly*" enhance the amount and impact of cyber attacks over the next two years in the UK and globally, because it enables cyber threat actors to analyse data faster and more effectively. AI also lowers the barrier for new cyber criminals: the NCSC finds that all cyber threat actors currently use AI to some extent.

Among other things, the report suggests that AI helps to lower the barrier to cybercrime by enabling unskilled threat actors to carry out effective reconnaissance and social engineering, finding that threat actors of all skill levels are currently using AI.

See the press release. The NCSC has also published guidance designed to help managers, board members, and senior executives to understand the cyber security risks and benefits of using AI tools within their organisations.

Call for views on new draft Cyber Governance Code of Practice

The DSIT published a new draft Cyber Governance Code of Practice that sets out actions directors and senior leaders should take to improve their cyber resilience. Among other things, it recommends providing training to employees to improve skills and awareness of cyber issues.

The government has launched a call for evidence on the draft code, which will closes on 19 March 2024. See the press release and the government's cyber resilience policy for business and organisations.

ESAs publish rules under DORA on classification of incidents and cyber threats

The three European Supervisory Authorities (EBA, EIOPA and ESMA) published the first set of draft technical standards under the Digital Operational Resilience Act (DORA), which aims to strengthen and harmonise the IT requirements and third-party risk management and incident reporting frameworks for financial entities. See the press release.

UK and Japan sign Memorandum of Cooperation on cyber

On 17 January 2024, Japan and the UK signed a Memorandum of Cooperation with the aim of deepening public-private partnerships in cyber at a National Cyber Advisory Board event. Topics discussed include securing digital supply chains, engaging businesses on cyber resilience and best practice recruitment to increase cyber skills in both countries.

Adoption of EU common criteria-based cybersecurity certification scheme

Please see Products.

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Data law

Data law

EDPB on the notion of main establishment – further erosion of one-stop-shop or merely clarification?

On 13 February 2024, the European Data Protection Board (EDPB) adopted an opinion on the notion of the main establishment of a controller in the EU under Article 4(16)(a) of the General Data Protection Regulation (GDPR). This is a cornerstone of the GDPR's one-stop-shop mechanism as it is key in determining which of the EU data protection authorities (if any) is the lead supervisory authority in cross-border data protection cases.

The EDPB's conclusions include that a controller's "place of central administration" in the EU can only be considered as a main establishment if it takes decisions on the purposes and means of the relevant data processing, and has the power to have such decisions implemented. As such, if decisions on the relevant processing are taken outside of the EU, there can be no main establishment and the one-stop-shop does not apply.

The EDPB also emphases that the burden of proof in relation to the "place of central administration" ultimately falls on the controller, pointing out that controllers have various ways of making/evidencing that determination, for example, in records of processing and privacy policies/notices.

EDPB's new website auditing tool

The EDPB has launched a new website auditing tool to help analyse website compliance with data protection laws. It is designed to assist both legal and technical auditors at data protection authorities, as well as businesses who would like to test their own websites.

The new tool allows users to prepare, conduct and assess audits directly by simply visiting the website in question. It uses free and open source software and is available for download.

ICO consults on its Enterprise Data Strategy – part of the ICO's 'show, not tell' approach

The UK Information Commissioner's Office (ICO) has launched a consultation to collect views on its draft Enterprise Data Strategy. The strategy sets out how the ICO will use the data it holds to inform and direct its corporate, regulatory and strategic priorities. Examples it gives of how it might make better use of data include:

- Translating data into insights using data visualisation tools; such as, by sharing insights around complaints data to help businesses proactively address potential issues and improve compliance, or using data to explore and evaluate the priority of new work requests (making best use of finite resources).
- Creating an "organisation 360 degree view" – the ICO says that by bringing together, or integrating data it has on an organisation into a single platform, potentially augmenting that with external datasets, and then making it available across the ICO's casework, audit, registrations and regulatory environment teams, it will be better able to make data-led decisions and more swiftly respond to emerging threats.
- Development of an AI-driven solution that is capable of swiftly assessing cookie banners on websites, thereby efficiently identifying and highlighting instances of non-compliance. Sound familiar (see above)?

The strategy document provides a fascinating insight into how the ICO is intending to use data and technology to drive efficiencies in how it regulates, with a view to having a greater impact using the (limited) resources available to it.

The ICO's consultation on its Enterprise Data Strategy closes on 12 March 2024. It intends to publish its final strategy and roadmap in May 2024.

ICO warns organisations to proactively make advertising cookies compliant

The ICO has received a positive response to its call to action, with 38 organisations having changed their cookie banners to be compliant and four having committed to reach compliance within the next month, out of the 53 organisations contacted. Others are working to develop alternative solutions, including contextual advertising and subscription models ("pay or OK").

The ICO is now turning to the rest of the top 100 websites, and then the next 100, and then the 100 after that…

The risk of ICO enforcement action arising from perceived non-compliance with the rules on cookies has increased significantly over the last few months, and will continue to be an area of focus for it through 2024.

Other EU data protection authorities have taken a similar stance on cookie banners; for example, the Dutch data protection authority has very recently issued new guidance on cookies, and has announced that it will intensify its oversight of the use of cookies – for more on this, please see our recent Insight.

New guidance from the ICO on content moderation and data protection

With the enactment of the UK Online Safety Act 2023 (OSA), which places duties on online platforms to protect online users from harmful content, the ICO has published new guidance to assist online platforms to comply with the UK GDPR and the Data Protection Act 2018 (DPA) when undertaking content moderation. This follows the ICO's call for views on the subject in June 2023 and is the first in a series of products it intends to publish to ensure regulatory consistency between the data protection and online safety regimes.

The guidance looks at what content moderation is and how personal data fits in. It also provides useful clarity for organisations on the appropriate lawful basis for processing personal data for content moderation activities, how to ensure compliance with data protection law principles (such as transparency and data minimisation), and the application of automated decision-making under Article 22 of the GDPR. This guidance forms part of the ICO's ongoing collaboration with Ofcom on data protection and online safety technologies. For more information on online safety regulatory developments, please consult our Insights.

Organisations that carry out content moderation, whether for compliance with new online safety laws or otherwise, should consider the ICO's guidance alongside their own data protection practices.

Responsible sharing – ICO announces campaign on sharing data to protect children

The ICO has announced a campaign titled "Think. Check. Share." which aims to show how data protection law can help organisations share personal information responsibly when required to safeguard children and young people.

As part of the campaign, the ICO has developed a toolkit of free resources to promote responsible data sharing, which includes posters, videos, infographics and content for social media.

On a similar theme, the ICO published a blog in December 2023 on data sharing within the housing sector, in which it sought to "*bust some data sharing myths that might mistakenly prevent an organisation from safeguarding its residents*".

The ICO is keen to emphasise that data protection law provides a framework for making decisions about sharing data appropriately; it is not a barrier to sharing information when needed.

House of Lords Committee on the Constitution publishes report on DPDI Bill

The Data Protection and Digital Information Bill (DPDI Bill) is currently at the committee stage in the House of Lords having previously passed through the House of Commons and two readings in the Lords.

The Lords' Committee has now published its report on the DPDI Bill, in which it has raised a number of comments, including on the following issues:

- the breadth of the secretary of state's power of discretion to determine and vary the conditions under which personal data can be processed;
- the broadening of the basis for refusal of a data access request on a *"vexatious or excessive"* request;.
- inadequate definition of key terms; and

- lack of information regarding the removal of "proportionality" requirements when assessing the impact of "high risk processing".

The DPDI Bill is expected to become law in the next few months and businesses should be keeping an eye on its progress. Businesses should consider what changes will be *needed*, or *could* be made, to their internal processes and procedures (such as records of processing) to ensure ongoing compliance or, potentially, to benefit from the changes being introduced.

For further information about the content and progress of the bill, please see our January edition.

ICO urges all app developers to prioritise privacy

Following the ICO's review of period and fertility apps last year, the ICO is reminding all app developers about the importance of protecting users' personal information. While no serious compliance issues were found in this review, the ICO has highlighted that transparency, valid consent, establishing a correct lawful basis and being accountable are four key pillars to ensure compliance and prioritise users' privacy.

App developers should make sure that data protection and privacy considerations are taken into account at the very early stages of the app design process and throughout it, both to ensure compliance and to minimise the risk of difficult (and costly) development/design changes having to be made once the app is operational.

ICO publishes second annual Tech Horizons Report

The ICO has announced its second annual Tech Horizons Report, in which it examines eight emerging technologies – including neurotechnologies, immersive worlds, drones and personalised AI – for possible data protection implications. The ICO's aim for the report is to explore how these technologies could potentially transform lives while nonetheless addressing any privacy risks.

We can expect the ICO to continue to focus on the implementation and use of these emerging/developing technologies over the next year and beyond.

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Employment and immigration

Employment and immigration

What would Labour do? Proposal for bill on temporary staffing, gig working and contracting

Angela Rayner, the deputy leader of the UK Labour Party (which polls suggest is likely to win the next UK general election, due to be held by the end of January 2025), spoke on Sky News (3 February 2024) about introducing a bill "*within 100 days*" of an election to make major changes in the world of temporary staffing, gig working and contracting, as part of its "*new deal for working people*".

These changes would include day one employment rights for all workers, a ban on "*exploitative*" zero-hours contracts (which is effectively the main agency worker and gig worker mode of engagement) and an end to "*bogus self-employment*".

The detail is not yet clear, but suppliers (including staffing companies and platforms) and users of temp and zero-hours workers and contractors should start thinking about the likely impact of the promised changes on their commercial models and costs, including longer-term supply arrangements to which they are already signed up. However, it may be difficult to introduce quick and effective legislation to implement many of these proposed changes. Read our Insight for more.

Payment services reform poses challenge for Europe's people platforms, MSPs and payroll companies

Proposed changes to European payments legislation will tighten up an exemption relied on by many people platforms, managed service providers (MSPs) and payroll providers that make payments to workers (or intermediaries through which workers are engaged) in the EU.

The EU is updating its regulatory regime governing payments and electronic money. Change is needed in order to reflect technological and commercial developments since the previous legislation was passed, iron out inconsistencies between payments and e-money legislation and ensure a more consistent application of the rules across all Member States.

If the reforms are passed, the changes will make it difficult for these platforms and providers to rely on the commercial agent exemption as their basis for making payments in the EU, unless they make major changes to their business models. See more in our Insight.

Dismissal and re-engagement: Government response to consultation and updated code published

Following a recent consultation, the government has published its response to the consultation on the draft statutory Code of Practice on Dismissal and Re-engagement together with an updated code.

The code sets out what steps employers should take when seeking to change terms and conditions of employment where dismissal and re-engagement is envisaged and seeks to ensure that dismissal and re-engagement is only used as a last resort. The new draft code states that employers should contact Acas for advice before they raise the prospect of dismissal and re-engagement with employees. It essentially reflects existing best practice and provides for information to be provided to employees (or their appropriate representatives as the case may be) and for consultation to take place with employees and/or their representatives with alternative options being properly considered. The code is clear that the prospect of dismissal should not be raised unreasonably early and the threat of dismissal should not be used as a negotiating tactic to put undue pressure on employees where dismissal is not envisaged.

Employers should note that the code will apply regardless of the number of employees affected or potentially affected by the employer's proposals and regardless of the employer's reasons for seeking the changes. The new draft code, however, now makes it clear that it will not apply where an employer is only envisaging making employees redundant.

Employment tribunals will have power to apply an uplift of 25% of an employee's compensation where an employer unreasonably fails to comply with the code.

EHRC publishes guidance on menopause and the Equality Act

The EHRC has published guidance on menopause in the workplace setting out an employer's legal obligations under the Equality Act 2010. The guidance has been published against the backdrop of increased awareness of the way in which the menopause can have an impact on an employee's working life and a focus on keeping older workers in the workplace or encouraging them to return. The EHRC press release notes that it is increasingly important for employers to know how

to support workers experiencing menopause symptoms not only to ensure they meet their legal responsibilities but also so that these women are able "*to continue to contribute to the workplace and benefit from work*".

The guidance clarifies an employer's legal obligations and confirms that "*if menopause symptoms have a long term and substantial impact on a woman's ability to carry out normal day-to-day activities, they may be considered a disability*" and an employer "*will be under a legal obligation to make reasonable adjustments and not to discriminate against the worker*".

Additionally workers experiencing menopause symptoms may be protected from less favourable treatment related to their menopause symptoms on the grounds of age and sex.

The guidance also provides practical tips for employers on making reasonable adjustments and fostering positive conversations about the menopause with their workers. Employers are "*encouraged to carefully consider the guidance*" and adapt their policies and practices accordingly.

UK Immigration Update | February 2024

Our latest immigration update covers a number of recent developments and changes on the horizon, including to arrangements for short-term visitors to the EU, increased flexibility for those visiting the UK, new requirements for anyone wishing to return to or join their family member in the UK, and further changes to e-visas.

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Environment

Environment

Understanding the biodiversity net gain regime

On 12 February 2024, the biodiversity net gain (BNG) regime went live in England. BNG refers to the principle whereby a developer is required as part of its planning application to evidence a net gain in the biodiversity of a site it is developing.

As a concept it has been around for a few years already, with different local authorities adopting varying approaches: some local authorities did not require it at all, some only required evidence that there would be no net loss in biodiversity, while others required evidence that a specific minimum gain would be achieved in order to approve the application.

As of 12 February 2024, a minimum gain of 10% will be a statutory requirement which applies to the majority of planning applications. Our Insight sets out what businesses need to understand about the new regime.

The requirements are implemented through the Environment Act 2021 (Commencement No. 8 and Transitional Provisions) Regulations 2024. These confirm that the BNG planning condition does not apply retrospectively where the application for planning permission was made before the implementation date. The transitional provisions also confirm that where the planning application was made or permission was granted before this date, the BNG planning condition will not apply to any subsequent planning permission granted for that development.

The government has also recently published a raft of guidance documents on the new regime, including both developer and land manager specific guidance.

Enforcement against polluting water companies to ramp up

The UK government has announced plans to significantly increase inspections on water companies in order to hold them accountable for their performance. This includes recruiting up to 500 additional staff for inspections and enforcement, and introducing stronger regulation over the next three years.

Inspections will more than quadruple, with the Environment Agency (EA) aiming to conduct 4,000 inspections per year by March 2025 and 10,000 inspections per year from April 2026, and this will include unannounced inspections. The government will provide around £55 million annually to support these increased inspections. Defra also recently announced that water company bosses will be banned from receiving bonuses if the company has committed serious criminal breaches.

With the EA taking significant measures to ramp up enforcement action, it is crucial that water companies comply with regulations to avoid enforcement action, and should remember that the EA now has the power to impose unlimited civil sanctions for environmental pollution offences, see this earlier Regulatory Outlook for more.

Consultation on increase charges for water discharges

On 29 January, the EA launched a consultation on proposed charges for water discharges (including groundwater activities). The EA notes that the charges have not been updated since 2018 and that an increase in charges is required in order to address current cost pressures within the body and to allow it to "*build capacity and capability, and regulate more effectively and efficiently*".

The press release adds that *"increased funding will allow for more boots on the ground working to regulate water companies, as well as the advancement of digital and data capabilities to target efforts in the right places. These changes will support the industry to implement good practice and allow the Environment Agency to act on pollution and non-compliance."*

Water companies will be those most affected, followed by those in agriculture, recreation and hospitality. Affected businesses may wish to respond to the consultation. Additionally, given the aim of the increase in charges to help with resourcing and capabilities of the regulator, this change could potentially increase enforcement by the EA and is something for businesses to have on their radar.

The consultation closes on 11 March 2024, with changes due to come into force in spring 2024.

EU to introduce new rules on limiting F-gases and ozone depleting substances

The European Parliament recently approved new regulations, which the European Commission welcomes, aimed at reducing emissions from fluorinated gases (F-gases) and ozone-depleting substances.

Under the new F-gas regulation, measures include a complete phase-out of hydrofluorocarbons by 2050, with a gradual reduction in EU consumption quotas from 2024 to 2049. The legislation also imposes stringent requirements that prohibit the sale of products containing F-gases on the Union market and establishes specific deadlines for phasing out their use in

sectors where there are alternatives that do not use F-gases, such as domestic refrigeration, air conditioning, and heat pumps.

In addition, the Parliament has adopted a regulation to address the emissions of ozone-depleting substances, with a focus on their recovery and recycling in building materials during renovation projects.

The Council adopted these two new regulations, which closed the adoption procedure.

The new regulation on F-gases was published in the EU Official Journal on 7 February and will enter into force on 11 March 2024.

The new regulation on ozone depleting substances was published in the EU Official Journal on 7 February and will enter into force on 11 March 2024.

European Parliament formally adopt position on Environmental Crime Directive
The European Parliament has formally adopted its position on the new directive on the protection of the environment through criminal law (27 February 2024). As noted in our November edition, the new law will replace the 2008 directive. It aims to improve the investigation and prosecution of environmental crime offences by increasing the number of offences from nine to eighteen. New offences include timber trafficking, the illegal recycling of polluting components of ships and serious breaches of legislation on chemicals. It is expected that the Council will formally adopt the directive on 19 March 2024.

It will enter into force on the twentieth day following its publication in the EU Official Journal and following this, Member States will have two years to transpose the rules into national law.

This new legislation will not only allow for companies committing environmental offences to receive fines, ranging from 5% of the total worldwide turnover or an amount corresponding to €40 million, but also introduces imprisonment against those companies' senior individuals who commit environmental offences. Businesses operating in the EU should therefore be aware that this legislation is on the horizon and understand the implications this will have, as high fines and imprisonment will become a possibility for eighteen environmental crimes.

Final vote on CSDD delayed

Please see ESG.

Two-year delay for certain sector specific standards under CSRD

Please see ESG.

Proposals to reduce food and textile waste across EU

Please see Products.

UK REACH 23/24 programme prioritises PFAS restrictions

Please see Products.

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Environmental, social and governance

Environmental, social and governance

Final vote on CSDD delayed

The final vote for the Corporate Sustainability Due Diligence Directive (CSDD) was due to take place on Friday 9 February 2024, but was cancelled last minute following reports that Member States, including Germany and Italy, were planning to abstain from the vote. At the time of writing, the vote in the Council of the EU has been re-scheduled for 28th February 2024.

Two-year delay for certain sector specific standards under CSRD

The sector-specific European Sustainability Reporting Standards (ESRS) have been delayed from 30 June 2024 to 30 June 2026 in a bid to ease the regulatory burden on companies. The sectors cover oil and gas, mining, road transport, food, cars, agriculture, energy production and textiles.

The ESRS are mandatory for use by companies that are required by the Accounting Directive, as amended by the Corporate Sustainability Reporting Directive (CSRD), to report certain sustainability information. First reports were to be due in June 2024. The ESRS takes a “double materiality” perspective: it obliges companies to report both on their impacts on people and the environment, and on how social and environmental issues create financial risks and opportunities for the company.

The European Parliament and Council have reached a provisional agreement, which was put forward by the Commission as part of its 2024 work programme, to postpone the deadline for the adoption of the sectoral ESRS. The provisional agreement now needs to be endorsed and formally adopted by both the Parliament and Council. The aim of this delay is to give companies time to focus on implementing the first set of standards under CSRD.

In the meantime, a consultation on the ESRS for both listed and non-listed small and medium sized enterprises has been launched.

Greenwashing in UK financial services

There is a huge market for sustainable investment products, resulting in a growing number of products marketed as such. As this demand grows, so does the risk of "greenwashing", a practice on which European regulators, including the UK's Financial Conduct Authority (FCA), have increasingly focused.

In November 2023, the FCA implemented the Sustainability Disclosure Requirements (SDR) regime. This regime includes a new anti-greenwashing rule, due to take effect from 31 May 2024. Our recent Insight considers what firms can do to ensure they will be compliant with the new requirements, and what indication the FCA has given in its guidance as to its regulatory approach.

Updates to corporate governance codes for AIM and UK-listed companies

The Quoted Companies Alliance (QCA) and Financial Reporting Council (FRC) have both recently published new editions of their corporate governance codes.

The QCA's Corporate Governance Code is the main corporate governance framework used by small and mid-sized publicly traded companies in the UK, including 93% of AIM companies.

The FRC's UK Corporate Governance Code applies to all companies with a premium listing on the London Stock Exchange. This scope is likely to widen under proposed reforms to the UK's listing regime which will create a single listing category for commercial companies.

Both codes are produced independently from each other – and it is understood to be a coincidence that both have been updated at the same time.

ESG considerations have been threaded through the new QCA Code, with the QCA stressing that they are crucial for small caps as they look to keep pace with investor expectations and reporting requirements. By contrast, although the new FRC Code was initially anticipated to involve some major changes with a particular focus on ESG, in the end the FRC stepped back from the bulk of its proposals due to the current "*wider debate about business reporting requirements and burdens across the economy*". See our recent Insight for more.

EU regulation on ESG rating activities

The EU Council and Parliament have reached a provisional political agreement on the text of a new proposed regulation that will govern ESG ratings providers.

Environmental, social and governance

Under the regulation, EU ESG ratings providers will have to apply for authorisation from ESMA (the EU's financial markets regulator and supervisor); non-EU ESG rating providers will be able to provide ESG ratings in the EU in limited circumstances. ESG ratings providers will be subject to ongoing supervision by ESMA.

Provisional agreement reached on the right to repair

Please see Products.

Directive to empower consumers for the green transition: EU Parliament and Council formally adopt their positions

Please see Advertising and marketing and Products.

Council adopts position on banning products made with forced labour

Please see Modern slavery.

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Fintech, digital assets, payments and consumer credit

BoE and HM Treasury respond to consultation on case for digital pound

On 25 January 2024, the Bank of England (BoE) and HM Treasury published a response to their joint consultation paper regarding a retail central bank digital currency (CBDC) (a "digital pound"), which provides an update on their plans.

The February 2023 consultation sought feedback on the policy and technical work undertaken with a view to informing the decision on whether to build and launch a digital pound. Feedback was also sought on the proposed design of a digital pound.

There were over 50,000 respondents to the consultation, most of which were largely supportive of the proposed design, although some respondents raised concerns including the potential impact on privacy, access to cash and freedom of choice. The feedback will inform priorities during the design stage of future work to develop the digital pound.

The response confirms that no final decision has been made on whether to go ahead with a digital pound. Nevertheless, the authorities believe that the proposed design of a digital pound remains appropriate. They confirm that primary legislation to guarantee users' privacy and control is an important aspect of the proposals, and that neither the BoE nor the government would have access to users' personal data. They also commit to maintaining access to cash.

The next stage is the development of a detailed design for the digital pound. A decision on whether to build a digital pound will be made after the design phase (2025 at the earliest). If it proceeds, a timetable will be set for further consultation before the introduction of primary legislation and a potential launch.

On 31 January 2024, the House of Commons Treasury Committee published a report setting out the response of HM Treasury and the BoE to the committee's report on the digital pound. The committee's December 2023 report summarised its views on the need for a digital pound. In their response, HM Treasury and the BoE respond to each of the committee's recommendations in turn, as well as other priority considerations.

Points of interest include:

- HM Treasury and the BoE agree that strong privacy safeguards would be vital if a digital pound were introduced. The government has committed to guaranteeing users' privacy in primary legislation.
- The BoE acknowledges the committee's request for transparency around costs of the development of the digital pound. Costs on a CBDC are currently reported in the BoE's annual report in combination with its wider range of fintech work.
- The criteria that will inform the decision whether to proceed, together with the wider assessment framework, will be developed as part of the design phase.

European developments

ESMA consults on draft guidelines under MiCA on qualification of cryptoassets as financial instruments, and reverse solicitation

On 29 January 2024, the European Securities and Markets Authority (ESMA) published a consultation paper on draft guidelines on the conditions and criteria for the qualification of cryptoassets as financial instruments under the regulation on markets in cryptoassets (MiCA). The guidelines aim to provide clarity on the delineation between the scope of MiCA and the Second Markets in Financial Instruments Directive (MiFID II).

The draft guidelines outline ESMA's proposal on the conditions and criteria to be used for determining whether a cryptoasset qualifies as a financial instrument. ESMA highlights that, under the MiCA mandate, it is not expected to clarify the entire scope of what constitutes a financial instrument, but only products that comply with both the cryptoasset definition in MiCA and the financial instrument definition in MiFID II.

Also on 29 January 2024, ESMA published a consultation paper on draft guidelines on reverse solicitation under MiCA.

The guidelines are intended to provide clarity (especially for third country firms) on the limited situations where the offer or provision of cryptoasset services to a clients established or situated in the EU will be regarded as initiated at the client's

exclusive own initiative. ESMA highlights that these situations should be understood as very limited and narrowly construed; reverse solicitation should not be assumed nor exploited to circumvent MiCA.

The draft guidelines focus on the means of solicitation, what "exclusive initiative" means, when a cryptoasset or a cryptoasset service is of the same type as another one, and supervision practices.

The consultations close on 29 April 2024. ESMA will consider the feedback and expects to publish final reports in Q4 2024.

EBA extends money laundering and counter terrorism financing risk factors guidelines to CASPs

On 16 January 2024, the European Banking Authority (EBA) published a final report setting out amending guidelines on customer due diligence (CDD) and the factors that credit and financial institutions should consider when assessing the money laundering (ML) and terrorist financing (TF) risk associated with individual business relationships and occasional transactions under the Fourth Money Laundering Directive (MLD4).

The original guidelines are being revised to extend their scope to cryptoasset service providers (CASPs), highlighting the ML and TF risk factors and mitigating measures CASPs need to consider. The guidelines are intended to help a CASP identify risks by providing a non-exhaustive list of factors that may indicate its exposure to higher or lower levels of ML and TF risk, for example due to its customers, products, delivery channels and geographical locations. This will allow them to develop an understanding of their customer base and identify which aspects of their business are most vulnerable to ML and TF.

The revised guidelines also explain how CASPs should adjust their mitigating measures, including the use of blockchain analytics tools.

The revised guidelines include guidance addressed to other credit and financial institutions that have CASPs as their customers or are exposed to cryptoassets.

The revised guidelines will apply from 30 December 2024.

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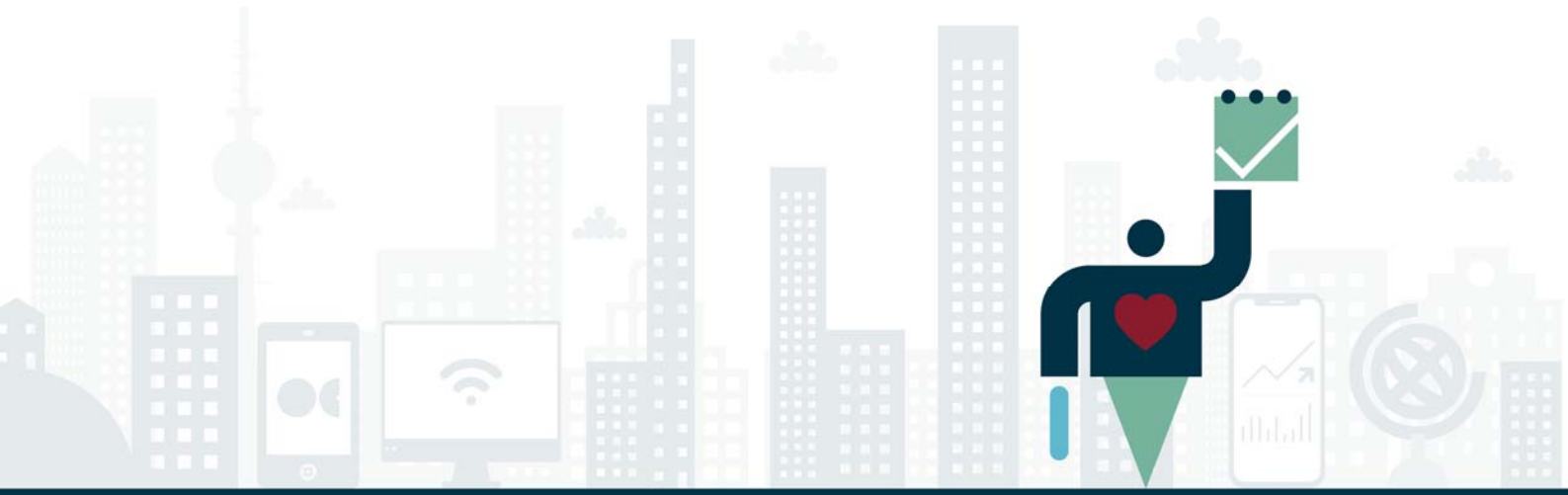

Food law

Food law

FSA to put forward novel food approval process in March

It has been reported that the Food Standards Agency (FSA) will put forward plans to modernise novel foods approvals at its next meeting on 20 March 2024.

As set out in its update on regulated products, the FSA was proposing to submit a bid for funding from the Department of Science, Innovation and technology to run a regulatory sandbox on cell-cultivated products (cultured meats). At the meeting in March, is it anticipated that the regulator will provide a further update on the progress of this bid.

Businesses should keep on top of any developments with regard to the sandbox, and we will be publishing further details once more information has been provided by the FSA.

ASA to be primary regulator for new HFSS advertising restrictions

Ofcom has designated the Advertising Standards Authority (ASA) as the regulatory authority for online advertising of high fat, salt and sugar (HFSS) food and drink.

The ASA is responsible for enforcing the relevant HFSS advertising restrictions requirements of the Communications Act 2003, which were introduced by the Health and Care Act, as well as creating guidance. Ofcom can revoke the designation if the ASA fails to fulfil its obligations or no longer meets the requirements.

Informal agreement reached on amending Breakfast Directives

On 30 January 2024, the European Parliament, Council of the EU and European Commission reached an informal trialogue agreement on the proposed directive amending several existing directives related to honey, fruit juices, fruit jams and dehydrated milk for human consumption. The directive aims to "*promote healthier diets, provide transparency on product origin, and simplify labelling*".

Changes include the following:

Honey:

- Country of origin will be indicated on the label in descending order, along with the percentage each country represents in the blend.
- Packages under 30 grams to use two-letter ISO codes instead of country names to ensure flexibility.

Fruit juices:

- Addition of new categories for reduced-sugar fruit juices: "reduced-sugar fruit juice", "reduced-sugar fruit juice from concentrate" and "concentrated reduced-sugar fruit juice".
- Option to use the label "fruit juices contain only naturally occurring sugars"

Fruit jams:

- Increase the minimum fruit content in jams and extra jams.
- 450g as a general rule for jam, and 500g as a general rule for extra jam.

Milk:

- Allowance for treatments that produce lactose-free dehydrated milk products.

The agreement is still subject to formal approval, and once published in the Official Journal of the European Union, Member States will have 18 months to transpose the provisions into national law before it applies throughout the EU.

European Parliament adopts position on gene-edited plants

The European Parliament has adopted its position on new genomic techniques (NGT) and agreed with the European Commission's proposal to have two different categories and two sets of rules for NGT plants.

Currently all plants obtained by NGTs are subject to the same rules as genetically modified organism (GMO). Under the proposal, NGT plants that could also occur naturally or by conventional breeding (NGT 1 plants) would be exempted from the requirements of the GMO legislation, and will be subject to a verification procedure set out in the proposal. For NGT 2

plants, the GMO framework still applies meaning they will be subject to the stricter requirements of GMO legislation including the authorisation procedure.

Under the Parliament's adopted position, mandatory labelling needs to be required for all products from NGT plants; whereas the Commission's proposal only required labelling for NGT 1 plants. In addition, for NGT 2 plants which will contribute to a more sustainable agri-food system, the Parliament agreed with the Commission to accelerate the risk assessment, but added that the precautionary principle must be respected when doing so.

The Parliament's proposal also introduces a ban on patents for NGT plants, plant material and parts thereof, genetic information and process features. This is to *"avoid legal uncertainties, increased costs and new dependencies for farmers and breeders"*. MEPs have requested a report by June 2025 on the impact of patents on breeders' and farmers' access to varied plant reproductive material, along with a proposal to update the EU intellectual property rules in line with the proposed patent ban.

Now that the Parliament has adopted its position, negotiations between EU Member States to agree on the final law can begin.

Consultation launched on 'Not for EU' labelling on agrifood products across Great Britain

On 31 January 2024, a "Safeguarding the Union" policy paper was published, which proposes amendments to the Windsor Framework agreement. It outlines that the government intends to introduce "Not for EU" labelling requirements, which are currently just for certain agrifood products being placed on the Northern Ireland market via the "green lane", to apply to agrifood products across Great Britain, and not just in Northern Ireland. The reason for this change is to ensure no incentive arises for businesses to avoid placing goods on the Northern Ireland market.

If implemented, these changes would start to apply with the next phase of labelling requirements under the Windsor Framework: from 1 October 2024 labels are required for prepacked meat, prepacked milk or prepacked dairy products; then from 1 October 2025 the requirement will apply to any other prepacked retail goods. For businesses placing products on the UK market that are not destined for the Union market, this will mean ensuring "Not for EU" labels are applied to necessary products to ensure compliance. A consultation on this change has been launched, which closes on 15 March 2024 and businesses that have views on this change should consider responding to the consultation.

The Food and Drink Federation has warned that requiring the "not for EU" label for the whole of the UK would cost a significant amount and could lead to manufacturers being forced to reduce the number of products they sell in the UK.

UK government to introduce improvement notices for breach of health and nutrition claims

There is a new lighter-touch enforcement regime for breach of the health nutrition claims regulation which is being brought in as part of the government's post-Brexit "smarter regulation" initiative.

Following its consultation on proposed changes to the nutrition labelling, composition and standards retained EU law (now known as assimilated EU law), the UK government confirmed in its response that it will be introducing legislation to enable improvement notices for breach of health and nutrition claims. See our Insight for more.

The amending regulations introducing these changes have been laid and come into force on 1 October 2024.

EFSA draft novel food guidance for public consultation

The European Food Safety Authority (EFSA) has launched a consultation on draft guidance for the scientific requirements of an application for authorisation of a novel food. This guidance is the first that envisages lab-grown meat and will sit alongside rules that the Commission will implement on administrative and scientific requirements for novel food applications.

The draft guidance provides advice on the scientific information that applicants need to provide to demonstrate the safety of a new type of food. This includes details about the food's description, how it is made, its ingredients, specifications, how it will be used, and how much of it people are expected to consume. This information will then be used by the EFSA to conclude whether or not the novel food is safe.

The consultation closes on 14 April 2024 and businesses that submit novel food applications should consider whether they wish respond to the consultation before the deadline.

Feedback period opened on EU restriction on BPA in food contact materials

Please see Products.

Food law

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Health and Safety

Health and Safety

Consultation launched on standard tiers under the Terrorism (Protection of Premises) Bill

The UK government has launched a consultation on the requirements proposed in relation to standard tier premises under the Terrorism (Protection of Premises) Bill. It follows on from the Select Committee's report, published in July 2023, which raised concerns about the significant burden on venues that would fall within the standard tier (those with capacity of 100 to 799).

The consultation closes on 18 March 2024 and those dutyholders who fall within the standard tier should use this opportunity to share their views on this. Additionally, for those in the enhanced tier (capacity of 800 or more), it may be worth engaging with this consultation, as duties imposed on standard tier dutyholders will form a baseline for duties to be imposed on enhanced tier dutyholders.

ONS report reminds businesses of importance of mental health

The Office for National Statistics this month published its labour market overview. The figures were analysed by the Health Foundation Commission, which found that that 2.8 million people aged 16-64 are not in the workforce due to ill health. This is a record high since 1993. This provides businesses with a timely reminder of the importance of employee mental health and of ensuring measures are in place to mitigate these risks. See our earlier Regulatory Outlook for more on mental health.

Building safety

Higher-Risk Buildings (Keeping and Provision of Information etc) (England) Regulations 2024

The Higher-Risk Buildings (Keeping and Provision of Information etc.) (England) Regulations 2024 were made on 13 January 2024. They outline what information and documents the Principal Accountable person and Accountable Persons must keep and share as "golden thread information" with those who have an interest in relation to a higher-risk building.

The explanatory memorandum provides a helpful outline of the requirements of these regulations and should be read in conjunction with the regulations.

Regulations on duty to assess and manage safety risks

New regulations have brought into force certain sections of Part 4 of the Building Safety Act 2022 from 16 January 2024 and provide the framework for the ongoing duty to assess and manage safety risks in occupied higher-risk buildings. These include:

- The duty of a Principal Accountable Person for an occupied higher-risk building to apply for building assessment certificates when requested to do so by the Building Safety Regulator;
- requirements to develop and maintain building safety case reports;
- ongoing assessment and management of building safety risks;
- reporting requirements and maintaining information about higher risk buildings;
- engagement with residents and duties imposed on residents not to create building safety risks, interfere with safety equipment and to comply with reasonable building safety requests made by Accountable Persons.

Those owners and managers who fall within the scope of these regulations need to ensure that they fully understand their legal duties and what measures they need to take to assess and manage safety in their buildings.

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Modern slavery

Modern slavery

Council adopts position on banning products made with forced labour

The Council of the EU has adopted its negotiating mandate on the regulation prohibiting products made with forced labour. The regulation is intended to prohibit all products made with forced labour being placed on an EU market, made available in the EU, or exported from the EU. See more in our Insight.

The Council's mandate introduces several changes to the Commission's proposal. It emphasises the establishment of the Union Network and the creation of a forced labour single portal to facilitate information sharing and access to relevant tools.

The Council's position also strengthens the role of the European Commission in assessing whether products are of Union interest. A “Union interest” is assumed to exist when one or more of the following criteria are met:

- the scale and severity of suspected forced labour is significant;
- the risks of suspected forced labour are located outside the territory of the Union;
- the products concerned have a significant impact on the internal market (they are presumed to have a significant impact when they are present in at least three Member States).

If there is a Union interest, under the Council's mandate, the Commission will automatically take over the pre-investigation phase. Otherwise, the pre-investigation phase will be carried out by a national competent authority.

The Council's position outlines that for inspections in third countries (that is, when inspections are required outside the Union), the Commission contacts third countries to conduct inspections on suspected cases of forced labour. If the third-country government rejects the Commission's request, it may be considered non-cooperation, and the Commission can make a decision based on other evidence.

Negotiations can now begin between the Council and the European Parliament to agree on the final version of the text.

Final vote on CSDD delayed

Please see ESG.

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Products

Products

General / digital products

UK

Guidance on implementing new connectable product security requirements

On 29 April 2024, the new connectable product security regime comes into effect. The Office for Products Safety and Standards (OPSS) has published new guidance for businesses that need to be complying with the new requirements.

The guidance outlines the products covered (those that can connect to the internet or a network), to whom the regulations apply and the security requirements imposed on manufacturers of connectable/digital products which are:

- restricting the use of default passwords;
- providing information to consumers on how to report security issues; and
- providing information on minimum periods for which devices will receive security updates.

The OPSS has also updated its guidance on enforcement actions and associated rights under the connectable product security regulations. It outlines the enforcement powers the OPSS has under the Product Security and Telecommunications Infrastructure Act which includes the service of a compliance notice, stop or recall notice, monetary penalties and application for a forfeiture order. It also sets out that the appeals process will be to the First-tier Tribunal (General Regulatory Chamber).

Businesses that place connected products onto the UK market should be preparing themselves for these upcoming changes and ensure that products in scope are compliant with these regulations come the end of April.

Retained EU Law – forthcoming product and medicine updates

On 22 January, the Department for Business and Trade published a report on the progress the government has made in reforming and revoking retained EU Law (now known as assimilated law) over the last six months. It also sets out, from page 23 onwards, the assimilated law updates it plans to introduce in 2024, which includes changes for product regulation and medicines.

Product regulation

- Introduce legislation to indefinitely recognise the CE mark for products (for example, toys and machinery);
- introduce digital labelling, such as a QR code, which will allow importers and manufacturers the ability to include relevant details and information via a digital label attached to the product; and
- introduce a "fast track UKCA" process, allowing manufacturers to use the UKCA marking to demonstrate compliance, in Great Britain, with either UKCA or recognised EU conformity processes.

Also see this government press release on these upcoming changes.

Medicines

- Facilitate a new point of care manufacturing regulatory framework for medicines manufactured at or close to the place of administration;
- remove the current power in the Human Medicines Regulations 2012 for the Medicines and Healthcare products Regulatory Agency (MHRA) to rely on the decision of the European Commission alone to approve a medicine in Great Britain;
- reform UK clinical trials legislation;
- reform the Ionising Radiation (Medical Exposure) Regulations 2017, noting that changes will "*better reflect the UK healthcare delivery model and permit the use of artificial intelligence*"; and
- reform the Veterinary Medicines Regulations 2013 to modernise the rules to reflect technological advancement and reduce regulatory burdens.

Plans to ban sale and supply of disposable vapes

Products

The government has published its response on legislating to create a smokefree generation which outlines that legislation will be brought forward at the "*earliest opportunity*" to introduce regulations to restrict flavours, point of sale and packaging and product presentation for vaping products (nicotine and non-nicotine) as well as other consumer nicotine products, such as pouches. It also adds that separately, the UK government, the Scottish government and the Welsh government intend to introduce legislation to implement a ban on the sale and supply of disposable vapes. Businesses that place disposable vapes on the UK market should remain vigilant about any forthcoming regulatory change in this area.

Autonomous Vehicles Bill finishes reading in House of Lords

The Autonomous Vehicles Bill completed its reading in the House of Lords on 19 February, just over three months after it was first introduced. The bill now moves onto the House of Commons and had its first reading on 20 February, with its second reading scheduled for 5 March 2024.

EU

Revised Product Liability Directive

Following informal negotiations, the final compromise text of the revised Product Liability Directive has been published. See our previous Regulatory Outlook for a reminder of the changes being made by the new legislation.

In terms of next steps, the European Parliament now needs to formally adopt the text, after which (if done at first sitting) the Council will also adopt the text, following which will the legislation will be adopted. The new rules will apply to products placed on the market 24 months after entry into force. The next plenary sitting date is scheduled for 11 March 2024.

European Parliament Committee agrees position on new toy safety regulation

The Internal Market and Consumer Protection Committee of the European Parliament has approved its position on the update to the EU Toy Safety Directive, which, following the revision, will become a regulation.

The committee's position agrees with the European Commission's proposal to ban harmful chemicals, including carcinogenic, mutagenic and toxic substances. In addition, MEPs agreed that manufacturers will need to create digital product passports for each toy. However, they have added that consumers should have easier access to information, giving the example of using QR codes.

The MEPs specify that there are to be no overlaps with existing EU legislation. In relation to the AI Act, the committee states that digital toys with AI will need to comply with the Act, which will mean third-party assessments, risk management, transparency and human oversight. In line with the EU Cyber Resilience Act, this will require third-party conformity assessments for internet-connected toys with social interactive features, such as speaking or filming. It also adds that toys must comply with the General Product Safety Regulation.

The draft report will be put to a vote at an upcoming plenary session and will constitute the Parliament’s position at first reading. Following this, the file will then be followed up by the new Parliament after the European elections on 6-9 June.

Adoption of EU common criteria-based cybersecurity certification scheme

On 31 January 2024, the European Commission adopted Implementing Regulation (EU) 2024/482 laying down rules for the European common criteria-based cybersecurity certification scheme (EUCC).

As previously reported, the EUCC scheme, developed under the EU Cybersecurity Act, will apply on a voluntary basis to all information and communication technologies products within the EU, focusing on certifying the cybersecurity of these products within their lifecycle. Certain provisions of the EUCC will enter into force on 27 February 2024, with remaining provisions applying from 27 February 2025. For further information on the EU's cyber security strategy for IT product design, please see our Insight.

Council adopts position on banning products made with forced labour

Please see Modern slavery.

Potential delay to Cyber Resilience Act

Products

Please see Cyber security.

Product sustainability

UK

UK REACH 23/24 programme prioritises PFAS restrictions

The UK REACH (UK regulation on the registration, evaluation, authorisation and restriction of chemicals) Programme 2023/2024 has been published and sets out the Health and Safety Executive (HSE)'s "operational activities" it will take in the financial year 2023 to 2024.

The HSE has identified five priorities, with one being "*a proposal to begin the development of a restriction on Per- and polyfluoroalkyl substances (PFAS) in fire-fighting foams (FFFs), and to explore restrictions on further wide dispersive uses of PFAS and PFAS likely to be released from consumer articles*." This follows on from the HSE's regulatory management option analysis (RMOA) on PFAS conducted last year, see this previous Regulatory Outlook.

While the initial restriction is focused on fire-fighting foams, the prioritisation of PFAS restrictions demonstrates that the HSE is actively seeking to further restrict the use and release of PFAS in order to address the potential risks associated with these substances. As such, businesses should start to understand the risks associated with PFAS and evaluate the extent of PFAS use within products and explore whether alternatives could be used as regulatory change is on the horizon with regard to restrictions on PFAS.

For information, the other four priorities set out in the work programme for 2023 to 2024 are as follows:

1. Formaldehyde and formaldehyde releasers in articles – continue the RMOA initiated under the 2022 to 2023 work programme and consider its recommendations.
2. Bisphenols in thermal paper – continue the RMOA initiated under the 2022 to 2023 work programme and consider its recommendations.
3. Hazardous flame retardants – develop the risk assessment on flame retardants and consider the recommendations.
4. Intentionally added microplastics – monitor progress of the evidence project initiated and commissioned under the 2022 to 2023 work programme.

Extended Producer Responsibility amending regulations

On 17 January 2024, the Draft Packaging Waste (Data Reporting) (England) (Amendment) Regulations 2024 were laid before Parliament and will be effective from 1 April 2024. These regulations amend the Packaging Waste (Data Reporting) (England) Regulations 2023, which will eventually be replaced by the Producer Responsibility Obligations (Packaging and Packaging Waste) Regulations which will implement the extended producer responsibility scheme for packaging. The key changes introduced by the amending regulations are:

- Requiring the Environment Agency to publish a public list of large producers.
- Shifting the obligation of reporting from the brand owner of empty packaging to the person who packs or fills the packaging.
- Making the importer responsible for imported, branded packaging unless the brand owner specifically requests the importation, and providing a clearer definition of importer to ensure proper obligations for importers who discard imported empty packaging.
- Imposing reporting obligations on distributors who supply unfilled packaging to a large producer, who then supplies it to a small or non-obligated producer. Currently, no one is required to report this packaging, and these amendments will place the obligation on the distributor.

Businesses that fall within the scope of the extended producer responsibility scheme should review these new regulations to determine if their obligations are affected.

Products

EU

Feedback period opened on EU restriction on BPA in food contact materials

The European Commission has opened a feedback period on its proposed regulation to ban the use of BPA in food contact materials (FCMs), including plastic and coated packaging. The regulation address the use of other bisphenols in FCMs to avoid replacing BPA with other harmful substances as well as imposing monitoring and reporting obligation on manufacturers. The feedback period closes on 8 March 2024 and Commission adoption of this draft regulation is planned for the first quarter of 2024.

Businesses that manufacture food contact materials should take the opportunity to give feedback on the regulation as this is likely to be their only opportunity to do so, as after the Commission adopts its draft, it will enter the legislative process between the EU institutions.

Provisional agreement reached on the right to repair

Earlier this month, EU negotiators reached a provisional agreement on the Right to Repair Directive (RTR), which will make repair mandatory for defective products, and impose new obligations on all businesses placing products on the EU market. While the final version of the text of the agreement is not yet available, the EU institutions' press releases have provided some clarification as to what the agreed text will look like:

1. **Manufacturer obligations**: manufacturers will be obligated to repair those products which have ecodesign requirements in place, such as washing machines, vacuum cleaners and smartphones. This reverts back to the original scope put forward by the Commission's proposal, as the European Parliament wanted to expand the scope of the RTR by giving the Commission the power to expand the list of the products the RTR applied to, outside of ecodesign requirements. However that proposal has not been taken forward and the RTR will only apply to products where ecodesign regulations are already in place. Over time though, this list will expand with the introduction of the Ecodesign for Sustainable Products Regulation, whereby the European Commission will be able to introduce delegated acts setting out ecodesign requirements for more products.
2. **Spare parts at a reasonable price**: manufacturers will have to make spare parts and tools available at a reasonable price and will need to provide this information on their website. In addition to this, manufacturers will be prohibited from using contractual clauses, hardware or software techniques to obstruct repairs and should not impede the use of second-hand or 3D issued spare parts by independent repairers.
3. **Consumer awareness**: manufacturers must inform consumers about their duty to repair and consumers will be able to request this information from manufacturers.
4. **Temporary replacements**: consumers will have the option to borrow a device while their own is being repaired or choose a refurbished unit as an alternative.

See the Consumer law section for the consumer aspects of the RTR.

In terms of next steps, the European Parliament and Council both need to formally adopt the text, following which it will be published in the EU Official Journal. We anticipate this will happen ahead of the European Parliament elections in June 2024. Once in force, Member States will have 24 months to transpose the RTR into national law.

We will be provide a fuller update once the final version of the text has been published, but for the time being, businesses should understand what this new legislation could mean for them. For more information, see the following press releases from the European Commission, European Parliament and European Council.

Proposals to reduce food and textile waste across EU

The Environment Committee of the European Parliament has adopted new measures to support the circular economy and reduce waste from food and textiles in the EU. The adopted measures include more ambitious targets for reducing food waste. The proposed targets are to achieve at least a 20% reduction in waste from food processing and manufacturing (compared to the current 10%) and a 40% reduction per capita in retail, restaurants, food services and households (compared to the current 30%).

These targets would need to be achieved by EU countries at the national level by 31 December 2030. Additionally, MEPs have called for the evaluation of higher targets for 2035, aiming for at least a 30% and 50% reduction.

In terms of textile waste, the new rules introduce extended producer responsibility (EPR) schemes. Under these schemes, economic operators that make textiles available on the EU market would be responsible for covering the costs of separate collection, sorting, and recycling. Member States would need to establish these schemes within 18 months of the directive's entry into force. Furthermore, EU countries would be required to ensure the separate collection of textiles for re-use, preparing for re-use, and recycling by 1 January 2025.

The rules cover various textile products, including clothing, accessories, blankets, bed linen, curtains, hats, footwear, mattresses and carpets. This also includes products that contain textile-related materials such as leather, composition leather, rubber or plastic.

The next steps involve the full European Parliament voting on its position during the March 2024 plenary session. After the European elections in June, the file will be followed up by the new Parliament.

EU Parliament and Council formally adopt their positions on directive to empower consumers for the green transition

The European Parliament has formally adopted a legislative resolution for a directive "empowering consumers for the green transition" at first reading. Following this, the Council of the EU has given its final approval for the directive. After this, it will be published in the Official Journal of the EU and will be subject to a transposition period of 24 months after directive comes into force to allow Member States to implement the changes.

The new directive, among other things, prohibits the display of sustainability labels on products that have not been certified via a certification scheme. The legislation notes that sustainability labels can remain without a certification scheme where they have been established by a public authority, such as logos.

In addition to this, the directive introduces the requirement of a harmonised label that will inform consumers about the producer's commercial guarantee of the durability of the good. The use of a harmonised label only applies to commercial guarantees of durability that offer a period of more than two years and will be offered at no additional cost. The label will need to be placed in a "*prominent manner*" and be clearly visible, such as on the packaging of the product.

The new directive also imposes bans on misleading ads and generic environmental claims. Please refer to the Advertising and marketing section for more information.

Lifesciences and healthcare

UK

Eight companies given funding under the new The Innovative Devices Access Pathway

As detailed in this previous Regulatory Outlook, the Medicines and Healthcare products Regulatory Agency last year launched the Innovative Devices Access Pathway (IDAP) pilot which aims to help businesses bring innovative medical devices into the UK market.

It has now announced, on 14 February, that eight companies have been given part of the £10 million funding package. The companies and medical devices benefiting from this investment include a blood test for Alzheimer's Disease by Roche Diagnostics Ltd, a device to predict hospitalisation risk for chronic obstructive pulmonary disease by Lenus Health Ltd, and an innovative approach to oxygen level monitoring by EarSwitch.

Other technologies such as a multiple sclerosis fatigue app, a self-test for neutropenia and an algorithm infection predictor will also receive funding.

Consultation response on reforms to the Veterinary Medicines Regulations 2013

Following its consultation last year on the review of the Veterinary Medicines Regulations 2013, the Veterinary Medicines Directorate (VMD) has responded saying it will implement most of the proposed changes put forward, with some proposals

being amended. For manufacturers, feed business operators and professional keepers of animals this will mean a change in the regulatory framework for veterinary medicines.

Changes include:

- EU Alignment: Single dossier submissions and labels will be permitted across GB and the EU - another example of (re)alignment with the EU.
- Medicated feed: The VMD's proposal for collection and disposal of medicated feed has been scrapped but it is still unclear what will be potentially introduced instead.
- UK generics market: The VMD has confirmed that there will be an extension of some data protection periods awarded to veterinary medicines, in a bid to encourage innovation and support generics.

Read our Insight for more.

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Regulated procurement

Regulated procurement

Transforming Public Procurement - February update
The Government Commercial Function has published its February update on "Transforming Public Procurement" which provides a helpful update on next steps towards the new procurement regime coming into force, with go live still expected in October 2024.

Following on from its consultation on secondary legislation published last year, the government expects to lay what will become the Procurement Regulations 2024 in mid to late March 2024. It will also be publishing a suite of technical guidance documents covering all aspects of the new regime, including transitional arrangements, covered procurement, pre-market engagement, award rules, exclusions and contract modifications. These documents will be released in phases starting in March and concluding by the end of June.

E-learning modules will be launching in April 2024 for procurement and commercial practitioners from contracting authorities.

Single Source Contract (Amendment) Regulations 2024

The draft Single Source Contract (Amendment) Regulations 2024 have been laid before Parliament and make changes to the Single Source Contract Regulations 2014 (SSCRs).

The SSCRs are made under Part 2 of the Defence Reform Act 2014 (DRA). The DRA and the SSCRs make provision for pricing of single source contracts, which are defence contracts entered into without competition.

These amending regulations have been made following the Ministry of Defence's response to its consultation on reforming the SSCRs, and are the first of two amending regulations the government plan to introduce. Changes introduced by the regulations include creating a regulatory framework for single source contracts, defining contracts which are "substantially for defence purposes", and inserting a new regulation in the SSCRs which describes the meaning of a component in a qualifying defence contract. The draft regulations come into force on 1 April 2024.

Court of Appeal upholds decision not to award damages in procurement case

The *Braceurself v NHS England* judgment dealt with a public procurement damages claim. The claimant had to prove both a breach of the Public Contract Regulations 2015 and that the breach was sufficiently serious to warrant damages, known as *Francovich* damages.

The lower court had established a breach in this case, which had resulted in the contract being awarded to the wrong bidder in a two-bidder race. However, the lower court ruled that the breach was not serious enough to merit damages.

On appeal, the Court of Appeal not only upheld the lower court's ruling on the seriousness of the breach, but also found that the trial judge had been mistaken on the facts and concluded that it was more likely than not that there had been no breach at all in the first instance.

The Court of Appeal addressed three main issues related to *Francovich* damages. First, it clarified that a multi-factorial assessment must be conducted in each case to determine the seriousness of the breach. It disagreed with the view that the breach in this case was sufficiently serious without further evidence.

Secondly, the Court of Appeal confirmed that the judge had correctly carried out the *Francovich* balancing exercise, taking into account all relevant factors, noting that disregarding factors such as excusability or state of mind would be contrary to authority. Additionally, it noted that a manifest error may be excusable.

Thirdly, the Court of Appeal determined that the principle of effectiveness of damages did not have a further or separate role in this case.

Furthermore, the Court of Appeal found that the trial judge had made an error in assessing the evidence concerning the proposed use of a "stair climber" in the procurement, rather than a "stair lift" in the procurement. It concluded that it was more likely than not that the scores given by the procurement assessors would have remained unchanged, indicating that the breach would not have affected the outcome.

This decision will be welcomed by contracting authorities as it illustrates that even when a minor error has been made, the court will not be quick to award damages to the claimant and will consider all relevant factors when assessing the seriousness of the breach.

For claimants, while not providing much confidence when bringing damages claims, the decision does provide helpful guidance as to what the courts will look to when assessing whether damages should be awarded and where strengths and weaknesses lie in certain factors.

NHS procurement: introduction to how the NHS buys from the private sector

The UK's NHS must comply with public procurement legislation when it buys medical devices, medicines and services or commissions healthcare services. The legislation is being overhauled with the coming into force of the Procurement Act in 2024, and the new NHS Provider Selection Regime which commenced on 1 January 2024.

If you missed it, watch our recent webinar where we examine:

- How public procurement legislation affects how the NHS buys non-healthcare goods and services, and what this means for suppliers.
- How the NHS Provider Selection Regime will affect how the NHS commissions healthcare services, and what this means for suppliers.
- The mandatory net zero commitments, and other social value commitments, that suppliers must make in order to do business with the NHS.

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Sanctions and Export Control

Sanctions and Export Control

UK publishes first sanctions strategy

On 22 February 2024, the UK government launched its first sanctions strategy, setting out the importance of collaboration with the private sector and international partners in addressing threats and the steps the UK is taking to strengthen sanctions implementation and enforcement. These include:

- the new Office of Trade Sanctions Implementation, which investigates potential breaches and ensures trade sanctions are properly implemented and enforced, with a range of civil enforcement tools including the ability to levy monetary penalties;
- additional support for HM Revenue and Customs to investigate and prosecute serious sanctions breaches, including expanded intelligence and data capabilities; and
- continued investment in sanctions staffing and expertise – for example, the Foreign, Commonwealth and Development Office has more than doubled the number of staff working on sanctions following Russia's invasion of Ukraine.

See the press release.

OFSI guidance on new reporting requirements for designated persons

The Office of Financial Sanctions Implementation (OFSI) published a blog on the new reporting measures that came into force in December 2023 alongside the government's latest tranche of trade sanctions against Russia:

- **immobilised assets reporting measure** – relevant firms are now required to infirm OFSI of any funds or economic resources they hold for the Central Bank of Russia, Russian Ministry of Finance, or Russian National Wealth Fund; and
- **designated persons asset reporting measure** – persons designated under the Russia financial sanctions regime must proactively provide details of their UK assets to OFSI.

From 13 February 2024, the OFSI will be transitioning to a new digital guidance format, designed to improve accessibility to its financial sanctions guidance.

Sanctions evasion risk alerts

On 1 February 2024, the UK government and G7+ Coalition partners issued an enforcement alert to help support governments and the industry to improve their compliance with the Russian oil price cap. The alert contains information on the key evasion methods and how to report suspected breaches of the oil price cap.

In January 2024, the National Crime Agency issued an amber alert warning the artwork storage sector of the risk of potential financial sanctions evasion through art storage facilities by high-net worth individuals. The alert advises the sector to conduct regular due diligence checks to ensure sanctioned individuals do not exploit these services to evade sanctions. See the press release.

UK updates Russia sanctions guidance

On 30 January 2024, the UK government updated its Russia sanctions guidance to include licensing grounds for Schedule 3DA (revenue generating goods). A licence may be granted for the provision of technical assistance, brokering services, financial services and funds relating to goods listed under Schedule 3DA.

UK government response to independent review of counter-terrorism sanctions

On 16 January 2024, the independent reviewer of terrorism legislation, Jonathan Hall KC, published his review of the Counter-Terrorism (International Sanctions) (EU Exit) Regulations 2019. The Foreign, Commonwealth and Development Office (FCDO) has issued its response to the report, in particular:

- the FCDO is working with HM Treasury and the Home Office to implement a humanitarian exception across all UK financial sanctions regimes; and
- OFSI will consider amending its charity sector guidance to reflect updated government guidance on the role of public officials and the exercise of control over public bodies.

House of Lords Committee report on Russia sanctions

Sanctions and Export Control

On 31 January 2024, the House of Lords European Affairs Committee published its first report on the "impact of Russia's invasion of Ukraine on the UK-EU relationship". The report welcomed the government's response and made the following policy recommendations:

- the government should consider introducing a process for periodic review of sanctions in force, so that were certain conditions are met, sanctioned entities may be removed from the sanctions list;
- the government should address concerns over the uncertainty over companies controlled by designated persons and the work of the NCA and OFSI in enforcing sanctions breaches; and
- to achieve a regular working arrangement between the UK and the EU on sanctions policy, the committee recommends the government to agree a memorandum of understanding with the EU on sanctions cooperation.

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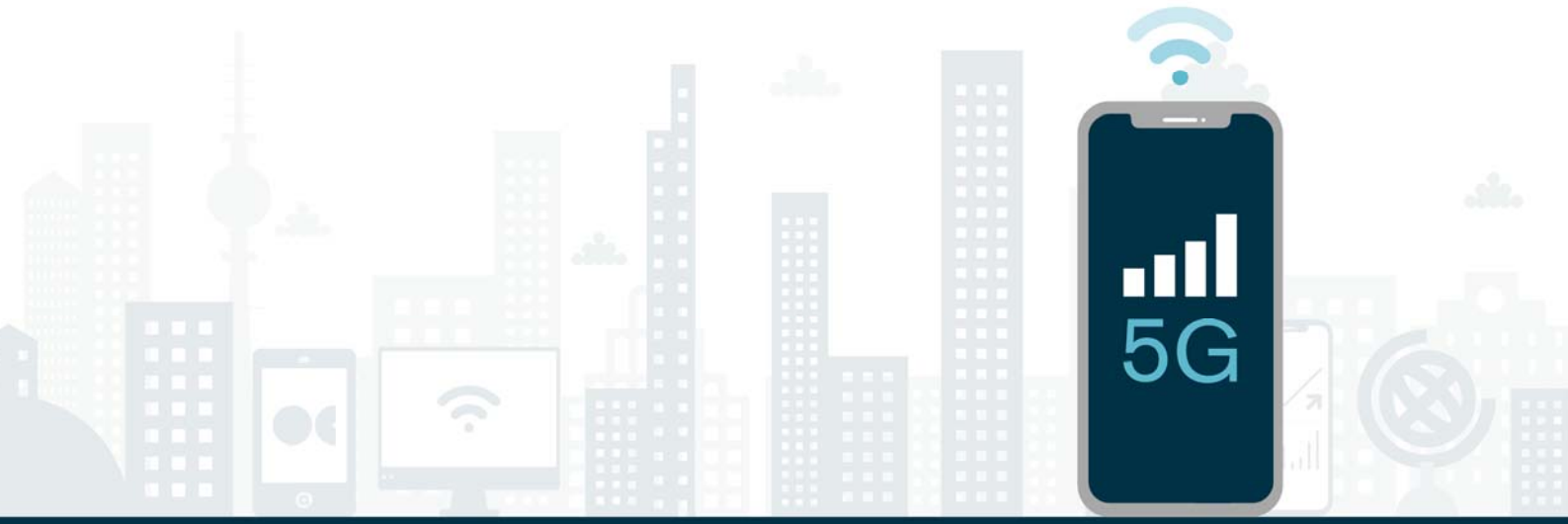

Telecoms

Telecoms

Ofcom consultation on regulations to update the fees for Wireless Telegraphy Act licences

Ofcom is currently consulting on a set of proposed regulations, which if implemented would amend the Wireless Telegraphy (Licence Charges) Regulations 2020. The proposed regulations would introduce three new licence products and their associated fees.

Ofcom is responsible for authorising civil use of the radio spectrum and does this by granting wireless telegraphy licences. Under the 2020 regulations, Ofcom is able to recover the cost of administering and managing licences, and is permitted to recover sums greater than those incurred in performing its spectrum management functions.

The proposed regulations would:

- extend Ofcom's Shared Access framework to the 26 GHz band (24.45-27.5 GHz) and in the 40 GHz band (40.5-43.5 GHz). Licences would be subject to fees ranging from £80 - £640;
- introduce a new licence product – the Enhanced Long-Range Navigation (eLoran) systems – following Ofcom's October 2023 decision to authorise use of the 90-110kHz spectrum band for these systems. Each licence would be subject to an annual licence fee of £200;
- introduce a new licence product – the Unmanned Aircraft Systems (UAS) Operator Radio Licence – following Ofcom's decision in December 2022 to introduce a new licence that authorises the use of a range of radio equipment on drones. Licences would have an indefinite duration would be subject to an annual fee of £75; and
- remove the High Duty Cycle Network Relay Points licence product and associated fee following Ofcom's decision in April 2021 to make equipment across the 870-874.4 MHz band exempt from the need to hold a licence.

The consultation closes on **12 March 2024**. After taking into account any responses, Ofcom expects to release a statement on the consultation in May 2024, and bring in the regulations as soon as practicable.

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