Welcome to our new year edition of the Regulatory Outlook. In this edition we have provided you with important forthcoming regulatory developments to be aware of in 2024, together with an interactive timeline illustrating key dates to be aware of, across all 18 areas that we cover.

Hot topics for the coming year include artificial intelligence, ESG/supply chains and greenwashing.

January 2024
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Advertising and marketing
Greenwashing

Greenwashing can be expected to appear this year among offences blacklisted in the UK. The proposal to add misleading environmental claims to a list of banned practices emerged in the Competition and Markets Authority's (CMA) response in October 2023 to the UK government's consultation on a range of consumer protection matters and in light of the UK Digital Markets, Competition and Consumers Bill. (See more in Consumer section.)

Last year, there were various enforcement and regulatory actions both in the UK and EU in relation to greenwashing.

In the UK, the CMA launched its second market investigation into greenwashing claims, looking specifically at consumer goods (including food, drink, toiletries, cleaning products and personal care items). The Committee of Advertising Practice (CAP) and Broadcast Committee of Advertising Practice (BCAP) provided a number of updates to their green claims advertising guidance (see here and here).

The most recent update includes new guidance on the use of green disposal claims. This follows the Advertising Standards Authority's (ASA) report on the outcome of its consumer research into the use of advertising claims relating to the green disposal of products relating to recyclability, biodegradability or composability.

Examples in the EU include the European Commission's proposal for a Green Claims Directive and the provisional agreement on a directive to empower consumers for the green transition reached by the Council of the European Union and Parliament.

UK Online Advertising Programme

The UK government published its response to the Online Advertising Programme in July 2023. (See our previous Regulatory Outlook for more information.) The government indicated that further consultations on the proposals outlined in its response to bring forward the respective legislation are expected "when parliamentary time allows".

However, the draft legislation relating to the Online Advertising Programme may not emerge until 2025.

'Dark patterns'

"Dark patterns" continue to be an area of focus and activity for the EU, the UK and more widely.

The EU Parliament has published a paper on the issues around addictive design and focus on endless scrolling, autoplay and temporary availability. (See previous Regulatory Outlook for more.)

The EU "fitness check" of consumer law is focusing on the lack of enforcement in relation to dark patterns and also their impact on vulnerable consumers. (See Consumer section for more details.) Additionally, in relation to advertising, the fitness check focuses on transparency in influencer marketing, personalisation of advertising and pricing, use of the word "free" when personal data is collected, subliminal techniques, and AI.

The CMA's Online Choice Architecture programme is currently focusing on urgency claims and timers. (See our previous Regulatory Outlook to find out more about the CMA's open letter on urgency claims and price reduction claims.)

The next wave of the CMA's Online Choice Architecture enforcement is expected to be in relation to lack of choice and meaningful control over personal data and privacy. In the EU, we do not expect that the EU will decide that an overarching digital fairness act is required; however, there might be express bans on dark patterns and specific transparency obligations for influencer marketing.

AI and advertising

Currently, there is no overarching UK artificial intelligence (AI) legislation yet; however, there might be movement towards centralised AI regulation before the next general election in the UK. (See AI section for more predictions in this area.)

The ASA has announced the launch of an AI-assisted collective ad regulation strategy. The five-year strategy strengthens the ASA's commitment to leveraging AI for the purposes of identifying incompliant ads. Previously, the ASA reported on how it uses AI capabilities in its work through AI-based Active Ad Monitoring system and its approach to the regulation of ads generated by AI. The ASA has confirmed that it will continue using its Active Ad Monitoring system to identify and act against incompliant online ads.
Advertising and marketing

Gambling

The UK’s white paper on gambling, “High stakes: gambling reform for the digital age”, was published in April 2023. The paper sets forth the government’s plans to reform gambling regulation, including measures relating to marketing and advertising. (See our previous Regulatory Outlook for details.)

We do not expect the measures envisaged under the white paper to be finalised before the next general election.

Data Protection and Digital Information Bill: advertising impacts

The UK Data Protection and Digital Information Bill was announced in the King’s Speech on 7 November 2023 and was reintroduced to Parliament. We expect the bill to become law in 2024. (See more in Data law section.)

In relation to advertising aspects of the bill, we expect direct marketing measures, including the expansion of "soft opt-in" for non-commercial organisations (for example, charities or political organisations) and potential for a future carve out from direct marketing rules for political campaigning.

Other anticipated measures are the addressing of unsolicited marketing calls (possible increased jeopardy not non-compliance) and Privacy and Electronic Communications Regulations enforcement, with potential fines up from £500,000 to the General Data Protection Regulation level.

Digitally altered images in ads

CAP and BCAP published an update statement in November 2023 on their work relating to the use of digitally altered images in ads. (See our previous Regulatory Outlook for more details.)

Although mandatory labelling is not required, we expect increased focus on body image and advertisers will be expected to be mindful of the conclusions of this consultation.

European Accessibility Act

The European Accessibility Act imposes accessibility requirements on e-commerce, which will catch some forms of advertising. Its broad principles concerns two areas.

It looks to make key information available in multiple senses and accessible by assistive technologies (including call centres) surface information about accessibility of products.

And it aims to make identification security processes and payment systems "perceivable, operable, understandable and robust".

The European Accessibility Act entering into force will give focus to accessibility and digital inclusion more generally. It will also likely result in interpreting equivalent obligations in the UK under the Equality Act through the lens of the European Accessibility Act.

High fat, salt or sugar products

CAP and BCAP have launched a consultation on the implementation of further restrictions on the advertising of high fat, salt or sugar (HFSS) food or drink products that come into force in October 2025. (See Food section for more details.)

The committees are consulting on new guidance to accompany the less healthy product advertising restrictions and to assist in the understanding of which ads are in scope of the rules, as well as on the wording of the new rules to be added to the advertising codes. They are also considering technical updates to the current rules and guidance in relation to food and drink advertising to ensure the new rules are aligned with the existing ones.

The consultation closes on 7 February 2024.
Advertising and marketing

Nick Johnson, Partner
T: +44 20 7105 7080
nick.johnson@osborneclarke.com

Anna Williams, Partner
T: +44 20 7105 7174
anna.williams@osborneclarke.com

Chloe Deng, Associate Director
T: +44 20 7105 7188
chloe.deng@osborneclarke.com

Katrina Anderson, Associate Director
T: +44 20 7105 7661
katrina.anderson@osborneclarke.com

Anna Williams, Partner
T: +44 20 7105 7174
anna.williams@osborneclarke.com
Artificial Intelligence
Artificial Intelligence

EU AI Act

On 8 December 2023, negotiators for the European Parliament and Council of the EU reached political agreement on the shape and contents of the ground-breaking EU regulation on AI – the AI Act. However, this represents the beginning of the end of the legislative process, rather than the end itself as much of the detail remains to be finalised, including areas that could still provoke disagreement.

The text that was agreed in December is not publicly available but our Insight summarises what we knew at the stage when the agreement was reached. Since then, the Commission has published this useful Questions and Answers document giving an overview of the Act. We understand that the final text must be finished by the end of February in order for there to be sufficient time for the formalities of adoption of the text by the Parliament and Council to take place before the European Parliament elections in early June. The full and final text will be published as part of the transparency around those votes.

We anticipate that the definitive text legislation will be published in the EU's Official Journal in around five to six months' time. It will become law 20 days after publication – likely to be late spring/summer 2024.

A staggered compliance period will follow after the AI Act becomes law:

- prohibitions on certain categories of AI will come into force after six months (the end of 2024);
- the provisions on general purpose AI will come into force after 12 months (summer 2025);
- most of the remainder (including the high risk AI regime) will come into force after 24 months (summer 2026); and
- the provisions working AI regulation into existing product safety regimes will come into force after 36 months (summer 2027).

AI liability directive

We do not expect the AI Liability Directive to be finalised before the EU elections taking place in June 2024, as there is not enough time. It will be for the new Commission (to be appointed by the newly elected Parliament) to decide whether to continue with this legislation – although it seems likely that it will. We expect the destiny and timings of this legislation to become clearer in the second half of the year.

Possible legislative initiative on AI in the workplace

Over the last couple of years, the EU Commission and European Parliament have been looking at the impact of AI in the workplace. It was the focus of the Commission's European Employment & Social Rights Forum 2023 event in November 2023. The new Commission may decide to develop these discussions into a new legislative initiative.

UK AI white paper

The UK government consulted on its white paper on AI last year and we currently expect its response to the consultation to be published early in 2024 (having been delayed from the end of 2023). The response is expected to set out the current UK government's policies around AI. The core of its approach is not to develop new legislation (and none was included in the King's Speech last November) but to issue high-level principles to guide the deployment by existing regulators of their existing powers.

Once the government's overarching strategy and principles have been published, we can expect to see more developed policies from the various UK regulators on how they are going to address AI within their particular areas of jurisdiction.

UK elections: a transition year for policy making?

There will be a general election in the UK by the end of January 2025 at the latest, with many commentators expecting it to take place in October 2024. If the current governing party were to be replaced, the new government is most likely to be formed by the Labour Party. Accordingly, if the elections take place at the expected date, this will be a transition year for policy making.

Our recent Insight on AI regulatory developments includes discussion of what might be expected from a Labour government in relation to AI. The party has stated AI to be a strategic priority and has indicated that it would look to provide "greater regulatory certainty" – suggesting new legislation?

IP negotiations

As we discussed in this Insight, the UK government has been working on a code of conduct around the interaction between AI, on the one hand, and intellectual property (IP) rights on the other. Many AI models – including powerful generative AI models – are understood to have been trained on data scraped from the internet, some of which may be protected by IP rights. However, there is debate around whether existing English law IP rules permit this.
Artificial Intelligence

database right holders consider that it does not, but AI developers consider it essential to the development of this transformative technology that they are able to use publicly available information from the internet. The code currently under negotiation is intended to find a path through this issue.

We expect the negotiations on the code to conclude this year.

**Next AI safety summits and the development of international initiatives**

At the first AI Safety Summit held in November 2023 in the UK, it was announced that the next summits are planned to take place in South Korea in six months and in France in 12 months.

In terms of other international developments on AI, such as the G7’s code of conduct for AI developers and guiding principles on AI (see our previous Regulatory Outlook and this Insight), we will start to understand the effect of these international initiatives – which mostly depend on voluntary adherence – and how much impact they will have.
Bribery, fraud and anti-money laundering
Bribery, fraud and anti-money laundering

EU Council and Parliament reach deal on new EU anti-money laundering authority

On 13 December 2023, the European Parliament and Council reached a provisional agreement on the establishment of a new Anti-Money Laundering Authority (AMLA).

The AMLA will be given direct and indirect supervisory powers over high-risk entities in the financial sector, including cryptoasset providers, where they are deemed to be high risk or operate internationally. The AMLA forms part of the EU’s anti-money laundering package, revealed in July 2021, with the aim of tackling money laundering and terrorist financing.

Following approval of the final text of the agreement by representatives of the Member States, the Council and the Parliament will formally adopt the texts. Negotiations between the Council and the Parliament are still in progress with regard to the regulation of anti-money laundering requirements for the private sector.

Expansion of UK corporate criminal attribution for economic crimes

On 26 December 2023, section 196 of the Economic Crime and Corporate Transparency Act (ECCTA) will enter into force, which expands the scope of the "corporate criminal attribution" test to include senior managers within the ambit of individuals deemed to represent the "controlling mind" of a company (see more in our Insight).

Accordingly, organisations will also be guilty of fraud and other specified economic crimes, where a "senior manager" is deemed to have committed those crimes during the course of their work.

However, as previously reported, the Criminal Justice Bill, which was introduced in the House of Commons in November 2023, seeks to further expand the "identification doctrine" to apply to all criminal offences. The bill is currently at the Committee Stage, with the next sitting scheduled for 11 January 2024.

The government is also expected to publish guidance for the new failure to prevent fraud offence under the ECCTA in 2024, upon which the offence will come into force.

To find out more about upcoming changes to the corporate criminal enforcement landscape, watch our video and webinar.

HM Treasury advisory notice on money laundering in high-risk third countries

On 4 December 2023, HM Treasury updated its money laundering advisory notice regarding the risks posed by jurisdictions with unsatisfactory money laundering and terrorist financing controls, to reflect the Money Laundering and Terrorist Financing (High-Risk Countries) (Amendment) (No. 2) Regulations 2023, which came into effect on 5 December 2023.

The notice has been updated to reflect changes to the UK's high-risk third countries list, and continues to align with the Financial Action Task Force's list of countries deemed as high risk, or under increased monitoring status.

Under the Money Laundering, Terrorist Financing and Transfer of Funds (Information on the Payer) Regulations 2017, regulated businesses must apply enhanced customer due diligence and enhanced ongoing monitoring in relation to transactions with any new and existing customers established in high-risk third countries.

Jeremy Summers, Partner
T: +44 20 7105 7394
jeremy.summers@osborneclarke.com

Chris Wrigley, Associate Director
T: +44 117 917 4322
chris.wrigley@osborneclarke.com
Competition
Digital Markets Competition and Consumer Bill – impact on digital markets

Digital regulation has been on the agenda for some time and 2024 promises a number of developments in both the UK and EU that will see it starting to have real impact.

In the UK, the Digital Markets, Competition and Consumer Bill (DMCCB) continues to make its way through the parliamentary process with the Lords committee stage of the bill scheduled for 22 January 2024. It is currently anticipated that this legislation will come into force in the first half of 2024.

The legislation brings sweeping reforms to competition, especially in the area of digital markets. In this regard the proposed legislation will target the most powerful digital firms. To fall within the scope of the new regime enforced by the Digital Markets Unit (DMU) regime, a firm must satisfy:

- a **UK nexus test** (that is, have a sufficient connection to the UK in a particular digital activity);
- a **revenue test**; and
- a **activity test** (that is, conduct a digital activity, or digital activities, that fall within the scope of the regime).

The DMU will have the power to designate a firm that meets these tests with strategic market status (SMS), following a nine-month investigation, where it considers if the firm has substantial and entrenched market power in a particular digital activity, and whether this market power provides the firm with a "strategic position" in that digital market.

The DMU will be able to impose specific, tailored conduct requirements on a firm designated with SMS. These requirements will be designed to prevent an SMS firm taking advantage of its market strength. Additionally, the DMU will have the power to make targeted procompetitive interventions (PCIs) and SMS firms will face additional reporting requirements in relation to M&A activity. The DMU will have the power to issue fines of up to 10% of annual worldwide turnover for breaches of these conduct requirements or failure to comply with a PCI.

The possible impact of the DMCCB (and especially the preparations for the digital markets competition regime and DMU) will be informed by the Competition and Markets Authority's (CMA) horizon scanning report into Trends In Digital Markets, published on 14 December 2023. The report “draws on available evidence to discuss and present possible future developments and potential implications for competition and consumers.”

For more details on the digital aspects of the DMCCB, please see our recent Insight covering this development.

Digital Markets Competition and Consumer Bill – changes to competition law

The DMCCB also stands to have a significant impact on the wider competition landscape in the UK. In this section, we analyse the three main updates to UK competition law proposed by the DMCCB.

The bill gives extraterritorial effect to the UK prohibition against anti-competitive agreements. Currently the prohibition only applies to agreements implemented or intended to be implemented in the UK. The bill extends the prohibition to cover agreements which are likely to have an immediate, substantial and foreseeable effect on trade within the UK, thereby including agreements that are not implemented or intended to be implemented in the UK.

This “qualified effects” test is intended to ensure that UK trade and businesses and consumers based in the UK are protected from the detrimental effects of anticompetitive conduct, regardless of where that conduct takes place, even when an agreement is implemented in another jurisdiction. The expanded scope of this prohibition currently only applies to agreements made after the DMCCB becomes law. By legislating to include this qualified effects test the government is bringing UK competition law into line with UK and EU case law.

The DMCCB also increases the level of the turnover test, when the CMA has jurisdiction to intervene in a merger. This increase changes the jurisdictional thresholds from requiring the target to have at least £70 million UK turnover to £100 million. This is simply to update the test following inflation – the initial turnover test was established in the early 2000s.

Also addressed by the DMCCB is the issue of litigation funding, but only in opt-out cases heard before the Competition Appeal Tribunal. This follows the Supreme Court ruling in PACCAR which held that litigation funding agreements can be damages based agreements (DBAs) and if they are, have to comply with the DBA regulations. Although broadly
welcomed by litigation funders, this amendment has been heavily criticised for not going far enough to address the ruling in PACCAR. Funders will be hoping changes are made to this section in the Lords committee stage of the DMCCB, scheduled for 22 January 2024.

Digital Markets Act

With the Digital Markets Act (DMA), the EU has already legislated to control competition in digital markets. The DMA has been in force since 2 May 2023 but the process for designating gatekeepers is not yet concluded – the first group of designations was completed on 6 September.

Gatekeepers will have six months after designation to comply (by or before 6 March 2024 for those already designated). Please see our previous Insight for an in-depth discussion of the DMA.

Six big tech companies have been designated in relation to social networks, online intermediation services, advertising, number independent communication services, video sharing, search, browsers and operating systems. Challenges have been lodged in relation to some of these designations. Notably there have been no designations or investigations launched into businesses offering cloud computing or virtual assistants. With the increased capability of virtual assistants based on artificial intelligence, they may play a bigger role in the future. The highly concentrated cloud computing market is arguably the most striking absence, given its critical role across both the private and public sectors – including its instrumentality in hosting generative AI models and apps.

The DMA allows the Commission to conduct market investigations to determine whether a service that does not meet the quantitative criteria should still be covered. It has launched such an investigation into iPadOS and we can expect more such investigations in other markets to come.

The DMA will have a substantial impact on digital markets and competition within the EU and beyond. As such, it is important for all businesses to remain aware of the DMA as the regulatory procedures it introduces bed in.

Changes to the National Security and Investment Act

On 13 November 2023, the Cabinet Office issued a call for evidence in relation to the National Security and Investment Act 2021 to collect views on how the national security and investment regime can be more business friendly while maintaining and refining the protections needed to protect national security. This call for evidence closes on 15 January.

The government is looking for views from cross-economy stakeholders in the UK and overseas. Oliver Dowden, the deputy prime minister, has indicated that the powers are to be pared back to make them "more business friendly" with the aim of "narrowing and refining" the scope of the regime. In particular, this evidence will help the government:

- hone the scope of the system's mandatory notification requirements;
- improve the notification and assessment processes under the NSIA; and
- develop the government's public guidance and communications on how the NSIA works and where the government tends to see risk arising.

Depending on the responses received, more detailed consultation on specific measures or legislative changes may be necessary. However, changes that require primary legislation are not currently being considered.

Notably, Dowden proposes removing internal restructures from the regime as the ultimate beneficial owner of the company remains the same in these scenarios. Additionally, junior business minister, Nus Ghani, has highlighted the need for the law to account for emerging threats, including the risk of hostile state actors accessing or buying companies with access to UK citizens’ data.

The call for evidence is open until 15 January 2024. Businesses involved in M&A and private equity activity should remain aware of this development as the proposed alterations would implement significant changes to a number of parts of the regime. To discuss responding to this call for evidence please get in touch with your usual Osborne Clarke contact.

Green Agreements Guidance
On 14 December 2023, the CMA published informal guidance given to Fairtrade Foundation UK on the applicability of the prohibition of anticompetitive agreements to its planned Shared Impact Initiative for the sourcing of Fairtrade banana, coffee and cocoa products by participating UK grocery retailers. Participating grocery retailers would agree to commit to purchase minimum additional Fairtrade volumes of bananas, coffee and/or cocoa from a pool of Fairtrade producers on long-term contracts. This is the first such request for informal guidance under the "open-door" policy in the CMA's Green Agreements Guidance.

The agreement is considered to be an "environmental sustainability agreement" by the CMA and therefore Fairtrade is eligible to receive informal guidance on whether this agreement is likely to infringe UK competition law.

Some key factors in the CMA's analysis of this agreement are that it preserves competition between retailers and, to the extent that there are competitive restrictions, they do not go beyond what is necessary for implementation of the agreement.

With regard to the preservation of competition between retailers, under the agreement, retailers are still free to set retail prices independently. Importantly this includes whether the additional cost of Fairtrade products will be passed to consumers or absorbed by the retailer.

Although the agreement involves the exchange of information relating to future conduct, it is unlikely to reduce competitive uncertainty.

As to competitive restrictions, data collection and management will be done by third parties and retailers will not share information about how they are going to unilaterally deliver the core requirements.

Notably in relation to market share, although the Green Agreements Guidance states that agreements between competing undertakings are more likely to be acceptable when the undertakings have an aggregate market share of less than 10%, in relation to the supply of fair trade bananas the agreement is described as covering "less than 15%" of the relevant market. This indicates that the CMA is willing to consider exempting agreements which exceed the market share thresholds discussed in its guidance.

The CMA encourages businesses to get in touch if they are considering entering into an environmental sustainability agreement but are uncertain as to how the guidelines would apply. Businesses should remain aware of the possibility of doing so – such guidance can prove invaluable especially considering that the CMA has indicated it would be unlikely to issue fines against companies that have approached it for informal guidance. Given the increasing importance of ensuring sustainable business practices this is a crucial opportunity for businesses to be aware of.

If you are considering entering into an agreement with environmental or climate change objectives, the CMA green agreements guidance and commitment to take limited enforcement action against companies which approach it for informal guidance are important factors to consider.

See our Insight.
Consumer law

Digital Markets, Competition and Consumers Bill

The UK Digital Markets, Competition and Consumers Bill (DMCCB) has completed its passage in the House of Commons and had its first and second reading in the House of Lords. A new version of the DMCCB has been published, incorporating the amendments passed on the third reading in the House of Commons. All the amendments the government tabled ahead of the third reading were incorporated into the bill.

The DMCCB is expected to be pushed through and become law in early 2024. Its implementation will bring a fundamental change about how we think about the risks and sanctions associated with non-compliance with consumer law in the UK.

We also expect to see further developments regarding the secondary legislation due to accompany the DMCCB in 2024. The government has recently consulted on a range of matters, including a new "blacklist" of offences under the DMCCB that relate to fake reviews and "dark patterns" in the form of hidden fees and drip pricing. The Competition and Markets Authority has responded to the consultation and agreed with the proposed list of banned practices. However, the UK regulator also suggested that misleading environmental claims should be added to the list under the DMCCB. Further government consultation is expected on the possibility of creating new banned practices around these issues.

Digital Services Act

The EU Digital Services Act (DSA) became enforceable for the first set of very large online platforms (VLOPs) and very large online search engines (VLOSEs) (as defined by the DSA) on 25 August 2023. The DSA will become applicable to all in-scope digital services from 17 February 2024. Therefore, 2024 will likely be the year when we start to see what "market practice" DSA compliance looks like for non-VLOPs and VLOSEs. Guidance from the EU on the DSA is also anticipated. (You can see our Insight to find out more about the scope of the DSA.)

Fitness check on EU consumer law

Last year, the European Commission consulted on its fitness check of EU consumer law on digital fairness, which was a follow-up to the public consultation launched in November 2022.

The consultations allowed us to have an understanding of the topics the Commission is focusing on as part of its review. The areas of focus that emerged in both consultations include dark patterns, the addictive use of digital products, subscriptions (including subscription cancellation), the misuse of personal data and personalisation practices, and influencer marketing. The targeted survey conducted last year widened the scope of topics, additionally addressing, among other things, artificial intelligence (AI) and the use of automation in consumer services (such as chatbots), virtual and augmented reality, and the use of connected products (that is, the Internet of Things).

It is not likely that legislation will be passed in 2024, but more concrete proposals regarding any new legislation or amends to existing legislation are expected, most likely around dark patterns and AI. There is a suggestion that this will take the form of standalone digital-fairness legislation to promote fairness for consumers in the digital world and to address the asymmetry in power caused by the ability of platforms to leverage data.

New guidance on professional diligence

We expect more guidance on what professional diligence means for businesses both in the UK and EU. In the UK, this issue was addressed as part of the government's consultation on a range of proposed measures across core consumer laws. The Department of Business and Trade (DBT) proposed to create new guidance on what "professional diligence" means in the context of online platforms. The DBT consulted on whether and how the government should build on the existing definition of professional diligence.

In the EU, this issue was addressed as part of the Commission's fitness check of consumer law, in which it sought views on whether the concept of "professional diligence" should be further clarified in the context of digital environment.

Definition of vulnerable consumers

A new definition of vulnerable consumers was incorporated in the DMCCB in the UK. As part of its fitness check of EU consumer law, the Commission also sought views on whether the concept of "vulnerability" (including situational vulnerability) in the digital space is sufficiently addressed in current EU consumer law. We could, therefore, expect a new definition to be introduced in the EU as well (which could be different to the one incorporated in the DMCCB).
Consultation on proposed regulation to improve security of UK data infrastructure

On 14 December 2023, the Department for Science, Innovation and Technology launched a consultation seeking views on a proposed regulation to improve the security and resilience of UK data infrastructure.

The proposals, which focus on third-party data centre services, seek to address cybersecurity threats, risks to the resilience of data centre services, and the perceived lack of information-sharing and cooperation across the data infrastructure industry through the creation of a new statutory framework.

The proposed measures include:

- introduction of a new regulatory function to implement and enforce the proposed framework;
- mandatory registration of relevant data centre providers with the designated regulator;
- introduction of a duty to comply with baseline security and resilience measures;
- introduction of a standards and assessment framework to enable the regulator to assess compliance with security and resilience measures; and
- incident reporting requirements to the regulator, customers and other affected parties.

The consultation follows government proposals to expand the existing Security of Network and Information Systems Regulations (NIS regulations) to include additional sub-sectors and will be of particular interest to data centre operators, cloud platform providers, managed service providers, as well as customers and suppliers of the above. You can respond to the consultation here. The consultation closes on 22 February 2024.

EU Parliament Committee adopts draft report of Cyber Solidarity Act

On 7 December 2023, the European Parliament's Committee on Industry, Research and Energy adopted the draft report of the Cyber Solidarity Act, which proposes to build a collective and more resilient EU response against cybersecurity threats. A decision to start negotiations with the EU Council was submitted during the 11-14 December plenary session.

Member States have until 17 October 2024 to adopt legislation to comply with the NIS 2 Directive, which repeals and replaces the NIS Directive, the first European cybersecurity legislation aimed at establishing a high level of security of organisations and harmonising cybersecurity requirements. For further information on NIS2 compliance see our Insight.

Further EU regulations on cybersecurity are expected to be finalised in 2024, following the European Council and Parliament's provisional agreement on the proposed Cyber Resilience Act, which will introduce EU-wide cybersecurity requirements for the design, development and distribution of Internet of Things (IoT) products. The regulation is expected to enter into force in early 2024, upon which manufacturers will have 36 months to apply the rules. For further information see our Insight.

In the UK, the Product Security and Telecommunications Infrastructure (Security Requirements for Relevant Connectable Products) Regulations 2023 will come into effect on 29 April 2024. It introduces the consumer connectable regime which specifies minimum requirements for manufacturers to enhance the security of IoT products that are made available to consumers in the UK.

NCSC guidance on Star Blizzard

On 7 December 2023, the National Cyber Security Centre (NCSC) released a report warning about the threat of spear-phishing attacks against targeted organisations and individuals in the UK by the Russia-based group Star Blizzard.

The NCSC has also updated its guidance for individuals at higher risk of being targeted by threat actors to improve their resilience against cyber threats. Read the press release.

It is anticipated that 2024 will see greater collaboration between the Information Commissioner's Office (ICO) and the NCSC on activities towards improving the UK's cyber resilience, as they signed a joint Memorandum of Understanding in September 2023. The memorandum sets out cooperation between the two organisations on the development of cyber standards and guidance, information-sharing procedures between the two organisations, and cross-government coordination in response to incidents.

Joint Committee report on ransomware and UK national security
Cyber security

On 13 December 2023, the House of Commons Joint Committee on National Security Strategy published a report on the scale and nature of ransomware threats against the UK. It notes key ransomware trends including:

- the growth of ransomware-as-a-service (RaaS) – which has increased the agility and speed of ransomware operations;
- innovations in marketing, recruitment, and communication of RaaS groups;
- a shift towards "big game hunting" – with threat actors targeting higher-value organisations with the aim of achieving larger ransom payments; and
- an increase in the use of double or triple extortion methods by threat groups – including exfiltration (removal) rather than encryption of data, threatening customers/suppliers with the release of sensitive data, and a premium subscription in exchange for exclusive rights over the stolen data.

The report concludes by making several recommendations including:

- transferring responsibility for tackling ransomware from the Home Office to the Cabinet Office, in partnership with the NCSC and the National Crime Agency (NCA);
- bringing forward legislation to reform the Computer Misuse Act 1990 to criminalise the theft and copying of data and introduce extra-territorial provisions for cybercrime; and
- investing more resources into the government and the NCA’s approach to disrupting ransomware operators.

CISA and ENISA sign working arrangement to enhance cooperation

On 7 December 2023, the European Union Agency for Cybersecurity (ENISA) announced that it had signed a working arrangement with the US Cybersecurity and Infrastructure Security Agency (CISA), with the aim of facilitating short-term cooperation actions and longer-term cooperation in cybersecurity policies and implementation approaches.

We anticipate the UK to continue to coordinate closely with international allies on cybersecurity measures in the coming year. For example, in November 2023, the National Cyber Security Centre (NCSC) and the National Intelligence Service of the Republic of Korea released a joint advisory about the rising risk of Democratic People's Republic of Korea (DPRK) state-linked cyber actors targeting software supply chain products. Members of the international Counter Ransomware Initiative, which includes the EU, US and the UK, also released a joint statement to publicly denounce ransomware and discourage ransom payments being made to cyber criminals.

Charlie Wedin, Partner
T: +44 117 917 4290
charlie.wedin@osborneclarke.com

Ashley Hurst, Partner
T: +44 20 7105 7302
ashley.hurst@osborneclarke.com

Philip Tansley, Partner
T: +44 20 7105 7041
philip.tansley@osborneclarke.com

Nina Lazic, Associate Director
T: +44 20 7105 7400
nina.lazic@osborneclarke.com
Data law

This year is shaping up already to be a busy one in the world of data protection and broader data regulation. For this January edition of our Regulatory Outlook, Osborne Clarke's data experts have provided an overview of data protection developments and predictions for 2024, the UK Information Commissioner's Office's (ICO) priorities for this year, broader data regulation trends, and finish with some key dates to be aware of for 2024.

We have renamed this section "Data law" as there are an increasing number of new data laws we are reporting on which are not specific to data protection (such as the EU's Data Act or the UK's Smart Data schemes) or areas of law which intersect with data protection (such as regulation of artificial intelligence or digital regulation).

To stay up to date with these developments, please keep an eye out for future editions of our Regulatory Outlook, our Dipping into Data series of webinars and our Annual Data Event which will return later this year.

Hot data protection topics for 2024

UK data protection reform

One of the main questions since the UK General Data Protection Regulation (GDPR) became its own distinct regime from the EU GDPR is how far will the UK GDPR diverge from the European framework?

The Data Protection and Digital Information (DPDI) Bill, which sets out the current proposal to reform UK data protection law, has completed its readings in the House of Commons and is currently progressing through the House of Lords with the expectation that it will become law in spring 2024.

It has undergone a number of amendments during its passage through Parliament – you can find our summary of the key changes here. Most recently, the DPDI Bill was amended to include potentially controversial provisions giving the secretary of state a new power to obtain information for social security purposes (i.e. benefits information), and giving Ofcom the power to require internet service providers (including social media companies) to retain information in connection with an investigation by a coroner into the death of a child suspected to have taken their own life.

The bill represents a balancing act between demands to give organisations the ability to use data responsibly (for example, setting out further circumstances where they can rely on legitimate interests to lawfully process personal data) and ensuing that personal data remains protected. It also reflects the need for the UK to maintain its adequacy decision with the EU (which enables the free flow of personal data from the EU to the UK).

Once the bill receives Royal Assent, businesses should consider what changes they could or should make to their existing governance frameworks, particularly to take advantage of potential relaxations in certain requirements (for example, around records of processing). Businesses with operations in both the UK and the EU will need to consider whether they can (and would want to) continue to adopt a single approach to compliance across both, irrespective of the changes being introduced by the DPDI Bill.

International data transfers

2023 saw a number of key changes in the sphere of international data transfers. On 11 July 2023, the new EU-US Data Privacy Framework (the much-anticipated replacement to the Privacy Shield) went live. Following hot on its heels, on 12 October 2023, the new UK-US Data Bridge was introduced, extending the mechanism (essentially a partial adequacy decision, which did not apply to the UK post-Brexit), to apply to transfers of personal data from the UK to the US. At the end of 2023, we saw the ICO issue guidance for organisations completing transfer risk assessments for transfers of personal data from the UK to the US.

Separately, the ICO has also introduced a UK Binding Corporate Rules (BCRs) Addendum, which will enable existing EU BCR holders to complement and widen the scope of their EU BCRs to cover UK data transfers without the need for a wholly separate UK BCR application and policy.

Further important developments are likely in 2024. To add to the utility of the EU-US Data Privacy Framework (as extended by the UK-US Data Bridge), we expect to see the Swiss government recognise the framework as adequate, enabling transfers of personal data from Switzerland to the US under the framework. Conversely, we expect to see further challenges to the EU-US Data Privacy Framework: privacy activist Max Schrems (who has challenged the previous two EU-US transfer mechanisms) has indicated an intention to commence legal proceedings on the basis that the framework does not do enough to protect EU citizens' personal data. A crucial question at that point would be whether the UK-US Data Bridge could survive even if the EU-US Data Privacy Framework failed.
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The EU-UK Adequacy Decision, which is a decision made by the European Commission that maintains the free flow of personal data from the EU to the UK under the EU GDPR, is expected to last until 27 June 2025. The European Commission will start work later in 2024 to determine whether to extend this adequacy status up to a maximum of another four years. We expect that the European Commission will be closely following the Data Protection and Digital Information Bill developments as part of this review.

Lastly, ahead of 21 March 2024, we expect to see a last flurry of businesses looking to implement the new EU standard contractual clauses (SCCs) and the UK Addendum or the UK standalone international data transfer agreement, as businesses still relying on the pre-GDPR SCCs to transfer personal data from the UK to non-adequate countries have until that date to transition to another transfer mechanism before the pre-GDPR SCCs cease to apply.

Harmful website designs (aka dark patterns)

In 2023, the ICO and UK Competition and Markets Authority (CMA) joined forces in warning businesses to stop using harmful website design tools (such as dark patterns) that can influence a consumer’s decision and online behaviour about the way their personal data is used; for example nudging them towards giving up more data than they would like. These designs include privacy-intrusive default settings and pop-ups that make it harder to refuse cookies than accept them.

Following this, the ICO made clear at its October ICO Data Protection Practitioner’s Conference that non-compliant cookie consent mechanisms (for advertising cookies) remains an important focus of its enforcement strategy. Then in November it issued warnings to some of the UK’s top websites that they face enforcement action if cookie consent mechanisms are not up to scratch, for example where it is not as easy for a user to “Reject All” advertising cookies on their website as it is to “Accept All” such cookies.

We predict continued regulatory focus from the ICO in 2024 on harmful website design practices, particularly on what the ICO perceives to be non-compliant cookie consent mechanisms (for which it plans to provide an update in January on its recent enforcement efforts), and increased collaboration with the CMA.

Businesses should review their website designs, particularly cookie consent mechanisms, to check whether they are adopting any of the dark patterns identified by the ICO and the CMA, and assess what changes (if any) to make as a result.

Online advertising

Increasing regulatory scrutiny of the online advertising ecosystem across Europe has been a consistent theme for 2023 – regulators (in the EU, in particular) and courts (specifically, the Court of Justice of the European Union (CJEU)) continue to push for consent as the only valid lawful basis for online advertising activities (away from legitimate interests and contractual necessity) and there has been further scrutiny over cookie consent practices. We can expect further developments throughout 2024.

In particular, towards the end of 2023, the European Data Protection Board (EDPB) published draft guidelines for consultation on the technical scope of the cookie requirements in Article 5(3) of the e-Privacy Directive. The draft guidelines clarify that the scope of the rules (that require user consent) apply beyond traditional cookies to a vast array of other technologies that are intended to track users online, including those often used in the online advertising industry. The public consultation closes on 18 January 2024 and therefore we can expect the final guidelines sometime thereafter.

The European Commission has also published a draft set of high-level principles in relation to advertising cookies (its “cookie pledge”), which is intended to address “cookie fatigue” by simplifying the management of cookies and personalised advertising choices by consumers. The European Commission is currently taking feedback, including from the EDPB (who has issued an opinion on the current draft), and aims to finalise the principles by April 2024. Even once finalised, the principles will be voluntary only.

In 2024, it is possible we will receive the CJEU’s highly anticipated judgment on a number of questions raised by IAB Europe in relation to the application of the EU GDPR to its Transparency and Consent Framework (TCF), following enforcement from the Belgium data protection authority. The TCF is a widely adopted tool across the adtech ecosystem for communicating users’ choices with respect to the use of their personal data for online advertising purposes, and uncertainty remains around the long-term viability of this framework pending this judgment.

As noted already above, in the UK, the ICO has announced its intention to enforce cookie requirements, particularly in relation to websites that fail to provide users with an easy “Reject All” button for advertising cookies within their cookie consent banner. In issuing this warning, the ICO noted that this “action is part of our broader work to ensure that people’s
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*rights are upheld by the online advertising industry*, perhaps indicating that further developments in this area can be expected in 2024.

In light of increasing scrutiny from regulators and courts we are seeing a growing number of organisations in Europe move to a "consent or pay" model, whereby an individual either consents to the use of their data for online advertising purposes or alternatively pays for the service. In Europe, this model has already attracted the attention of privacy activists (in relation to whether this is valid consent under the GDPR) and, as such, we predict that we will hear further comments from the regulators on the viability of this model in 2024.

Businesses that use personal data for online advertising purposes should review what lawful basis they are currently relying on in respect of that processing, and – if relying on legitimate interests or contractual necessity – they should assess whether that is still the appropriate lawful basis (in light of the developments set out above). Organisations that operate in the UK and the EU should consider how that assessment may vary between the two regions, particularly as most of the case law and enforcement action on this issue is currently coming out of the EU (although that is changing with the ICO's action on cookie banners).

Artificial intelligence

Data protection issues related to the increasing use of artificial intelligence (AI) in our daily lives has been a focus area for the ICO for some time. A number of developments on the topic of AI from the ICO in the form of guidance (such as a warning to businesses on the data protection risks of generative AI, as well as guidance for developers on the same) and enforcement (its fine of Clearview AI).

Towards the end of 2023, the Information Commissioner warned companies about consumers' trust in AI, reminding businesses in a *speech* at TechUK's Digital Ethics Summit 2023 that "privacy and AI go hand in hand – there is no either/or here". We expect in 2024 that privacy and AI will continue to be a principal focus for the ICO.

This will be coupled with an increase in wider AI regulation. Late on Friday 8 December, negotiators for the European Parliament and Council of the EU reached political agreement on the shape and contents of the EU AI Act. The agreed text is not yet available, and the first full draft may not be ready before the end of January or later. Nevertheless, from the press releases from the Parliament and Council, and various other press reports and posts, we can build a picture of the scope and structure it will take. For the Parliament to have sufficient time to adopt the text before the June elections, the technical drafting must be complete by the end of February. While the EU AI Act will not apply in the UK, it will affect UK businesses operating in the EU, making it necessary to establish an AI governance programme in good time for the relevant deadlines.

Businesses that are developing or considering using AI should properly assess the data protection (and other) risks of doing so prior to implementation.

Certifications

As previously reported, in 2022 we saw the first GDPR certification scheme called "Europrivacy" receive formal approval. Europrivacy enables organisations to assess and certify the compliance of their data processing with the EU GDPR and complementary national data protection regulations. Organisations with certified data processing activities can identify and reduce their risks and demonstrate their compliance to help enhance their business reputation and improve access to markets.

Throughout 2023, we have seen these schemes gradually improve and they have the potential to become something much more significant through the course of 2024.

Osborne Clarke is an official partner for the scheme and our team of experts can assist with your compliance – see [more information](#). As the benefit of such initiatives start to bear fruit, we expect many more organisations to seek accreditation and further organic growth of industry codes of conduct.

ICO priorities for 2024

ICO25 plan

In 2022, the ICO published the [ICO25 plan](#), which established its targets for the next few years and its annual action plan for October 2022 to October 2023. This included a number of actions to safeguard and empower people, to empower
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responsible innovation and sustainable economic growth, to promote openness and transparency, and to develop the ICO's culture, capacity and capability.

In 2023, we saw the ICO follow through on a number of its proposed actions (although certainly not all of them), such as developing a subject access request tool to help individuals submit subject access requests in a way that is more helpful for organisations to be able to respond, and a series of new guidance.

At this time, we are still waiting for the ICO to publish its 2023-2024 annual action plan, although we would predict the ICO's priorities and actions are likely to remain the same for 2024.

ICO guidance

2024 promises to be another year of new and updated ICO guidance following consultations on employment data, biometrics and data transfer risk assessments to the US. We are still waiting for the ICO’s much-anticipated guidance pipeline (part of its ICO25 plan), at which point it will become clear what more we can expect from the ICO.

This year we are hoping that the clause-by-clause guidance on how to use the International Data Transfer Agreement and UK Addendum will finally be published. Further guidance is also expected on new technologies and further sector-specific guidance as part of its ICO25 plan.

Enforcement predictions

In accordance with its ICO25 plan, the regulator is likely to continue to focus its enforcement on certain areas where it sees the greater risks to society (including the most vulnerable). As was the case in 2023, we expect the ICO to continue to enforce through a combination of fines, warnings and reprimands with increasing publicity for its enforcement action.

Those areas on which we predict the ICO will focus its attention in 2024 are:

- **Cookie compliance/online advertising.** As already mentioned, one area we expect will receive increasingly more of the ICO’s attention is harmful online designs, most notably the use of advertising cookies without adequate cookie consent mechanisms. We can expect an update from the ICO on its enforcement action in this area at the start of 2024.

- **Children’s data.** Following on from its work on its Age Appropriate Design Code, a clear focus for the ICO continues to be on ensuring that organisations are following the code - we expect this to continue, particularly in the context of an expected focus by online platforms on wider child-harm issues as a result of the UK’s Online Safety Act.

- **New technologies (such as AI and biometric data).** 2023 saw the ICO increase its scrutiny on organisations’ use of AI and biometric technologies (such as Clearview AI’s facial recognition technology and a generative AI chatbot used by a social media service), and we predict this will continue into 2024 as more and more organisations are looking to implement these technologies into their businesses.

- **Direct marketing.** The ICO continues to actively enforce spam-marketing and cold-calling requirements, and we expect this to continue throughout 2024.

Data regulation – beyond data protection in 2024

Data protection law is a fundamental pillar of the data regulation world, but its importance is at risk of being eclipsed by the wave of other data regulation set to tantalise lawyers through 2024 and beyond.

In the EU, there is an increasing body of regulation governing (certain) organisations’ access to, use and sharing of data (whether personal data or otherwise). In particular, the Digital Markets Act, Digital Services Act, the Data Governance Act and the Data Act have each either come into effect recently or will come into effect over the next couple of years. Many aspects of that new regulation intersect with existing data protection laws.

The UK is taking a different approach, at least in the short to medium term. Although the UK has a similar objective to the EU of unlocking the value of data across the economy, it is not currently pursuing horizontal, cross-sector regulation; instead choosing to take a more sector-specific approach. Part 3 of the DPDJ Bill proposes to introduces new regulation-making powers to enable Smart Data schemes to be introduced in any given sector. At the same time, the Department for Science, Innovation and Technology is consulting on the potential benefits and challenges of introducing a smart data scheme into the UK telecoms market, in the form of the Open Communications scheme. The Financial Conduct Authority
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has also published a call for input on the potential competition impacts from the data asymmetry between Big Tech firms and financial services firms.

It is more important than ever for data teams to be aware of the intersection of data protection with other areas of existing (or pending) regulation and to work together with other teams and experts to address issues in a holistic, forward-thinking and practical manner.

Mark Taylor, Partner
T: +44 20 7105 7640
mark.taylor@osborneclarke.com

Tamara Quinn, Partner
T: +44 20 7105 7066
tamara.quinn@osborneclarke.com

Georgina Graham, Associate Director
T: +44 117 917 3556
georgina.graham@osborneclarke.com

Gemma Nash, Senior Associate
T: +44 117 917 3962
gemma.nash@osborneclarke.com
Employment and immigration
Employment and immigration

Employment changes coming into effect in January and April 2024

At the end of last year, the government introduced a number of new laws which bring into effect a number of employment law changes relating to:

- working time;
- TUPE;
- flexible working;
- carer’s leave;
- special protection on redundancy;
- neonatal leave;
- statutory right to request a more predictable working pattern; and
- a new duty to prevent sexual harassment.

Changes to working time and TUPE came into force on 1 January 2024 (although changes relating to holiday entitlement/pay for part-year and irregular-hour workers only relate to holiday years falling on or after 1 April 2024).

Changes related to flexible working, carer’s leave and special protection on redundancy for those who are pregnant or who have taken a period of statutory family leave are set to come into force in April 2024. A new duty to prevent sexual harassment is due to take effect in October 2024 and, while we do not yet have a date for when they will take effect, regulations have also been passed which permit workers to make a statutory request for a predictable working pattern subject to meeting certain requirements. The new statutory right to neo-natal leave is not expected to take effect until 2025.

For more details on these and what actions you should be taking now, together with new statutory pay rates which will take effect during 2024, read our Insight.

Looking ahead

As we move into 2024, many employers will be keeping hybrid working arrangements under review; the end of 2023 has already seen some large businesses bring more clarity around their policies to ensure that expectations on attendance at a place of work are clear. We are likely to see employers continue to review and adapt working arrangements to address client and workforce demands, while keeping in mind their contractual and statutory obligations to each employee, and employee relations issues and the benefits of a diversified employee pool more generally.

The increasing role of artificial intelligence is also set to drive HR agendas during 2024. While for many businesses, we do not anticipate that it will replace current jobs in their entirety, it is becoming clear that generative AI tools are a potential replacement for some of the tasks that employees have routinely performed and employers will need to assist employees in re-focusing their duties and ensuring that they have the appropriate skill set to do so. Employers will need to be alive to the potential need for restructurings involving changes to terms and conditions and/or redundancies and the legal and practical issues these processes bring.

HR and employment counsel must also remain aware of the inherent risks within other AI tools that they may use directly or indirectly within their business: it is well recognised that AI tools may in fact produce discriminatory results or inaccuracies. It will be important to ensure that appropriate checks and balances are in place and practices reflect regulatory and other guidance on the use of AI in the workplace. International employers will also need to keep in mind the different legal frameworks governing AI across jurisdictions, with the EU and other countries taking different approaches to regulation.

Read more on the emerging trends we expect to see in 2024 here.

Update on regulating umbrella companies

As reported in an earlier Regulatory Outlook, last year a consultation ran on proposals to regulate so-called umbrella companies (the UK equivalent of Employers of Record, or EORs). In 2024 we expect the outcome of the consultation to be published which is likely to provide more clarity about what checks need to be carried out on umbrellas and whether end users will be liable for compliance breaches (including tax-related) by umbrellas they use. We anticipate that changes will not come in until 2025, but companies should review the consultation outcome once published and start thinking about what actions they may need to take to prepare for any changes. There is a chance that legislation will come in earlier than 2025, given anecdotal evidence of the growth in “dodgy” umbrella schemes in recent times.
IR35 enforcement under private sector regime

HMRC compliance enquiries and enforcement activity is already increasing, and are likely to step up in 2024 as the four year time limit for claims (for tax year 21/22) approaches in April 2025. With fines and interest meaning that end users, staffing intermediaries and payment intermediaries may be liable for tax payments more or less equivalent to the amount they paid the contractors for the relevant work, companies should be ready to cooperate with any enquiries against them and be prepared to answer detailed labour supply chain questions by HMRC.

Immigration changes coming in 2024

Sponsored Workers

The UK government announced significant changes to salary requirements for sponsored workers in an attempt to reduce net migration. The proposed minimum salary will rise to £38,700. While this may restrict who can apply as a skilled worker, it will especially affect industries with talent shortages in certain sectors such as hospitality and construction. In addition, the current salary "discount" for shortage roles will end, and a further review into suitability of the Shortage Occupation List is proposed. There is likely to be some transitional arrangements for existing skilled workers already in the UK. It is anticipated these changes will be brought in in the first quarter of 2024.

Graduate visa

The Home Office will commission the Migration Advisory Committee to consider policy options for reforming the graduate visa route so that it better supports a pathway into high quality jobs for graduates and to "prevent abuse". Whether we will see further developments for this category or a closing of this category (which happened to its predecessor – Post Study Worker) is yet to be seen.

Students

New rules now mean specific requirements need to be met in order for students (and student dependants) to switch into the skilled worker route. From 1 January 2024, changes to the UK student visa rules mean that international students will no longer be able to bring their dependant partner or children to the UK, unless they are enrolled in a PhD or postgraduate research programme.

Spouses of British or settled nationals

As part of the expected changes in 2024, the income requirement for British nationals will increase from the current £18,600 (no children) to £38,700. There will be an initial jump to £29,000 with the remaining increase being phased in over the next 12 months. The additional income requirement to sponsor children is yet to be clarified, as is the application of these new rules to extension applications.

ETA visa waiver programme

The Electronic Travel Authorisation (ETA) visa waiver programme for visitors from the EU and other countries whose nationals do not require a visa to visit the UK will continued to be phased out in 2024. Qatari nationals have been the first to use this system and while decisions appear to be made quickly there have still been reports of some refusals. It remains to be seen whether airlines and ground staff will receive the appropriate support from the Home Office in relation to checking ETA permissions of travellers before boarding and whether some travellers may be incorrectly denied permission to board.

Julian Hemming, Partner
T: +44 117 917 3582
julian.hemming@osborneclarke.com

Kevin Barrow, Partner
T: +44 20 7105 7030
kevin.barrow@osborneclarke.com

Catherine Shepherd, Knowledge Lawyer Director
T: +44 117 917 3644
catherine.shepherd@osborneclarke.com

Kath Sadler-Smith, Knowledge Lawyer Director
T: +44 118 925 2078
kath.sadler-smith@osborneclarke.com
Employment and immigration

Gavin Jones, Head of Immigration
T: +44 20 7105 7626
gavin.jones@osborneclarke.com

Helga Butler, Immigration Manager
T: +44 117 917 3789
Helga.butler@osborneclarke.com
Environment
Government delays mandatory Biodiversity Net Gain to January 2024 and publishes first statutory instruments

The Department for Environment, Food and Rural Affairs announced that the government is delaying the implementation of mandatory Biodiversity Net Gain (BNG) requirements.

BNG was due to come into force in November 2023 but has been delayed until January 2024 (April 2024 for small sites).

A government blog post, published on 29 November 2023, set out the six statutory instruments that will become law in January to deliver the BNG framework. These cover:

- **Site register regulations** – set out the processes and requirements for biodiversity gain sites to be registered and allocated to developments.
- **Exemptions** – which sites and developments will not need to comply with BNG regulations.
- **Penalties and fees** – the fees associated with registering sites and also the penalties for providing false or misleading information during registration.
- **Irreplaceable habitats** – contains the list of habitats classed as irreplaceable as well as the differences in how applications relating to them will be determined.
- **Modifications and amendments** – adds provisions for phased developments, sets out what needs to be included in a planning application in relation to BNG, details the timescales for submission of a biodiversity gain plan as well as the application, determination and appeal process in relation to gain plans. Notably the amendments state that the earliest a biodiversity gain plan can be submitted is the day after planning permission is granted.
- **Consequential amendments** – minor amendments to other pieces of planning legislation.

BNG will not apply to nationally significant infrastructure projects until November 2025, with further guidance to be published throughout 2024.

Government launches consultation on the proposed rules to govern carbon capture transportation and storage networks

The department for Energy Security and Net Zero (DESNZ) is inviting consultation on the Carbon Capture and Storage Network Code. The code will set out the arrangements that will govern the networks to transport carbon from where it is emitted and captured to storage facilities.

Any feedback on the potential drafting and contents of the code should be submitted to DESNZ before 16 February 2024.

UK Sustainability Disclosure Requirements

The UK Sustainability Disclosure Standards (SDS) will set out the necessary disclosures for companies in relation to sustainability-related risks and opportunities. The standards will form the basis of future reporting requirements in the UK.

These standards will be based on the International Sustainability Standards Board IFRS disclosure standards, and will only divert for UK specific matters where absolutely necessary. The IFRS standards incorporate and expand upon the Taskforce for Climate-related Financial Disclosure's recommendations, so firms already voluntarily reporting in line with these requirements will be at an advantage. The secretary of state for Business and Trade will consider the endorsement of the IFRS standards and creation the UK SDS by July 2024.

The decision as to whether to require disclosure in line with the UK SDS will be taken independently by the UK government for UK registered companies and LLPs and by the FCA for UK listed companies.

UK government confirms plans for Carbon Border Adjustment Mechanism

Where carbon intensive goods are imported to the UK they may be subject to carbon levies from 2027. Aluminium, glass, cement, ceramics, fertiliser, hydrogen, iron, and steel will be affected by the new scheme.

The liability under the UK Carbon Border Adjustment Mechanism (CBAM) will depend on the greenhouse gas emissions of the imported product and the difference between the carbon price applied in the country of origin and the carbon price
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that would have been applied if the goods had been made in the UK. Liability to pay this levy will be with the importer of the goods.

The government hopes the scheme will:

- support UK firms in implementing net zero transition plans for their products and manufacturing;
- create a more equitable market between UK goods and imported goods with a higher embedded carbon footprint; and
- incentivise firms outside the UK to decarbonise their products to remain competitive.

Further detail of the precise goods in scope will be subject to consultation in 2024.

Vehicle Emissions Trading Scheme Order 2023 has been made

The Vehicle Emissions Trading Schemes Order 2023 was made on 13 December 2023 and came into force on 3 January 2024.

The order forms part of the UK’s zero emissions vehicle (ZEV) transition, which includes the recently delayed ban on new petrol and diesel cars from 2035.

It establishes four UK-wide trading schemes two in relation to ZEV production and two in relation to CO2 emissions.

The ZEV production schemes relate to the number of vehicle registrations made by manufacturers, and the allowances for non-ZEVs will decrease annually from 2024. If fewer non-ZEVs are registered than their target then the manufacturer will have surplus allowances; if they register more than their target then they will be in deficit and will need to purchase additional allowances. Surplus allowances can be traded or banked.

The CO2 standard schemes work in a similar way, however allowances are based on a baseline per-vehicle emissions target. Manufacturers must have one allowance for every gram CO2/km they emit on average across their entire fleet. Sufficient allowances will be given for manufacturers to meet their targets and surpluses can be traded and banked. If there are deficits, allowances must be bought or can be transferred from ZEV scheme surpluses.

Provisional agreement has been reached on CSDD

Please see ESG.

EU deforestation-free products regulation set to come into force

Please see ESG.

First reporting obligations under the Corporate Sustainability Reporting Directive

Please see ESG.
Environmental, social and governance
FCA publishes Sustainability Disclosure Requirements

As set out in the November edition of our international ESG knowledge update, the Financial Conduct Authority (FCA) has published its long-awaited Sustainability Disclosure Requirements. The rules aim to bring trust and transparency to the UK market for sustainable investment products and represent a major ESG shift for the UK financial services sector.

Most significantly, the rules bring in a new general anti-greenwashing rule for all FCA-authorised firms. This will come into force on 31 May 2024 (the FCA is currently consulting on guidance about how it will operate). The other new rules, aimed at UK asset managers, include an investment labelling regime, which firms will be able to use from 31 July 2024, as well as new naming and marketing rules and disclosure obligations, which will come into force from 2 December 2024 onwards. See our Insight for more on what businesses should be doing now to prepare for these upcoming changes.

How UK and EU regulators plan to hold financial service providers accountable for greenwashing

There have been significant recent supervisory developments in the UK and EU regarding the risks of greenwashing in the financial services sector. Our Insight explores some of these developments and what financial service providers can do in 2024 to mitigate the risk of accusations of greenwashing.

Continuation of regulatory scrutiny of green claims

Throughout 2023, both the Competition and Markets Authority (CMA) and the Advertising Standards Authority (ASA) have taken enforcement action against misleading environmental claims. In 2024, we expect this scrutiny to continue, in particular with the CMA focusing on the fashion industry and fast-moving consumer goods sectors.

The ASA has also recently taken greenwashing action in the aviation sector, and the CMA has hinted that the travel and transport sector is one that it could look at in the future as part of its sector investigations into greenwashing.

Ultimately, in 2024 businesses need to continue to be cautious as to what claims they make, as any claim that is unclear in scope is at a high risk of being considered misleading by regulators.

Provisional agreement has been reached on Corporate Sustainability Due Diligence Directive

The European Parliament and Council has reached a provisional agreement on the Corporate Sustainability Due Diligence Directive (CSDD).

The final text is not yet available, but below are some of the key points from the press releases:

- **Scope of the directive**: The directive applies to large companies with more than 500 employees and a net worldwide turnover of €150 million. For non-EU companies, it applies if they have a €150 million net turnover generated in the EU, three years after the directive comes into force. The Commission will publish a list of non-EU companies falling under the directive's scope. The European Parliament's press release also outlines that it will apply to companies with over 250 employees and with a turnover of more than €40 million if at least €20 million are generated in one of the following sectors: manufacture and wholesale trade of textiles, clothing and footwear, agriculture including forestry and fisheries, manufacture of food and trade of raw agricultural materials, extraction and wholesale trade of mineral resources or manufacture of related products and construction.

- **Financial sector exclusion**: The financial sector is temporarily excluded from the directive's scope, but there is a review clause for possible inclusion in the future based on impact assessment.

- **Climate change and civil liability**: The directive requires large companies to adopt a transition plan for climate change mitigation. It also strengthens access to justice for affected individuals and establishes a five-year period to bring claims. Companies must end business relationships with partners causing adverse impacts if prevention or resolution is not possible.

- **Penalties**: Companies violating the directive may face fines of up to 5% of their net worldwide turnover.

- **Definitions**: The directive clarifies the obligations for companies described in Annex I, a list of specific rights and prohibitions that constitutes an adverse human rights impact when they are abused or violated. The list makes references to international instruments that have been ratified by all Member States and that set sufficiently clear standards that can be observed by companies.
Environmental, social and governance

The provisional agreement reached now needs to be formally approved by both institutions, which are expected to vote early next year.

Full implementation of the directive is expected by the end of 2024.

In the UK, a private member's bill has been introduced: the Commercial Organisations and Public Authorities Duty (Human Rights and Environment) Bill. Its aim is to introduce similar obligations as set out under the CSDD by mandating commercial organisations and public authorities to conduct due diligence on their supply chains to prevent human rights and environmental harms.

The bill had its first reading in the House of Lords on 28 November 2023 and the second reading is yet to be scheduled. However, as a private member's bill, it will not be given as much time as other public bills and a minority of private members' bills actually become law. Therefore we do not anticipate this bill to progress very far, or how far it will get in its legislative process, but businesses should have this on their radar in case the House of Lords continue to push it through.

First reporting obligations under the Corporate Sustainability Reporting Directive

The Corporate Sustainability Reporting Directive (CSRD) entered into force on 3 January 2023. It extends existing requirements under the Non-Financial Reporting Directive (NFRD) and requires firms to report on the impact of their activities on the environment and society. The CSRD will extend the reporting obligations under the NFRD to all large companies and imposes an obligation to report accurate and verified information on environmental factors (such as climate change mitigation and adaptation, water and marine resources, resource use and circular economy, pollution, biodiversity, and ecosystems). An audit of the reported information will also be required as a form of assurance. For more on which companies are in scope and the information that must be reported, see our Insight.

Member States of the EU must bring into force the laws, regulations and the administrative provisions necessary to implement CSRD by 6 July 2024. An estimated 50,000 companies will be caught by the newly extended NFRD as opposed to the 11,000 currently obligated to report.

EU public interest entities already subject to the existing reporting requirements need to begin reporting from 2025 for financial years starting on or after 1 January 2024.

EU large companies need to begin reporting from 2026 for financial years starting on or after 1 January 2025.

EU small or medium-sized companies need to begin reporting from 2027 for financial years starting on or after 1 January 2026.

Non-EU companies need to begin reporting from 2029 for financial years starting on or after 1 January 2028.

With the first reports due in 2025, companies due to report should collect and prepare the relevant information throughout 2024 ready to meet this first deadline.

UK Sustainability Disclosure Requirements

The UK Sustainability Disclosure Standards (SDS) will set out the necessary disclosures for companies in relation to sustainability-related risks and opportunities. The standards will form the basis of future reporting requirements in the UK.

These standards will be based on the International Sustainability Standards Board IFRS disclosure standards, and will only divert for UK specific matters where absolutely necessary. The IFRS standards incorporate and expand upon the Taskforce for Climate-related Financial Disclosure's recommendations, so firms already voluntarily reporting in line with these requirements will be at an advantage. The secretary of state for Business and Trade will consider the endorsement of the IFRS standards and creation the UK SDS by July 2024.

The decision as to whether to require disclosure in line with the UK SDS will be taken independently by the UK government for UK registered companies and LLPs and by the FCA for UK listed companies.

Transition Plan Taskforce publishes disclosure framework

On 9 October 2023, the Transition Plan Taskforce published its disclosure framework, which sets out good practice recommendations to assist companies in making robust and credible disclosures about their climate-related transition plans.

The FCA expects to consult in 2024 on proposals for UK listed companies to publish their transition plans.
EU deforestation-free products regulation set to come into force

As part of the EU's effort to reduce global deforestation, new legislation is being introduced requiring companies to carry out extensive supply chain due diligence before a product is placed on the market in the EU, or exported from the EU.

The Regulation on Deforestation-free products (EUDR) covers seven commodities: cattle, cocoa, coffee, oil palm, rubber, soya and wood. Many products deriving from these materials (such as leather and chocolate) are included in the annex of the regulation. However, there have been recent discussions that other commodities, such as tea, could be bought within scope and so businesses should be alive to a potentially broader scope.

In order to place these products on the market in the EU or export them from the EU, a company must show that they are:

- deforestation-free (from land that has not been converted from forest to agricultural use after 31 December 2020);
- produced in accordance with relevant legislation in the country of production; and
- covered by a due diligence statement that there is no or negligible risk of non-compliance.

Penalties for non-compliance will be set out in national law, but they may include fines of up to 4% of the company's EU turnover or confiscation of products.

The regulation will come into effect on 30 December 2024.

The UK has recently announced it will be introducing similar measures to tackle deforestation. The Forest Risk Commodities Scheme will be introduced through provisions in Schedule 17 of the Environment Act 2021. This proposed new legal framework in the UK will place a similar duty on businesses and prevent the placement of regulated commodities on UK markets unless a due diligence statement is supplied which confirms that the commodities are deforestation-free.

The new laws will apply to businesses with a global annual turnover of over £50 million and who use over 500 tonnes of regulated commodities a year. The list of commodities in scope is non-dairy cattle products (beef and leather), cocoa, palm and soy (which diverges from the EUDR as neither coffee nor rubber are included in the UK scheme, but are under EUDR).

Enforcement and the detailed requirements of the duty are subject to secondary legislation being implemented, which will be introduced "when parliamentary time allows".

Increasing scrutiny and enforcement for greenwashing relating to food

Please see Food law.

Regulation prohibiting products made with forced labour on the Union market

Please see Modern slavery.
Fintech, digital assets, payments and consumer credit
Reforms to the financial promotions regime

The financial promotions regime has been amended by the Financial Services and Markets Act 2023 (FSMA 2023) to establish a regulatory gateway through which an authorised firm must pass before it is able to approve the financial promotions of unauthorised firms. It will launch on 7 February 2024. The UK Financial Conduct Authority (FCA) published a policy statement and near-final rules in September 2023.

All FCA-authorised firms that approve, or intend to approve, financial promotions for unauthorised firms will need to apply to the regulator for permission to do so, unless an exemption applies.

Firms have been able to apply for permission from 6 November 2023, and the initial application window will close on 6 February 2024. Only firms that have applied for permission to approve financial promotions during this window, or that have been approved by the FCA already, will be able to continue approving from 7 February 2024 onwards without breaching the new requirements. Firms that miss this window will have to cease all approving activities until they apply and obtain FCA permission.

Qualifying cryptoassets have been brought within the scope of the financial promotions regime from 8 October 2023, and the FCA has been taking a proactive approach to supervision. Firms that were granted a modification by consent to delay the implementation of certain direct offer financial promotion rules by three months must be prepared to comply with these rules from 8 January 2024.

Designation of critical third parties to the financial sector

HM Treasury intends to introduce a new regulatory regime applicable to certain third-party service providers, such as providers of cloud services, bringing material services they provide to the financial sector under the direct supervision of the Prudential Regulation Authority (PRA) and FCA.

This regime is being set up in response to growing concern that, with so many financial institutions relying on a very small group of major service providers, the collapse of only one service provider has the potential to trigger a crash in the financial markets.

HM Treasury will have the power to designate certain service providers as critical third parties (CTPs) if, in its opinion, a failure of or disruption to those services could threaten the stability of or confidence in the UK financial system. In practice, it is expected that the regulators may recommend third parties for designation (for example, based on factors such as aggregation risk, substitutability of services, and how firms could secure the continuity or prompt recovery of services).

The regulators will have rule-making, information-gathering and enforcement powers over CTPs, which will be subject to minimum resilience standards and resilience testing in respect of material services provided to the UK finance sector. Cloud providers will not be caught by the CTP regime if they are not designated.

On 7 December 2023, the Bank of England (BoE), PRA and FCA published a joint consultation paper on operational resilience and CTPs in the UK financial sector. It sets out the proposed requirements to be established in rules and accompanying expectations for CTPs. The consultation closes on 15 March 2024.

The PRA and the BoE intend to publish a further consultation paper relating to CTPs, containing a draft statement of policy on their approach to the use of disciplinary powers. This will be published in due course ahead of the final policy statement that will follow this consultation paper and contain the final rules and expectations for CTPs. To maintain a joint approach to the regime, the FCA plans to consult on its statement of policy on the use of disciplinary powers over CTPs around the same time.

Regulatory work on account closures

The possibility that payment service providers might be closing customers’ accounts due to their political beliefs has attracted significant press attention during 2023.

In October 2023, HM Treasury published a statement on rule changes relating to payment service contract termination, following its July 2023 policy statement. The principal changes are that the minimum termination period will be extended from two months to 90 days, and firms will need set out “clear and tailored” reasons for termination.

These requirements will be subject to limited exceptions, for example if complying would be unlawful. In addition, the corporate opt-out will be available in respect to the new requirements, meaning that where the customer is not a
Fintech, digital assets, payments and consumer credit

consumer, a micro-enterprise or a charity with annual income of less than £1 million, the parties to a framework contract for payment services may agree that the new requirements do not apply.

The government plans to publish a draft statutory instrument by the end of 2023 and make the amendments, subject to parliamentary approval, as soon as parliamentary time allows.

The FCA published a report on payment account access and closures in September 2023 which indicated that the most common reported reasons for account applications being declined, suspended or terminated were financial crime suspicions, due diligence concerns, and inactive or dormant accounts. Information provided by firms surveyed suggests that no firm closed an account primarily due to a customer’s political views between July 2022 and June 2023.

The regulator expects payment firms to consider the findings of the report and whether they should take any actions. Among other things, firms should consider the management information they collect to monitor the nature, scale and impact of account declines, suspensions and terminations, and satisfy themselves they are able to define, monitor, evidence and stand behind the outcomes their customers are getting in line with their Consumer Duty obligations.

The FCA is planning further work on account closures, including:

- follow-up work to understand the accuracy of data reported, concentrating on outlier firms;
- additional supervisory work to be sure of the conclusions reached with regard to accounts closed for political reasons, and closer analysis of account closures for reasons of reputational risk;
- further review of account declines for basic bank accounts, as these appear relatively high;
- further research into the unbanked population;
- engagement with consumer groups and organisations to understand their experiences and the impact of account declines, terminations and suspensions; and
- a financial inclusion sprint in Q1 2024, focusing on improving consumer access to financial services.

UK regulation of stablecoins used as a means of payment

FSMA 2023 introduced a new broad definition of cryptoassets, and amended powers relating to regulated activities and financial promotions to clarify that they can be used to regulate cryptoassets and activities relating to cryptoassets.

The government intends to bring activities relating to fiat-backed stablecoins into the regulatory perimeter in Phase 1 of cryptoasset regulation, on the basis that they have the potential to become a widespread means of retail payment. Regulation of activities relating to other cryptoassets is expected to follow as Phase 2.

A package of publications issued by the FCA, BoE and PRA in November 2023 set out more detail on the forthcoming stablecoin regime. At a high level, responsibility for regulating UK-issued fiat-backed stablecoins will be divided as follows:

- the FCA will regulate issuers and non-bank custodians which are non-systemic, as well as regulating the use of stablecoins as a means of payment under the Payment Services Regulations 2017 (PSRs);
- the BoE will prudentially regulate systemic stablecoin issuers and related service providers, while the FCA regulates conduct – the BoE will also regulate systemic payment systems using stablecoins;
- the PRA will prudentially regulate banks undertaking stablecoin custody activities and deposit-taking activity with respect to tokenised deposits, while the FCA will regulate conduct; and
- the Payment Systems Regulator will regulate designated payment systems and service providers for competition and innovation purposes.

The FCA discussion paper (DP23/4) sets out the regulator’s thinking across areas such as custody and organisational requirements, conduct of business rules, consumer redress, prudential requirements (including a dedicated new prudential sourcebook, CRYPTOPRU), and managing firm failures.
Fintech, digital assets, payments and consumer credit

HM Treasury is exploring how to regulate the use of overseas stablecoins in UK payment chains, including whether to give the FCA powers under the PSRs to authorise payment arrangers who would then assess overseas stablecoins against the regulator's standards.

Much detail remains to be confirmed as the proposals for the new regime progress. HM Treasury intends to bring forward secondary legislation by early 2024, subject to available parliamentary time. Regulators aim to finalise rules for consultation in H2 2024 (subject to secondary legislation being laid), with the new stablecoin regime being implemented in 2025.

UK regulation of cryptoassets

In February 2023, HM Treasury consulted on the second phase of the UK regulatory approach to cryptoassets, proposing a FSMA-style authorisation regime for cryptoasset firms. The response to the consultation in October 2023 confirmed the government largely intends to proceed with these proposals.

The list of specified investments in the Regulated Activities Order 2001 will be expanded, meaning that (subject to certain exceptions) a firm will generally need to be authorised by the FCA under Part 4A of FSMA if:

- they are undertaking one of the regulated cryptoasset activities, which cover the categories of issuance, exchange, investment and risk management, lending, borrowing and leverage, and custody activities;
- by way of business; and
- they are providing a service in or to the UK, with the overseas person exclusion not being extended to cryptoasset activities (the government's position is that firms dealing directly with UK retail consumers should be required to be authorised wherever they are located).

As a general principle, the government's intention is that cryptoassets not being used for one of the regulated activities in Table 4A of the consultation in financial services markets or used as a financial services instrument, product or investment should fall outside the future financial services regulatory regime.

The government's aim is for secondary legislation to be laid in 2024, subject to parliamentary time; this will be accompanied by FCA publications.

Certain cryptoassets came within scope of the financial promotions regime from 8 October 2023, and the FCA has been taking a proactive approach to supervising firms promoting cryptoassets.

Regulation of buy-now-pay-later products

The government has confirmed its plans to expand the regulatory perimeter to include interest-free buy-now-pay-later products (BNPL) and other currently unregulated short-term interest-free credit products provided by third-party lenders.

Once the new rules come into force, BNPL providers and products will be subject to a range of new requirements, including pre-contractual disclosures, creditworthiness assessments, and in relation to the form and content of the credit agreement.

There will be exemptions for some agreements where there is limited risk of consumer detriment and where regulation would otherwise adversely affect day-to-day business activities.

HM Treasury published a second consultation seeking views on the draft legislation in February 2023. This consultation confirmed the government's view that the scope of regulation should be limited to agreements offered by third-party lenders, and should not extend to agreements provided by merchants (the providers of the goods or services being financed) online or at a distance.

The draft legislation narrows the exemption in Article 60F(2) of the Financial Services and Markets Act 2000 (Regulated Activities) Order 2001 by removing from its scope two types of borrower-lender-supplier agreement:

- firstly, agreements that would otherwise fall within the exemption but where the lender and the supplier are not the same person (that is, where the credit is provided by a person that is not the provider of the goods or services being financed) will now be regulated; and
- secondly, agreements where the lender purchases products from the supplier and resells them to the consumer on finance will become regulated.
Fintech, digital assets, payments and consumer credit

Retailers introducing customers to newly in-scope products will continue to be exempt from credit broking regulation. However, this exemption will not apply to "domestic premises suppliers", in order to account for a perceived higher risk of pressure when selling to vulnerable consumers where sales routinely take place inside the home.

The rules as proposed are likely to have a significant impact on the BNPL market as it currently operates. The government will put in place a transition period from the point at which the legislation is made until the day on which regulation commences.

The government has not yet published a consultation response. In the meantime, there is some uncertainty in the industry as to whether the government may now intend to roll the regulation of BNPL into the wider project of Consumer Credit Act reform, which could potentially push out the timeframe significantly.

As part of its Financial Lives research, the FCA has published a research note exploring the use of BNPL by consumers in the UK. The note, which refers to BNPL as deferred payment credit, covers the increase in BNPL use, user demographics, how and why it is used, and the impact of its use, as well as its interaction with other credit products.

Nikki Worden, Partner
T: +44 20 7105 7290
nikki.worden@osborneclarke.com

Paul Anning, Partner
T: +44 20 7105 7446
paul.anning@osborneclarke.com

Paul Harris, Partner
T: +44 20 7105 7441
paul.harris@osborneclarke.com

Seirian Thomas, Senior Knowledge Lawyer
T: +44 20 7105 7337
seirian.thomas@osborneclarke.com
Food law
Food label changes for non-UK FBOs from 1 January 2024

As of 1 January 2024, pre-packaged food sold in Great Britain must include a UK address for the Food Business Operator (FBO). If the FBO is not based in the UK, an address based in the EU or Northern Ireland is no longer acceptable. The UK Food Standards Agency (FSA) has published details for food businesses on the legal requirements around food and packaging.

The government guidance also outlines that the address needs to be a physical address where businesses can be contacted by post; you cannot use an email address or phone number.

Increasing scrutiny and enforcement for greenwashing relating to food

The European Consumer Organisation (BEUC) has recently raised concerns about plastic bottle recycling claims, illustrating the growing scrutiny of environmental claims (and associated risk of these claims) within the EU. In the complaint, the BEUC identified the following three environmental claims that it considered to be problematic because they were vague, factually inaccurate or unsubstantiated: "100% recycled material"; "100% recyclable material"; and the use of circular and green imagery with generic environmental statements. The external alert highlights the growing scrutiny of environmental claims within the EU and, in particular, of claims being used within the food and drinks industry.

In the UK, the risk for these types of claims is also high. While UK claims are not the subject of the complaint, the rules on environmental claims are similar and are likely to be influenced by the concerns raised by BEUC. This is particularly relevant given that both the UK Competition and Markets Authority (CMA) and Advertising Standards Authority (ASA) are currently looking at green claims, with the CMA currently applying particular focus on food and drink products.

Uncertainty on food waste reporting

As reported in our previous Regulatory Outlook, the UK government has recently U-turned on its decision not to implement mandatory food waste reporting for large companies. However, with the government stating that it will now be reconsidering whether to make food waste reporting mandatory, businesses should be alert for any further developments on this throughout 2024.

One step closer to further UK HFSS restrictions

The next tranche of restrictions on high in fat, sugar or salt (HFSS) products are finally due to come into force in October 2025. This will include the delayed ban on so-called "volume promotions", such as "buy one, get one free" and "get three for the price of two," as well as the advertising ban for HFSS products.

While these restrictions are over a year away, businesses should consider how they will apply to them and the steps they need to start taking to prepare for compliance. Businesses should also keep an eye on what the other UK nations are doing (see our earlier Regulatory Outlook) as Scotland and Wales have also consulted on similar restrictions.

With the likelihood of a general election in 2024, businesses should also be aware that this may affect any upcoming changes. Nevertheless, recent reports have suggested that even if Labour were to win the election, Keir Starmer will go ahead with the HFSS bans but has ruled out imposing a tax on HFSS foods.

The Committee of Advertising Practice (CAP) and the Broadcast Committee of Advertising Practice (BPAP) have launched a consultation on how the advertising rules should be reflected in the codes. The consultation is an opportunity for further insight into the current thinking on unanswered questions about the legislation such as what will amount to "paid" advertising for the online restrictions. This is due to close on 7 February 2024, and this may also lead to further or updated restrictions. (See more in the advertising and marketing section.)

UK novel food framework

Last year, the FSA published its review of the approvals process for placing novel foods on the market in the UK. While there have not been any further details on this since our last update, the report highlights that no regulatory changes can be made without public consultation. There are a number of proposals on how the FSA may change novel food regulation.

It is expected that there will be developments on this in the run up to the FSA's board meeting in March, which may result in additional guidance or proposals to make substantive regulatory changes.
Food law

While the UK is taking measures to push forward the regulation of alternative proteins placed on the market, the position is more mixed internationally. Some EU Member States, notably Italy and Romania, have already introduced draft legislation to ban lab-grown meats in 2023.

However, food safety authorities in the US, Australia, Korea and Singapore have approved synthetic meat, including "cell-cultured meat". This highlights how the position on alternative proteins differs internationally and businesses should ensure they understand the regulatory framework in different countries before trying to place an alternative protein on a market. (For more information, we recently wrote an article on getting novel foods to market.)

Consultation on new regulatory framework for the use of precision-bred organisms

As detailed in our previous Regulatory Outlook, at the end of 2023, the FSA launched a consultation on proposals for a new framework under the Genetic Technology (Precision Breeding) Act 2023 in England for the regulation of precision-bred organisms (PBOs) used for food and animal feed. This is part of the UK government's wider intention for legislation to be brought forward to "unlock the potential of new technologies to promote sustainable and efficient farming and food production".

The consultation closed on 8 January 2024 and the FSA aims to publish a summary of responses three months from this date. As the responses will help to establish a regulatory framework in England for PBOs for food and feed, we expect that the FSA will provide an update and more details on the proposed regulatory changes in this area later in 2024.

CMA updates on groceries sector review

At the start of 2023, the Competition and Markets Authority (CMA) launched its investigation into unit pricing practices – both online and instore – within the groceries sector (see this earlier Regulatory Outlook). While the investigation continues, the CMA has outlined that it is conducting a further review of compliance with the Price Marking Order 2004. This will involve in-store and online checks to assess whether stores are displaying unit prices correctly and consistently, noting that it will consider whether further action, including enforcement, is required. An update on this work will be published in spring 2024.

This press release also outlines the CMA’s latest focus on baby formula, where they have provisionally indicated that prices may have risen by 25% over the past two years, and that this may be more than the price increase of the manufacturers’ own input costs. This theory has yet to be fully tested and the CMA is working with baby formula manufacturers to gain a better understanding of inflation-driven pricing pressures. However, while consumers for other products have mostly been able to locate and switch to cheaper alternatives, the CMA’s report notes that there is concern that lack of consumer understanding of the relative merits of infant formula may be leading to parents being unwilling to switch to lower-priced baby formula brands. The CMA therefore plans to undertake further work in the infant formula market and will publish an update on its work in mid-2024, including an update on any proposed changes to the regulatory framework.

The CMA has also announced plans to launch a review of the use of loyalty scheme pricing by supermarkets in January 2024. In particular, it is interested in the impact of grocery loyalty schemes on consumers and competition (where many price promotions are only available to those who sign up for loyalty schemes) and whether regulations that currently prohibit inclusion of baby formula in loyalty schemes might be relaxed.

Insects as animal feed

In 2021, the EU relaxed the rules around insects for feed in regards to pigs and poultry as a result of an opinion from the European Food Safety Authority (EFSA) that the risk of the disease BSE (bovine spongiform encephalopathy) is negligible. Since the UK was not part of the EU when these changes were made, they do not apply in the UK: insects for feed can still only be used for fish.

In 2023, the FSA published research looking into the “future of animal feed” including the possibility of using animal by-products and insects. The research noted benefits such as potentially reducing land-use requirements for protein production, lower levels of generated greenhouse gas emissions and lower overall water requirements for mass insect rearing compared to conventional protein-crop production. The research also highlighted various risks of using insects in animal feed, such as potential contamination of insects (non-native species) into new ecosystems, changes in manure composition of livestock, and high start-up costs.

The FSA is clearly considering the possibility of using insects in animal feed and how best to regulate this process to maintain high levels of feed safety, as well as protecting the wider ecosystem and environmental priorities.
Placing edible insects on the GB market

As noted in our earlier Regulatory Outlook, only edible insect species that are subject to an application for novel food authorisation submitted to the appropriate GB authorities (the FSA and Food Standards Scotland) will be permitted to remain on the market beyond 31 December 2023. The FSA has confirmed it received valid novel-food applications for three species:

yellow mealworm (Tenebrio molitor), house cricket (Acheta domesticus) and banded cricket (Gryllodes sigillatus).

As of 1 January 2024, any products containing any other edible insect species will need to be removed from the GB market.

Commission seeks feedback on revision of the definition of engineered nanomaterial in food

The European Commission has opened a feedback period on a draft delegated regulation that updates the definition of "engineered nanomaterial" set out in the Novel Food Regulation (EU) 2015/2283.

The proposed definition will be updated to "include in its scope the size limit (< 100 nm), applicability (external dimension and shape of the material), the exclusion from the definition of materials with a surface to volume ratio above a certain value, the definitions of 'particle', 'aggregate' and 'agglomerate', and the default threshold value of 50% of particles being at the nanoscale for a material to be considered a nanomaterial". The intention of the updated definition is to reflect the latest technical and scientific updates in this area.

However, BEUC sent a response on 7 December 2023 outlining its concerns that this revision could be "a serious setback for food safety and consumer protection and information". In particular, it has urged the European Commission to lower the threshold value of nanoparticles to as low as possible. It states that this is because the higher the threshold, the higher "the risk that some foods/ingredients containing nanoparticles will slip through the net and escape the safety risk assessment requirements that apply to engineered nanomaterials as novel foods."

The feedback period closes on 12 January 2024. We will provide further updates on the amendments made to the Novel Food Regulation following this.

Food hypersensitivity: improving the provision of allergy information

During the FSA's December Board meeting, a paper was presented on the progress and options for improving the provision of allergy information that outlined proposals for the non-prepacked sector. These include the creation of a presumption that there should be both written information and a conversation to ensure consumers with a food hypersensitivity can make informed decisions on where and what to eat. There has also been press coverage that the FSA is backing calls for "Owen's Law" which will introduce guidance for food businesses on how best to provide written allergen information.

The board agreed that written allergen information should be mandated in the non-prepacked sector and will be writing to ministers to discuss this. We expect an update on this in 2024.

EU proposal on plants obtained by new genomic techniques

In our October issue of the Regulatory Outlook, we outlined that the European Commission had put forward a proposal for a new legal framework for plants developed using new genomic techniques (NGTs). The Commission's impact assessment argued that the current genetically modified organism legislation is not fit for NGTs. This may result in limited uptake in the EU and missed opportunities to meet EU’s wider sustainability objectives.

The feedback period closed on 5 November 2023, and we expect the Commission to consider the feedback and to take further steps in 2024 to progress the regulation of NGTs so that the EU can begin to take advantage of NGTs.

Following the introduction of the UK’s Genetic Technology (Precision Breeding) Act, it will also be interesting to see whether there will be any further developments for genomic techniques on animals, as the current EU proposals are in relation to plants only.

Could CBD products finally get authorised in 2024?

Over the past year, we have been keeping an eye on the developments in relation to the authorisation of cannabidiol (CBD) products. As reported, the FSA recently said that these products will not be able to be signed off until at least 2024.
With businesses waiting for some indication of certainty that they will be able to keep their CBD products on the GB market, it is hoped that further clarification will be given by the FSA in 2024.

In the interim, the current grace period for enforcement applies to CBD products that have submitted a valid novel foods application and appear on the FSA list.

Reforms to the wine sector to begin in 2024

As noted in our previous Regulatory Outlook, the government will introduce a number of reforms for the wine sector in 2024 including increased freedoms on bottle shapes, blending (coupage) of imported wines and piquette; this may therefore lead to an increase in new types of wine being introduced onto the GB market in 2024. As of 1 January 2024, English sparkling wine producers are no longer required to use mushroom-shaped stoppers and foil covers on bottlenecks, and the government have also removed the ban on making and selling of piquette. The government confirmed the change on the 31 December 2023, as well as announcing that they will remove the requirement for imported wines to have an importer address on the label.

In addition, the government has recently announced plans for businesses to be able to sell prepacked still and sparkling wine in 500ml and 200ml sizes as well as a new 568ml "pint" quantity.

Labelling guidance for no- and low-alcohol alternatives expected in 2024

As noted in our previous Regulatory Outlook, the government held a consultation seeking views on whether to raise the threshold set out in guidance for describing a drink as "alcohol free" to 0.5% alcohol by volume (ABV). The current ABV threshold in the UK is 0.05%.

The consultation closed on 23 November 2023, and we expect that updated labelling guidance is published in 2024. Based on the consultation, this may introduce guidance on multiple labelling aspects, including when descriptors such as "alcohol-free", "de-alcoholised", "non-alcoholic" and "low-alcohol" can be used. As the sales of no and low-alcohol alternatives increase, more clarity on labelling guidance is welcomed. For more information on the consultation, please see more here.

UK government to consult on clearer food labels to support British farmers

During his speech at the Oxford Farming Conference on 4 January 2024, Environment Secretary Steve Barclay announced that the government is set to launch a consultation seeking views on whether country of origin labelling rules can be strengthened, and making it clearer when imported products do not meet UK animal welfare standards. Mr Barclay said the UK government will "rapidly consult on clearer labelling so we can tackle the unfairness created by misleading labelling and protect farmers and consumers". The consultation will consider options such as mandating how and where origin information is displayed and how to clearly differentiate labels of food produced to "lower welfare standards" found overseas. Businesses should be alert to this upcoming consultation and decide whether they would like to respond.

UK government decide not to revert back to imperial units

Back in June 2022, the UK government launched a consultation seeking views on whether to revert back to using imperial units of measurement. However, on 27 December 2023, it confirmed that it would not be going ahead with these changes, having found that only 1.3% of consultation respondents answered in favour of increased use of imperial units, with the remaining 98.7% happy with the continued use of metric units. As such, in 2024 businesses will not need to be considering whether unit changes are on the horizon as metric measurements are to stay in place in the UK. The government's response notes that "whilst the government is not making any changes to the law, new guidance will be published to promote awareness of the current freedoms that exist to display imperial units, alongside a more prominent metric equivalent.”

Katie Vickery, Partner
T: +44 20 7105 7250
katie.vickery@osborneclarke.com

Katrina Anderson, Associate Director
T: +44 20 7105 7661
katrina.anderson@osborneclarke.com
Health and Safety
Health and Safety

The Terrorism (Protection of Premises) Bill

The Terrorism (Protection of Premises) Bill was included in last year's King's Speech and you can read more on the bill in this earlier Regulatory Outlook.

Ahead of formal introduction of the bill into Parliament, the government has said it will launch a consultation on which premises will be caught in the "standard tier" to ensure the right balance is struck between protecting the public and avoiding burdens on small premises. At the time of writing, we are still waiting for the government to launch the consultation, and for its response to the Select Committee's report of July 2023, but expect next steps to be taken early in 2024.

Higher risk buildings

All existing higher risk buildings had to be registered by 1 October 2023. The Building Safety Regulator (BSR) expects to publish a register in the first quarter of 2024, this will list the Principal Accountable Person (PAP), contact details and potentially some basic information about the building. This may be a useful tool for businesses dealing with building owners.

For higher risk buildings in development, there is currently a transitional period in force, until 6 April 2024. This will apply provided construction has sufficiently progressed, and these buildings will continue to be governed by the existing building control regime. However, for new build higher risk buildings in planning and development, the building application process requires additional information and new approvals from the regulator.

The Health and Safety Executive (HSE) has recently published its first three-year strategic plan as BSR. Its roadmap highlights that in spring 2024, the HSE will start to require building assessment certificate applications from PAPs. Once the BSR has required the application, it must be made within 28 days with all the associated information to demonstrate compliance. The duties on PAPs are in force and so they should be collating information and implementing building safety management processes now to ensure compliance with the BSA and in preparation for a building assessment certificate application being made.

Keep mental health of your people on the business agenda

The most recent statistics published by the HSE highlighted, once more, the upward trend in cases of work-related stress, depression and anxiety. With mental health at the forefront of the HSE's Protecting People and Places strategy for 2022 to 2032, we anticipate that it will expect businesses to develop their own strategies to reduce risk and support their people, and active inspections or investigations seem possible.

The HSE has launched a new free online interactive tool for employers. The tool provides six short modules designed to help employers ensure they understand what the law requires of them in relation to stress and mental health and what they must be doing to be compliant.

Online Safety Act

The Online Safety Act received Royal Assent at the end of last year. It introduces significant duties for platforms with users in the UK that host user-generated content or facilitate interaction between users online. We have published a range of Insights on the new Act, including top 10 takeaways for online service providers.

Notable is the introduction of a potential criminal offence for corporate officers if an offence under the Act is committed by the platform that can be said to have been committed as the result of the "consent, connivance or neglect" of an individual officer of the company. This sits around a number of potential enforcement actions Ofcom could take under the Act. It will be interesting to see the approach Ofcom takes to enforcement, and affected businesses/platforms will be well advised to consider the roles and responsibilities they put in place and their overall governance structure for online safety.

Ofcom has also launched two of its four consultations. The first consultation is to help shape the guidance it provides businesses once the Act is in force. The deadline for responses to this first consultation (on illegal harms) is 5pm on Friday 23 February 2024 (see our Insight for more on this).

The second consultation concerns Part 5 of the Act, which imposes specific duties on service providers that display or publish pornographic content on their online services. Under the Act, these service providers must introduce age
assurance tools that are "highly effective" at correctly determining whether a user is a child to prevent children from being able to access such content.

Ofcom’s draft guidance aims to assist providers comply with their duties under the Act. It sets out the criteria that age checks must meet to be considered highly effective, which are that they should be technically accurate, robust, reliable and fair.

The consultation closes on 5 March 2024.

**Grenfell inquiry report delayed**

The Grenfell Tower Inquiry announced in its November update that the official findings on what caused the Grenfell Tower incident has been delayed once again. The report was due to be published last autumn, but the Inquiry has now said that the report will not be published before April 2024. Once the report has been published, we expect to see an increase in action taken by the HSE for breaches of health and safety duties, particularly in relation to fire safety.

**Will sentences in health and safety cases increase dramatically as with environmental prosecutions?**

In 2024, trends we have seen following prosecutions brought by the Environment Agency (EA) may be followed by courts when the HSE prosecutes health and safety cases.

Southern Water was subject to a record fine of £90 million in 2021, an aggravating feature was failing to cooperate with the EA. The court took a wide approach to "non-cooperation" determining that in not attending in-person interviews under caution when requested (an often standard approach in regulatory cases) and refusing to share information with the EA, the business was considered non-cooperative. It remains to be seen if the HSE, which allows written responses to in-person interviews as its usual practice, will start to insist on in-person attendance and raise this with courts if this is declined. This feature, coupled with the size of the fine generally, are potential indicators as to the direction of travel for health and safety prosecutions which already share a similar sentencing guideline.

We have also seen the Department for Environment, Food and Rural Affairs strengthen its civil sanction scheme and remove the cap of £250,000 for variable monetary penalties. It will be interesting to see whether the HSE might take heed and ask the government to strengthen its own civil sanction regime (beyond the "Fees for Intervention" scheme) to allow for it to impose such penalties rather than rely on sentencing by the courts.

Finally, with an increasing trend of EA prosecutions against individuals, we wonder whether the HSE might be encouraged to investigate and prosecute more individuals.

While the HSE has not explicitly stated any intentions of following the EA’s approach, with the crossovers between environmental and health and safety issues, we think this is something to monitor and see whether the HSE differs in its prosecution tactics in 2024.

**Changes within the HSE**

It has been reported that HSE's budget has reduced by 43% over the last decade and that staff numbers are half that of twenty years ago (now 2400).

In April 2022, the HSE adopted a new system to bring its investigation and enforcement processes in line with other prosecuting bodies. The system provides for an independent legal decision on prosecution, providing an inspector can seek early legal advice on investigations, but also on charging decisions once a principal investigator decides that a case is evidentially ready.

The HSE has restructured its teams – to those advising/inspecting and those investigating (potentially for prosecution) – and an in-house legal team has been created. Additionally, as set out in earlier sections, it is readying itself for its new Building Safety Regulator role.

What does this all mean for health and safety prosecutions or the model adopted by HSE as a regulator? We expect increasing use of enforcement notices and fees for intervention powers that do not mean costly court hearings and great room for challenge – however, following the number of public disasters over the last ten years which have led to calls for
increased investigation and prosecution, we wonder if HSE will be revisiting the way in which it supports occupational health and safety in the UK.

**HSE issues revised home working guidance**

As many businesses continue with a hybrid working format post-pandemic, the HSE has re-issued its [home working guidance](#) and provided more resources on what actions employers need to take to protect home workers’ health and safety.

This includes resources on the risks of [stress and poor mental health](#) as well as [working with display screen equipment (DSE)](#). In 2024, businesses should continue to ensure that home workers’ health and safety is protected and implement the necessary measures required to comply with their health and safety duties.
Modern slavery
Modern slavery

Regulation prohibiting products made with forced labour on the Union market

In October, the Internal Market and Consumer Protection Committee (IMCO) adopted its position on the proposal for a regulation on prohibiting products made with forced labour on the EU market. In November, it was confirmed at the plenary session that this position will be the basis for the European Parliament's negotiating mandate.

Most recently, on 7 December, the Competitiveness Council (part of the Council of the European Union) held a debate on the proposal whereby all Member States supported the overall objective of the regulation. However, issues raised by Member States included needing to streamline the EU’s efforts in the area of forced labour and modern slavery by aligning the proposed regulation with both international standards and EU legislation already in place, in particular with the CSDD and the Deforestation Regulation.

The Council now need to adopts its negotiating position on the regulation before informal trialogue negotiations can begin.

As a reminder, this regulation is intended to prohibit all products made with forced labour being placed on an EU market, made available in the EU, or exported from the EU. The proposal covers all products, namely those made in the EU for domestic consumption and exports, and imported goods, without targeting specific companies or industries. See more in our Insight.

Businesses should note that some countries may introduce their own legislation on this, or have already done so. For example, Switzerland has introduced legislation that requires companies to undertake due diligence to ensure products have not been produced or provided using child labour.

Eradicating modern slavery in UK government supply chains

Last year new guidance was issued on tackling modern slavery in UK government supply chains which applied to existing contracts and new procurement activity from 1 April 2023. Contracting authorities should already have put in place measures to eradicate potential modern slavery risks and in 2024 this should be a continued focus for these authorities.

Companies should continue to review and amend contract management processes and any related documentation, for both new and existing contracts, in line with the guidance.

Additionally, the Health and Care Act 2022 (HCA) requires the secretary of state for Health and Social Care to assess the potential risks of slavery and human trafficking within NHS supply chains. This review was published on 18 December 2023. It found that almost two-thirds of suppliers were identified as having a low risk of modern slavery, and approximately a fifth of suppliers were required to have a Modern Slavery Statement. Almost half of all suppliers had chosen to complete a Modern Slavery Statement which illustrated "proactive steps towards eradicating modern slavery". However, the review acknowledges limitations in available risk data, the reliance on supplier submissions, the complexity of risk identification and the need for increased supply chain transparency.

The review adds that to strengthen last year's guidance, regulations (as required under the HCA) should be introduced. The recommendations section states that these regulations are to be introduced to ensure that modern slavery due diligence is embedded within the NHS procurement process.

Other recommendations include standardising risk assessments and upskilling NHS staff and the supply chain on modern slavery risk and the new processes. It is extremely likely that the government will introduce these regulations in 2024, as well as taking further steps to eradicate modern slavery in the NHS supply chain. While there are no government plans to introduce legislation akin to the EU's Corporate Sustainability Due Diligence Directive (see the ESG section), in specific areas, in particular NHS contracting, there is a move towards greater transparency of supply chain risk.

Provisional agreement has been reached on Corporate Sustainability Due Diligence Directive

Please see ESG.

First reporting obligations under the Corporate Sustainability Reporting Directive

Please see ESG.
Modern slavery

Chris Wrigley, Associate Director
T: +44 117 917 4322
chris.wrigley@osborneclarke.com

Alice Babington, Associate
T: +44 117 917 3918
alice.babington@osborneclarke.com
Products
General / digital products

General Product Safety Regulation comes into effect

The EU General Product Safety Regulation (EU) 2023/998 (GPSR) came into force on 12 June 2023, with an 18-month implementation period which ends on 13 December 2024.

Businesses should adapt now to what has been described by legislators as "the most important update to EU product safety regulation in a generation".

The GPSR contains sweeping reforms that will significantly change the way that both modern and traditional products are produced, supplied and monitored across the EU. It raises safety and adds to the compliance obligations of all non-food products and the businesses involved in manufacturing and supplying them to end users.

The GPSR updates the definition of a "product" and includes new factors to take into account when assessing safety, so that the EU's product safety regime adequately addresses modern technologies.

The GPSR also makes clear that connected devices are products that fall within its scope and that will be subject to the general safety requirement. In addition, when assessing whether a product is safe, economic operators will have to take into account the effect that other products might have on their product; its cybersecurity features; and any evolving, learning and predictive functionalities of their product.

The legislation also seeks to address the increasing digitalisation of supply chains, in particular the growth of e-commerce, and places a number of obligations on online marketplaces, such as:

- mandatory cooperation with market surveillance authorities if they detect a dangerous product on their platform, including directly contacting affected consumers who bought through their platform in the event of a product recall;
- ensuring there is a single point of contact within the business responsible for product safety;
- requiring contact and traceability information to be displayed alongside product listings along with any relevant product identifiers, warnings or safety information;
- requiring marketplace operators to take steps to identify dangerous products made available on their platforms; and
- requiring non-compliant traders to be suspended from marketplace platforms.

Market surveillance authorities will also be able to order online platforms to remove dangerous products from their platforms or disable access to them altogether.

Cyber Resilience Act

The Cyber Resilience Act (CRA) will introduce cybersecurity requirements for products with digital elements. These will aim to protect consumers and businesses from products with inadequate security features. The CRA will require manufacturers to ensure that the cybersecurity of their products is in conformity with minimum technical requirements from the design and development phase and throughout the whole lifecycle of the product. This could include carrying out mandatory security assessments.

Certain types of products with digital elements deemed safety critical will be subject to stricter conformity assessment procedures, reflecting the increased cybersecurity risks they present.

The proposal also introduces transparency requirements, by requiring manufacturers to disclose certain cyber security aspects to consumers.

The CRA will apply to all products that are connected either directly or indirectly to another device or network, with some exceptions such as medical devices, aviation or cars.

When the proposed CRA enters into force, software and products connected to the internet will be required to apply the CE mark to indicate they comply with the applicable standards.
The European Parliament and Council have reached a provisional agreement, but the full text of the CRA is not yet available. The main amendments made to the European Commission’s initial proposal include a simpler methodology for classifying digital products and the determination of the expected product lifetime by manufacturers. For the expected product lifetime, “a support period of at least five years is indicated, except for those products that are expected to be in use for a shorter period of time.”

Work will continue to agree the final text of the CRA, which is expected to enter into force in first or second quarter of 2024, following which manufacturers will have 36 months to apply the rules. We will provide further updates once we have the final text.

**EU Product Liability Directive informally agreed**

On 14 December 2023, the EU informally agreed rules updating the existing Product Liability Directive (PLD) on the liability of defective products.

The provisional agreement intends to provide easier access to compensation for consumers who suffer damage from defective products and includes amendments relating to the directive’s scope, treatment of psychological damage, and allocation of liability regarding software manufacturers.

The update to the existing product liability framework, dating from 1985, will:

- Update definitions and scope to resolve inconsistencies and legal uncertainty, notably regarding the meaning of the term “product”. The legislation also amends the scope of the potentially liable parties (to include companies that substantially modify products and providers of software and of digital services).
- Modernise liability rules for digital or connected products. The revised PLD will allow compensation for damages when connected products are made unsafe by software updates, when artificial intelligence (AI) or digital services cause damage, when manufacturers fail to address cybersecurity vulnerabilities and where defective products cause a loss or corruption of data.
- Ensure that 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.
- Change rules on disclosure of evidence and the burden of proof. Manufacturers will be required to disclose evidence where a defective product has caused damage; in complex cases, where it is considered excessively difficult for a claimant to prove that a product is defective, the burden of proof will be switched to the defendant entity.
- Consumers will also be able to seek compensation for non-material losses such as medically recognised damage to psychological health.

With a provisional agreement reached, we anticipate a final version of the text to be agreed and published in early 2024 and we will publish further updates accordingly.

**General product safety review**

The UK government published the Product Safety Review on 2 August 2023: its proposals for reform to the product regulatory framework. The government launched a consultation to gauge the views of stakeholders and to help develop the detail of the reform. This consultation closed on 24 October 2023.

Under the Product Safety Review, the government is seeking to streamline product regulation. The proposed new approach would be risk based, where product safety requirements are determined in relation to the hazard presented by the product. Product-specific regulation will only be used where strictly necessary. This is a significant departure from the EU position.

In addition, the government proposes to introduce the following requirements for digital services and products:

- Voluntary e-labelling – introduction of e-labelling, such as the use of a QR code to display certain markings and compliance information. This proposal is limited in scope, applying only to products with integrated screens.
- Online marketplaces must exercise due care and remove unsafe product listings.
Products

- Online marketplaces must have a compliance function established in the UK.
- Online marketplaces will have to collect information about third-party sellers for high-risk products.
- Online marketplaces will be under an obligation to gather their own information about products and sellers which could indicate a product is unsafe.
- Strengthening consumer information online as part of online product listings to support informed purchasing decisions. This may include displaying warnings to consumers, details of the checks carried out by the seller, and a clear and prominent indication of whether the product has been listed by a third-party seller.

The government is currently analysing the feedback it received and we expect further updates in 2024.

New security requirements for products come in from April 2024

Part 1 of The Product Security and Telecommunications Infrastructure Act 2022 (PSTIA) sets out powers for UK government ministers to specify security requirements relating to relevant connectable products (a product which is internet or network connectable).

On 14 September 2023, the Product Security and Telecommunications Infrastructure (Security Requirements for Relevant Connectable Products) Regulations 2023 were introduced under the PSTIA 2022. The security requirements imposed on manufacturers of connectable/digital products include:

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

Businesses may face liability where cybersecurity vulnerabilities lead to the loss or corruption of consumer data.

The PSTIA also imposes obligations on manufacturers, importers and distributors not to make products available in the UK unless they are accompanied by a statement of compliance with applicable security requirements.

These new security requirements will come into force on 29 April 2024 and those who will be obligated under the new regulations need to ensure necessary changes are made to their products in order to comply with the regime ahead of this rapidly approaching deadline.

Autonomous Vehicles Bill

As mentioned in the AI section of the previous Regulatory Outlook, new legislation to provide a regulatory framework for AI-powered autonomous vehicles has been introduced in the UK Parliament.

The Automated Vehicles Bill will create a definition of "self-driving" and will create a rigorous safety and authorisation regime for self-driving vehicles. Vehicles with automated systems will be subject to a technical assessment and approval for the purposes of safety and cybersecurity. Authorisation will also be required for the organisation responsible for how they drive, plus a licensing regime will be introduced for companies responsible for the operation of "no user in charge" (NUiC) vehicles. The bill will remove liability from users of an NUiC vehicle for the driving-related aspects of its use, and it will impose liability on the companies, making them liable for the way their self-driving vehicles behave on the road.

The focus of the legislation, which implements the recommendations of a four-year-long review of the law, is on safety and clarity of responsibility and liability. The Department for Transport has said that it will "ensure in-use compliance with the safety standards" which, if not followed, could lead to fines, requirements to take corrective action, suspension of operations and criminal offences in serious cases.

The bill is due to be read at committee stage in the House of Lords on 10 January 2024. It is in the early stages of its legislative procedure, with it needing to first complete its reading in the Lords before it can be read in the House of Commons. We expect there to be a number of changes made to the legislation and will continue to report on its progress. However, manufacturers of autonomous vehicles need to understand what the intention of the bill is and the obligations it envisages to introduce.

Regulation prohibiting products made with forced labour on the Union market
EU institutions reach agreement on the Ecodesign for Sustainable Products Regulation

On 4 December 2023, a provisional agreement was reached on the Ecodesign for Sustainable Products Regulation. Below are some of the key points businesses should be aware of and start preparing for:

- Introduction of digital "product passports" for almost every product placed on the European Union market. These will provide both consumers and repair shops with product information to make it easier for products to be repaired, upgraded and recycled. According to the agreed text, the European Commission will manage a public web portal allowing consumers to search and compare information included in these product passports.

- The regulations introduce a ban on destroying unsold clothing and footwear. This will be applicable two years after the regulation enters into force. The Commission will also be empowered to introduce new bans for to the destruction of other unsold products by delegated acts.

- The new regulation empowers the Commission to adopt specific ecodesign rules for individual product categories to improve their environmental sustainability. These will be introduced via delegated acts, which is a fast-track procedure in which the European Parliament and Council can only reject the proposed rules put forward by the Commission and cannot amend them. The industry, as well as national administrations, will have 18 months after the adoption of the delegated act to adapt to the new the eco-design requirements. However, in some duly justified cases, the Commission can set an earlier date of application.

- Parliament has said that there are products to be addressed in an order of priority, which include iron, steel, aluminium, textiles – notably garments and footwear – furniture, tyres, detergents, paints, lubricants and chemicals.

- In regard to penalties, it will be down to the competent authorities of the Member States to determine which penalties should be imposed. The provisional agreement establishes some harmonisation criteria for penalties in case of non-compliance with the ecodesign requirements. It notes that the penalties shall be "effective, proportionate and dissuasive."

- The provisional agreement aligns the obligations of online marketplaces to the Digital Services Act, in regards to cooperation with Member States’ market surveillance authorities.

The Parliament and Council now need to formally approve the agreement before it can come into force. We anticipate this will happen early in 2024 following which it will then be published in the Official Journal of the European Union and will enter into force 20 days later.

Specific ecodesign requirements for smartphones and mobile phones are already in place and set to come into force in June 2025, see below for more.

Start preparing for new ecodesign requirements for smartphones and mobile phones

Last year, a new regulation setting out the ecodesign requirements for smartphones, mobile phones other than smartphones, cordless phones and slate tablets was published in the EU Official Journal. This legislation requires, among other things, that devices are able to be effectively repaired and that spare parts should be available to professional repairers or end users, and it introduces requirements to ensure devices are protected from dust and water and are resistant to accidental drops.

The rules will apply from 20 June 2025 and in 2024 manufacturers should ready themselves for these new requirements. Examples of practical steps businesses could be taking includes communicating with supply chains regarding the requirement for spare parts and thinking about the design of products and how these might be made more durable or more easily repairable.

Energy labelling of smartphones and slate tablets
As detailed in an earlier Regulatory Outlook, the European Commission proposed new rules relating to the energy labelling of smartphones and tablets which have now been published in the EU Official Journal.

Devices that are put onto the Union market will have to display information on their energy efficiency, battery endurance, protection from dust and water, and resistance to accidental drops, as well as displaying a repairability score. These rules will apply from 20 June 2025. In 2024, manufacturers should ensure they will be ready to comply with the new rules when they come into effect. This will include understanding how to calculate repairability scores and ensuring the correct energy efficiency labels are being applied to products in scope of the new rules.

Right to repair – what’s next in 2024?

In March 2023, the European Commission proposed the “Right to Repair” Directive to promote sustainability by increasing the repair and reuse of defective products. It introduces obligations for producers to repair goods and amends consumer rights for defective products. As reported in our previous Regulatory Outlook, both the European Parliament and Council of the EU adopted their respective positions at the end of 2023, and we anticipate an agreement will be reached on the final version of the text in early 2024.

As a reminder, the directive does two things: it amends the rights that consumers have when they are sold defective products to have them repaired; and it creates a new general obligation on “producers” to repair goods. The directive also introduces new obligations on producers to ensure access to spare parts, repair-related information, and tools for independent repairers, remanufacturers, refurbishers and end-users.

While obligations under the directive will not take effect until at least 2026, throughout 2024 businesses can start taking steps to prepare for the upcoming changes, including:

- Communicating with their supply chain about upcoming changes and the need for spare parts for older products.
- Ensuring sufficient stock of spare parts for older models.
- Simplifying product design to facilitate third-party repairs.
- Exploring business model opportunities, such as offering more repairs and refurbishments.

See also our recent Eating Compliance for Breakfast webinar recording and relevant slides on the directive.

Single use plastics - tethered caps become a requirement in EU and new UK bans

From 3 July 2024, caps and lids for single use plastic beverage containers, with a capacity up to 3L, must remain attached during use. These are known as "tethered caps" and under the Single Use Plastic Directive (SUPD), Member States must introduce legislation to ensure that only plastic beverage containers with tethered caps are placed on the market from 3 July 2024. Businesses that are within scope of this requirement must, if they have not already done so, ensure that after 3 July 2024 their bottles placed on the EU market have tethered caps as otherwise they could face enforcement action from Member States.

In the UK, businesses should remember that a ban on further single-use plastic items in England came into force on 1 October 2023. The regulations ban the supply of single-use plastic cutlery, balloon sticks, and expanded and foamed extruded polystyrene food and drinks containers. The regulation also bans the supply of single-use plastic plates, trays and bowls to the end-user in England. This ban does not apply to the supply of a single-use plastic plate, tray or bowl that is packaging (as defined in regulation 3 of the Packaging (Essential Requirements) Regulations 2015). For example, this would include a bowl pre-filled with food before sale or a bowl filled with food at the counter of a takeaway.

Will Deposit Return Schemes in the UK be delayed further in 2024?

Over the past couple of years there have been numerous issues and delays with the implementation of deposit return schemes (DRS) across the UK. Scotland was set to introduce its DRS in August 2023, but due to the UK government's refusal to agree to a full exclusion from the Internal Market Act (it would not allow glass to be included in the Scottish DRS), the Scottish government announced that its DRS would be delayed until at least October 2025; the same time as all the other DRS across the UK are due to be implemented.

However, as previously reported, there was recent speculation that the implementation of England, Wales and Northern Ireland DRS would be delayed until 2026; since then, there have not been any further developments. With both Scotland and Wales wanting to include glass within scope of their schemes, we anticipate that in 2024 discussions will continue...
between the governments to come to an agreement on whether the schemes will differ in scope with some including glass, and others not.

In the EU, DRS are being set up across the union as a result of a combination of the extended producer responsibility obligations under the Packaging and Packaging Waste Directive, the SUPD and other local and national laws. Businesses located within EU Member States must be alert to where DRS are being set up, or are already established, and ensure they are aware of their obligations under these schemes to remain compliant.

Sustainable batteries
The EU Sustainable Batteries Regulation 2023/1542 will start to apply from 18 February 2024 except for certain provisions relating to:
- treatment and recycling, which will continue to apply until 31 December 2025;
- labelling, which will continue to apply until 18 August 2026; and
- the removal of waste batteries and accumulators, which will continue to apply until 18 February 2027.

The new EU regulation introduces a range of new rules for all operators in the supply chain covering every type of battery placed on the EU market, from portable batteries to industrial batteries. New requirements include:
- Implementing battery due diligence policies. These obligations do not apply to those businesses which do not exceed €40 million in the previous financial year.
- To promote the EU’s vision of a circular economy and high quality recycling, the regulation ensures the removability and replaceability of portable batteries and LMT batteries (batteries for light means of transport).
- From 18 February 2027, batteries must be marked with a QR code.
- Introduction of battery passports for LMT batteries, electric vehicle batteries and selected industrial batteries to increase traceability of batteries lifecycle.

With the new EU batteries regulation starting to apply in 2024, those businesses affected need to understand what the new rules require of them and the actions they need to take to ensure compliance. It will also be important to have a due diligence system in place that can track not just what is in batteries, but all products used in the supply chain, as more due diligence requirements are being introduced across numerous pieces of EU legislation.

In the UK, the government has now published the UK batteries strategy. Within this it outlines that the Department for Environment, Food and Rural Affairs (Defra) will be publishing a consultation and call for evidence "as early as possible in 2024" which will focus on increasing collection rates for batteries and encouraging best practice in end-of-life management of all battery types. It further adds that Defra will work with the "whole supply chain to consider regulation for the entire eco-system."

The report outlines that responses to the call for evidence suggested establishing battery passports, which would mirror that of the new EU battery regulation, in order to provide better traceability of batteries. However the government has not explicitly said it will introduce battery passports; rather, it has just stated the following: "Technology will have a key role in facilitating green trade. For example, digital trade will be important, as data on a battery pack’s historical performance and cycles will remove barriers to their efficient repair, reuse, and repurposing by re-manufacturing businesses, reducing environmental damage. In the EU, a Battery Passport will become a mandatory requirement by 2026 to support sustainable battery life cycles, with other regions likely to follow."

We will continue to strike the right balance, when developing our international trade policy, between attracting domestic value add in the battery supply chain and making it easy and economical for businesses to import critical battery inputs."

With the UK government aware that other regions are likely to follow the EU's decision to implement battery passports, it will be interesting to see whether it decides to follow suit or not, and we expect more information to be published in 2024 following the consultation.

Packaging and Packaging Waste Regulation
At the end of last year, both the European Parliament and the Council of the EU adopted their negotiating positions on the proposal for a regulation on a new packaging and packaging waste regulation.

As detailed in our previous Regulatory Outlook, changes made by the European Parliament included removing the requirement that single-use plastic or composite packaging for foods and beverages filled consumed on premises cannot be used from 1 January 2030. They also introduced provisions banning the use of PFAS and Bisphenol A in food contact
packaging. The Council's amendments include, among others, clarifying that packaging is considered recyclable when designed for material recycling and ensuring implementation of DRS in Member States by 2029 for at least 90% annually of single-use plastic bottles and metal beverage containers. Unlike the Parliament, the Council has included the restrictions on single-use plastic packaging for food and beverages.

Reports suggest that the Council's objective is to close negotiations before the end of February 2024. Any provisional agreement reached in trialogues is informal and has therefore to be approved by the formal procedures applicable to the European Parliament and the Council under the Ordinary Legislative Procedure. We expect the institutions to reach an agreement on the final version of the regulation after this. Although we are still waiting for the final version, the regulation will introduce a vast range of new obligations which businesses should start to understand the impact of on them.

**Will the EU impose further restrictions on endocrine disruptors?**

The EU's Chemicals Strategy for Sustainability calls for “consolidation and simplification” of the regulatory framework in regard to endocrine disruptors. In 2023, as part of this, we saw the European Commission adopt new measures to help push forward that aim, in particular with regard to toy safety whereby the adopted proposal for a Regulation of the European Parliament and of the Council on the safety of toys introduces new requirements to prohibit the use of chemicals that are endocrine disruptors. We anticipate that in 2024, in order to fulfil the objective of the chemical strategy, the Commission will take further steps to prohibit the use of the endocrine disruptors in other products, in addition to toys.

**PFAS in the UK and the EU**

Over the past year, both the UK and the EU have been looking into restricting PFAS (poly and per-fluoroalkyl substances).

In early 2023, the European Chemicals Agency (ECHA) announced details of a proposal which would restrict around 10,000 PFAS. The restriction will be on the manufacture, placing on the market and use of PFAS. A consultation was launched on the proposal and closed in September 2023. We expect the EU to provide further updates in 2024.

In the UK, as previously reported, in 2023 the Health and Safety Executive (HSE) published a Regulatory Management Option Analysis (RMOA). The HSE outlined that next steps/recommendations would be set out in the UK REACH Work Programme for 2023-2024, which we are currently still awaiting. We are also currently waiting on the government's UK Chemicals Strategy, which is due to be published early 2024. Therefore we anticipate that the government's chemical strategy will shed light on what steps it intends to take to restrict PFAS, which will be provided by the HSE's work programme.

The difference between the UK and EU's approach is that the EU's approach looks to regulate PFAS as a group, whereas the UK does not yet have any plans for such broad scope regulation.

Further, in the HSE report, the UK has adopted a narrower definition of PFAS than the EU used within its REACH restriction proposals. As a result, the HSE report has hundreds of substances in scope, whereas the number of chemicals in scope in the EU's proposal was in the tens of thousands. With both the UK and EU expecting to take further steps in 2024, businesses should keep on top of these developments as well as ensuring they understand the different requirements that could be introduced in the EU and UK.

If you missed our recent Eating Compliance for Breakfast on PFAS, you can find the recording here and the slides here.

**UK EPR – remember to collect and report your data!**

As reported in an earlier Regulatory Outlook, the extended producer responsibility (EPR) scheme for packaging has been pushed back to October 2025. In 2024 we therefore anticipate the government to provide further information on the scheme, especially now that the EPR scheme administrator has been appointed. However, with a general election on the cards for 2024, it would not be surprising if EPR is pushed down the agenda.

In 2024, businesses within scope of the EPR must continue to collect and report their data; the government's guidance outlines who is in scope and when the reporting deadlines are. For large organisations in England, the first reporting period was on 1 October 2023, for the period January to June 2023. The next reporting deadline for large organisations is 1 April 2024 for data collected for July to December 2023. The government has stated that no enforcement action will be taken for late submission if businesses data is submitted by 31 May 2024, but every effort should be made to submit this data on time.
EU deforestation-free products regulation set to come into force

Please see ESG.

Lifesciences and healthcare products

Consultation outcome on GB Veterinary Medicines Regulations to be published

The consultation on the Veterinary Medicines Regulations 2013 closed on 31 March 2023. While an update was provided in June 2023 that the consultation report was due to be released in September 2023, it has still not yet been published. We expect that it will be published in early 2024 and we will be keen to see which of the proposals will be taken forward.

In the meantime, manufacturers of veterinary medicines should keep an eye out on any updates which may lead to new requirements (such as more onerous record keeping for traceability purposes) and also further opportunities to innovate (such as the potential of using pictograms/QR codes on product labelling). For more, please see our Insight.

UK veterinary services under CMA scrutiny – next steps of the investigation

We previously reported that the Competition and Markets Authority (CMA) launched an investigation into the provision of veterinary services in the UK for household pets, including pricing, how prescriptions and medications are sold, chain practices, and out-of-hours options. We understand that the CMA will provide an update on the next steps of its investigation in 2024.

Companies that provide veterinary services should keep an eye on the update, and also be particularly mindful for their commercial strategies for 2024 (and how this may affect end consumers) in light of the CMA's increased interest and scrutiny in this area.

A 'smokefree generation' and more restrictions on vapes in the UK?

It has been clear that the current government is keen to cut down on the number of people who use cigarettes and vapes, particularly the younger generation. It was announced, in October 2023, that the government plans to introduce a new law to prevent anyone born on or after 1 January 2009 from being legally sold tobacco products.

The government has also recognised the importance of balancing the need to protect children (who are increasingly using vapes) and supporting adult smokers who use vapes as a tool to quit smoking. As a result, the government held a consultation on proposed restrictions in relation to youth vaping, which closed on 6 December 2023. We expect there to be updates and proposals regarding laws and guidance relating to vaping and smoking products to be announced in 2024.

Tobacco manufacturers should keep an eye on the consultation responses, and also remain vigilant as to the use of their products by youths. There is a clear trend showing a clampdown on under-age vaping, and tobacco manufacturers should reflect on their current practices and take this time to consider any opportunities to ensure that their products are targeted to (and only used by) adults. Based on the consultation proposals, this could include measures such as restricting the flavours and descriptions of vapes, as well as the point-of-sale displays in retail outlets so that they do not appeal to children.

UK's new International Recognition Procedure goes live!

The Medicines and Healthcare products Regulatory Agency (MHRA) has announced that as of 1 January 2024, the EC Decision Reliance Procedure (ECDRP) will be replaced by the new International Recognition procedure (IRP).

The IRP aims to take into account the expertise and decision-making of trusted regulatory partners for the benefit of UK patients, meaning that medicinal products that are successfully placed on the market in certain trusted jurisdictions will then be able to access the UK market more quickly. The trusted "reference regulator" countries are: Australia, Canada, Switzerland, Singapore, Japan, the US and the EU.

Pharmaceutical manufacturers should seriously consider the IRP as part of their wider commercial strategy plans in 2024, particularly where they have global portfolios and may have identified any initial jurisdictions in which to launch their product, before applying for equivalent recognition to get their product onto the UK market. However, care should also be
taken of the two different recognition routes under IRP (and the varying associated timelines) and that despite the intentions of the IRP, the MHRA still maintains sovereignty and retains the right to reject applications where the evidence provided is insufficiently robust.

The MHRA have an online eligibility checker tool which can be accessed here and guidance on IRP can be found here. For businesses looking to place new medicines on the UK market in 2024, the tool will provide helpful guidance as to what route they will need to follow in order to do so.

EU orphan drugs reform

In April 2023, the European Commission published its proposal to introduce a new regulation to govern orphan medicines, which will repeal previous orphan medicine regulations. The aim of the reform is to "ensure that patients across the EU have timely and equitable access to medicine". At the end of 2023, the proposal has been considered in the first reading by the Council of the European Union, we expect this to move up to be considered by the European Parliament in 2024.

For pharmaceutical manufacturers intending to produce orphan drugs, or hoping to produce generics or biosimilars based on the originator medicine, we suggest keeping an eye on the orphan drugs reform taking place in the EU and considering how the new proposals may affect aspects of the product journey such as market exclusivity periods and the timings around when an application for market authorisation can be submitted for similar products.

MHRA AI regulatory sandbox ('AI-Airlock') to launch April 2024

As reported in our previous Regulatory Outlook, the MHRA has published plans to launch a "regulatory sandbox", known as the AI-Airlock in April 2024. It aims to provide a regulator-monitored virtual area for developers to generate robust evidence for their advanced technologies. With the date now becoming more imminent, we expect a further update from the MHRA shortly to provide further information on how manufacturers will be able to take advantage of the sandbox.

For manufacturers who are hoping to develop AI healthcare, this appears to be an exciting opportunity to better understand the real-word viability of their devices, and also benefit from the UK's "world-leading mechanism to assist in safe development and deployment of software and AI medical devices". With various international recognition procedures, manufacturers may also wish to consider the UK as a market to streamline their route to market for AI medical devices.

New voluntary scheme and statutory scheme for branded medicines to come into force on 1 January 2024

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). Based on the published text (outlined in the summary heads of agreement released last November), there will be several significant changes introduced in the new scheme – such as a new method of calculating rebates based on whether a medicine is classified as a "newer" or "older" medicine. There are also potentially further changes possible, with reviews due to take place in autumn 2025 and spring 2027 by the Department of Health and Social Care (DHSC), NHS England and the Association of the British Pharmaceutical Industry (ABPI).

Separately, the statutory scheme for branded medicines is also due to be further updated in early 2024, to "maintain equivalence with the final version of VPAG". More recently, the government published the consultation outcome into the review of the statutory scheme with key points raised that the government intends to:

- continue to operate the statutory scheme in a way that is "broadly commercially equivalent" to the voluntary scheme;
- set amended payment percentages for 2024 to 2026 based on an allowed growth rate that has been increased to 2%;
- implement an exemption from payment for medicines containing a new active substance for 36 months after marketing authorisation in the statutory scheme;
- include exemptions from payment for exceptional central procurements and centrally procured vaccines;
not implement the proposals for a life cycle adjustment in the statutory scheme on 1 January 2024. The response notes that the government intends to consult on alternative proposals aligned to those agreed in the 2024 VPAG for setting statutory scheme payment percentages in a way that differentiates between medicines at different stages in the product life cycle; and

• apply the statutory scheme to all biological medicines, whether or not they are branded, in order to provide clarity as to whether the statutory scheme applies to all biological medicines.

Pharmaceutical companies hoping to sell medicines to the UK NHS should closely review the final text versions of VPAG and the statutory scheme (along with any further amendments in early 2024) to understand the financial consequences for joining each of the schemes.

Medical device reform in the UK
The MHRA ran a consultation on the future of medical device regulations in 2021, in which the government responded outlining its intention to amend the regulatory framework for medical devices. On 9 January, the MHRA set out its ‘roadmap’ for the implementation of new regulations which are “designed to deliver greater international harmonisation, with more patient-centred, proportionate requirements for medical devices which are responsive to technological advances”. The timeline outlines the key action points taken between 2021 and 2023, as well as numerous stakeholder discussions that will take place throughout 2024, with plans for priority measures to be in place this year and future core regulations to be introduced during 2025.

ABPI and PMCPA consult on changes to the pharmaceutical industry code of practice
The Association of the British Pharmaceutical Industry (ABPI) and the Prescription Medicines Code of Practice Authority (PMCPA) have launched a consultation on the ABPI Code of Practice for the pharmaceutical industry. The consultation is seeking views on proposed changes to the code such as including the use of QR codes to access “Prescribing Information” from printed materials, as well as changes to the constitution and procedure of the PMCPA, including changes to the complaints process.

Dr Amit Aggarwal, Executive Director of Medical Affairs at the ABPI said: “This consultation aims to tighten up and simplify some elements of the Code itself, while strengthening the powers of the PMCPA as a robust and efficient regulator. The use of QR codes on printed materials as an option to access prescribing information is an example of the continuous process of modernising the Code, which will give healthcare professionals greater ease of reference to essential and up-to-date information for their work.”

The consultation closes 29 February, after which the 2024 Code will be published in Q2 2024 to come into force three months after publication date. The current 2021 ABPI Code of Practice will remain in force until then. Manufacturers should keep an eye on any updates and be prepared to update their 2024 strategy and relevant practices to ensure compliance with the latest industry standards where possible.

CMA to support pharmaceutical companies working together on access to combination therapies
The UK Competition and Markets Authority (CMA) has published a statement confirming that it will support pharmaceutical companies working together specifically on making combination therapies available to NHS patients in the UK.

The statement clarifies that it will not prioritise enforcement action against medicine manufacturers when the parties have implemented a specific “negotiation framework” and are engaging in good faith. The APHI has welcomed this statement stating: “It is a major step forward for the many patients who need and deserve access to these ground-breaking therapies. It is a world-first and a great example of the UK setting the standard for other health systems faced with similar challenges. The ABPI will continue to work with NICE and NHS England on further steps to support access to combination therapies.”

For those companies working together to bring to market combination therapies, this statement that the CMA will not be taking action against these practices will be welcomed. At the same time, companies should be mindful of the statement and the conditions that are required to avoid investigation by the CMA.
Products

Katie Vickery, Partner
T: +44 20 7105 7250
katie.vickery@osborneclarke.com

Peter Rudd-Clarke, Partner
T: +44 20 7105 7315
peter.ruddclarke@osborneclarke.com

Veronica Webster Celda, Senior Associate
T: +44 20 7105 7630
veronica.webster@osborneclarke.com

Thomas Stables, Senior Associate
T: +44 20 7105 7928
thomas.stables@osborneclarke.com

Stefanie Lo, Associate
T: +44 20 7105 7649
stefanie.lo@osborneclarke.com

Abigail Pinkerton, Associate
T: +44 20 7105 7966
Abigail.pinkerton@osborneclarke.com
Regulated procurement
New procurement regime to go live

The Procurement Act 2023 received Royal Assent in October last year and the Cabinet Office is anticipating a "go-live" date for the new regime of October 2024. However, with the likelihood of a general election this year and "resource changes" that may result from this, the government has indicated that the go-live date may slip.

In addition, following consultations that ran last year, secondary legislation will be introduced early this year to confirm detailed requirements for transparency notices and the scope of the light touch regime. The government has also said it will start publishing formal guidance on the new regime from February 2024.

We have published a series of webinars and Insight articles on the key changes in the new Act on our microsite and we have released the first in a series of podcasts. In the first podcast, Craig McCarthy and Millie Smith discuss the interaction between public procurement and net zero, and whether the new Act goes far enough in its commitments to net zero. Listen to the podcast.

The Government Commercial Function has released “knowledge drops” on the new Procurement Act. These provide high level overviews of the changes and are the only training materials for suppliers that will be made available by the government.

In terms of the transition to the new regime, only those new procurements launched after the go-live date will be governed under the new Act. Any procurement already started at go-live (or contracts already awarded) will remain under the existing regulations, including in relation to any future modifications or extensions. The government has said there will be no mixing of the two regimes and the end point for the application of the old regime is the termination of the relevant contract or framework or procurement where no contract is awarded.

Provider Selection Regime comes into force

As detailed in our Insight, NHS procurement is changing with the introduction of the new Provider Selection Regime (PSR), which came into force on 1 January 2024.

The PSR will provide a new set of rules for procuring healthcare services by “relevant authorities”; this includes NHS England, integrated care boards, NHS trusts and foundation trusts, as well as local authorities and combined authorities.

The new rules include the introduction of three provider selection processes which relevant authorities can follow to award healthcare services: direct award process, most suitable provider process, and a competitive process.

The PSR regulations, made on 6 December 2023, make provision for mixed procurements (for example, covering healthcare and non-healthcare services) and require that where the PSR is used:

- the main subject matter of the contract is healthcare services; and
- the other goods or services could not reasonably be supplied under a separate contract.

The guidance sets out that the main subject matter of a contract is determined by reference to the respective value of the different elements. Whether other goods and services could have been separately procured includes consideration of whether a separate procurement would have a material adverse impact on the authority's ability to act in accordance with the procurement principles.

The PSR legislation removes the procurement of health services by relevant authorities from the scope of the current legislation. Where a procurement exercise has started before 1 January 2024 (with definitions of started found here), it will not be affected by the PSR and can continue under the current rules.

April 2024 marks the next milestone in NHS net zero supplier roadmap

In April 2024, the NHS will adopt a two-tiered approach to the next milestone on its net zero supplier roadmap. This aims to proportionately extend the requirement for suppliers to prepare carbon reduction plans to all procurements, not just those for contracts with a value above £5 million (as is currently required).

A supplier who fails to meet the minimum requirements for a carbon reduction plan or the net zero commitment will not proceed to the next stage of the procurement process. See more on the requirements coming into force.
Regulated procurement

As part of Osborne Clarke's latest Health Check webinar series, Kate Davies and Millie Smith will be discussing NHS procurement on 30 January 2024: they will examine how the NHS buys from the private sector, the impact of the new Procurement Act and PSR, and what this means for suppliers. Sign up here.

What procurement questions should contracting parties have in mind when anticipating the expiry of UK PFI contracts?

The Private Finance Initiative (PFI) projects agreed in the 1990s are starting to draw towards the end of their terms with a large number expiring in the next two to five years.

Managing arrangements for expiry requires early planning and, following our first Insight in this series, our latest Insight considers some of the procurement questions that the parties should bear in mind.

New thresholds come into force

As outlined in our November 2023 issue of the Regulatory Outlook, the new financial thresholds that govern the procedures for the award of public contracts for goods, works and services came into force on 1 January 2024. See the new thresholds.

MPs call for improved value and competitive measures in UK public procurement

The House of Commons' public accounts committee released a report on 13 December 2023 containing recommendations to the government on competition in public procurement. The committee thinks there is a lot of room for improvement in government procurement and is concerned the "government may not have sufficiently considered the time, money, and resources required to provide the commercial capabilities to successfully implement the Procurement Act 2023." Read our Insight for more.

New guidance on assessing suppliers payments performance comes into force 1 April 2024

As detailed in our previous Regulatory Outlook, Procurement Policy Note (PPN) 10/23: Taking account of a bidder’s approach to payment in the procurement of major contracts, which sets out how payment approaches can be taken into account in the procurement of major government contracts, comes into force from 1 April 2024. A key change introduced by the new PPN is that bidders, when bidding for government contracts exceeding £5 million, will be required to show that they settle their invoices within an average of 55 days. Therefore in 2024, suppliers bidding for these contracts should ensure they have the necessary documents to illustrate their payment performance to the contracting authority.

Catherine Wolfenden, Partner
T: +44 117 917 3600
catherine.wolfenden@osborneclarke.com

Craig McCarthy, Partner
T: +44 117 917 4160
craig.mccarthy@osborneclarke.com

Laura Thornton, Associate Director
T: +44 20 7105 7845
laura.thornton@osborneclarke.com

Kate Davies, Senior Associate
T: +44 117 917 3151
kate.davies@osborneclarke.com

Ashlie Whelan-Johnson, Associate Director (Barrister)
T: +44 20 7105 7295
a.whelanjohnson@osborneclarke.com

John Cleverly, Senior Associate
T: +44 20 7105 7758
john.cleverly@osborneclarke.com

Millie Smith, Associate
T: +44 117 917 3868
millie.smith@osborneclarke.com

Elliot Pawley, Associate
T: +44 117 917 3474
elliot.pawley@osborneclarke.com
Regulated procurement

Gabrielle Li, Associate
T: +44 117 917 3233
Gabrielle.li@osborneclarke.com
Sanctions and Export Control
Sanctions and Export Control

New trade and financial sanctions against Russia

On 14 December 2023, the UK government introduced its seventh trade sanctions package against Russia as well as a separate ban on the import of diamonds from Russia.

The legislation aims to prohibit the export of goods that carry a risk of being used in Russia's war on and invasion of Ukraine, and includes financial measures aimed at supporting businesses divesting from Russia.

See the government's research briefing on sanctions against Russia.

OFSI updates correspondent banking restrictions and oil price cap

On 15 December 2023, Regulation 17A of the Russia (Sanctions) (EU Exit) Regulations 2019 was amended, prohibiting UK banks from processing payments previously processed by designated banks or which were intended for a designated bank. For further guidance, see the Office of Financial Sanctions Implementation (OFSI) blog-post update on correspondent banking restrictions.

On 20 December 2023, OFSI amended the record-keeping requirements within its oil price cap general licence, and updated its industry guidance for the maritime services ban and oil price cap accordingly.

New unit to crack down on sanctions evasion

On 11 December 2023, the government announced the creation of a new Office of Trade Sanctions Implementation (OSTI), which will be responsible for the enforcement of trade sanctions.

OSTI will also help businesses comply with sanctions, investigate potential breaches, issue civil penalties, and refer cases to HM Revenue and Customs (HMRC) for criminal enforcement where necessary.

There has been increased scrutiny of trade sanction circumvention – the National Crime Agency (NCA) recently issued an alert to financial institutions and the UK regulated sector warning of Russia's attempts to procure sanctioned goods and services through intermediary companies. A similar alert was issued in November 2023 with the aim of increasing awareness over Russia's use of gold as a means of undermining UK sanctions.

It is anticipated that the UK will continue to target items used to supply and fund Russia's war in Ukraine, such as machine parts and electronics. Between August and November 2023 alone, HMRC has issued compound settlement offers to three exporters totalling over £77,000, for unlicensed exports of dual use goods and breach of the Russia Regulations. See the full collection of notices to exporters collection.

New general licences for sanctioned Russian iron and steel and payments to local authorities

On 11 December 2023, the Department for Business and Trade introduced a new general trade licence for sanctioned iron and steel, which permits the import into the UK of goods otherwise prohibited under the Russia Regulations.

The licence also permits the provision of services and actions related to the import of these goods. The licence implements record-keeping requirements and individual conditions for each of the three goods categories. The licence takes effect from 11 December 2023 and is of indefinite duration.

On 9 December 2023, OFSI issued a general licence under all UK Autonomous Sanctions Regulations, which allows permitted payments, including council tax as well as rates charged on domestic and non-domestic properties, to be made by or on behalf of designated persons. The general licence took effect from 9 December 2023 and is of indefinite duration.

OFSI will likely continue to focus its work on the Russian sanctions regime in the coming year: to date, there has been relatively little enforcement activity, but that is likely to change during 2024 as OFSI seeks to give teeth to the multiple measures adopted by the UK government and to make use of its growing powers.

See the full collection of OFSI general licences.

Greg Fullelove, Partner
T: +44 20 7105 7564
greg.fullelove@osborneclarke.com

Kristian Assirati, Senior Associate
T: +44 20 7105 7847
kristian.assirati@osborneclarke.com
Ofcom plan of work consultation

Ofcom has published its proposed "Plan of Work" for 2024/25, which sets out its key focus areas for the next financial year.

The regulator's priority outcomes are:

- fast and reliable internet connections and services for everyone, everywhere;
- a wide range of trusted and highly valued media and protection for audiences across the UK;
- the reduction of online harms, making consumers feel safer on online platforms; and
- ensuring the efficient use of spectrum and supporting the growth of wireless services across the economy.

Ofcom notes that it will continue to monitor communications providers’ compliance with the new security framework, using its powers introduced by the Telecommunications (Security) Act 2021. It will submit its first report to the secretary of state on telecoms security by October 2024.

Under the Network and Information Systems (NIS) Regulations responsibilities, Ofcom will continue to make sure operators of essential services are managing security risks and will engage with industry to carry out its intelligence-led penetration testing scheme (TBEST) on telecoms and digital infrastructure.

The regulator has asked for responses to its proposed plan of work by 5pm on 9 February 2024. It will publish its final plan in March 2024.

Ofcom proposes ban on mid-contract price rises linked to inflation

Following over 800 complaints related to price rises between January and October 2023, Ofcom has concluded that inflation-linked mid-contract price rise terms can cause substantial amounts of consumer harm by complicating the process of shopping for a deal, limiting consumer engagement, and making competition less effective as a result.

Ofcom has found that consumers tend to be confused by the inflation-linked “CPI + 3.9%” messaging that providers tend to use, and it wants to ensure that consumers can make more informed choices about the best deals for them, including about bundle deals, without the need to forecast what their monthly price will be at a later date.

As a result, Ofcom has proposed the introduction of a new rule requiring that telco providers tell customers upfront (at the point of sale) in pounds and pence about any price rises that they include in their contracts (the "£/p requirement").

Ofcom considers that where a number of services are taken together as a bundle (such as mobile, broadband, pay-tv), information about any changes to the core subscription price (being the sum that customers must pay at regular intervals for the services) should be presented as the price of the whole bundle. Providers are not expected to provide a breakdown of the price changes for each separate element of the bundle.

The proposed scope of the £/p requirement applies to new contracts for all broadband, landline, mobile and pay-tv services; including where they are taken in combination as a bundle.

Ofcom is consulting on the proposed new requirement until 13 February 2024, and plans to publish its final decision in spring 2024. Subject to the responses it receives, the regulator intends for the new rule to come into effect four months after the publication of its final decision. This period reflects the concern about the scale of consumer harm balanced against the need to give providers sufficient time to make the necessary changes to their processes and business plans.

Ofcom proposes updated guidance for telecoms network resilience

Ofcom is consulting to propose updates to its resilience guidance, to help provide greater clarity on how UK telecoms companies can reduce the risk of network outages.

The regulator views resilient telecoms networks as vitally important to consumers and businesses in the UK. As more social and economic activities move online in the coming years, it is important that the telecoms networks that underpin them are sufficiently resilient to meet the increased demand.

Ofcom proposes to introduce an updated version of its guidance for communications providers, which sets out the measures expected of them in relation to the resilience of their networks. Public electronic communications services and
networks are subject to new duties with respect to security and resilience, following the introduction of the Telecoms Security Act.

The update guidance includes:

- making sure networks are designed to avoid, or reduce, single points of failure;
- making sure key infrastructure points have automatic failover functionality built in, so that traffic is immediately diverted to another device or site when equipment fails; and
- setting out the processes, tools and training that should be considered to support the requirements on resilience.

Ofcom invites responses to its consultation by Friday 1 March 2024. It intends to publish its decision on the resilience guidance, and next steps on mobile power resilience, in summer 2024.

Jon Fell, Partner
T: +44 20 7105 7436
jon.fell@osborneclarke.com

Eleanor Williams, Associate Director
T: +44 117 917 3630
eleanor.williams@osborneclarke.com

Hannah Drew, Legal Director
T: +44 20 7105 7184
hannah.drew@osborneclarke.com

TK Spiff, Associate
T: +44 20 7105 7615
tk.spiff@osborneclarke.com
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