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 that the UK government has confirmed that the new procurement regime will go live on Monday 28 October 2024, giving businesses six months' time to prepare. See the Regulated Procurement section for more.

April 2024

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Advertising and marketing

Advertising and marketing

ASA publishes 2023 annual report

The UK Advertising Standards Authority (ASA) has published its 2023 annual report highlighting its progress in regulating the digital advertising world using artificial intelligence (AI) and tech-assisted tools and the shift it has made from complaints-led investigations towards proactive, ASA-led monitoring and enforcement.

The 2023 work highlights and future plans include:

- AI-assisted collective ad regulation: this 2024-2028 strategy, which uses the ASA's AI-based Active Ad Monitoring System, was introduced last year (see this Regulatory Outlook). The ASA says that in 2023, a total of 3 million ads were processed using the system across various areas, including climate change and the environment, youth vaping, gambling and prescription-only medicines. This year, the regulator plans to expand its use and the areas covered.
- Misleading environmental claims: climate change and the environment remain priority areas for 2024. The ASA also intends to publish the outcome of its research on claims in ads for meat, dairy and plant-based substitutes early in 2024.
- Body image and cosmetic surgery abroad: in 2024, as part of its wider communication on its Body Image project, the ASA will publish its insights from both the roundtable that it held with stakeholders and the evidence it received in response to its call for input.
- Youth vaping: in 2024, the ASA will continue monitoring ads for vaping products that are targeted at or likely to appeal to under-18s and plans to issue an enforcement notice.
- Intermediary and Platform Principles (IPP): following the successful pilot of the IPP, the ASA now sees it as a "*tried and tested way in which platforms and intermediaries can play a part … in supporting the ASA to help secure responsible advertising online*" and is committed to developing the regulatory framework further.

FCA publishes finalised guidance on financial promotions on social media

The UK Financial Conduct Authority (FCA) has released its finalised guidance on financial promotions on social media, which provides direction for firms and influencers on how to navigate financial promotions using social media. See our Insight for more details.

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Artificial Intelligence

Artificial Intelligence

UK updates

Guidance on responsible use of AI in recruitment

The UK Department for Science, Innovation and Technology (DSIT) has published guidance around the responsible use of AI in the HR and recruitment sector, as was trailed in the government's response to the AI white paper.

The "Responsible AI in Recruitment" guide is designed for a non-technical audience and assumes a minimal understanding of AI. It outlines key considerations to bear in mind when procuring and deploying AI responsibly in the recruitment context; assurance mechanisms for procurement of an AI system from third-party suppliers and deployment, to make sure the organisation's practices align with the UK AI regulatory approach and principles; and outlines potential ethical risks associated with using AI in recruitment and hiring processes, accompanied by examples.

The non-binding guidance stands in contrast to the EU's approach, where AI used in recruitment will be classified as "high risk" under the EU's AI Act. In addition, specific prohibitions and obligations will be imposed under the EU platform workers directive in relation to monitoring or decision-making by AI-powered recruitment systems.

Responsible AI toolkit

DSIT has published a "Responsible AI Toolkit" which collects guidance published to support organisations in developing and deploying AI systems safely and responsibly. It will be updated over time to include new resources.

CMA publishes update paper on AI foundation models

The UK Competition and Markets Authority (CMA) has published an update paper on AI foundation models. The CMA provides an overview of how the sector has developed since its initial report published in September 2023 (see this Regulatory Outlook) highlighting the ongoing increase in the use of foundation models by businesses and consumers.

The CMA has updated its guidance for foundation model developers to reflect feedback from stakeholders. The report also outlined three key interlinked risks that the CMA has identified in relation to maintaining fair, open and effective competition in foundation model markets. See this Competition section for more.

ICO publishes third call for evidence on generative AI and data protection

The UK Information Commissioner's Office (ICO) has published a third consultation on generative AI and data protection. This call for evidence focuses on how the general UK GDPR principle of accuracy applies to the outputs of generative AI models, and the impact that the accuracy of training data has on the output.

The first consultation looked at "The lawful basis for web scraping to train generative AI models" and the second consultation focused on "Purpose limitation in the generative AI lifecycle".

The third consultation closes on 10 May 2024 and responses can be submitted in this form.

UK Culture, Media and Sport Committee calls on government to ensure fair remuneration for the use of creators' work by AI developers

The UK House of Commons Culture, Media and Sport Committee has published a report on remuneration in the creative industries which, among other things, discussed the issue of a voluntary code of practice on copyright and AI. The committee addressed the government's response to the consultation on its AI white paper where it announced that no agreement had been reached on the voluntary code.

The committee highlights that, despite the government's announcement that it would consider legislating if there was no agreement on a code of conduct, the government has not yet indicated its intention to do so. It calls on the government to ensure that there is an effective mechanism in place for obtaining creators' consent for the use of their work by AI developers and that creators are fairly compensated for this. The committee also recommends that the government should set out a clear deadline by which it will intervene to introduce legislation to break any deadlock.

International updates

UN adopts resolution on AI

The United Nations General Assembly has adopted a resolution on the promotion of safe, secure and trustworthy AI, with an emphasis on the sustainability of this technology. The resolution is addressed to businesses and private sector

organisations as well as UN member states and calls on all to "*develop and support regulatory and governance approaches and frameworks related to safe, secure and trustworthy artificial intelligence systems*".

It emphasises the need to act in accordance with human rights principles when using AI (which might mean deciding not to use AI where this cannot be done in compliance with international human rights law) and also includes repeated references to the UN's 17 sustainable development goals.

WIPO factsheet on generative AI and intellectual property

The World Intellectual Property Organisation (WIPO) has published a factsheet focused on risks and safeguards to consider in relation to IP when adopting generative AI tools. The document provides an overview of risks and possible solutions to mitigate them, as well as a checklist of ways to use AI responsibly. The latter may be useful for businesses.

And finally…

Do you want to know what's on the horizon for digital regulation? Our digital regulatory timeline offers an overview of major UK and EU digital regulation that is on the horizon, is in the legislative process, or is coming into force soon and covers a very wide range of topics including AI, platforms, digital services, content and connected products, data, cybersecurity and other regulation. We update it regularly, and add new content as it comes into view on the horizon.

We have also produced a video series setting out the four key stages in a business' journey to deploying, governing and managing AI. You can watch them here.

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Bribery, fraud and anti-money laundering

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Financial Conduct Authority 2024/2025 Business Plan

The Financial Conduct Authority (FCA) has published its 2024/25 Business Plan, as a useful reminder of its objectives and areas of regulatory focus for the financial sector.

Over the next year, the FCA will focus on reducing and preventing financial crime, prioritising the needs of consumers and strengthening the UK's position in global wholesale markets. This follows its work update published in February 2024 (as reported in our previous Regulatory Outlook), which highlighted the need for firms to tackle fraud and ensure their systems keep up with the increasing sophistication of criminal groups.

For further information see our Insight.

Delegated regulation amending list of high-risk third countries under MLD4

The European Commission adopted a delegated regulation to amend the list of high-risk third countries that have been identified as having strategic deficiencies in their anti-money laundering and counter-terrorism financing regimes that pose significant threats to the financial system of the EU, under Article 9(2) of the Fourth Money Laundering Directive (MLD4).

The delegated regulation will amend the table in point I of the Annex by:

- removing Barbados, Gibraltar, Panama, Uganda and the United Arab Emirates; and
- adding Kenya and Namibia.

The delegated act will now need to be submitted to the EU Parliament and Council for review and will enter into force on the twentieth day following its publication in the Official Journal of the EU.

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Competition

Competition

CMA Green Agreements Guidance

The Competition and Markets Authority (CMA) recently issued informal guidance under its Green Agreements Guidance. The informal guidance relates to a proposal to extend a joint commitment between the WWF and leading supermarkets. The proposal aims to reduce greenhouse gas emissions in grocery supply chains by requiring supermarket suppliers to set science-based, net-zero targets by an agreed date. This is the second informal guidance issued by the CMA.

In assessing it, the CMA noted that while there may be some competition risks associated with the proposal, such as potential cost increases or reduced product range, it believes that the potential benefits, including significant environmental benefits and potential cost savings for consumers, could outweigh any potential harm to competition. The CMA's assessment made use of the new and substantially more permissive approach when assessing the benefits of "climate change agreements."

The guidance does mention that the proposal shares similarities with a phasing out agreement. Phasing out agreements involve the gradual elimination of non-sustainable products or processes over time. The guidance states that phasing out agreements are unlikely to raise competition concerns if they do not result in an appreciable increase in price or reduction in product quality or choice for consumers and do not have the objective of eliminating or harming competitors or market sharing.

Overall, the CMA's guidance provides businesses with an opportunity to obtain clarity and assurance for their own agreements with competitors. It is important to note that the CMA has pledged not to fine the parties to an agreement it has approved under its Green Agreements Guidance, even if it were to subsequently conclude that the arrangements infringed competition law. Please see our Insight for more in-depth discussion of this development.

AI foundation models update report

The CMA has published an update report on AI foundation models (FMs), identifying three key risks to competition. These risks relate to firms controlling critical inputs, powerful incumbents distorting choice in FM services, and partnerships reinforcing market power. The CMA expressed concerns about potential exploitation of market power and unintended consequences. It updated its AI Principles to ensure fair competition, which include access, diversity, choice, transparency and accountability.

The CMA will consider these risks when prioritising its enforcement under the Digital Markets Competition and Consumers Bill (DMCCB), currently completing the parliamentary process. It also highlighted the potential benefits and harms to consumers from the development of FMs. While higher quality products and services are possible, there is also the risk of unfair practices and flaws in the technology. The CMA will have new powers to enforce consumer protection law under the DMCCB, including imposing fines of up to 10% of worldwide turnover for non-compliance.

The CMA acknowledges the potential chilling effect of excessive regulation, which may create barriers to entry for smaller firms. It supports the policy objective of promoting market competition in AI and endorses the House of Lords Communications and Digital Committee's recommendation in this regard.

The CMA is actively participating in the Digital Regulation Cooperation Forum (DRCF), engaging in joint research on consumer understanding and use of foundation models. It is also part of the DRCF AI and Digital Hub pilot.

In addition to the update report, the CMA plans to publish further updates on FMs: a paper on AI accelerator chips and their role in the FM value chain, and a joint statement with the Information Commissioner's Office (ICO) on the interaction between competition, consumer protection and data protection. The CMA's work on AI extends beyond foundation models, and it has been asked to report its strategic approach to AI to the government by 30 April.

UK mass antitrust claim founded on sewage dumping

A number of UK water companies are facing collective action claims at the Competition Appeal Tribunal (CAT). The claims are based on the alleged underreporting of the number of pollution incidents that the companies caused, which the claimant suggests amounts to an abuse of dominance due to the consequent overcharging of customers.

This is a novel claim to bring to the CAT. While seemingly an environmental or data-related issue, the claim is premised on the alleged status of the water companies as monopolies and their ability to use their market power to mislead regulators. The CAT will have to review the evidence and assess whether the claim meets the criteria for a collective action under competition law. This will involve assessing whether there is a sufficient nexus between competition law

litigation and water sector regulation. The claim is complicated by the fact that many of the companies targeted by the action are already being investigated by Ofwat and the Environment Agency/National Resources Wales for the same alleged issues.

While it is unclear what the outcome of this assessment will be, this is an interesting claim that reflects the increasingly diverse matters being brought to the CAT.

Foreign Subsidies Regulation

The European Commission has recently launched a probe into Chinese companies' involvement in public procurements across a number of EU jurisdictions using powers granted under the Foreign Subsidies Regulation (FSR). The regulator has commented that this probe and the regulation more broadly is intended to protect the economic security of the EU, particularly following the impact of Chinese imports on the European solar panel industry. As a result, it will be taking a case-by-case approach to reviewing foreign subsidies. One such investigation looked at the involvement of a Chinese company in a Bulgarian public procurement procedure relating to the supply of electric trains. Notably, the investigation was closed after the Chinese company withdrew from the procurement process.

The FSR is intended to protect the EU's internal market. It requires companies, whether established in the EU or not, to notify the Commission of EU-based public procurement tenders that (i) have an estimated contract value exceeding €250 million and (ii) include a company that was granted at least €4 million in foreign financial contributions from at least one third country in the three years before notification. The regulator will investigate the deal and, if it finds that the company has benefitted from a foreign subsidy that distorts the internal market, it may reject the tender or approve the tender subject to commitments.

The Commission can also launch investigations on its own initiative to assess whether subsidies might distort the internal market. Its investigative powers include requests for information, interviews, or on-site inspections. Redressive measures can includes structural or non-structural measures, including the repayment of subsidies, and it can issue fines for non-compliance with commitments or redressive measures. For more details on the FSR, please see our previous Insight on this regime.

While there is a particular focus on Chinese firms at the moment, the regulatory regime is intended to be territorially agnostic and therefore is relevant for all international companies whose operations may have an impact on the EU internal market. In particular, companies should be aware of the regime when undertaking M&A activity in the EU or participating in EU tender processes.

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Consumer law

Consumer law

Ofcom publishes call for evidence on additional duties for categorised services under the Online Safety Act 2023

Ofcom has published a call for evidence to inform its codes of practice and guidance on the additional duties that will apply to categorised services under the Online Safety Act 2023.

This call for evidence is part of the third phase of the regulator's work to implement the online safety regime. Part three consists of:

- identifying the service providers that are subject to additional duties;
- consulting on draft codes and guidance on those additional duties (first consulting on guidance on the transparency reporting regime in summer 2024 and then consulting on additional duties for categorised services in early 2025); and
- publishing final codes and guidance.

This call for evidence aims to support the early 2025 consultation.

The Act introduces a system categorising some regulated online services, based on their key characteristics and whether they meet certain numerical thresholds, as category 1, 2A or 2B services. Alongside the call for evidence, Ofcom has published its advice to the government on setting the thresholds, which was sent to the Secretary of State for Science, Innovation and Technology on 29 February 2024.

Based on this advice, the Secretary of State will set out the thresholds in secondary legislation and Ofcom will, once it has assessed the services against the final thresholds, publish a register of categorised services, as well as a list of emerging category 1 services.

Following Ofcom's advice, the Secretary of State wrote to Ofcom asking for further information on how the regulator arrived at the various assessments it makes in its advice.

EU Commission publishes DSA guidelines on the mitigation of systemic risks for electoral processes

The European Commission has published guidelines under the Digital Services Act (DSA) on mitigating against systemic risks in relation to electoral processes for providers of Very Large Online Platforms (VLOPs) and Very Large Online Search Engines (VLOSEs).

The guidelines aim to support VLOPs and VLOSEs with their compliance obligations under Article 35 of the DSA (mitigation of risks) and with other obligations relevant to elections. As well as mitigation measures, the guidelines cover best practice for before, during and after electoral events.

The guidelines highlight the importance of clearly labelling political advertising, in anticipation of the new regulation on the transparency and targeting of political advertising, which came into force on 9 April 2024.

The guidelines also state that VLOPs and VLOSEs should:

- reinforce their internal processes, including adopting an incident response mechanism during an electoral period; and
- adopt specific mitigation measures linked to generative AI, for example by clearly labelling content generated by artificial intelligence, such as deepfakes.

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Cyber-security

Cyber-security

Cyber Security Breaches Survey 2024

On 9 April 2024, the UK government published the latest Cyber Security Breaches Survey, an annual survey looking at the cost and impact of cyber attacks on businesses, charities and educational institutions, and their approach to cybersecurity.

The survey revealed that cyber attacks continue to pose a common threat, with 50% of businesses and 32% of charities having identified a cyber breach or attack in the past 12 months.

As expected, board-level responsibility for cyber security was more prevalent in larger businesses, where the management board is likely to be bigger. However, there remain a number of barriers preventing boards from becoming more engaged with cyber security, including a lack of understanding or interest, a lack of training, insufficient time and a perception that organisations of their kind face a relatively low risk from cyber attacks.

Organisations of all sizes should take a proactive approach to incident management and ensure that board members have oversight of the organisation's cyber strategy. Senior engagement can result in quicker approval for new measures and enables organisations to demonstrate compliance to regulators. The National Cyber Security Centre's Cyber Security Toolkit for Boards is aimed at helping board members across all sectors to better understand their obligations and discuss issues with technical experts within their organisation.

Our international team of Osborne Clarke lawyers can advise on regulatory compliance and crisis readiness through our "war game" exercises, so please get in touch should you need assistance. You can also sign up for our "Dipping into Data" webinar where our experts will take you through the developing legal landscape of cyber security for businesses.

BoE Committee approach to operational resilience

The Bank of England (BoE) has published "Financial Stability in Focus", setting out the Financial Policy Committee's (FPC) approach to operational resilience, in particular the ability of financial firms vital to UK financial stability (including payments, deposits and insurance services) to prevent and mitigate disruptions such as cyber attacks and internal process failures.

The FPC expects to review the existing policies on operational resilience on a regular basis, with the next cyber stress test due to start in spring 2024 and findings expected to be published in the first half of 2025.

Geopolitical and cyber attack risk were the most frequently cited risks to the UK Financial system among financial firms in the BoE's biannual Systemic Risk Survey H1 2024.

In the EU, the new Digital Operational Resilience Regulation (DORA) introduces legal and regulatory requirements to strengthen the ability of financial services firms in preventing and mitigating ICT-related disruptions and threats. See more in our Insight.

Cyber Security Longitudinal Survey: wave three results

The Department for Science, Innovation and Technology (DSIT) published wave three results of the Cyber Security Longitudinal Survey, a three-year study which analyses the cyber security behaviours of UK medium and large businesses and high-income charities.

A majority of businesses reported taking steps to expand or improve their cyber security. However, only a small minority of organisations took steps to formally assess or manage the cyber threat presented by third-party suppliers or partners, despite the rising threat of cyber attacks resulting from vulnerabilities within a supply chain.

In the last 12 months, 24% of medium business, and 39% of large business reported having assessed their supplier risks. This indicates that, as with previous waves of the survey, larger businesses are likely to adopt a more sophisticated approach to cyber security. To find out more, register for our webinar where Katherine Kearns, Head of Proactive Legal Services at S-RM, and Osborne Clarke's Philip Tansley will take a look at identifying and reducing exposure to cyber risk in supply chains.

Cyber-security

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Data law

Data law

ICO publishes new fining guidance

The UK Information Commissioner's Office (ICO) has published new data protection fining guidance, outlining the statutory framework (in greater detail than previously) within which the Commissioner must operate when deciding whether it is appropriate to issue a penalty notice and the factors he will take into account. It also explains how the amount of any fine is determined.

The guidance does not appear to indicate any major change in approach, but does provide a clearer explanation of the process the Commissioner will go through when deciding the appropriate level of fine and provides greater transparency. It shows just how much discretion the Commissioner has when deciding whether, and how much, to fine, but it remains to be seen if it heralds any changes to the ICO's approach to enforcement in practice or results in a reduction in the number of successful appeals against its fines. See our Insight for more details.

ICO outlines 2024-2025 priorities to protect children's privacy online

The ICO has set out its 2024-2025 priorities for protecting children's personal information online and called on social media and video-sharing platforms to do more to ensure their safety. The new strategy builds on the progress achieved so far in implementing the Age Appropriate Design Code of Practice 2021 and outlines priority areas where further progress is needed, including:

- ensuring that children's profiles are private by default, and that geolocation settings are turned off by default;
- ensuring that profiling children for targeted advertisements is turned off by default unless there is a compelling reason to use profiling;
- the use of children's information in, and the design of, recommender systems, since algorithmically-generated content feeds can expose children to harmful content, as well as leading them to spend more time on a platform than they otherwise would, which in turn increases the probability of them giving away more personal information; and
- ensuring that parental consent is obtained for processing the personal data of children under 13 years old.

As part of this work the ICO will:

- gather further evidence, including by way of a call for evidence to be published in summer 2024;
- engage with parents, carers, children and organisations to identify areas for further improvement and provide additional guidance and advice where needed; and
- focus on the most serious risks to children's privacy rights and take enforcement action where appropriate.

Call for evidence on data adequacy and its implications for the UK-EU relationship

The House of Lords European Affairs Select Committee has launched an inquiry into the data adequacy decision granted by the EU post-Brexit and the implications of any divergence by the UK from the EU's data protection regime for the UK-EU relationship.

The European Commission granted "data adequacy" to the UK after Brexit in 2021. The adequacy decision allows for the free flow of commercial and criminal investigation related personal data from the EU to the UK under the GDPR and the Law Enforcement Directive.

The decision is due to be considered for renewal by the EU, which must decide by June 2025 (although it also has the power to withdraw adequacy at any time). The inquiry will consider the existing adequacy arrangement, any challenges to the adequacy regime, the implications if the Commission were to withdraw or fail to renew the adequacy decision, and the experience of other countries with the EU's adequacy system, including their encounters with the Commission's process. The committee encourages anyone with expertise or experience in this area to submit written evidence to the inquiry by 3 May 2024.

There have already been rumblings of discontent from the EU as a result of the UK's plans to reform its data protection regime with the Data Protection and Digital Information Bill, currently going through Parliament, but the UK government has so far insisted that the bill maintains adequacy. See this Regulatory Outlook for details.

The committee will hold public evidence sessions between now and June and aims to report to the House by July 2024.

Information Commissioner publishes response to Ofcom's consultation on protecting people from illegal harms online

The Information Commissioner has published its response to Ofcom's consultation on protecting people from illegal harms online, which Ofcom launched in November last year as part of its implementation of the new online safety regime under the Online Safety Act 2023.

In its response, the ICO says that it expects organisations to fully comply with their data protection obligations when meeting their online safety duties and highlights the importance of data protection compliance when undertaking content moderation.

Broadly speaking, the ICO agrees with Ofcom's recommended content moderation measures, but disagrees with Ofcom's assertion (in its draft codes of practice) that the privacy impact of automated scanning is minimal. The ICO believes that the privacy safeguards around the use of automated measures should also explicitly refer to data protection requirements. The ICO recently published guidance on content moderation and data protection compliance. See this Regulatory Outlook for details.

The ICO also thinks that Ofcom's draft guidance currently lacks certainty about whether content is communicated "publicly" or "privately", potentially stopping services from making a confident assessment of this question when deciding whether to use proactive technology. The ICO is concerned that this might lead to services incorrectly evaluating content as public when in fact it is private. In the ICO's view, the default position, when assessment is difficult, should be that the content is private.

As for Ofcom's risk assessment guidance, while the ICO agrees that encrypted messaging and anonymity/pseudonymity functionality are risks for illegal harm, it is concerned that the guidance could, in practice, stop services from deploying these functionalities due to perceived risks under online safety law. The ICO would therefore like the guidance to clarify that these measures are not prohibited, but do require appropriate safeguards.

The ICO also urges Ofcom to consider the data minimisation principle when finalising its guidance to ensure that services are not incentivised to process more personal data than necessary.

Ofcom is due to publish its final decisions on the draft documents and submit them to the Secretary of State for approval in autumn 2024. In the meantime, organisations within the scope of the new online safety regime should prepare for compliance, ensuring that their measures also align with data protection requirements.

UK ICO launches third consultation on generative AI

See AI section.

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Employment and immigration

Employment and immigration

UK government makes announcement on tackling non-compliance in the 'umbrella' companies market

The UK government has announced as one of its annual Tax Administration and Maintenance Day actions that it will publish its response to the "umbrella" consultation "*in due course*". Umbrella companies, staffing suppliers, end users and contractors will now have to wait to find out what, if anything, the government will do to regulate the umbrella market.

The announcement provides little detail about the likely outcome of the consultation other than to confirm that the government will publish guidance later this year to support workers and businesses that use umbrella companies, including an online pay-checking tool to help umbrella works to check whether the correct deductions are being made from their pay.

The announcement also hints that its preferred option is to introduce a statutory due diligence regime for businesses that use umbrella companies, but that it needs to work further with the recruitment industry to understand the impacts of this approach and whether it would reduce umbrella non-compliance. Read more in our Insight. Also see the recording of our Eating Compliance for Breakfast webinar on this announcement.

New Vento bands

Together with the other changes that came into force this month (see our previous Regulatory Outlook), new Presidential Guidance on Employment Tribunal awards for injury to feelings in line with the Vento bands has been published. For claims presented on or after 6 April 2024, the Vento bands are as follows:

- A lower band of £1,200 to £11,700 for less serious cases;
- A middle band of £11,700 to £35,200 for case that do not merit an award in the upper band; and
- An upper band of £35,200 to £58,700 for the most serious cases. The most exceptional cases are capable of exceeding £58,700.

These new bands will need to be considered when assessing the financial liabilities associated with a discrimination claim where an award for injury to feelings is sought.

Labour's plans to crack down on tax avoidance and close the tax gap

Rachael Reeves, the shadow chancellor, has pledged to close the gap between tax owed and tax collected if the Labour Party wins the next election (which opinion polls suggest is likely).

In 2021/2022 that gap is reported to have been £36 billion, up from £31 billion the year before. The number of civil investigations into tax fraud by HMRC is stated to have fallen by more than half in five years. Part of the £5.1 billion a year, which Ms Reeves aims to raise by the end of the next Parliament by cracking down on tax avoidance, will be used to pay for Labour’s plans to bring down NHS waiting lists and introduce breakfast clubs in every primary school.

To achieve her aims, she has announced funding of an additional £855 million a year into HMRC to digitalise and modernise it and to boost the number of HMRC compliance officers by up to 5,000. With more HMRC fire power and planned legal and regulatory changes (including widening the range of reportable tax schemes under the disclosure of tax avoidance schemes regime), there is likely to be greater HMRC focus not only on umbrella companies but also on IR35 and other tax compliance. This inevitably has serious implications for the staffing and workforce solutions sectors and those who use their services.

We are entering the fourth year following the implementation of the Off-Payroll rules in the private sector. Four years is the time window HMRC has for investigating taxpayers suspected of making innocent errors. Customarily it waits until the end of that period before launching any investigations, thereby maximising the period over which it can look back. If an error is deemed to have been careless or negligent it can look back over a further two years and, where there is suspicion of deliberate tax evasion, the period over which HMRC can investigate increases to 20 years. So staffing companies and end user clients should not take comfort from any perceived absence of HMRC activity thus far. The sensible money is on those who ensure they have robust processes in place, not only to assess the IR35 status of contractors' working arrangements but also to regularly review those processes and to record the steps taken, so that if and when HMRC does come looking, the records and procedures tell the right story.

Employment and immigration

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Environment

Environment

European Parliament adopts new certification framework for carbon removals

On 10 April, the European Parliament formally adopted its position on a regulation to introduce a voluntary certification framework for carbon removals, which aims to boost the bloc's ability to monitor and verify such activities to counter greenwashing.

The regulation covers different types of carbon removals: permanent carbon storage through industrial technologies and carbon storage in long-lasting products and carbon farming, which includes practices that reduce emissions from soils. In addition, to ensure transparency, a public EU registry for carbon removals and soil emission reductions will be set up by the European Commission.

The regulation now has to be adopted by the Council, which it is expected to adopt it at first reading. After this it will be published in the EU Official Journal and enter into force 20 days later.

European Parliament adopts position on soil monitoring directive

The European Parliament adopted its position on the proposal for a Soil Monitoring Law, which is the first piece of EU legislation dedicated to soils.

The new legislation will require EU Member States to monitor and assess soil health and will require polluters to pay for soil contamination in line with the "polluter pays" principle. The file will be followed up by the new European Parliament after the 6-9 June 2024 elections.

The legislation will have a direct impact on the agricultural sector, but is also likely to have a significant impact on other sectors where the supply chain relies on natural products, for example the food and fashion sectors.

EU Environmental Crime Directive receives formal approval

The European Parliament and the Council of the EU have both now formally adopted the Environmental Crime Directive.

This substantially broadens the scope of offences covered by environmental criminal law, increasing the list from nine to twenty. New offences include timber trafficking, the illegal recycling of polluting components of ships and serious breaches of legislation on chemicals.

The legislation also increases the penalties for those who commit offences. For companies, fines will be at least 5% of the total worldwide turnover for the most serious offences or an amount corresponding to €40 million. It also introduces imprisonment against those companies' senior individuals who commit environmental offences.

The directive will now be published in the Official Journal and will enter into force on the twentieth day following its publication. Member States will have two years to transpose the rules into national law. See our Insight for more.

What is natural capital and what does it mean for investors and lenders in the UK and Europe?

While some natural capital-related regulatory requirements may currently only be voluntary, or not yet catch financial institutions, there may be merit in complying early. Our recent Insight gives a brief overview of how natural capital might affect investors and lenders and provide an opportunity for the financial sector to play a leading role in driving this important agenda.

Council of EU formally adopts directive on energy performance of buildings

On 12 April 2024, the Council of the EU formally adopted its position on a revised directive on the energy performance of buildings, which outlines a vision to have zero emission buildings by 2050.

The directive sets out that by 2030 all new buildings should be zero-emission buildings, and by 2050 the EU’s building stock should be transformed into zero-emission building stock.

In addition, the directive also introduces minimum energy performance standards which will aim to lead to a gradual phase-out of the worst performing non-residential buildings.

Further, to help decarbonise the building sector, Member States will need to outline in national building renovation plans a roadmap to phase out fossil fuel boilers by 2040. Financial incentives for the installation of stand-alone fossil fuel boilers will be prohibited as of 1 January 2025.

Environment

The European Parliament formally adopted its position last month. The directive will now be signed and published in the Official Journal of the EU. Member States will have two years to incorporate the provisions into their national legislation.

TPT publish sector-specific guidance

Please see Environmental, social and governance.

HSE launches call for evidence on PFAS in firefighting foams

Please see Products.

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Environmental, social and governance

Environmental, social and governance

TPT publish sector-specific guidance

The Transition Pathway Taskforce (TPT) has published its final set of sector-specific guidance to assist companies in preparing climate transition plans.

There is specific guidance for asset owners, asset managers, banks, electric utilities and power generators, food and beverage, metals and mining, and oil and gas.

The TPT has also published a sector summary which gives practical guidance for thirty financial and real economy sectors. This new guidance will assist companies in preparing their climate transition plans.

European Parliament adopts directive on delaying European sustainability reporting standards

Following the provisional agreement reached between the European Parliament and Council on postponing sector-specific European Sustainability Reporting Standards (ESRS), the European Parliament has, on 10 April, formally adopted a directive implementing the delay.

Under the directive, the ESRS will be delayed from 30 June 2024 to 30 June 2026 in a bid to ease the regulatory burden on companies.

The council is expected to formally adopt the directive at one of its next meetings, after which it will be published in the Official Journal of the European Union and enter into force.

UK competition regulator issues fresh guidance on green collaborations for sustainability

As businesses strive to develop more sustainable practices, the Competition and Markets Authority has published its second informal guidance under its "open door" policy in relation to green agreements. Its willingness to provide such guidance provides businesses with an opportunity to obtain clarity and assurance for their own agreements with competitors on sustainability collaborations.

EU Environmental Crime Directive receives formal approval

Please see Environment.

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Fintech, digital assets, payments and consumer credit

HM Treasury policy note on delaying payments processing and draft amending regulations

On 12 March 2024, HM Treasury published a near-final version of the Payment Services (Amendment) Regulations 2024, which aim to delay payments processing when there are reasonable grounds to suspect fraud or dishonesty. The publication is part of the government's work to tackle authorised push payment (APP) fraud.

The draft regulations amend provisions in the Payment Services Regulations 2017 which require payment service providers (PSPs) to execute payment transactions within maximum time limits (regulation 86). The amendments give a payer's PSP the ability to delay the execution of certain payment orders where, within a specified time, it establishes reasonable grounds to suspect the order has been executed subsequent to fraud or dishonesty perpetrated by a third party (which may include the payee). The delay should be used to enable the PSP to determine whether the order should be executed and must not exceed a specified time limit.

PSPs will be required to inform customers of any delays, the reasons for their decision, and what information or actions are needed to help the PSP decide whether to execute the order. However, this will not be required to the extent complying would be unlawful (for example, under anti-money laundering legislation).

HM Treasury intends to lay the regulations before parliament in summer 2024, and bring them into force at the same time as the new rules on mandatory reimbursement for APP fraud in October 2024.

HM Treasury policy note on amending payment services contract termination provisions and draft regulations

On 14 March 2024, HM Treasury published a near-final version of the Payment Services and Payment Accounts (Contract Terminations) (Amendment) Regulations 2024, which aim to amend the requirements relating to provider-initiated terminations of payment service contracts.

The draft regulations amend the PSRs to impose new requirements relating to payment service framework contracts concluded for an indefinite period which are terminated by a PSP. The minimum termination notice period will increase from two months to 90 days, and PSPs will be required to explain the reasons for the termination. The draft regulations also amend the Payment Accounts Regulations 2015 to bring the notice period and related requirement to give reasons into line with the new requirements in the PSRs.

The policy note sets out the rationale for the changes and explains the intended exceptions to the requirements, as well as wider scenarios the government has considered. These changes will not extend to framework contracts that are regulated running account credit facilities (such as credit cards). Instead, section 98A of the Consumer Credit Act 1974 will continue to apply.

HM Treasury intends to lay the regulations before parliament in summer 2024, subject to parliamentary timing, and for them to commence as soon as practicable thereafter.

HM Treasury sets out approach to designation of critical third parties

On 21 March 2024, HM Treasury published a document setting out its approach to designating critical third parties (CTPs).

HM Treasury has power under the Financial Services and Markets Act 2023 (FSMA 2023) to designate a third-party service provider to the UK financial services sector as "critical". FSMA 2023 gives the financial regulators (the Bank of England, the PRA and the FCA) power to set and enforce rules for designated CTPs, as well as the ability to gather information and conduct investigations on designated CTPs.

HM Treasury expects to base designations of CTPs on recommendations from the financial regulators, but may also designate a CTP without a recommendation from the financial regulators. The document sets out an indicative process for designation and how a designation decision will be communicated.

As the regime aims to mitigate a systemic risk of over-reliance by the financial services sector on a few major providers, HM Treasury expects that CTPs will represent a small proportion of third-party service providers to the industry, with the list changing over time.

Delegated regulation amending list of high-risk third countries under MLD4

See Bribery, fraud and anti-money laundering section.

Fintech, digital assets, payments and consumer credit

FCA's social media financial promotion guidance

See Advertising and Marketing section, and our Insight.

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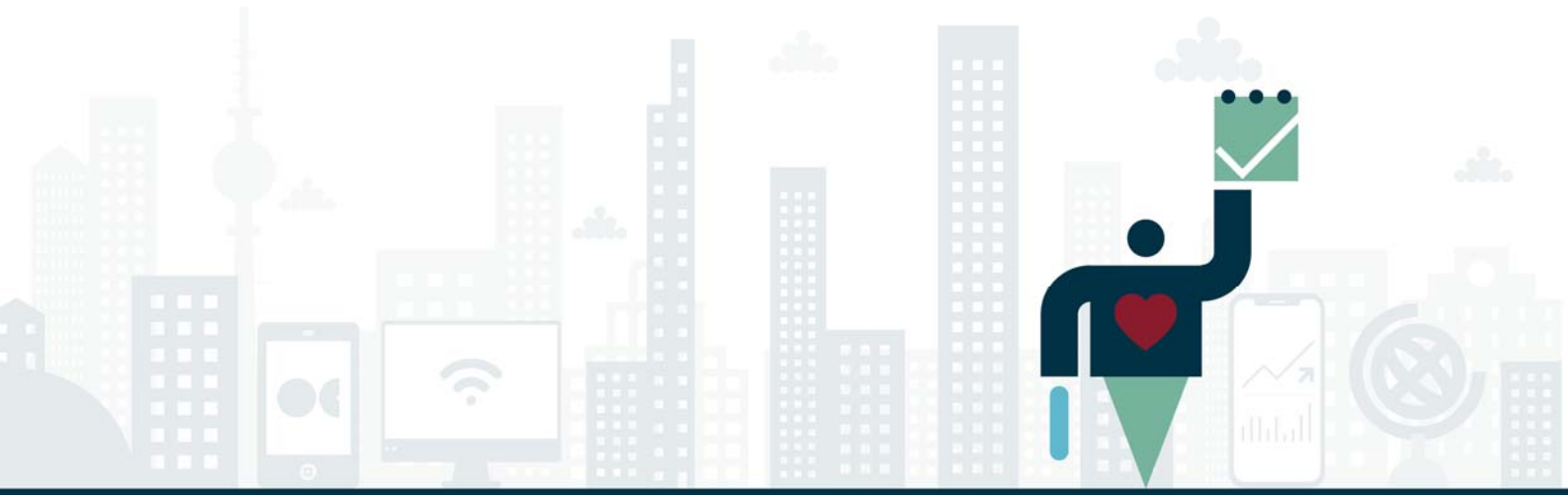

Food law

Food law

FSA launch consultation on regulated products regime

The Food Standards Agency (FSA), alongside Food Standards Scotland (FSS), launched a consultation on proposals to reform the authorisation process for regulated products on 3 April 2024.

Regulated products are food and feed products which require authorisation before they can be sold and include food additives, flavourings, novel foods, genetically modified organisms (GMOs) as food and feed, food contact materials and feed additives. Currently the process is slow and burdensome on the regulator, meaning few applications have been authorised under the current regime. Two proposals to reform the regime have been put forward:

1. to remove renewal requirements (currently every ten years) for feed additives, food or feed containing, consisting of or produced from GMOs and smoke flavourings; and

2. to remove the process of laying legislation after ministerial authorisation of a regulated product, which currently slows down the approval process. Instead the authorisation would be added to an official register, following a ministerial decision, which the FSA said will speed up the process.

The FSA hopes to introduce these legislative changes ahead of the general election. The consultation closes on 5 June 2024. Further information on the longer-term from plans will be presented to the FSA and FSS Boards in June 2024 and, if taken forward, will be subject to separate consultation.

If implemented, this reform will speed up the authorisation process which in turn could allow more innovative products to be placed on the market. The FSA has stated that failing to take urgent action will result in an inability to cope with the increasing caseload, further underscoring the pressing need for progress in this space.

FSA publish response to consultation on regulation of precision bred organisms

The FSA ran a consultation from November 2023 to January 2024 on proposals for the new framework for the regulation of precision bred organisms (PBOs) and plants and animals used for food or feed. Its proposal revolves around introducing a two-tiered regulatory approach for pre-market authorisation, meaning that those PBOs similar to traditionally bred organisms would benefit from a simpler route to market.

The FSA published its response on 5 March 2024 which outlines that the secondary legislation is currently being drafted and will be laid before Parliament in the summer, along with technical guidance. The aim is to implement the new process by the end of 2024. The response outlines how the framework will look and provides an interesting insight into how this may contrast to the EU position, which you can read more about in our Insight.

European Parliament formally adopts position on Breakfast Directive

The European Parliament has, on 10 April, adopted its formal position on the amending Breakfast Directive (see our February Regulatory Outlook for the changes being introduced). The Council now needs to adopt the directive, before being published in the EU Official Journal and entering into force 20 days later. EU Member States will have two years to transpose the news rules into national law after entry into force.

Defra opens consultation on wine reforms

We previously reported on the results of a public consultation into the wine sector, including the ending of rules on bottle shapes and the mandatory use of mushroom-shaped stopper and foil sheaths on sparkling wines.

The government has now announced its intention to continue reforms in this area, with the third phase of consultations, opened on 16 April 2024, that will close on 10 May 2024.

The new areas for consultation include proposals to:

- remove the ban on transforming imported still wine into sparkling wine (with hopes to address the current inefficiencies with transporting sparkling wines in glass bottles into the UK);
- allow imported wine to be sweetened or otherwise adapted in the UK;
- allow the production of wine from imported grapes and "grape must";
- provide more clarity around the term "British wine";
- introduce new thresholds and labelling requirements in relation to no and low alcohol wine; and

- update the approved oenological practices and processes.

Potential further delay to implementation of DRS

Please see Products.

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Health and Safety

Health and Safety

Stress awareness month

April is stress awareness month and the Health and Safety Executive (HSE) has invited businesses to follow five steps to take to tackle stress in the workplace.

These are: reach out and have conversations, recognise the signs and causes of stress, respond to any identified risks, reflect on actions agreed and taken, and make it routine.

The HSE notes the six main areas that can lead to work-related stress if they are not managed properly are: demands, control, support, relationships, role and change.

With April casting a spotlight on the issue of work-related stress, it provides businesses with a timely reminder that they should be continually ensuring that measures are in place to mitigate the risks posed by work-related stress and that it is being managed properly.

Health and Safety Executive updates RIDDOR guidance

The HSE has updated the Report of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) guidance and forms.

There have been no changes made to the legal requirements and these updates are to assist businesses with how and when to submit a RIDDOR.

The main changes to the guidance are: more direct links to guidance on types of reportable incidents to help businesses decide whether a report is required; improved guidance on who should and should not report under RIDDOR; improved guidance on what is meant by a "work-related" accident; information on when an occupational disease is not reportable; and increased clarity on when an "over-7-day" absence should be reported.

The main changes to the forms are: questions about severity of injuries have been frontloaded to help businesses quickly decide if the incident is reportable; pop-up messages now redirect notifiers if the incident is not reportable; and, guidance has been improved to make the forms easier to use.

Government invest £1.5million into innovative occupational health services

Following the announcement last month of the creation of the new Occupational Health Taskforce, the government has announced on 14 April that £1.5 million will be invested into five projects that will share the funding in a bid to improve occupational health services.

At the heart of these projects is innovation, with the funding being used to increase the use of artificial intelligence and new technology. This will allow the expansion of remote services, digital health hubs and long covid support which overall will improve occupational health services.

The announcement also outlines that the voluntary framework the taskforce is currently developing is expected to be published this summer. When published, businesses should review the framework to decide if it is something they wish to implement alongside the measures they already have in place in relation to occupational health.

Building Safety

New building control regime

From 6 April, the updated building control regime applies to all new developments after the transition period came to an end. See our previous Insight for more on the regime.

While the new rules have been introduced pursuant to the Building Safety Act, it is important to note that they relate to all buildings, not just the higher-risk buildings subject to sign-off by the Building Safety Regulator. The new rules aim to raise standards across the built environment and require increased coordination between competent and accountable duty-holders.

Relevant building works to existing higher- risk buildings and the construction of new ones are subject to a much more involved application process made to the Building Safey Regulator, whose approval is needed before any work can start.

Health and Safety

At practical completion of works on new builds, a further application is required for certification before the building can be registered and occupied.

Failing to comply can result in enforcement proceedings and criminal sanctions. It is essential that those involved with the development and/or management of higher risk buildings are familiar with their legal duties and the requirements in place to progress works.

The old building control regime applies if plans were deposited with the local authority by 1 October 2023 and works sufficiently progressed by 6 April 2024.

Higher-risk residential Building Assessment Certificates

The Building Safety Regulator has started contacting Principal Accountable Persons to warn them that they will shortly be requesting applications for a Building Assessment Certificate.

Once requested, the response must be provided within 28 days by those involved with the management of higher-risk residential buildings (18 metres/7 storeys). Fundamental to an application is the provision of a Safety Case Report, Mandatory Occurrence Regime and Resident Engagement Strategy, all of which should be being developed/already be in place. More information can be found here.

Updated second staircases guidance

On 29 March, the government updated its guidance making it a requirement for second staircases in all new tall residential buildings over 18 metres.

The changes will take effect in England on 30 September 2026.

Projects that receive approval prior to this date and are based on the old rules must be "sufficiently progressed" within 18 months of this date. The announcement was accompanied by the publication of the government's response to the related consultation.

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Modern slavery

Modern slavery

Nothing further to report this month.

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Products

Products

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

General/ digital products

UK

Government introduce legislation to indefinitely recognise the CE mark

On 15 April, the draft Product Safety and Metrology etc. (Amendment) Regulations 2024 were laid before Parliament.

These regulations amend 21 product regulations, including toys and radio equipment (see the full list), by removing the expiry of the provision that recognises the EU conformity assessment (that is, CE marking). This means that businesses can continue to use either the CE or UKCA mark indefinitely when placing products covered by the regulation on the Great Britain (GB) market.

The regulation also introduces a new "fast track" UKCA process, allowing manufacturers to use the UKCA marking to demonstrate compliance in GB with either UKCA or recognised EU conformity processes. This process is optional and can only be used for placing products on the GB market.

It allows manufacturers to rely on EU conformity assessment procedures for the purposes of the UKCA regime. This recognition provision is aimed to help avoid costly and duplicative testing for all regulations that apply to a product, especially in cases where products are subject to multiple regulations, even if the EU regime continues to be recognised for some of those regulations.

Certain sectors, such as medical devices and construction products, have specific arrangements led by relevant government departments and are not covered by these measures.

29 April 2024: Are you ready for the security regime for connected products?

The Product Security and Telecommunication Infrastructure Act introduces new security requirements for connected products which come into force on 29 April 2024 (see this Regulatory Outlook). Our Eating Compliance for Breakfast session on Thursday 25 April will cover what these new requirements are and what you need to be doing in order to comply with the new regime from 29 April. Register here.

Further import checks from 30 April 2024

Following recent media speculation that health and safety checks for EU imports would not be coming into force, Defra has stated that this is not the case and that the checks will come into place from 30 April 2024. This means that from 30 April, health certification on imports of medium-risk animal products, plants, plant products and high-risk food and feed of non-animal origin from the EU will be required.

Pre-notification requirements for low-risk plant and plant products from the EU will be removed. These checks are being introduced under the Border Target Operating Model.

EU

Consultation launched on indicators for reporting on the General Product Safety Regulation

The European Commission has opened a four-week feedback period on the indicators for reporting on the General Product Safety Regulation (GPSR). These indicators will be implemented by Member States in order to communicate the application of the GPSR, the results of their investigations and the measures imposed for breaches of the regulation.

Businesses operating in the EU that will be subject to the GPSR should review the draft implementing regulation on these indicators and decide whether they wish to provide feedback. The feedback period closes on 14 May 2024.

Product sustainability

EPR: enforcement action to start from next month (31 May)

Products

The UK is in the process of introducing a system of extended producer responsibility (EPR) for packaging. This means that packaging producers are now responsible for covering 100% of the net cost associated with processing their packaging waste.

While the payment of EPR fees was delayed until October 2025, the reporting obligations for packaging under the new extended producer responsibility scheme (EPR) have already begun.

Large organisations were required to submit their data on 1 October 2023 for the period of 1 January to 30 June 2023, and another submission was due on 1 April 2024 for the period of July to December 2023. However, the government announced last September that no enforcement action would be taken for late data submission until 31 May 2024.

This deadline for data reporting is fast approaching. It is crucial for businesses to ensure they have assessed which packaging they are responsible for and submit the relevant data in accordance with the new regulations and guidance to avoid any potential enforcement measures being taken against them from next month.

Potential further delay to implementation of DRS

The implementation of deposit return schemes (DRS) in the UK has been continually pushed back over the past few years.

Most recently, on 26 March, the Secretary of State for Environment, Food and Rural Affairs, Steve Barclay told the Environment, Food and Rural Affairs Committee that the 2025 implementation date is unrealistic. He stated: "*Given this balance between the benefits of the scheme versus the benefits of having something interoperable, I don't think 2025 is now realistic, and certainly I don't think business would view it as a realistic deadline. It is an issue that is still an ongoing area of discussion within Government, but I suspect, if I was pushed on it, that a 2027 deadline is probably more likely*." This announcement of further delay has been welcomed by supermarkets.

Following on from this comment, Scottish Circular Economy Minister, Lorna Slater, has sent Mr Barclay a letter setting out her concerns about further delays and notes that had the UK government not stopped the Scottish DRS from going ahead (see this previous Regulatory Outlook) they would now have an operational DRS. She added that the government should set "*a realistic timescale for delivery which is agreed across the four nations, rather than creating speculation without consultation*."

At time of writing there has not been any further communication of this delay from the government, but businesses should continue to keep abreast of the development of DRS across the UK.

HSE launches call for evidence on PFAS in firefighting foams

The Health and Safety Executive (HSE) has launched a call for evidence on firefighting foams which contain per- and polyfluoroalkyl substances (PFAS).

This follows the Regulatory Management Option Analysis published by the HSE last year, which recommended that action should be taken to restrict the use of PFAS in firefighting foams. The consultation closes on 3 June 2024. Businesses that deal with firefighting foams (manufacturers, importers, distributors, retailers) should review this call for evidence and decide whether they wish to respond.

This call for evidence is the first step following the review on the regulation of PFAS and, while focused on firefighting foams, it illustrates the forthcoming change for the use of PFAS. We are still awaiting the UK Chemicals Strategy, which is the cross-governmental strategy for the UK, which we anticipate may provide further information on future changes to the regulation of PFAS and will provide further updates once this has been published.

Guidance on workplace recycling in Wales

On 6 April 2024, new rules came into force in Wales which legally requires all businesses, charities and public sector organisations to separate collections of waste materials for recycling. In line with this, new statutory guidance has been published for organisations on the rules.

The following materials will need to be separated for collection, and collected separately: food; paper and card; glass; metal, plastic and cartons; unsold textiles; and unsold small waste electrical and electronic equipment.

There is also a ban on sending food waste to sewer (any amount); separately collected waste going to incineration and landfill; and all wood waste going to landfill.

The guidance also notes that paper and card can be mixed in the same container together, and metal, plastic and cartons can be mixed together. Businesses in Wales should make sure that their waste is being separately collected otherwise enforcement action may be taken.

Government to ban wet wipes containing plastic

The government has published its response to the consultation on wet wipes containing plastic. It confirms that legislation will be introduced later this year to ban the supply and sale of wet wipes containing plastic across the UK. The legislation is expected to be in place by the end of 2024 and will include an exemption for the supply and sale of wet wipes containing plastic for industrial and medical purposes. There will also be an 18-month transition period to allow manufacturers adequate time to transition to producing plastic-free wet wipes.

The consultation response notes that manufacturing wet wipes containing plastic will not be in scope of the ban due to the size of the industry in the UK. UK manufacturers will be able to continue to export wet wipes containing plastic to other countries that do not have the same restrictions.

Life sciences and healthcare

New guidance on medicines under the Windsor Framework

The Medicines and Healthcare products Regulatory Agency (MHRA) has published two new guidance documents ahead of the changes to medicines being implemented under the Windsor Framework in 2025.

Labelling and packaging

Guidance has been published on the labelling and packaging of medicinal products for human use under the Windsor Framework. From 1 January 2025 all new medicines and medicines in Northern Ireland that currently fall under the scope of the EU Central Authorisation Procedure will be authorised by the MHRA for the UK market. See further guidance on the transition of licences.

These products will only be able to be sold in the UK, and will not be available on the market in Ireland, or elsewhere in the EU. Those products for the UK market must carry a clearly legible "*UK Only*" label to be allowed onto the UK market, including in Northern Ireland.

The guidance outlines that the "UK Only" statement can be applied via a sticker for a limited period of six months, to 30 June 2025, but after this date, "UK Only" must be printed directly onto the packaging.

In addition, from 1 January 2025, the EU Falsified Medicines Directive (FMD) will no longer apply in Northern Ireland. Therefore, medicines entering Northern Ireland will not need to display features required under the FMD, including 2D barcodes and serialisation numbers, but the marketing authorisation can choose to apply them.

The MHRA will continue to encourage anti-tamper devices to be used on medicine packaging.

Parallel Import Licences

Under the Windsor Framework, from 1 January 2025, the MHRA will license all medicines across the whole of the UK. Currently, Parallel Distribution Notices (PDNs) remain valid when placing medicines on the NI market.

PDNs are notice letters which parallel distributors must obtain from the European Medicines Agency before placing a centrally authorised product on the market. They are no longer valid in Great Britain and were replaced by Parallel Import Licences (PLPIs) which allow the products to be marketed in Great Britain only.

From 1 January 2025, PDNs will no longer be valid in Northern Ireland. This means that:

- all parallel imports (including Centrally Authorised Products) will be authorised to be marketed across the whole of the UK;

- all parallel imports will need a valid PLPI licence; and
- all PLPIs with a current territorial limitation of GB will be converted to UK-wide authorisation automatically. Including all previous PDNs that were converted to UK PLPIs and any other PLPI licences that have a current GB territorial limitation. A variation will not be required to change the territory from GB to UK-wide.

The medical technology strategy: one year on

In February last year, the Department of Health and Social Care (DHSC) published its first medical technology (medtech) strategy (see this Regulatory Outlook) which aims to ensure health and care systems and patients have access to innovative medical technologies.

The DHSC has published a report The medical technology strategy: one year on which looks at what it has achieved over the past 12 months as well as next steps. The report outlines that the core regulatory changes for medical devices are expected to be laid in Parliament in 2025, see our Insight for more.

Additionally, it sets out that in 2024 the next phase of the "Design for Life" programme to support a move towards a circular economy for medtech will be launched. Businesses should keep an eye on further developments in this space.

Medical technology innovation classification framework

In line with the above strategy, and after consultation with stakeholders across the sector, the DHSC has also published the medical technology innovation classification framework.

The framework will establish a common language for discussing innovation across the medical technology sector, establish clear criteria for a device to be described as innovative in different forms, clearly convey the change in a device compared to what already exists on the market and benefits to patients and the system, and support prioritisation and adoption of the most impactful innovations. The framework applies to medical devices and only applies to devices that are incremental, transformative or disruptive.

In the first instance, the framework is to be used as guidance to support the classification of innovative technologies and in six months' time, the DHSC will seek feedback on the "*relevance and utility*" of the framework.

Those in the medtech sector should review the framework and decide whether it applies to their products and if so, what type of innovation applies to their products.

Decision time for UK medical device regulation: diverge or converge with the EU?

As the MHRA progresses with its roadmap, industry will be looking forward to receiving more information on proposed new UK medical devices regulations. Read more.

European Parliament adopts proposal on reforming EU pharmaceutical legislation

On 10 April, the European Parliament adopted its position on proposals to reform the EU pharmaceutical legislation which consists of a new directive and regulation.

Measures include orphan drugs benefiting from up to 11 years of market exclusivity if they address high unmet medical needs, a minimum data protection period of seven and a half years for new medicines, along with a two-year market protection period after authorisation. The file will now be followed up by the new Parliament after the 6 - 9 June European elections.

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Regulated procurement

Regulated procurement

Procurement Act to go live on 28 October 2024

It has been confirmed that the new procurement regime will go live on Monday 28 October 2024, giving six months' time to prepare. For more on the changes coming into force, take a look at our microsite.

The government's Procurement Act 2023 e-learning modules have also now been made available to public sector organisations only and are otherwise not generally available. Please get in touch if you would like training on the Act and are not within the cohorts able to access the public sector training materials.

Procurement Act 2023: second batch of guidance added

The second tranche of Procurement Act 2023 guidance has been published and covers the pre-procurement phase: national procurement policy statement, pipeline notice, technical specifications, planned procurement notice and preliminary market engagement.

Transitional and saving arrangements guidance has also been published which confirms that procurements that commence after the Act enters into force, i.e. 28th October 2024, will be conducted under the new regime. Those contracts awarded under the previous legislation must continue to be procured and managed under that legislation, which includes if the contract is modified.

While the guidance documents are aimed at contracting authorities, suppliers should also review them (in particular the notices-related documents as these provide further clarity on what information will be published by contracting authorities).

Our recently published infographic on procurement notices provides further information on the various notices required at each stage of a procurement and throughout the life of a contract. This provides an overview of each notice's purpose, specifies the requirements and confirms where a notice is mandatory or voluntary.

Also see our Insight, following the publication of the draft procurement regulations, as detailed in last month's Regulatory Outlook.

PPN 03/24: Standard Selection Questionnaire

Procurement policy note (PPN 03/24) updates the selection questionnaire (SQ) and accompanying statutory guidance. This PPN applies to all contracting authorities in England, and contracting authorities in Wales and Northern Ireland when undertaking above threshold procurements within part 2 of the Public Contracts Regulations 2015 (PCR 2015).

The SQ updates and replaces PPN 03/23 and introduces the following changes: updated payment-related questions in relation to changes set out in this Regulatory Outlook; updated steel-related questions; clarity for contracting authorities on considering bids from Russian/Belarusian suppliers as set out in PPN 01/22: contracts with suppliers from Russia and Belarus; and removed references to PAS91 which has now been withdrawn by the BSI.

Authorities must implement PPN 03/24 within three months, and can implement it immediately.

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Sanctions and Export Control

Sanctions and Export Control

UK Sanctions Perceptions Survey

The Foreign, Commonwealth & Development Office is seeking feedback from UK private sector businesses and non-governmental organisations (NGOs) on their perceptions of UK sanctions and their impact on organisations.

The study aims to identify ways in which the government can support businesses and NGOs with sanctions compliance and will contribute to ongoing work to improve and develop policy and guidance.

The government aims to conduct a follow-up survey in early 2025 to measure changes in industry perceptions as a result of the government's efforts in supporting the industry, informed by the recommendations from this survey. Participate in the survey here.

UK and US crackdown on trade of Russian metals

The UK and US announced joint action targeting the export of prohibited Russian metal with the aim of reducing an important source of revenue supporting Russia's war effort.

In the UK, the London Metal Exchange will no longer trade new Russian-produced aluminium, copper and nickel. See the notice on the UK's Russian metals sanctions. The Department for Business and Trade general trade licence for the acquisition of metals, which was introduced in December 2023, has also been amended with effect from 12 April 2024.

OFSI issues maritime sector guidance

The Office of Financial Sanctions Implementation (OFSI) has published a blog post on how maritime businesses, including shipping companies, port operators, insurers and financial institutions can stay compliant with financial sanctions.

The tips could be applied more generally, though, and include actions such as conducting Know Your Customer (KYC) and due diligence checks to verify the identity of customers, partners and third-party intermediaries before engaging in any business transactions; implementing an appropriate compliance policy; investing in innovative technology and screening tools; organising regular training sessions; and engaging with compliance experts and other industry stakeholders.

OFSI amends Companies House general licence

OFSI has amended the Companies House general licence, which allows UK designated persons or persons acting on behalf of designated persons to make certain payments to Companies House.

The list of permitted payments has been expanded to include:

- the payment of fees owed by or due from UK designated persons to Companies House for filing an overseas entity update statement in respect of entities on the Register of Overseas Entities; and
- the payment of penalty fees owed by or due from UK designated persons to Companies House as a result of failure to register entities on the Register of Overseas Entities, or failure to provide an overseas entity update statement.

Updated guidance on reporting export control breaches

The UK government has updated its guidance on licensing requirements, restrictions for trade control, and export controls for military goods, software and technology.

The guidance clarifies that where exporters identify irregularities during a compliance audit, including those conducted by the Export Control Joint Unit, it should be reported to HM Revenue and Customs as soon as possible.

Where exporters have exported strategic/sanctioned goods, transferred controlled technology without an export licence or imported goods subject to sanctions, a voluntary disclosure should also be made to HM Revenue and Customs.

Sanctions and Export Control

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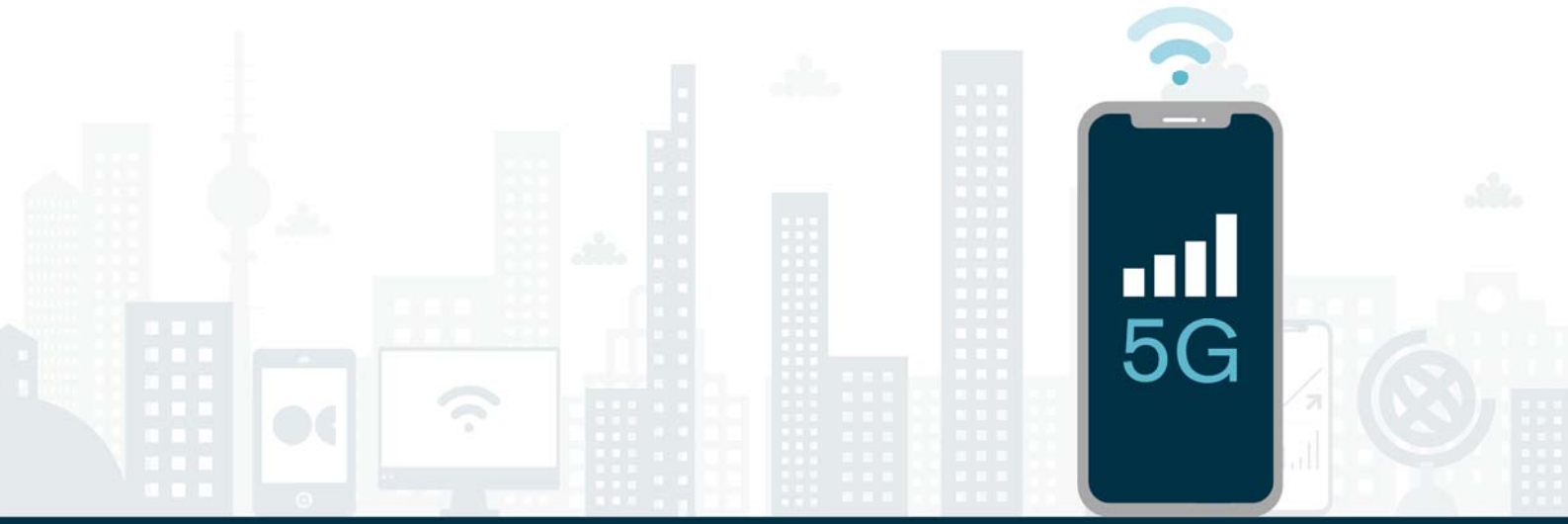

Telecoms

Telecoms

CMA responds to Ofcom's consultation on inflation-linked price rises

The Competition and Markets Authority (CMA) has responded to Ofcom's consultation on the prohibition of inflation-linked price rises. Ofcom is proposing to ban telecoms companies from providing inflation-linked price rises and price rises which are set out in percentages in their contracts. The telecoms regulator proposes that companies' contracts must be set out upfront in pounds and pence.

The regulator has welcomed Ofcom's proposal, and encourages Ofcom to keep under consideration whether any further action will be needed to protect consumers and promote greater competition in the telecoms sector.

The CMA agrees with Ofcom's assessment that the existing market practice of providers including inflation-linked price variation provisions in their terms and conditions are likely to cause harm to consumers, given the complexity and lack of clarity surrounding these clauses.

The CMA also encourages Ofcom to ensure providers fully comply with the requirements under the Consumer Protection from Unfair Trading Regulations 2008 when making any changes to their contract prices. The main consideration surrounds consumers being able to make transactional decisions based on full and transparent pricing information.

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