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.

The spotlight development this month is the UK government's consultation on the proposal to introduce a UK carbon border adjustment mechanism (CBAM) from 1 January 2027. The consultation closes on 13 June 2024 and businesses should review the consultation and decide whether they wish to respond. See the Environment section for more.

March 2024

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EU directive to empower consumers for the green transition published in the Official Journal of the EU

The EU directive to empower consumers for the green transition (2024/825/EU), which seeks to improve consumers' position as regards greenwashing, was published in the Official Journal of the EU on 6 March 2024. It enters into force on the twentieth day following its publication, on 26 March 2024. See this Regulatory Outlook for background.

Member States must adopt and publish the measures necessary to comply with the directive. Those measures will become applicable from 27 September 2026.

European Parliament adopts first reading position on Green Claims Directive

Please see Environmental, social and governance.

EU Parliament and Council of the EU adopt proposal for regulation on political advertising

On 27 February 2024, the EU Parliament adopted a legislative resolution on the proposal for a regulation on the transparency and targeting of political advertising. On 11 March, the Council of the EU adopted the regulation.

The new rules will regulate political advertising, including online ads, and will provide more transparency. Political ads will need to be clearly identified and supported by key information, such as their sponsor, the election or referendum to which they relate, the amounts paid and whether any targeting techniques are being used.

The regulation was published in the Official Journal of the EU on 20 March 2024. It will enter into force on the twentieth day following publication (on 9 April 2024) and will be applicable from 10 October 2025 (with exceptions for Article 3 and Article 5(1) which will apply from the date of its entry into force).

CJEU clarifies rules under GDPR in relation to targeted online advertising

The Court of Justice of the European Union has delivered its judgment in Case C-604/22 *IAB Europe v Gegevenbeschermingsautoriteit*, in relation to the processing of personal data by IAB Europe, the digital marketing and advertising association, through the use of its Transparency and Consent Framework (TCF). The TCF is widely used across the digital advertising industry, particularly in relation to real time bidding, as a means of ensuring compliance with the General Data Protection Regulation.

The CJEU found that IAB Europe's TC String (in which a user's preferences as regards use of their personal data are recorded pursuant to the TCF) constitutes personal data and that IAB Europe is a joint controller in relation to the processing involved in recording that personal data in the TC String, but not in respect of subsequent processing.

As a result of this ruling, businesses that participate in the TCF that act as controllers will need to implement changes to their cookie consent mechanism, as well as their related policies and agreements.

See this Insight for a detailed case overview and for further information on its implications for the adtech industry, and also Data law.

ASA launches investigation into the supplier pathway of irresponsible ads online

The UK Advertising Standards Authority (ASA) has launched two projects which will look into the supplier pathway of online ads that are found to be non-compliant with the UK Code of Non-broadcast Advertising and Direct & Promotional Marketing (CAP Code).

The first project uses innovative technology to monitor for ads for age-restricted products, such as alcohol, gambling and foods high in fat, salt or sugar (HFSS), on websites of particular interest to under-18s. The second project focuses on seriously offensive and potentially harmful ads appearing in mobile quiz and game apps.

The ASA aims to conduct a number of in-depth case studies based on the outcome of these projects to identify the parties involved in the supply chain of the ads in breach and understand their role. The ASA expects to report on the outcome of the projects later this year.

Scotland launches consultation on stricter HFSS restrictions

Advertising and marketing

Please see Food law.

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Artificial Intelligence

Artificial Intelligence

EU updates

EU AI Act adopted by Parliament

The EU AI Act was formally adopted by the European Parliament on 13 March 2024 – see the adopted text. This is not the last step in the legislative process but is an important milestone.

The speed at which the texts were finalised for this vote means that final checks and corrections are outstanding. A corrigendum is expected, and scheduled to be accepted by a quick Parliament vote on 11 or 12 April.

The next step after the Parliament's second vote will be formal adoption of the text by the Council of the EU. We have not yet seen a date for this vote, but it is expected in April. The Act will then be published in the Official Journal of the EU and enter into force twenty days after – expected to be late May.

UK updates

ICO launches second consultation on generative AI

The UK Information Commissioner's Office (ICO) has launched a second call for evidence in its series of consultations on generative AI. This consultation looks at "Purpose limitation in the generative AI lifecycle" and is focused on how the data protection principle of purpose limitation should be applied at different stages in the generative AI lifecycle.

The call for evidence closes on 12 April 2024 and the responses can be submitted here.

The first consultation focused on the lawful basis for web scraping to train generative AI models and closed on 1 March 2024.

International updates

Council of Europe reaches agreement on convention on AI

After a final week of talks, the Council of Europe announced that political agreement has been reached on the Artificial Intelligence, Human Rights, Democracy and the Rule of Law Framework Convention.

However, as many feared, this is not a convention with universal scope and application. It has been reported that the treaty will only apply to public authorities or private actors acting on their behalf.

Council of Europe member countries will vote on the text in May, after which signatory countries will need to ratify it at national level.

Separately, the European Data Protection Supervisor (EDPS) published a statement on the negotiations around the convention. The EDPS is concerned that the convention could be "*a missed opportunity to lay down a strong and effective legal framework for the development and uptake of trustworthy AI*." Its concerns relate to: (1) the very high level of generality of the legal provisions of the treaty; (2) its largely declarative nature which would lead to different applications across signatories; (3) limitation of the scope only to public authorities; and (4) the lack of "red lines" and criteria for banning AI applications that pose unacceptable threat.

G7 discussions on AI

The G7 countries (Canada, France, Germany, Italy, Japan, UK and USA, with the EU also participating) issued a Ministerial Declaration on 15 March at the end of a two-day summit on digital and technology matters. AI-related matters in the communiqué included:

- developing tools and mechanisms to hold accountable businesses that commit to their non-binding code of conduct (issued as part of the G7 Hiroshima AI process);
- addressing the topics of how to ensure continuing effective competition in AI markets at the next G7 summit, scheduled for later this year in Rome;

- developing a toolkit for "*the safe, secure, and trustworthy development, deployment, and use of AI in the public sector*";
- producing a report on the "*factors and challenges of AI adoption*" by the private sector, particularly small and medium businesses, to inform policymaking and initiatives to support adoption.

OECD explanatory memorandum on the definition of AI system

The Organisation for Economic Co-operation and Development has published an explanatory memorandum on its updated definition of AI. It has also published an accompanying blog post explaining the main points. This definition formed the basis for the definition of AI under the EU's AI Act.

And finally …

We have updated our overview of the risks to be considered by a business using AI to reflect the current position with the AI Act and in the UK.

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Bribery, fraud and anti-money laundering

Bribery, fraud and anti-money laundering

Fraud

The Payment Services (Amendment) Regulations 2024
HM Treasury has published the draft Payment Services (Amendment) Regulations 2024. These aim to tackle push payment fraud by enabling banks and payment service providers to delay outbound payments processing in order to investigate suspicious payments where there are reasonable grounds to suspect fraud or dishonesty.

The government intends to lay the legislation before Parliament in summer 2024. See the policy note.

ECCTA 2023 explanatory notes
The government published explanatory notes on the Economic Crime and Corporate Transparency Act 2023. These cover the legal and policy background to it, and provide explanations of various provisions, including the new offence of failure to prevent fraud.

Government updates AI-powered fraud detection tool with sanctions data
The government has updated its AI-powered fraud detection tool, the Single Networks Analytics Platform (SNAP), which supports public sector organisations in detecting fraudulent claims on public funds.

The addition of UK and US sanctions data and debarment records will enable SNAP to better detect suspicious activity and users for investigation into organised crime and sanctions evasion.

The Public Sector Fraud Authority has also published the Government Counter Fraud Function Strategy 2024-2027, setting out the objectives for over 300 departments and government bodies in targeting fraud against the public sector.

Anti-money laundering

Consultation on Money Laundering Regulations
HM Treasury has launched a consultation, with the aim of improving the effectiveness of the Money Laundering, Terrorist Financing and Transfer of Funds (Information on the Payer) Regulations 2017 (MLRs), which requires businesses to identify and prevent money laundering and terrorist financing.

Reform of the MLRs form part of the government's commitment to reducing money laundering as set out in its Economic Crime Plan 2023-2026.

The consultation seeks views from a range of stakeholders including regulated businesses, large firms and their customers. It closes on 9 June 2024, after which the government will publish a response outlining its next steps, which may include draft legislation where appropriate.

FCA 'Dear CEO' letter on AML control failings
On 5 March 2024, the FCA published a Dear CEO letter sent to Annex I financial institutions about common control failings in anti-money laundering (AML) frameworks. Broadly, Annex I financial institutions are financial services firms that are caught by the Money Laundering, Terrorist Financing and Transfer of Funds (Information on the Payer) Regulations 2017 (MLRs 2017) and required to register with the FCA, but are not authorised under the Financial Services and Markets Act 2000.
The letter sets out details of common weaknesses the regulator has observed in assessments of

Annex I financial institutions' AML frameworks, including the following:

- Discrepancies between firms' registered and actual activities, and the failure of financial crime controls to keep pace with business growth.
- Weaknesses in firms' business-wide and customer risk assessments.
- Insufficient detail in firms' customer due diligence and monitoring policies, resulting in ambiguity around the actions staff should take to comply with their obligations under the MLRs 2017.

- Lack of resources at firms relating to financial crime and inadequate financial crime training, and absence of a clear audit trail for financial crime-related decision-making, with a failure by some firms to document how they had responded to risks or why they had made decisions.

The FCA expects firms to complete a gap analysis against each of these weaknesses within six months, and take steps to close any gaps identified. The FCA is likely to ask firms to provide their findings, evidence of actions taken to address gaps, and progress on any remedial work and testing to show that policies, controls and procedures are effective and working as intended.

Updated HM Treasury advisory notice on money laundering and terrorist financing controls in high-risk third countries

On 26 February 2024, HM Treasury updated its Money Laundering Advisory Notice: High Risk Third Countries. The notice includes changes made to the list of high-risk third countries in Schedule 3ZA of the Money Laundering Terrorist Financing and Transfer of Funds (Information on the Payer) Regulations 2017 (MLRs).

The new list will continue to align with the Financial Action Task Force's (FATF) "Jurisdictions under increased monitoring" and "High-risk jurisdictions subject to a call for action". Schedule 3ZA consolidates these into a single list, as all countries included in either of the FATF lists have significant shortcomings in their anti-money laundering, counter-terrorist financing, and counter-proliferation financing controls. Each of the countries specified is now subject to the requirement of enhanced customer due diligence under the MLRs.

Barbados, Gibraltar, Uganda and the United Arab Emirates have been removed from the list of high-risk third countries; Kenya and Namibia have been added.

FATF guidance on beneficial ownership and transparency of legal arrangements

The Financial Action Task Force (FATF) has published updated risk-based guidance of interest to the public and private sectors that regulate, supervise, manage or administer trusts or similar legal arrangements.

The guidance seeks to enhance their understanding of how to assess the money laundering and terrorist financing risks associated with trusts and similar legal arrangements by identifying and identifying the beneficial owners of these arrangements. It is intended to be read alongside the FATF's Recommendation 24.

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Competition

Competition

Long-term land interests and housebuilding

The Competition and Markets Authority (CMA), in its much-anticipated market study report into the housebuilding sector in Great Britain published at the end of last month, granted a momentary reprieve for the practice of so-called "land banking" while delivering a scathing assessment of the planning system. Alongside the conclusions to its study of the housebuilding market that it opened in February 2023, the CMA also announced the launch of a follow-up competition investigation into whether certain information sharing between housebuilders is anti-competitive.

The competition regulator views the increasing amount of land being tied up in options-to-purchase and promotion agreements – more than one million plots of land according to the study – as a symptom of wider problems in the market. These are primarily driven by the duration and uncertainty of the planning process. Crucially, the report says that "*artificially reducing the levels of land banks*" would likely have a negative effect on the amount of housing being built if the underlying drivers of the under-delivery of housing are not addressed. While identifying the planning system as a topic for legislative amendment, the CMA has proposed that the UK, Scottish and Welsh governments consider a range of changes to the planning system.

The CMA has indicated that its follow-up investigation into suspected anti-competitive information sharing, including information gathering, analysis and review of information gathered, will run until December this year. In the conduct of this investigation, the CMA will have broad information-gathering powers, extending to documents held on domestic premises. An unjustified refusal to comply with its information requests can attract substantial fines and even criminal sanctions. The CMA has discretion to widen its investigation should further information come to light in the course of the investigation. In the past, this has included investigating additional companies as well as broadening the scope of the investigation to incorporate different conduct. (See our Insight.)

Digital Markets Act workshops

The European Commission is convening a number of all-day workshops for designated gatekeepers to showcase their compliance solutions for the most critical Digital Market Act (DMA) obligations and for third parties to ask questions and comments. At the time of writing only the Apple workshop had taken place, with the Commission subsequently confirming an official investigation into the company.

The DMA requires Apple to allow users to transact with iPhone apps via different payment processors or directly on their website, outside the iPhone ecosystem. It requires Apple to let users install apps on iPhone via alternative app stores or directly from developers websites. The DMA also requires Apple's business terms for developers on the App Store to be fair, reasonable and non-discriminatory (FRAND). There was significant debate around how far Apple's compliance plan addresses these and other topics covered by the DMA.

The EU has not published a specific schedule beyond dates for hearings in March 2024 regarding each of the Big Tech firms covered by the DMA. Regardless of whether these hearings lead to specific action, the EU will continually monitor Apple and the designated gatekeepers.

CMA annual plan

On 14 March the CMA published its Annual Plan 2024 to 2025. It outlines the CMA's strategic approach and priorities for the coming year. Businesses should be aware of the CMA's expanded powers and responsibilities, particularly in relation to the regulation of digital markets under the proposed Digital Markets, Competition and Consumer (DMCC) Bill. When enacted, this legislation will provide the CMA with new tools and powers to regulate digital markets. Businesses operating in digital markets should anticipate increased scrutiny and potential enforcement actions from the CMA.

Competition

The CMA's focus on promoting fair competition and protecting consumers extends beyond digital markets. Businesses should be aware of its priorities in areas of essential spending, such as travel, accommodation, and caring for oneself and others. The CMA aims to ensure that consumers have great choices and fair deals in these areas, which may involve investigations into anti-competitive behaviour or harmful practices.

Sustainability is another key area of focus for the CMA. Businesses involved in sustainable products and services should be mindful of the CMA's efforts to promote competitive markets for climate technology. Additionally all businesses need to be aware of the CMA's Green Agreements Guidance, which aims to provide guidance on agreements between competitors with environmental sustainability objectives. Please see our previous Insights for a discussion of the guidance and analysis of the first informal guidance publication for more details on this.

In its latest Annual Plan, the CMA has emphasised the importance of fair and competitive labour markets. It plans to tackle potential competition issues in UK labour markets (such as non-poach and non-solicit arrangements), ensuring that workers are not disadvantaged by anti-competitive practices. Competition in labour markets is a focus of several competition authorities around the globe, including the European Commission, the US FTC and DOJ and the Canadian Competition Bureau.

Overall, businesses should closely monitor developments related to the DMCC Bill and the CMA's activities in digital markets. They should also stay informed about the CMA's priorities in areas such as essential spending, sustainability and anti-competitive behaviour. By proactively ensuring compliance and promoting fair competition, businesses can navigate the evolving regulatory landscape and mitigate potential risks.

Consultation on competition and consumer protection-related information sharing

Please see Regulated procurement.

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Consumer law

Consumer law

Update on the UK DMCC Bill

The UK Digital Markets, Competition and Consumers Bill (DMCC Bill) has completed the report stage in the House of Lords. A new version has been published which incorporates various consumer law-related amendments.

The Lords agreed to add various activities relating to the submission, commission or publication of fake reviews to the list of banned commercial practices in Schedule 19 of the bill. They also changed the way in which a trader must enable a consumer to bring a subscription contract to an end so that it does not have to be done "*in a single communication*", but "*in a way which is straightforward*". With this change, the Lords are aiming to set a general principle for traders to abide by in this area.

The Lords also agreed that Parliament ought to be able to make secondary regulations to provide that a consumer may lose the right to cancel a subscription contract during a cooling-off period and would not be entitled to a refund of any payments made if they chose to receive digital content or services during that cooling-off period.

The Lords discussed reminder notices and whether traders should be able to provide marketing and promotional information at the same time. No changes were agreed, but the government said that it would bring forward amendments at third reading to "*strike the right balance*" in this area.

To reduce fraud, the Lords also agreed amendments to impose requirements on secondary ticket sites (to obtain proof of purchase or evidence of title to tickets to be resold) before allowing a trader to be listed on the site. They would also not be allowed to let a reseller sell more tickets to an event than they can legally purchase from the primary market.

The third reading of the DMCC Bill in the House of Lords took place on 26 March 2024. It will now return to the House of Commons for consideration of the Lords' amendments, which may or may not be accepted. It is still expected to receive Royal Assent in April 2024.

Delegated act on independent audits under the DSA enters into force

On 22 February 2024, the delegated regulation on independent audits under the EU Digital Services Act (DSA) entered into force.

Article 37 of the DSA requires providers of very large online platforms (VLOPs) and very large online search engines (VLOSEs) to undergo annual independent audits to assess compliance with the DSA and any commitments made pursuant to codes of conduct and crisis protocols that they might have adopted.

The delegated regulation provides a framework to guide VLOPs and VLOSEs when preparing audits. It also provides mandatory templates for auditors to use when completing an audit report, as well as mandatory templates for the VLOPs and VLOSEs to use when completing their audit implementation reports.

EU directive to empower consumers for the green transition published in the Official Journal of the EU

See Advertising and Marketing.

CMA consults on proposal to launch a market investigation of the UK vet sector

Please see Consumer law.

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Cyber-security

Cyber-security

NCSC advisory on tactics used by APT29

The National Cyber Security Centre published an advisory detailing the recent tactics, techniques and procedures used by APT29 (a cyber espionage group believed to be part of the Russian intelligence services) in gaining initial access into cloud infrastructure.

Organisations, particularly those in the aviation and education sectors, as well as public bodies, should take note of the guidance to help detect and mitigate potential malicious activity.

NIST releases Cybersecurity Framework 2.0

The US National Institute of Standards and Technology (NIST) has published version 2.0 of its Cybersecurity Framework, which is widely adopted by organisations around the world.

The updated framework expands the scope to help a wider range of organisations manage and reduce cyber risks. Version 2.0 place greater emphasis on the importance of cyber security governance and supply chain risk management and should be used by organisations as a tool to design an effective cyber security strategy.

Government response to ransomware inquiry

On 11 March 2024, the Joint Committee on the National Security Strategy published the government's response to its inquiry into ransomware and UK national security.

The committee expressed concerns that the government's current approach will leave the UK exposed and unprepared for ransomware attacks. The committee stated that it will continue to monitor and follow up on issues raised in the report, including the extension of the NIS Regulations 2018 and further guidance on ransom payments.

See the press release.

EU Parliament and Council reach agreement on Cyber Solidarity Act

On 6 March 2024, the European Commission and Parliament reached a political agreement on the Cyber Solidarity Act, which aims to strengthen the EU's ability to detect, prepare and respond to cyber threats.

Among other things, the Act establishes mechanisms to support coordination of preparedness testing for critical national infrastructure and provision of financial support to Member States assisting another state affected by a significant cyber security incident. It will need to be approved by the EU Parliament before it can be formally adopted. It will enter into force on the twentieth day following its publication in the Official Journal.

To find out about more, register to attend our "Dipping into Data" webinar where Osborne Clarke's experts will discuss the developing regulatory landscape around cyber security.

EU Parliament adopts Cyber Resilience Act

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Data law

Data law

ICO collects views on 'consent or pay' business models in relation to advertising cookies

The UK Information Commissioner's Office (ICO) has launched a call for views on "consent or pay" business models in relation to the use of advertising cookies, setting out its regulatory approach to the model and providing organisations thinking about adopting it with the factors they need to consider. The consultation closes on 17 April 2024.

"Consent or pay" or "pay or okay" models are where businesses give users a choice of either consenting to their personal information being used for personalised advertising and gaining free access to a website, or refusing consent, paying to access the site and not being tracked.

The call for views sets out the different factors that organisations should think about when assessing whether their model will result in valid consent being given for personalised ads, such as:

- the power balance between the provider and its users;
- whether the ad-funded and the paid-for services are equivalent;
- whether the fee is appropriate; and
- whether the choices are presented fairly and equally.

The ICO cautions that this call for views sets out its initial thinking on "consent or pay" models and should not be interpreted as confirmation that the approach expressed in the document is legally compliant.

This is an interesting development, suggesting that the ICO is now potentially more receptive to a concept that it has specifically warned businesses (including US-based newspapers) was non-compliant in the past.

IAB Europe a 'joint controller' for consent in TCF processing for online advertising

The Court of Justice of the EU has delivered its judgment in Case C-604/22 *IAB Europe v Gegevensbeschermingsautoriteit*, stating that IAB Europe is a joint controller in collecting a record of consent to online advertising (but not in relation to subsequent processing by the website and app providers) and providing some (arguably confirmatory) direction on the definition of personal data. As a result, businesses relying on IAB's online advertising framework needing to consider (and possibly amend) their policies and user-facing information.

This decision is part of recent EU-level case law demonstrating the broad interpretation of joint controllership under the EU General Data Protection Regulation (GDPR). In this case, the IAB Europe's role as a sector organisation providing a framework and setting technical standards was deemed sufficient to find joint controllership, despite the advertising association not itself accessing the personal data in question. This will undoubtedly be persuasive guidance for UK organisations operating both within the advertising sector (where joint controllership, transparency and consent are all hot topics) and also other sectors where joint controllership may arise.

Please see our more detailed Insight on this topic.

ICO guidance on using biometric data

The ICO has published new guidance on using biometric data. The guidance explains how data protection law applies when organisations use biometric data in biometric recognition systems and applies to users of such systems alongside vendors and developers.

The guidance explains what biometric data is – namely information which:

- relates to someone’s physical, physiological or behavioural characteristics (such as your voice, fingerprints, or face);

- has been processed using specific technologies (for example, an audio recording of someone talking is analysed with specific software to detect qualities like tone, pitch, accents and inflections); and
- can uniquely identify (recognise) the person it relates to.

The ICO guidance then specifies that biometric data should be treated as special category personal data only when it is actually used to uniquely identify someone (for example, a biometric passport is only treated as special category personal data when scanned using biometric readers to identify an individual) and a scanned copy kept on file (for example, for "know your customer" (KYC) purposes) will not necessarily be special category personal data. This is important due to the additional restrictions around handling special category personal data in the UK.

This guidance is likely to be of wide interest, especially for employers looking to use biometric recognition systems to allow their employees access to facilities or to track attendance which has always been a complex area. Often, the only practical lawful basis for using such systems under UK GDPR is consent.

The guidance stresses the importance of offering employees genuine choice if employers are relying on their consent as their lawful basis (for instance, by offering another means of access such as a PIN or password). It also gives useful practical tips on how to comply with UK GDPR principles when using biometric data, such as how to comply with the accuracy and transparency requirement.

EDPB launches coordinated enforcement framework on the right of access

The European Data Protection Board (EDPB) has launched its Coordinated Enforcement Framework (CEF) action for 2024, focusing on the implementation of the right of access. During the year, 31 Data Protection Authorities (DPAs) across the European Economic Area will take part in the initiative, which aims to enhance cooperation among DPAs.

Last year, the EDPB adopted guidelines on the right of access to help organisations comply with the requirements outlined in the GDPR when responding to data access requests. The CEF aims to assess the level of compliance with the guidelines. Participating DPAs will implement the framework by:

- sending out questionnaires to organisations;
- commencing formal investigations if necessary; and/or
- following-up ongoing investigations.

Although the relevant guidelines are EU level, it will be interesting for both UK and EU businesses to consider how their own internal policies and procedures in relation to data subject access requests measure up against the organisations being investigated.

UK ICO launches second consultation on generative AI

See AI section.

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Employment and immigration

Employment and immigration

Actions for employers in March/April

With a number of new employment rights, as well as adjustments to existing entitlements, coming into force in April, employers will need to ensure that they are aware of the changes and have taken the necessary steps to reflect them in any processes and policies, as well as training for staff and managers.

March and April will also see some employees, and other individuals with whom businesses engage, such as customers and suppliers, observing religious holy days and festivals; appropriate accommodations will need to be carefully considered and addressed sensitively, reflecting individual needs. See our Insight for more.

EU agrees watered-down Platform Workers Directive – what will platforms and staffing companies need to prepare for?

EU ministers have finally agreed, on 11 March, a provisional deal for the Platform Workers Directive (PWD). Importantly, it includes a presumption of employment status in certain circumstances, such that where those circumstances apply, it will be for the "employer" or platform to prove that the worker is not an employee.

But it does not introduce an EU-wide "test" for determining the circumstances when employment status will apply, with the original proposal for an "if you pass three of these five tests you are an employee" mechanism having been dropped as a result of opposition from a blocking minority of four EU countries. In other words, it will be down to each country to decide what control features will constitute the circumstances which give rise to the presumption of employment, and each country will be free to decide what classes as "control" or "direction" for these purposes. Read more in our Insight.

All change for staffing and platform worker arrangements in the UK – new consultations, announcements and likely manifesto commitments

The next 12 to 18 months seem likely to involve what may be the biggest changes to the UK staffing and platform worker landscape since Michael Heseltine ended the old UK recruitment licensing regime 30 years ago. Users and suppliers of contract and gig workers are already beginning to work out how the Labour Party plans might affect them, and the Spring Budget announcement and some related developments add other things to the mix. Read more in our Insight.

Statement of changes HC 590: salary requirement increased, shortage occupation list replaced

On 14 March 2024 a statement of changes and explanatory memorandum to the immigration rules was published, to bring in changes to the immigration rules following the government's announcement earlier this year.

The immigration minister made a statement summarising the changes relating to the skilled worker, appendix FM partner, the EU settlement scheme, the new immigration salary list (which replaces the shortage occupation list), and administrative review for EU settlement scheme applications.

Some notable changes:

Skilled Workers

Applications that have been made using a certificate of sponsorship issued before 4 April 2024 will be decided under the rules in place on 3 April 2024.

Employers must from 4 April 2024 pay those entering the skilled worker route a general salary threshold of £38,700 or the going rate for the role (as per the SOC Codes 2020), whichever is higher.

Spouse of a British or settled individual

Employment and immigration

Those applying under the five year route to settlement as a partner (under Appendix FM of the rules) will need to meet a minimum income requirement of £29,000 for applications made on or after 11 April 2024. There will be no additional income requirement for children.

EU Settlement Scheme

On 4 April 2024 Appendix Administrative Review (EU) will be amended to remove the ability to make an out of time application for administrative review of an eligible EUSS decision made before 5 October 2023.

There are still a significant amount of questions in relation to how changes will apply in practice (for example to skilled workers already in the UK), and fuller guidance is anticipated in due course.

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Environment

Environment

BNG requirements for small sites come into effect from April 2024

As detailed in last month's Regulatory Outlook, the biodiversity net gain (BNG) regime went live in England on 12 February 2024, with a temporary exemption for small sites. However, from 2 April 2024 these obligations will start to apply to small sites, for example a residential development where the number of dwellings is between one and nine – or if this is unknown, where the site area is less than 0.5 hectares. Read our Insight for more on these obligations and what businesses should do.

UK government consultation on introduction of CBAM

Following its announcement of plans to introduce a UK carbon border adjustment mechanism (CBAM) from 1 January 2027, the government has, on 21 March, launched a consultation on the proposal.

The CBAM will be applied to imports of certain carbon-intensive imported goods from the following sectors aluminium, cement, ceramics, fertilisers, glass, hydrogen, and iron and steel. The government is seeking views on the scope of sector and goods to which the CBAM will apply, calculating the UK CBAM liability, and the administration, payment and compliance of the mechanism.

The consultation closes on 13 June 2024 and businesses should review the consultation and decide whether they wish to respond.

The consultation document also notes that the government will look to establish voluntary product standards that businesses could choose to adopt to help promote their low carbon products to consumers. This will be subject to a further technical consultation in 2024.

Extended producer responsibility for packaging waste: reporting changes coming into force 1 April 2024

Please see Products.

CSDD gets through vote from Council of the EU

Please see ESG.

European Parliament adopts first reading position on Green Claims Directive

Please see ESG.

EU directive to empower consumers for the green transition published in the Official Journal of the EU

Please see Advertising and marketing.

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Environmental, social and governance

Environmental, social and governance

CSDD gets through vote from Council of the EU

The Council of the European Union, on 15 March, reached a significant milestone by finally agreeing on the text of the Corporate Sustainability Due Diligence Directive (CSDDD), following a series of meetings since the provisional political agreement was reached between the Council and the European Parliament.

The most significant change to the CSDDD is the increase in the scope of thresholds. Initially, the directive aimed to apply to EU companies with a minimum of 500 employees and a turnover of €150 million. These thresholds have been adjusted to include EU companies with a minimum of 1000 employees and a net turnover of €450 million. Other changes include removal of the high-risk sectors approach, narrowing the definition of the supply chain and introducing a staged approach.

The text now needs to be formally approved by the European Parliament in April, after which it will be formally adopted by the Council before being published in the Official Journal of the EU and entering into force 20 days later.

Companies, both in the EU and outside, now face the task of reassessing whether they fall within its scope, understanding when the measures will take effect and what actions they will need to start taking to ensure compliance with the new rules. Read our Insight for more.

European Parliament adopts first reading position on Green Claims Directive

The European Parliament has adopted its position on the Green Claims Directive – the new rules setting out what types of information companies need to provide to justify their environmental marketing claims (see our Insight for further information).

The directive will be followed up by the new Parliament after the EU elections, which take place on 6-9 June 2024.

The UK's sustainability disclosure requirements for fund managers

The Financial Conduct Authority (FCA) published its much-anticipated policy document in November last year setting out the core components of its new sustainability disclosure requirements (SDR) and investment labels regime and who it will affect.

The questions fund managers now need to address about the application of the SDR are what sustainability information must be provided, and when and how it must be provided. Find out in our Insight.

For sustainable funds, fund managers should consider whether they wish to opt in to using a SDR label for each fund and, if so, which one. For more, see our Insight.

UK government consultation on introduction of CBAM

Please see Environment.

EU directive to empower consumers for the green transition published in the Official Journal of the EU

Please see Advertising and marketing.

Update on regulations to eradicate modern slavery in NHS supply chains

Please see Modern slavery.

Political agreement reached on Forced Labour Products Regulation

Please see Modern slavery.

Extended producer responsibility for packaging waste: reporting changes coming into force 1 April 2024

Please see Products.

Environmental, social and governance

Please also see our latest international ESG Knowledge Update, for a round-up of legal, regulatory and market news.

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Fintech, digital assets, payments and consumer credit

Treasury Committee highlights levels of SME bank account closures by major banks

On 28 February 2024, the House of Commons Treasury Committee published a press release and correspondence with certain banks relating to the closure of small and medium enterprise (SME) bank accounts.

As part of its inquiry into SME finance, the committee sent letters to bank CEOs requesting data on forced account closures. It was seeking to understand the breakdown of SME customer accounts and the rate of forced account closure across the market (known as "debanking"). The banks responded to the committee in January 2024, and it has made their letters available.

In its press release, the committee notes that:

- The data provided by the banks (with the exception of one, which does not provide current accounts to SMEs) shows that more than 140,000 SME accounts were closed over the last year, representing 2.7% of SME accounts.
- The reasons given for the closure of SME accounts include risk appetite, financial crime concerns and lack of information sharing.
- The categorisation of reasons for account closures varies. Only three banks listed risk appetite as a criterion for bank closures, with 4,214 cases listed. However, this does not rule out the possibility of risk appetite being considered by banks that did not explicitly list it as a criterion. The chair of the committee, Harriet Baldwin, comments that this raises questions over whether decisions on the debanking of SMEs, based on what banks perceive as a risk, are happening informally with discussions not being systematically recorded.

FCA's key findings of review of claims management companies carrying out unregulated claims

On 15 February 2024, the Financial Conduct Authority published the key findings of its multi-firm work on claims management companies (CMCs) carrying out unregulated claims activity to assess whether firms were using their FCA authorisation to legitimise unregulated services.

The FCA is concerned that consumers might wrongly assume all CMC services were regulated. It explains that it has issued information requests to 26 CMCs that offer unregulated claims services relating to matters including tax, timeshare, diesel emissions and flight delay claims. The FCA found that some of these firms had:

- undertaken very little to no regulated claims management activity – the FCA requires firms to review their regulatory permissions regularly to ensure they are up to date, and to apply for unneeded permissions to be removed;
- inadequate systems and controls to distinguish between regulated and unregulated claims activity;
- charged significantly higher fees for unregulated claims activity – where fees for unregulated claims are higher than for regulated claims services, the FCA urges CMCs to bear in mind the spirit of the Consumer Duty, and whether the services they provide represent fair value for the consumer; and/or
- issued non-compliant financial promotions.

The regulator explains that where CMCs offer unregulated claims services, they are expected to be clear with consumers about which products and services are regulated and which are not. Where the Consumer Duty applies, firms must ensure that communications are likely to be understood by consumers, and enable consumers to make effective, timely and informed decisions.

The FCA reminds CMCs to pay attention to how clear they have made it to consumers that a particular service is not regulated, and to review all customer communications, including financial promotions. In addition, CMCs should review the terms and conditions of their unregulated claims services to ensure they are clear and fair.

Fintech, digital assets, payments and consumer credit

Law Commission consultation on draft digital assets bill

On 22 February 2024, the Law Commission consulted on a draft bill to confirm that digital assets (such as crypto tokens) are capable of being recognised as property by the law.

In June 2023, it published Digital assets: Final report, which concluded broadly that certain types of digital assets are capable of being things to which personal property rights can relate, even though they do not easily fit within the traditional categories of personal property, and are better regarded as belonging to a separate category. The Commission concluded that the common law system is well placed to determine which things properly can and should be objects of personal property rights, and which are "third category things" (that is, a category of thing distinct from both things in possession and things in action). Nevertheless, the report recommended that statutory confirmation of the common law position would provide greater legal certainty. (See our Insight for more on the report.)

The draft bill implements those recommendations, stating that a thing (including a thing that is digital in nature) is capable of being an object of personal property rights even though it is neither a thing in possession nor a thing in action. The clauses leave questions for common law, including what things fall within the third category, what personal property rights attach to third category things, and the consequences of this (such as tortious liability and applicable remedies).

The Law Commission requested input from stakeholders on whether the draft clauses successfully implement the final report's recommendations, as well as potential costs, benefits and unintended consequences. It closed on 22 March 2024.

FCA 'Dear CEO' letter on AML control failings

Please see Bribery, fraud and anti-money laundering.

Updated HM Treasury advisory notice on money laundering and terrorist financing controls in high-risk third countries

Please see Bribery, fraud and anti-money laundering.

Treasury Committee inquiry into effectiveness of UK's Russia sanctions regime

Please see Sanctions.

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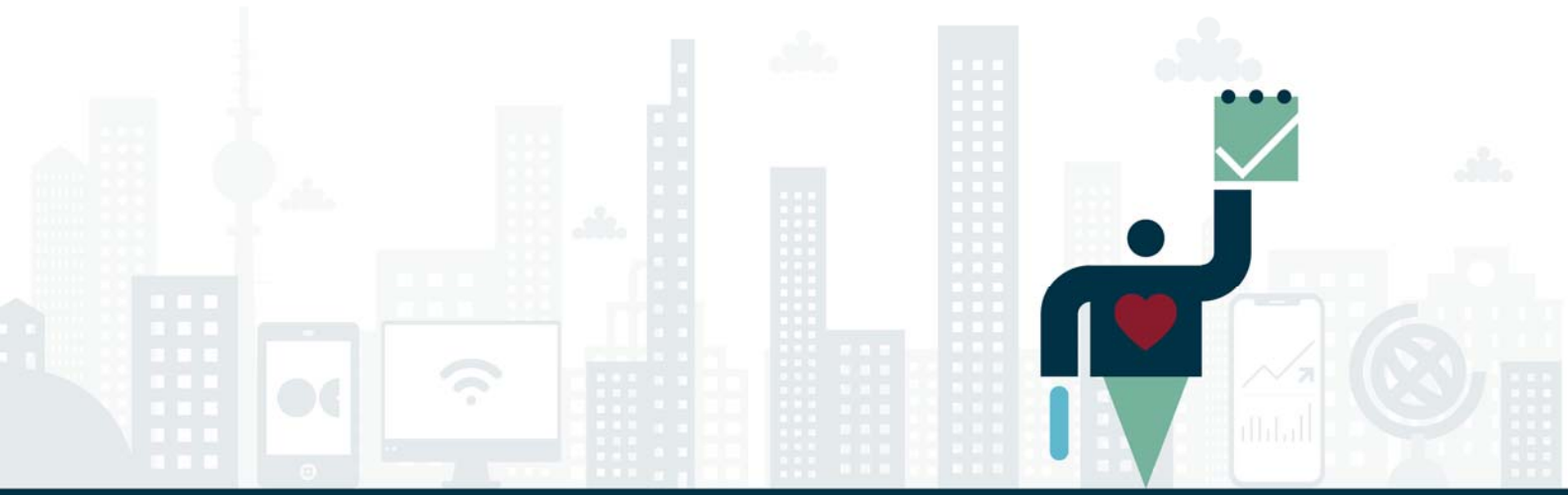

Food law

Food law

UK

Scotland launches consultation on stricter HFSS restrictions

The Scottish government has launched a consultation on the detail of proposed regulations to restrict the promotions and location restrictions of foods high in fat, sugar or salt (HFSS). These would be the equivalent restrictions of the ones that have entered into law in England (although the promotion restrictions have not yet come into force).

The proposals differ somewhat to those in England with meal deal offers and temporary price reductions being included in the Scottish proposals. However the Scottish government states the definition for volume price promotions will be consistent with that set out in the UK government regulations, and that it will use the same nutrient profiling model definition as in England to define the products in scope. The consultation closes on 21 May.

If the regulations are implemented as envisaged, this would mean that businesses would have to comply with a different set of regulations in Scotland compared to England. This would be particularly challenging in relation to price promotions offered online, as it is not yet clear how a trader would determine when to apply the English rules and when to apply the Scottish rules.

FSA launch campaign on allergy risks with vegan labelling

Recent research released by the Foods Standards Agency (FSA) showed that 62% of people who react to animal-based products are confident that products labelled as "vegan" are safe to eat. The regulator says such confidence is incorrect and may be putting these consumers at risk due to cross-contamination. It has launched the "Vegan Food and Allergens Campaign" to make people aware that they must also be checking labels for a "may contain" label.

Emily Miles, CEO of the FSA said: "*It's concerning that so many people who are allergic to milk, eggs, fish and crustaceans or molluscs believe food labelled as 'Vegan' is safe for them to eat because they assume it doesn't contain products of animal origin. Unfortunately, the reality of food production means there is still a risk of cross-contamination with animal-based allergens in vegan and plant-based products if produced in the same factory as animal-based products*."

Businesses should remember the importance of using precautionary allergen labelling, for example using the "may contain" statement, where there is a known risk of cross-contamination to ensure they are clearly communicating these risks to the consumer.

Consultation launched on fairer food labelling

The government has launched a consultation on fairer food labelling to provide consumers with information on where pork, chicken and eggs products comes from and how production methods align to welfare standards. This follows the announcement made by the environment secretary, Steve Barclay, earlier this year (see our January Regulatory Outlook). The labelling proposals being put forward are as follows:

- a label with five tiers, underpinning standards that are primarily based on method of production, differentiating between products that fall below, meet and exceed relevant baseline UK welfare regulations; and
- this would be required on all domestic and imported unprocessed pork, chicken and eggs and certain prepacked and loose minimally processed products with pork, chicken or egg.

The consultation closes on 7 May 2024.

Businesses should read the consultation document and decide whether they would like to respond.

Sector calls for mandatory food waste reporting

Campaign group, Too Good To Go, has sent an open letter to Steve Barclay calling on the government to mandate food waste reporting. The letter follows the government's announcement at the end of last year that it was reconsidering mandatory food waste reporting after it had initially said it would not implement the rules.

Businesses warned that the cost of food being wasted outweighs the cost of extra reporting requirements, noting that reporting requirements would provide them with necessary data to see where there are inefficiencies within the supply chain.

FSA set out plans for novel food process

At the latest board meeting of the FSA on 20 March, the topic of discussion was the acceleration of novel food approval procedures.

One of the key proposals put forward was the elimination of the requirement for a statutory instrument to be created after the FSA's risk assessment in order to approve the decision, which currently slows down the approval process. Instead, it proposes to establish a publicly available official register, following ministerial approval. Additionally, it proposes to remove the need for 10-year renewals of products, which would put a strain on its resources. The FSA will still retain the power to reconsider any product authorisation at any time. These changes are being put forward using powers under the Retained EU Law (Revocation and Reform) Act 2023. If implemented, they would significantly speed up the process of bringing regulated products to market in the UK.

The FSA intends to put forward these legislative changes ahead of the general election, and will publish the outcome of its consultation in April, with an aim to lay the statutory instruments in July. Read more.

EU

European Parliament and Council approve regulation on geographical indications on products

The European Parliament has approved the reform of EU rules to enhance the protection of geographical indications (GIs) for wine, spirit drinks and agricultural products.

Notably, the new regulation require national authorities to take action against the illegal use of GIs on the internet, including shutting down domain names or implementing geo-blocking. Additionally, the regulations codify existing case law to say that GIs can only be used in the name, labelling or advertising of related processed products if the GI ingredient is used in sufficient quantities to confer an essential characteristic and no comparable product is used.

The Council of the EU formally adopted the regulation on 26 March. It will now regulation will now be signed and published in the Official Journal of the EU and will enter into force on the twentieth day following its publication.

Feedback period open on plastic food contact materials

The European Commission has, on 13 March, opened a feedback period on the draft amending regulation on recycled plastic materials and articles intended to come into contact with food, and also the amending regulation on good manufacturing practice and quality control for materials and articles intended to come into contact with food.

The amending regulation will require that these materials and articles comply with restrictions of certain substances, have been subject to a risk assessment and have been subject to an individual toxicological assessment. The feedback period is open until 10 April 2024.

Businesses should review the proposed changes and decide whether they wish to provide feedback on the amending regulations.

Food law

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Health and Safety

Health and Safety

Building Safety Act update: transition period coming to an end

As detailed in our January Regulatory Outlook, 6 April 2024 is the deadline for the following measures which have been introduced under the Building Safety Act 2022:

- The transition period for the safety regime for the construction of (and work to existing) higher-risk buildings will end. The transition period (which allows the previous building control regime to apply) applies only where an initial notice is given to/full plans are deposited with the local authority before 1 October; and work is "sufficiently progressed" by 6 April 2024.
- Public and private building inspectors and building control approvers will need to be registered with the Building Safety Regulator (BSR) in order to continue to operate in the building control industry (subject to transition period arrangements). As further discussed below, this will apply in both England and Wales.

However, due to delays in completing the competence assessments for those seeking to become registered at the BSR, the following amendments to the deadline have been made:

- In England, the Health and Safety Executive (HSE) announced on 14 March 2024 that a competence assessment extension period of 13 weeks will be introduced for Registered Building Inspectors (RBIs) from 6 April 2024 to 6 July 2024 to enable those who meet specific criteria to continue to operate. Note however that this is not an opportunity to delay completing registration as an RBI and there will be no extension to these arrangements.
- In Wales, the deadline has been extended for building inspectors so they will be able to carry on working between 6 April 2024 and 1 October 2024, provided that they meet certain criteria.

New Occupational Health Taskforce

The government has launched a new Occupational Health Taskforce "*to improve employer awareness of the benefits of Occupational Health in the workplace*" as part of its plans to tackle in-work sickness.

The taskforce will produce a voluntary occupational health framework for businesses which will include setting out minimum levels of occupational health needed to stop sickness-related job losses, and help businesses better support those returning to work after a period of ill-health.

The taskforce will aim to increase access and uptake of occupational health by increasing information and visibility for employers on occupational health and empowering them to play an active role in improving employee health.

Businesses should consider whether the voluntary framework, when published, is something they wish to implement alongside the measures they already have in place in relation to occupational health.

RIDDOR review

The government has provided an update on the implementation of recommendations coming out of the HSE's second post-implementation review of the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013 (RIDDOR) conducted in July 2023.

From this review, the HSE has published five recommendations.

Two recommendations that do not require legislative changes are:

- review and revise RIDDOR guidance to ensure that reporting requirements are clear and unambiguous; and
- revise the RIDDOR reporting form to ensure that it is clear, easy to complete and ensures reports are made in line with the reporting criteria and submitted under the correct category.

Three of the recommendations require legislative changes, which are:

- to make the definitions more clear and unambiguous;
- to review the list of occupational diseases with a view to expanding it to include areas where HSE regulatory intervention can add value, with potential to increase the list of occupational diseases to include pneumoconiosis (for example, silicosis), decompression illness and pulmonary barotrauma, and hypersensitivity pneumonitis; and
- reviewing the list of reportable dangerous occurrences in Schedule 2 to ensure all necessary dangerous occurrences are captured.

Last month Paul Maynard (parliamentary under-secretary of state for work and pensions) said: " *Of the five recommendations, work is already underway on the first two, regarding guidance and online reporting. HSE will start the process of reviewing the remaining recommendations […], within the next business year.*"

Businesses should therefore be aware that changes to RIDDOR are forthcoming and be ready to proactively implement these changes when they are made.

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Modern slavery

Modern slavery

House of Lords Committee publishes call for evidence on Modern Slavery Act 2015

On 28 February 2024, the House of Lords Committee on the Modern Slavery Act 2015 published a call for evidence for its inquiry into the impact and effectiveness of the Act.

The inquiry is interested in hearing from both individuals and organisations. Issues the committee is seeking views on include: the efficacy of the provisions of the Act relating to supply chains; whether it has kept up-to-date with developments in modern slavery and human trafficking, both within the UK and internationally; the role of the Independent Anti-Slavery Commissioner, including whether the post is sufficiently resourced and the appointment process; and any suggestions for improving the Act to better achieve its aims. Responses are to be submitted by 10am on 27 March 2024 and the committee will report by 30 November 2024.

Businesses should consider whether it is worth engaging with the inquiry, as this is an opportunity to express any concerns that they may have with the Act as it currently stands or, alternatively, views on what works well under it.

Political agreement reached on Forced Labour Products Regulation

The European Parliament and Council have reached a provisional agreement on the proposed Forced Labour Products Regulation, which will ban products made with forced labour from being placed on the EU market. Below are some of the main points

Investigations: The agreed text clarifies that national authorities (or, if third countries are involved, the EU Commission) will investigate suspected use of forced labour in companies' supply chains. If the investigation concludes that forced labour has been used, the authorities can demand that relevant goods be withdrawn from the EU market and online marketplaces, and confiscated at the borders. If companies show they have removed forced labour from their supply chains, then the banned products can be allowed back on the market.

According to the Council's press release, the agreed text clarifies that if a part of the product is found to be made with forced labour, only that part will be disposed of, not the whole product. An example is given of a car: if a part of a car is made with forced labour, that part will have to be disposed of, but not the whole car. The car manufacturer would have to find a new supplier for that part or make sure that it is not made with forced labour.

High-risk goods and areas: The Parliament has insisted that the agreed text requires the Commission to draw up a list of specific economic sectors in specific geographical areas where state-imposed forced labour exists. This will then become a criterion to assess the need to open an investigation.

Risk-based approach: Criteria has been set to be applied by the Commission and national authorities when assessing the likelihood of violations of this regulation. These criteria are: the scale and severity of the suspected forced labour, including whether state-imposed forced labour may be a concern; the quantity or volume of products placed or made available on the Union market; the share of the parts of the product likely to be made with forced labour in the final product; and the proximity of economic operators to the suspected forced labour risks in their supply chain as well as their leverage to address them.

The Council has formally adopted its position and the Parliament is due to take the final vote during its plenary session in April. After this it will be published in the Official Journal. The new rules will apply three years after the regulation enters into force.

Update on regulations to eradicate modern slavery in NHS supply chains

On 14 March 2024, the Department of Health and Social Care published a statement setting out the government's plans to introduce regulations to eradicate modern slavery in NHS supply chains, which are required under the Health and Care Act 2022.

The statement confirms that a public consultation will be launched in spring 2024, which the draft regulations will be published alongside, in order to gather views on the legislation.

The regulations will place legal duties on public bodies to assess modern slavery risk in procurement and contract activities and take reasonable steps to address and, where possible, eliminate that risk. The statement outlines that the reason for the delay in introducing these regulations is so the government "*can ensure they are fit for purpose and interact with the current legislation and updated policies*."

Businesses should keep an eye out for the publication of the consultation and decide whether they wish to respond.

CSDD gets through vote from Council of the EU

Please see Environmental, social and governance.

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Products

Products

Jump to: General / digital products | Product sustainability | Life Sciences and healthcare

General/ digital products

UK

Legislation introduced to cut smoking and vaping

Following its consultation on measures to create a smokefree generation and tackle youth vaping, the government has, on 20 March, introduced the new Tobacco and Vapes Bill into Parliament. The legislation will:

- make it an offence for anyone born on or after 1 January 2009 to be sold tobacco products;
- prohibit proxy sales in line with the change in age of sale legislation;
- include all tobacco products, herbal smoking products and cigarette papers, in scope; and
- require warning notices in retail premises to read "it is illegal to sell tobacco products to anyone born on or after 1 January 2009" when the smokefree legislation comes into effect.

Under the bill, regulations can be made to: restrict vape flavours; restrict how vapes are displayed in stores; restrict packaging and product presentation for vapes; and apply the restrictions to non-nicotine vapes and other consumer nicotine products such as nicotine pouches. See our Insight for more.

The minister of health has confirmed that Northern Ireland will be included in the proposed legislation, subject to the approval by the NI Assembly.

Draft regulations on banning the supply and sale of disposable vapes

The government's consultation response, as referenced above, also highlighted that legislation would be brought forward to ban the sale and supply of disposable vapes and the draft regulations were published on 11 March.

The regulations will prevent anyone from supplying disposable vapes in the course of a business, whether or not by way of sale. Scotland and Wales will also implement these regulations, but Northern Ireland is considering its next steps. The explanatory memorandum explains that: *"The ban will be brought into force at least 6 months after the instrument has been introduced to ensure businesses have sufficient time to adapt and run-down stocks."*

The regulations are set to enter into force on 1 April 2025 and businesses that place disposable vapes on the UK market should remain vigilant about this forthcoming regulatory change.

Webinars for using the UKCA and CE markings to place products on the market in GB and NI

The Department for Business and Trade has published a list of upcoming webinars on the UK's approach to product marking and placing products on the market in Great Britain and Northern Ireland.

With the government's recent announcement that it intends to introduce legislation to indefinitely recognise the CE mark for products, we anticipate that these webinars will provide an update on when this legislation will be introduced and provide further details on the proposals. Businesses should sign up to attend these webinars so they are aware of the forthcoming changes and to take the an opportunity to ask questions.

EU

European Parliament formally adopts Product Liability Directive

The European Parliament, on 12 March, formally adopted the new Product Liability Directive.

As a reminder, changes under the new rules include consumers being able to seek compensation for medically recognised damage to psychological health and damage in the form of destroyed or corrupted data.

Businesses will need to ensure there is always a business in the EU (that is, a manufacturer, importer or authorised representative) that can be held liable for a product, even if the product was not purchased in the EU. Another change is that the liability period has been extended to 25 years in exceptional cases.

The Council now needs to adopt the directive formally, after which it will be published in the EU Official Journal. The new rules will apply to products placed on the market 24 months after entry into force.

Once the final text of the directive has been published, businesses should familiarise themselves with the new rules to understand the impact on them and what changes they may need to implement.

European Court of Justice overturns decision on accessibility of technical standards on toy safety

The technical "harmonised" standards which enable compliance with the product regulations applicable in the EU and UK have historically only been made available to the public from commercial organisations at a cost. Access to these documents can be refused if disclosing them would undermine the protection of commercial interests, including intellectual property, unless there is an overriding public interest in disclosure.

In 2018, the European Commission refused a request for harmonised technical standards on toy safety to be made available to the public. This refusal was upheld by the General Court in 2021.

However, earlier this month, the European Court of Justice overturned this ruling. It found that there is an overriding public interest in disclosing the respective harmonised standards. This will have dramatic implications for standards bodies, as well as cost savings for manufacturers of products as they will no longer need to buy the standards.

European Parliament adopts position on new toy safety rules

The European Parliament has formally adopted its final position on the new toy safety regulation.

As detailed in the previous Regulatory Outlook, the Parliament's position includes a further ban on harmful chemicals (to include endocrine disruptors), the introduction of digital product passports for all toys sold in the EU, and ensures toys comply with other EU legislation such as the AI Act and the General Product Safety Regulation. The text constitutes Parliament’s position at first reading. The file will be followed up by the new Parliament after the European elections on 6-9 June.

While the legislation is still yet to be formally approved, businesses should start to familiarise themselves with the changes.

European Parliament formally adopt Cyber Resilience Act

The European Parliament has formally adopted its position on the Cyber Resilience Act. The Act seeks to introduce new cybersecurity requirements for products with digital elements to enhance their resilience against cyber threats and provide consumers with more information about the security of these products.

It introduces a large raft of requirements for manufacturers of products with digital feature on the market. Under the Parliament's proposal, these include: to report cyber vulnerabilities of components; documenting and updating cybersecurity risk assessments; determining the support period to reflect the length of time during which the product is expected to be in use and ensuring this support period is specified at the time the product is purchased; and to ensure each security update made available to users remains available for a minimum of 10 years after the product has been placed on the market.

The text will now need to be formally adopted by the Council. It is anticipated that the Council will also adopt the Act at its next meeting, having reached an informal agreement on the act in November 2023 (see our previous Regulatory

Outlook). Once adopted by both institutions, it will be published in the Official Journal, after which it will enter into force 20 days later.

Political agreement reached on Forced Labour Products Regulation

Please see Modern Slavery.

Sustainable products

UK

Extended producer responsibility for packaging waste: reporting changes coming into force 1 April 2024

As detailed in last month's Regulatory Outlook, amending regulations have been made which amend the Packaging Waste (Data Reporting) (England) Regulations 2023.

The amending regulations amend the definition of "household packaging" to add an additional test and clarify that sellers must report packaging supplied to businesses.

The regulations also impose reporting obligations on distributors that supply unfilled packaging to a large producer, which 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.

These changes come into effect on 1 April 2024 and the guidance on the data that must be reported has been updated in line with these changes.

Businesses that fall within the scope of the extended producer responsibility scheme should review these new regulations and updated guidance to determine if their obligations are affected and whether they need to report additional data.

The amending regulations also require the Environment Agency to publish a list of large producers which will be published on this guidance page in April 2024 and will be regularly updated.

In line with these upcoming changes, Defra has published new guidance for businesses on assessing household and non-household packaging under the extended producer responsibility for packaging. The guidance addresses how to assess packaging and what evidence businesses must collect and keep if they are reporting any primary or shipment packaging as non-household packaging.

EU

Provisional agreement reached on Packaging and Packaging Waste Regulation

On 4 March 2023, a provisional political agreement was reached on the Packaging and Packaging Waste Regulation (PPWR). Below are some of the takeaway points from the latest draft:

- From 1 January 2030, certain single use plastic packaging formats will be banned, such as packaging for unprocessed fresh fruit and vegetables, packaging for foods and beverages filled and consumed in cafés and restaurants, individual portions (for example condiments, sauces, creamer, sugar), accommodation miniature packaging for toiletry products and shrink-wrap for suitcases in airports.
- Ban on “forever chemicals” (PFAS) in food contact packaging. The agreed text outlines that this ban would come into force 18 months after the PPWR enters into force.
- Final distributors of beverages and take-away food in the food service sector would be obliged to offer consumers the option of bringing their own container. They would also be required to offer 10% of products in a reusable packaging format by 2030.

- Minimum recycled content targets for any plastic part of packaging.
- Minimum recycling targets by weight of packaging waste generated and increased recyclability requirements.
- Mandatory deposit return schemes – 90% of single use plastic and metal beverage containers (up to three litres) to be collected separately by 2029.
- Change to the definition for post-consumer recycled plastic.

The provisional agreement now needs to be formally adopted by both the Council of the EU and the European Parliament, after which it can be published in the EU's Official Journal and enter into force. The regulation will be applied from 18 months after the date of entry into force. However, there have been recent reports of lobbying against the PPWR and so we anticipate that there could be some delays to the final votes.

European Parliament adopts position on reducing textiles and food waste

The European Parliament has adopted its final proposal on reducing food and textile waste.

Its position, as set out in last month's Regulatory Outlook, agrees with the Commission's proposal to introduce extend producer responsibility (EPR) schemes for textiles, but states that Member States are required to establish these schemes within 18 months after the directive comes into force (compared to 30 months proposed by the Commission).

Additionally, the Parliament's position sets out higher waste reduction targets to be met at national level by 31 December 2030, including in food processing and manufacturing which are at least 20% (instead of 10% as proposed by the Commission). The file will be followed up by the new Parliament after the June elections, but businesses should start to understand the impact the new legislation may have on them.

Next steps for EU PFAS restriction proposal

The European Chemicals Agency (ECHA) has this month provided an update on the next steps for the proposal to restrict per- and polyfluoroalkyl substances (PFAS) (see our January Regulatory Outlook for more).

The ECHA's scientific committees for Risk Assessment and for Socio-Economic Analysis will evaluate the proposed restriction on the manufacture, placing on the market and use of PFAS alongside the comments received from the consultation, focusing on the different sectors that may be affected. In parallel, the five countries that prepared the proposal will also evaluate the consultation comments received and will update their initial report to address them. This updated report will be assessed by the committees and be the foundation for their opinions.

At the next committee meetings, which are scheduled for March, June and September 2024, the ECHA and committees will discuss specific sectors and elements of the proposal. More information on next procedural steps will be announced as work advances.

EU directive to empower consumers for the green transition published in the Official Journal of the EU

Please see Advertising and marketing.

UK government consultation on introduction of CBAM

Please see Environment.

Life Sciences and Healthcare

Consultation on proposed update to the statutory scheme to control the cost of branded health service medicines

The Department of Health and Social Care has launched a consultation on proposals to update the statutory scheme to control the cost of branded health service medicines.

Products

As detailed in the January Regulatory Outlook, the 2019 voluntary scheme for branded medicines pricing and access (VPAS) expired at the end of 2023, and has now been replaced by the new voluntary scheme for branded medicines, pricing, access and growth (VPAG). However, the government noted, when implementing VPAG, that further updates would need to be made to the statutory scheme for branded medicines and this latest consultation is in relation to those.

The consultation is proposing to introduce a differentiated approach to setting payment percentages for newer and older medicines:

- For newer medicines, setting a headline payment percentage of 11.6% in Q3 to Q4 2024, 14.1% in 2025 and 16.5% in 2026.
- For older medicines, setting a basic rate of 10.03% in Q3 to Q4 2024, 10.6% in 2025 and 11% in 2026, and a top-up rate of between 1% and 25%.
- Increasing the threshold for an exemption from scheme payments for small companies.
- Calculating the price decline of older medicines.

Pharmaceutical companies hoping to sell medicines to the UK NHS should review the consultation and decide whether it is worth responding. It closes on 26 April 2024.

MHRA publishes new guidance for assessment of established medicines

The Medicines and Healthcare products Regulatory Agency (MHRA) has published new guidance outlining the process changes for "Established Medicines" which comes into effect on 1 March 2024. “Established Medicines” includes products that are not new active substances and line extensions to new active substances.

The key change to the assessment process is that the MHRA will carry out a technical completeness check of the application. This check will ensure that it has all necessary information to proceed with the assessment at the start of its review, which will enable it to assess applications more efficiently.

The Veterinary Medicines (Amendment etc.) Regulations 2024

The draft Veterinary Medicines (Amendment etc.) Regulations 2024 have been published. These regulations have been made following the consultation response published last month (see previous Regulatory Outlook).

Changes made to the Veterinary Medicines Regulation 2013 include clarifying rules on advertising veterinary medicines, requiring additional information for an application for generic medicines to explain differences from the reference product, and requiring manufacturers to record more detail on the medicines they manufacture, to improve traceability.

CMA consults on proposal to launch a market investigation of the UK vet sector

Please see Consumer law.

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Regulated procurement

Regulated procurement

Procurement Act 2023: Government publishes draft Procurement Regulations
Following its two consultations on draft regulations implementing certain aspects of the Procurement Act 2023, the government has now published its response and has also published the draft regulations. The consultation response notes the draft regulations have been amended to improve them in line with comments received, although no significant changes are being made.

The consultation response adds that the government will provide a minimum of six months' notice of go-live of the new regime and that the laying of the regulations would be the earliest point that this notice would be given. Its expectation continues to be that the new regime will come into force from October 2024.

Some of the key takeaways from the consultation response are:

- With regard to the Act and the Provider Selection Regime (PSR), the response states that healthcare services will be included in the schedule of light touch services covered by the Act to ensure that those bodies that are not covered by the PSR are regulated under the Act when buying healthcare services. Guidance will be published on how the Act and the PSR interact.
- For pipeline notices, the response confirms that contracting authorities are not held to the information in the notice which could change over time as plans for the procurements become clearer and they are not legally obliged to indicate when a contract will not be procured.
- For tender notices, an amendment will be made to the regulations to require contracting authorities to state whether or not they consider the contract would be particularly suitable for small and medium-sized enterprises and voluntary, charitable or social enterprises.
- Guidance will be published on practical aspects of transparency notices, such as timings for publication.
- The government is considering an optional field for termination notices for authorities to use voluntarily to provide reasons for termination. Termination notices are new under the Act and will be used to tell the market that a procurement has been discontinued.
- For assessment summaries, the government will remove the requirement for contracting authorities to explain why the next available score was not achieved. This change was made because it was being misinterpreted as requiring a separate statement, whereas it was intended to be included in the overall explanation for the score. Further, the obligation to provide suppliers with information regarding the most advantageous tender remains, but the new approach will be less burdensome than the current requirement.
- For contract award notices, the naming of unsuccessful bidders has been removed for lower value contracts and will only be a requirement for public contracts valued at £5m or above. Guidance will provide further clarity on practical concerns about contract change notices.
- No changes will be made to the transitional provisions in terms of the length. Guidance will confirm questions raised around transition of procurements under the new regime, but it is understood that those conducted under the current regime, including when modified, will continue to be regulated under the current regime rather than under the Act.

Procurement Act 2023 guidance
The government has published its first tranche of guidance for stakeholders to help prepare for the Act, which is aims to provide technical guidance to help understand the new regime. It will be publishing the guidance documents in batches, with the aim to have the full suite published by the end of June 2024.

The first suite covers the following topics:

- contracting authority definition;
- covered procurement definition;
- valuation of contracts;
- mixed procurement;
- exempted contracts; and
- thresholds.

The government also states that transition guidance will also be published shortly.

Regulated procurement

Crown Commercial Service publishes its updated commercial pipeline under the Procurement Act 2023

The new Procurement Act 2023 introduces a new requirement on authorities to publish their pipeline notices detailing their upcoming procurements. These notices are mandatory for authorities planning to spend more than £100m on regulated contracts in the coming year.

Pipeline notices are intended to help suppliers plan better for upcoming contract opportunities and allow them to resource the bidding, which can be time consuming. In order to take full advantage, suppliers should become practiced in monitoring pipeline notices.

Ahead of the Act coming into force (expected to be October 2024), the Crown Commercial Service (CCS) has published its pipeline priority list of commercial agreements anticipated to be awarded from October 2024 under the new regime. The article states that the Procurement Act 2023 is not retroactive adding that: *"All current live commercial agreements will continue operating under the Public Contract Regulations 2015 (PCR 2015). We will operate agreements under both PCR 2015 and the Procurement Act 2023 for a period of time; at least until existing agreements expire, are replaced, or cease to exist."*

Suppliers interested in bidding for CCS framework agreements should review the list so they are aware of which upcoming agreements will be run under the new regime.

PPN 01/24 Carbon Reduction Contract Schedule

The Cabinet Office has published Procurement Policy Note (PPN) 01/24 that introduces an optional standard carbon reduction contract schedule that can be included in government contracts. Use of the Carbon Reduction Schedule is optional and should be included where relevant to the subject matter of the contract and proportionate to do so. The PPN can be applied with immediate effect.

The Carbon Reduction Schedule published alongside this PPN provides standard terms and conditions to support contract specific decarbonisation objectives to be set and delivered, and provides a framework to monitor and assess the supplier's decarbonisation performance. These include contract specific greenhouse gas (GHG) emissions reporting, setting supplier GHG emissions reduction targets and monitoring and reducing GHG emissions throughout the life of the contract though a supplier GHG emissions reduction plan.

PPN 01/24 applies to all central government departments, their executive agencies and non-departmental public bodies, but other public sector contracting authorities may also wish to apply the approach set out in this PPN.

Consultation on competition and consumer protection-related information sharing
The government is consulting on two proposals which would amend the Enterprise Act 2002 to enable the exchange of competition and consumer protection-related information between relevant UK public authorities to assist them in exercising their statutory functions.

This includes adding the Procurement Act 2023 to the list of legislation in schedule 15 of the Enterprise Act in order to allow information sharing between the CMA Competition and Markets Authority (CMA) and contracting authorities and the Procurement Review Unit. This is in relation to the mandatory and discretionary exclusion grounds under the Act.

Adding the Procurement Act 2023 to the Enterprise Act will create an information-sharing gateway to allow contracting authorities to contact the CMA to know whether a supplier has or is being investigated. Under the 2023 Act, the mandatory exclusion ground includes where the CMA has made a decision that a particular supplier has infringed Chapter I of the Competition Act 1998 within the last five years. Under the discretionary grounds, it covers decisions by the CMA in relation to infringement of Chapter II prohibition (abuse of dominance) and situations where an alleged competition infringement has not been investigated, or where a case is being investigated but has not yet concluded.

Regulated procurement

Update on regulations to eradicate modern slavery in NHS supply chains

Please see Modern slavery.

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Sanctions and Export Control

Sanctions and Export Control

UK government sanctions strategy paper

The Foreign, Commonwealth & Development Office (FCDO) has published a policy paper setting out the UK government's approach to using sanctions as a foreign and security policy tool. The paper sets out several case studies illustrating the effectiveness of the UK sanctions regime, noting that as of October 2023, over £22 billion Russian assets have been reported frozen as a result of financial sanctions.

In order to deliver the strategy, the FCDO announced that:

- The new Office of Trade Sanctions Implementation (OTSI), which will be responsible for the implementation and civil enforcement of certain trade sanctions, will be operational in 2024. See more in our previous Regulatory Outlook.
- 2024 will see the introduction of a new type of prohibition to make it unlawful for a designated party under the UK's autonomous sanctions regimes to act as a director of a UK company.
- The FCDO is developing a voluntary process to allow sanctioned individuals to apply for sanctioned funds to be released for the purpose of supporting Ukraine's recovery and reconstruction.
- Legislation will be introduced "*when parliamentary time allows*" to create a humanitarian exception across the UK's financial sanctions, as set out in the 2023 white paper on International Development.

Treasury Committee inquiry into effectiveness of UK's Russia sanctions regime

The Treasury Committee launched an inquiry on 29 February 2024 into the effectiveness of the UK's financial sanctions on Russia in impeding Russia's war effort against Ukraine. The call for evidence follows a 2022 report from the committee on the impact of economic sanctions on Russia.

The committee seeks views on the UK's financial sanctions on Russia, including the effectiveness of the work of OFSI and whether financial sanctions should be widened to include purchasers of Russian oil and gas. The deadline for submissions is 28 March 2024.

Russia (Sanctions) (Overseas Territories) (Amendment) Order 2024

The Russia (Sanctions) (Overseas Territories) (Amendment) Order 2024 came into force on 14 March 2024. The order extends the Russia (Sanctions) (EU Exit) Regulations 2019 to all British overseas territories except Bermuda and Gibraltar.

Export Control (Amendment) Regulations 2024

The Export Control (Amendment) Regulations 2024 come into force on 1 April 2024, amending:

- Export Control Order 2008 Schedule 2 (military goods, software and technology), to implement technical updates made to the Wassenaar Arrangement munitions list.
- Export Control Order 2008 Schedule 3 (dual-use goods, software and technology), to introduce new export licence requirements for the export of equipment in relation to quantum technologies, cryogenic technologies, semiconductor technologies, additive manufacturing equipment and advanced materials.
- Council Regulation (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items (Recast) Annex 1 (dual-use goods, software and technology), to reflect technical updates to the Wassenaar Arrangement dual-use list and control lists administered by other multilateral export control regimes.

See the full consolidated list of controlled strategic military and dual-use items.

Sanctions and Export Control

Office of Financial Sanctions Implementation updates

OFSI has published a new factsheet on the UK's financial sanctions in relation to maritime shipping.

OFSI has issued a new general licence permitting the payment of monies owed to designated persons pursuant to a court order to pay these to the Court Funds Office.

The deadline for providing additional attestations or items ancillary costs under the Russia Oil Price Cap has been increased from 28 to 30 days. See OFSI's industry guidance.

Ban on import of Russian diamonds processed in a third country

The prohibition on the import of Russian diamonds processed in a third country in relation to diamonds equal to or larger than one carat in weight came into effect on 1 March 2024.

The guidance on third-country processed Russian diamonds, which gives an explanation of the regulations, how to demonstrate compliance and sets out the relevant licencing provisions can be found here. A general licence has also been introduced, permitting the import of diamonds that were outside of Russia on 1 March 2024 and have remained outside of Russia since that date, as well as certain services and actions in relation to their import.

A further prohibition on the import of diamonds equal to or larger than 0.5 carats will come into effect from 1 September 2024.

Policy paper on the Sanctions and Anti-Money Laundering Act 2018

The FCDO published a post-legislative scrutiny memorandum on the Sanctions and Anti-Money Laundering Act 2018 (SAMLA).

It helpfully summarises the UK's sanctions legislation, court challenges, secondary legislation, statutory reports and statutory guidance linked to the sanctions regimes and the SAMLA's anti-money laundering provision.

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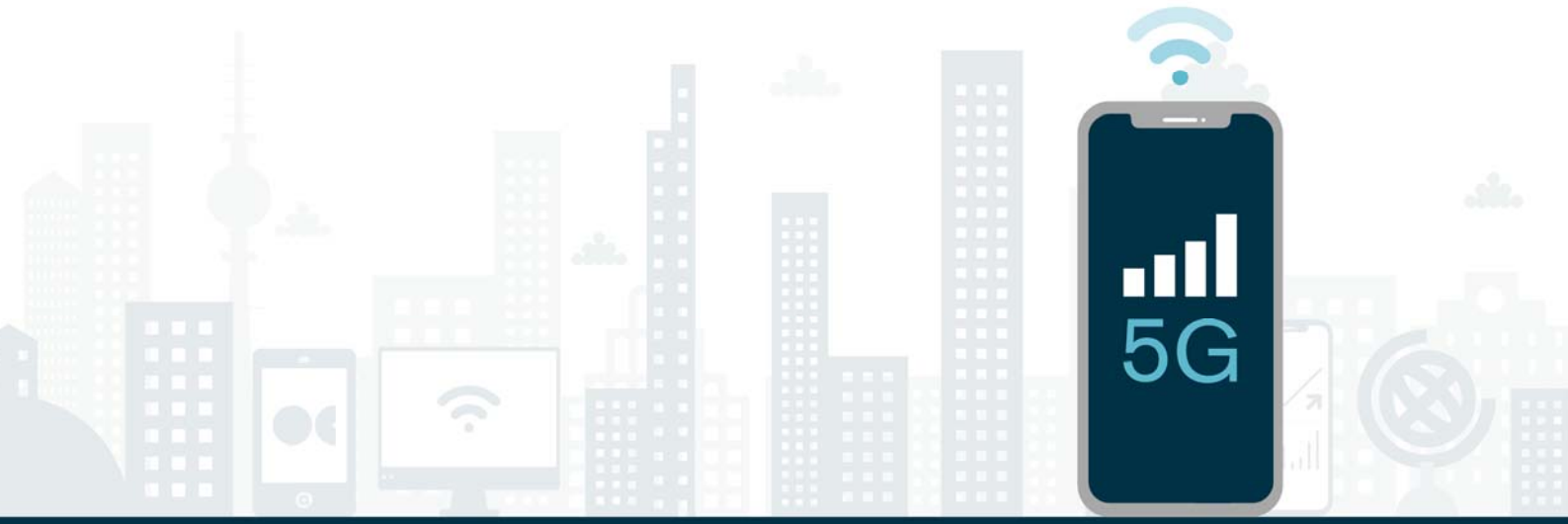

Telecoms

Telecoms

Nothing further to report this month.

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