



## Regulatory Outlook

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

*The spotlight development this month is that the UK government has published its much-anticipated draft data legislation, the Data (Use and Access) Bill. The bill is about a lot more than data protection, standardising information sharing across the NHS or (potentially) removing (some) barriers to the implementation of AI systems. It encourages data use across sectors, including for example by creating a framework for smart data schemes, introducing a certification framework for digital identity verification systems; and by changes to UK data protection laws. See [Data law](#) for more.*

October 2024

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## Advertising and marketing

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# Advertising and marketing

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## UK CAP and BCAP publish final statement on body image in advertising review

The UK Committee of Advertising Practice (CAP) and the Broadcast Committee of Advertising Practice (BCAP) have published their [final statement](#) in relation to their review of body image in advertising.

An interim statement was published in November 2022, following the committees' call for evidence, in which CAP and BCAP identified three areas worthy of further assessment and research in order to decide whether regulatory change is needed (see this [Regulatory Outlook](#)):

- digitally altered images in advertising and labelling;
- the depiction of muscularity in advertising; and
- the depiction of women from minority ethnic backgrounds and the potential for developing new and unattainable body image ideals.

In their final statement, the committees say that, having completed their assessments, there is no need at present for new regulatory intervention, as the evidence on the specific role that advertising plays in contributing to potential harms is still developing.

They conclude that there are probably other environmental factors, such as cultural and social influences, that are driving concerns. For example, in respect of digitally altered images, it can be difficult to ascertain the impact of advertising, given the way it is incorporated into the social media landscape where the boundaries between organic and influencer content are often blurred.

The statement concludes that the existing UK advertising codes are sufficient in terms of protecting consumers in this area. The committees note also that efforts within the advertising industry are already under way to tackle body image issues.

The news that no further regulation will be immediately forthcoming will be welcomed by the industry, but this is not necessarily the end of the story, as the regulators say that they will continue to monitor developments, including in relation to the use of AI in advertising.

## UK CAP publishes guidance note on affiliate marketing

CAP has issued a new [advice note](#) summarising the rules on affiliate marketing.

CAP sees individuals who provide affiliate links as secondary advertisers, meaning that they too must comply with the CAP Code. The note highlights that, while most affiliate marketing appears in social media, it can appear in any online space managed by the affiliate, including emails, newsletters and blogs.

The note reminds readers that ads must be identifiable as such. Where it is not clear that the content consists of or includes affiliate links (for example, influencer social media content), the best way to identify content as advertising is to label it clearly using "Ad" or similar. However, marketers should not use "Aff" (short for "affiliate") to denote ad content.

The advice note explains when different aspects of content containing affiliate links need to be identified as advertising, reminding all those involved, be they marketers (brands) or affiliates (including influencers), that they are jointly responsible under the CAP Code for this type of content.

This is the case even if the brand has no control over the content containing the link and/or if no products have been gifted to the person who includes the affiliate link. It is also likely to be the case where brands use an affiliate partner or a third-party sales platform to direct affiliate traffic to their brand, even if the brand is not aware that the influencer/affiliate had an arrangement with that affiliate partner/third party or is not aware of the content being produced.

CAP concludes by reminding brands to ensure that they have safeguards in place so that ads promoting their brand are always obviously identifiable as such, including when working with third party intermediaries.

The note is a good reminder to brands that they need to keep track of their affiliates/influencers as they are just as responsible as the affiliate/influencer for ensuring compliance with the rules.

## Labour confirms it will continue with Online Advertising Taskforce

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The Internet Advertising Bureau (IAB) UK has published [key takeaways](#) from the Labour Party Conference held in September 2024. These include Labour's decision to continue with, and potentially extend, the [Online Advertising Taskforce](#) that is working to bolster self-regulatory initiatives within the digital ad industry. The Online Advertising Taskforce was launched by the previous Conservative government to support the [Online Advertising Programme](#), which aims to review the regulatory framework of paid-for online advertising.

The IAB notes that, at the same time, "*there are clear indications that the Labour Government will go beyond self-regulation in some areas such as to strengthen online safety, protect personal data and privacy and create greater alignment with the EU on these subjects.*"

## **BCAP publishes new rule banning ads for certain types of cryptoasset products from being broadcast to mainstream, non-specialist audiences**

BCAP has [published](#) new rule 14.5.5 of the UK Code of Broadcast Advertising (BCAP Code), which explicitly bans ads for certain types of cryptoasset products from being broadcast to mainstream, non-specialist audiences.

Advertising of these products was already subject to such a restriction under BCAP Code rule 14.5.4, (as products not regulated by the Financial Conduct Authority (FCA)). However, in October 2023, [new rules on promoting cryptoassets](#) came into force, and the FCA assumed regulation of the advertising of ads for "qualifying cryptoassets" (covering cryptoassets that are fungible and transferable, such as cryptocurrencies and utility (fan) tokens).

BCAP considers that explicitly adding this category to the BCAP Code will maintain the existing restriction, adding certainty to the rule, and will remind broadcasters of the statutory restrictions that apply to advertising them. BCAP highlights that cryptoassets that are not included in the "qualifying cryptoassets" category will continue to be caught under rule 14.5.4, which covers unregulated investments more generally.

## **BCAP consults on technical issue in relation to the broadcast restriction of ads for unregulated investments**

BCAP has published for consultation an amendment to the BCAP Code that restricts the advertisement of certain types of financial products to specialised financial channels, stations and programming, with the [consultation](#) closing on 31 October 2024.

[BCAP Code rule 14.5](#) sets out a list of complex financial products which can only be advertised on specialised financial channels, stations or programming, meaning that these ads are prohibited from being advertised on TV and radio to a general audience. The restriction was put in place by the Independent Television Commission, the predecessor to Ofcom, due to concerns that these channels are not well-suited to promoting high-risk or specialist investment products.

A review of the code has revealed that the current wording technically has the unintended effect of banning TV ads for mass market financial products that, in fact, the average consumer would not consider an "investment" product.

The consultation seeks to clarify that the restriction in rule 14.5.4 applies to unregulated investment products that are regarded as "investments" in the conventional sense, and not products that are unlikely to be regarded by the public as "investments".

## **Ofcom renews co-regulatory arrangements with ASA for regulation of broadcast, ODP and VSP advertising**

Ofcom has [announced](#) that it has renewed the co-regulatory arrangement that designates responsibility for the day-to-day regulation of broadcast, on demand programme service (ODPS) and video-sharing platform (VSP) advertising to the Advertising Standards Authority (ASA) for a further period of ten years, until 31 October 2034. This follows Ofcom's [consultation](#) conducted over the summer.

## **Updated advertising code of practice for pharmaceutical industry**

The Association of the British Pharmaceutical Industry (ABPI) and the Prescription Medicines Code of Practice Authority have [published](#) an updated code of practice for the pharmaceutical industry, which sets out, among other things, voluntary industry rules for the promotion of prescription-only medicines.

The updated code incorporates most of the proposals set out in the extensive consultation published by the ABPI in December 2023, as well as changes made in response to consultation feedback.

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Clause 12 of the code sets out the prescribing information that must be included in all promotional material for a medicine, except for abbreviated advertisements (covered by clause 13), and has been completely rewritten in consultation with the Medicines and Healthcare products Regulatory Agency. The most significant change is that, for printed promotional material and digital promotional material shown to a recipient in person, the prescribing information can now be provided via a QR code, which must be of sufficient size and clarity so that it can be easily scanned.

The updated code came into effect on 1 October 2024, however no activity will be regarded to be in breach until 31 December 2024, after which date the code will come into full force.

## ICC publishes new edition of Advertising and Marketing Communications Code

The International Chamber of Commerce (ICC), the world's largest business association, has [published](#) the 11<sup>th</sup> edition of its [Advertising and Marketing Communications Code](#), a self-regulatory code for best practice marketing standards.

According to the ICC, significant changes to the code include, among other things:

- new guidelines on the use of algorithms and AI in preparing and delivering marketing communications;
- encouraging advertisers to be mindful of diversity and the importance of avoiding objectification stereotypes;
- clear provisions on influencer marketing and the responsibility of influencers and content creators;
- updated standards for green claims; and
- clearer rules regarding children, teens and minors



**Nick Johnson, Partner**

T: +44 20 7105 7080

[nick.johnson@osborneclarke.com](mailto:nick.johnson@osborneclarke.com)



**Chloe Deng, Associate Director**

T: +44 20 7105 7188

[chloe.deng@osborneclarke.com](mailto:chloe.deng@osborneclarke.com)



**Anna Williams, Partner**

T: +44 20 7105 7174

[anna.williams@osborneclarke.com](mailto:anna.williams@osborneclarke.com)



# Artificial Intelligence

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## UK updates

### UK government launches the Regulatory Innovation Office

The government has announced the launch of the new Regulatory Innovation Office (RIO), as promised in its manifesto. The RIO will initially support four technology areas, including:

- AI and digital in healthcare to accelerate the NHS's efficiency and patient care; and
- connected and autonomous technology including autonomous vehicles such as delivery drones.

See more in our [Insight](#) on the topic.

### FCA launches AI Lab

The Financial Conduct Authority (FCA) has launched an [AI Lab](#), designed to help firms overcome challenges in building and implementing AI solutions. It will provide AI-related insights, discussions and case studies, helping the FCA understand AI risks and opportunities.

### UK government's Industrial Strategy recognises the importance of AI

In its recent [Industrial Strategy Green Paper](#), the government has included "Digital and Technologies", which includes AI, as one of eight areas that it wants to focus on growing.

The strategy highlights the AI Opportunities Action Plan, led by Matt Clifford (see this [Regulatory Outlook](#)), that "*will propose an ambitious approach to grow the AI sector and drive responsible adoption across the economy.*"

The government is consulting on its strategy with responses welcomed by 24 November 2024.

## EU updates

### EU Commission – first plenary session and workshop on a Code of Practice for general-purpose AI

On 30 September 2024, the European Artificial Intelligence Office (AI Office) kicked off the process for the creation of the first Code of Practice for general-purpose AI (GPAI) models under the EU AI Act by convening [the first plenary session](#).

The online session was attended by close to 1000 participants, including those from general-purpose AI model providers, downstream providers, industry, civil society, academia and independent experts. At the session, the AI Office presented a preliminary overview of the results of its multi-stakeholder consultation on the code of practice. See this [Regulatory Outlook](#) for background and details of the drafting process.

The [first workshop](#) on the code of practice took place on 23 October. The attendees included the GPAI model providers who discussed the content of the code with the [chairs and vice-chairs of the code](#). The first workshop covered:

- systemic risk assessment, technical mitigation and governance; and
- transparency and copyright-related rules.

The first draft code is expected in November 2024.

### Study on AI liability directive proposes to transform it into a software liability regulation

The EU Parliament's Think Tank has [published](#) a complementary impact assessment on the Commission's proposal for a directive on adapting non-contractual civil liability rules to AI (the [AI liability directive](#)). The proposed directive only reached an early stage in the legislative process and was not enacted before the EU Parliament elections in June 2024. Whether or not to continue this legislation will be a decision for the new Commission.

The report outlines some recommendations, among other things, to:



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- align the concepts and definitions in the proposal with those of the EU AI Act;
- classify generative AI systems under the new "high-impact" category since the current framework of the AI liability directive *"does not adequately cover general-purpose AI systems"*;
- expand the scope of the AI liability directive *"into a more comprehensive software liability instrument"* (preferably a regulation) which covers not only AI, but all other types of software; and
- re-consider the implementation of the strict liability framework, particularly for high-risk AI systems.

## US updates

### California will not enact controversial AI bill SB 1047

California's governor, Gavin Newsom, has vetoed the state's controversial "Safe and Secure Innovation for Frontier Artificial Intelligence Systems Act" (SB 1047), breaking his recent run of signing draft AI bills into the state's law (see this [Regulatory Outlook](#) for background). In a [letter](#), the governor gives several reasons for not signing the act:

- It could give the public a false sense of security by focusing only on the most expensive and large-scale AI models, while ignoring smaller or more specialised AI models which could create dangers.
- It would not take into account deployment contexts, so would apply strict standards to basic functions, even if they were not being deployed into risky environments.
- The area is fast-moving, with *"strategies and solutions for addressing the risk of catastrophic harm"* *"rapidly evolving"* – noting that further legislation may be needed in future, but must be *"based on empirical evidence and science"*.

At the same time, Mr Newsom has announced a range of related AI safety initiatives:

- Appointing experts on generative AI to help develop guardrails, focusing on developing an *"empirical, science-based trajectory analysis of frontier models and their capabilities and attendant risks"*.
- Engaging academics to convene workers representatives and the private sector to *"explore approaches to use GenAI technology in the workplace"*.
- Expanding the state's work assessing potential threats from the use of generative AI to California's critical infrastructure, such as energy and water, *"including those that could lead to mass casualty events"*.

### US FTC takes action against five companies for allegedly using AI to deceive consumers

The US Federal Trade Commission (FTC) has [taken action](#) against five companies for using AI in illegal ways which harmed consumers, as part of its new law enforcement sweep, Operation AI Comply. The actions taken are against:

- DoNotPay, a company which claimed that its AI service was *"the world's first robot lawyer"* and could generate legal documents and replace lawyers. The FTC alleges that the company could not substantiate these claims and did not test whether its AI chatbot's output was equal to the level of a human lawyer.
- A lawsuit against an online business opportunity scheme, Ascend Ecom, which allegedly claimed that its AI tools could help consumers earn thousands of dollars monthly through online stores. The FTC claims the scheme defrauded consumers of at least \$25 million.
- A business opportunity scheme, Ecommerce Empire Builders, for falsely claiming to help consumers build an "AI-powered Ecommerce Empire" and make millions by participating in training programmes or buying online storefronts. The FTC says the company could not substantiate these claims.
- Rytr, which has marketed and sold an AI "writing assistant" – one of which generated consumer reviews. The FTC claims these AI-generated reviews often deceived potential consumers.
- FBA Machine, a business opportunity scheme that allegedly falsely promised consumers guaranteed income through AI-powered software for online storefronts. The FTC claims the promised earnings rarely materialised

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**John Buyers, Partner**  
T: +44 20 7105 7105  
john.buyers@osborneclarke.com



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



**Tom Sharpe, Associate Director**  
T: +44 20 7105 7808  
tom.sharpe@osborneclarke.com



**Katherine Douse, Senior Associate**  
T: +44 117 917 4428  
katherine.douse@osborneclarke.com



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



**James Edmonds, Associate**  
T: +44 20 7105 7607  
james.edmonds@osborneclarke.com



**Emily Tombs, Associate (New Zealand Qualified)**  
T: +44 20 7105 7909  
emily.tombs@osborneclarke.com



## **Bribery, fraud and anti-money laundering**

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# Bribery, fraud and anti-money laundering

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## Guidance on information sharing measures in ECCTA 2023

The UK government has published [guidance](#) on the information sharing measures in the Economic Crime and Corporate Transparency Act 2023 (ECCTA) which came into force on 15 January 2024.

The ECCTA allows the direct and indirect sharing of information between businesses in the anti-money laundering regulated sector to prevent, detect and facilitate the investigation of economic crime.

The guidance sets out:

- provisions to ensure that businesses comply with the new measures;
- practical considerations for businesses including mechanisms for cross-sector sharing; and
- requirements for law enforcement reporting, UK General Data Protection Regulation (GDPR) compliance, and customer redress.

Regulated firms, statutory and non-statutory professional body supervisors and trade bodies are encouraged to consider how they can apply the overarching principles in the guidance to develop a consistent approach to sharing within their own sector.

## Speech on FCA's evolving approach to enforcement

Therese Chambers, Financial Conduct Authority (FCA) joint executive director of enforcement and market oversight, delivered a speech at the [AFME Annual European Compliance and Legal Conference](#). Ms Chambers outlined the FCA's plans to take a data and technology-driven approach, streamline its caseload and focus on identifying cases where there may be conduct creating the greatest risk of harm.

The speech also addressed the industry response to its [February consultation paper](#), which proposed publishing investigation announcements, including the identity of the individual or firm subject to investigation. The FCA "*heard loud and clear*" that the criteria consulted on "*were too high level and lacked specificity*" and clarified that it would take a case-by-case approach, including consideration of the potential impact of an announcement on the firm.

In a separate speech, the FCA's chief executive, Nikhil Rathi, [confirmed](#) that the regulator will provide "*more data and case studies*" on how a public interest test could work in practice in November, and that the board plans to take a final decision on the proposals in early 2025.

See Osborne Clarke's [response](#) to the consultation.

## JMLSG AML and CTF guidance on wholesale markets

The Joint Money Laundering Steering Group (JMLSG) [published](#) revisions to Sector 18 (wholesale markets) in Part II of its anti-money laundering and counter-terrorist financing guidance for the financial services sector.

The [revisions](#), which were open for [consultation](#) in April 2024, have been submitted to HM Treasury for ministerial approval.

The revised guidance can be found the JMLSG's [revisions webpage](#).



**Jeremy Summers, Partner**  
T: +44 20 7105 7394  
[jeremy.summers@osborneclarke.com](mailto:jeremy.summers@osborneclarke.com)



**Chris Wrigley, Associate Director**  
T: +44 117 917 4322  
[chris.wrigley@osborneclarke.com](mailto:chris.wrigley@osborneclarke.com)

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# Bribery, fraud and anti-money laundering

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**Capucine de Hennin, Associate**

T: +44 20 7105 7864

[capucine.dehennin@osborneclarke.com](mailto:capucine.dehennin@osborneclarke.com)



# Competition

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# Competition

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## Competition and sport

FIFA has said it will [negotiate changes to its rules on the transfer of players](#), after the EU's Court of Justice said the rules are not in line with competition and free-movement laws. This is only the latest instalment in the long-running saga involving various sports authorities and competition regulators. We are closely tracking a number of these developments. Please see our previous Insights on the [independent regulator for English football, Manchester City v Premier League](#) and the [European Super League](#) for more detail.

On 4 October, the ECJ ruled that some aspects of FIFA's transfer rules regarding financial compensation and imposing additional sporting sanctions on both club and player in case of early contract termination without "just cause" are incompatible with the guarantee of freedom of movement and EU competition law. As a result FIFA has opened a global dialogue on the transfer system, involving key stakeholders, to adapt article 17 of the Regulations on the Status and Transfer of Players.

As an initial measure, FIFA has already invited key stakeholders, including representatives from the European Club Association, FIFPRO and the World Leagues Association, to analyse the conclusions to be drawn from the decision of the ECJ in the *Diarra* case. Additionally, FIFA has established [a platform](#) that will enable all interested parties to submit feedback by 15 November 2024 as part of the consultation process.

FIFA sees the *Diarra* decision as an opportunity to keep modernising its regulatory framework, which has been one of the declared objectives of the FIFA president since 2016. As part of this dialogue, it has indicated that it will consider "*parameters to calculate compensation for breach of contract, sanctions for breach of contract and a mechanism to issue the International Transfer Certificate*".

Several competition authorities have undertaken reviews of various sports. This has included new sporting competitions (such as the European Super League) and the rules of a number of sporting organisations (football authorities being a prime candidate here but competition authorities have also addressed the rules of World Sailing and the International Skating Union). It is clear that businesses are unable to use the often quoted justifications of sport having certain specific characteristics that make the imposition of seemingly anti-competitive rules proportionate and necessary.

## The future of competition

Both the UK and EU are assessing their respective approaches to the regulation of competition. On the EU side this is covered by the Draghi report on "[The Future of European Competitiveness](#)" and the UK has published a [consultation](#) on its green paper – "[Invest 2035: The UK's Modern Industrial Strategy](#)".

The Draghi report contains a number of recommendations in relation to competition policy aimed at ensuring that competition law is not "*a barrier to Europe's goals*", while still maintaining the benefits that can be brought about by competition. The recommendations set out in the Draghi report are not legally binding. Ultimately, it will be up to Ursula von der Leyen and the new Commission to decide how many of them will be taken forward. However, the "mission letters" for the new Commissioners-designate, which were released on 17 September 2024, make it clear that all Members of the College should draw on the recommendations of the Draghi report in the context of their individual missions.

The publishing of the UK's green paper on its modern industrial strategy was preceded by Keir Starmer, the prime minister, who was addressing the investment summit in London, stating an intention to "*rip up the bureaucracy that blocks investment*" and "*make sure that every regulator in this country, especially our economic and competition regulators, takes growth as seriously as this room does.*" In the days following this several senior regulators publicly claimed that their work was entirely consistent with this growth mission.

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## Competition

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However, the green paper is markedly different from these comments by the PM. The green paper discussed how "*competition policy creates incentives for businesses to innovate*" and states that the government will "*investigate ways to boost competition... whether through competition law and economic regulation, or through integrating competition considerations into other government policies*".



**Simon Neill, Partner**

T: +44 20 7105 7028

[simon.neill@osborneclarke.com](mailto:simon.neill@osborneclarke.com)



**Katherine Kirrage, Partner**

T: +44 20 7105 7514

[katherine.kirrage@osborneclarke.com](mailto:katherine.kirrage@osborneclarke.com)



**Marc Shrimpling, Partner**

T: +44 117 917 3490

[marc.shrimpling@osborneclarke.com](mailto:marc.shrimpling@osborneclarke.com)





## Consumer law

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# Consumer law

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## UK updates

### UK government requests Ofcom to prepare report on designation of Tier 1 services under Media Act 2024

The secretary of state for culture, media and sport has [written](#) to Ofcom asking it to prepare a report on the operation of the UK market for on-demand programme services, following commencement of the video-on-demand (VoD) regulation provisions in the Media Act 2024 via [the Media Act 2024 \(Commencement No. 1\) Regulations 2024](#).

The secretary of state writes that she is keen to begin the consideration of Tier 1 regulation of appropriate on-demand services "*as soon as is practically possible*". To do this, she is required to take into consideration the market report from Ofcom.

For further information, see our recent [Insight](#).

### CMA update on its market investigation into the UK vet sector

The UK Competition and Markets Authority (CMA) has published an [update](#) on its "behind the scenes" work in its market investigation into the UK vet sector (see this [Regulatory Outlook](#) for background).

The CMA has announced the appointment of a veterinary advisory panel, consisting of two veterinary nurses and four veterinary surgeons, to assist the Inquiry Group by providing clinical and practical insight and analysis on an *ad hoc* basis. To date, the Inquiry Group has conducted:

- site visits to talk to veterinary professionals to understand their work;
- roundtables with veterinary professionals and representatives from animal charities; and
- "teach-in" sessions with various organisations in the sector to gather insights on how the veterinary market works, their concerns about the investigation and how regulation is currently working.

The CMA has also used its formal information-gathering powers to require vets and vet businesses to provide information on the way their businesses operate. The statutory deadline for the CMA to conclude the investigation is 22 November 2025.

### Amendments to Price Marking Order: one year to comply

The [Price Marking \(Amendment\) Order 2024](#) was made on 21 October 2024 to amend the [Price Marking Order 2004](#) (PMO), which sets out the pricing information that a trader, whether online or offline, must include on price labels for the goods it is selling.

The new amendment order comes into force on **1 October 2025** and aims to make it easier for consumers to identify and compare selling and unit prices and to make compliance with the PMO simpler for businesses. The amendment order:

- Amends the definitions of "selling price" and "unit price" explicitly to exclude any payable deposit.
- Adds a requirement that all price information is displayed clearly and legibly.
- Adds an obligation that where goods are sold at more than one price, for example, a loyalty scheme price and a full price, both the selling price and the unit price for each type of price must be displayed, together with any conditions applicable to the different prices. Such conditions must be prominently and legibly displayed; available to consumers without them having to seek assistance; and displayed close by the product.
- Adds that, when offering products at a reduction, businesses must indicate both the reduced selling price and the reduced unit price.

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- Revokes the provisions on units of quantity and mandates, in the definition of "unit price", that the price be displayed by metric units (kilogram, litre, metre).
- Amends the exemption from having to display a unit price for products sold as an assortment to cover not only assortments sold in a single package, but also those sold at a lower price if bought in bulk or in combination with other products, and those where some of the items are sold according to weight and some according to volume, or are sold at different prices when sold separately.

By the time the amendment order comes into force on 1 October 2025, the Competition and Markets Authority's strengthened consumer enforcement powers under the [Digital Markets, Competition and Consumers Act 2024](#) (see this [Regulatory Outlook](#)) should also be in force (currently planned for spring 2025). Businesses should therefore be prepared for the new rules to ensure compliance by next October.

### **Ofcom publishes update on implementation of the Online Safety Act 2023, confirming that duties to comply with illegal content safety requirements should come into force in March 2025**

See Digital regulation section for this and other updates on the Online Safety Act 2023.

### **EU updates**

#### **EU Commission publishes outcome of its digital fairness fitness check of EU consumer law**

The European Commission has published the outcome of its long-awaited [Digital Fairness Fitness Check](#) which aimed to assess the effectiveness of current EU consumer law in the digital environment. See our [Insight](#) exploring the main report's findings.

#### **Council of the EU adopts position on measures to facilitate dispute resolution in digital age**

See Digital regulation section.

#### **Council of the EU adopts the new Product Liability Directive**

See Products section.

#### **Council of the EU adopts Cyber Resilience Act**

See Products section.

### **International updates**

#### **OECD committee on consumer policy adopts declaration on protecting and empowering consumers in the digital and green transitions**

The first meeting of the Organisation's for Economic Co-operation and Development (OECD) Committee on Consumer Policy took place on 8-9 October 2024. At the meeting, the committee was presented with the findings of a new OECD survey, which found that nine out of ten consumers have been affected by harmful "dark commercial patterns".

The committee adopted a [declaration](#), in which it committed to strengthening efforts to identify and take action against harmful practices, such as manipulative, coercive, deceptive or addictive online design techniques, fake reviews, exploitative personalisation and data tracking. The Committee will also encourage businesses to "*pay due regard*" to the interests of consumers and act in accordance with fair business practices and good faith. It also called on the OECD to update the 2016 Recommendation on Consumer Protection in E-commerce.

As for the green transition, the committee recognised that consumers often lack access to accurate and easy-to-understand information on the environment and committed to taking action to improve this.

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## Consumer law

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The committee also [launched](#) a new Global Forum on Consumer Policy, which will bring together policymakers, academics, businesses and experts to collaborate on consumer issues, behavioural economics, technological trends and emerging consumer policy research



**Tom Harding, Partner**  
T: +44 117 917 3060  
tom.harding@osborneclarke.com



**John Davidson-Kelly, Partner**  
T: +44 20 7105 7024  
john.davidson-kelly@osborneclarke.com



**Ben Dunham, Partner**  
T: +44 20 7105 7554  
ben.dunham@osborneclarke.com



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



# Cyber-security

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# Cyber-security

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## Cyber Security and Resilience Bill to be introduced in 2025

As announced in the King's Speech, the government will bring forward the [Cyber Security and Resilience Bill](#) in 2025, in the first session of the new Parliament.

As [previously reported](#), the bill was first announced in the King's Speech in July 2024, and aims to strengthen the cyber defences of the country's critical infrastructure and digital services.

The Department for Science, Innovation and Technology (DSIT) [revealed](#) that it has received a number of enquiries from individuals and organisations wishing to discuss the bill. The government therefore plans to engage with stakeholders to gather input and issue further communications on this in due course.

Read more about progress of other measures affecting business announced by the government in the King's Speech in our [Insight](#).

## Cyber Essentials supply chain commitment

On 23 October 2024, DSIT and the National Cyber Security Centre (NCSC) [published](#) a joint statement with a group of six UK banks, encouraging organisations within critical national supply chains to take steps to manage their supply chain cyber security risk.

The statement sets out the importance of good cyber security in the supply chain, and encourages businesses to manage their supply chain cyber security risk more effectively through adoption of the Cyber Essentials certification scheme as a supply chain assurance tool.

For more information, see the [Cyber Essentials](#) website.

## NIS2 Directive

On 17 October 2024, the European Commission [adopted](#) the implementing regulation setting out the technical and methodological requirements of the cybersecurity risk management measures referred to in the Network and Information Systems Directive (NIS2). The rules apply to certain categories of companies providing digital services, including cloud service providers, online search engines and social networking platforms.

The implementing regulation is expected to be published in the Official Journal shortly, whereupon it will enter into force 20 days later.

The deadline for Member States to transpose the various provisions of NIS2 into national legislation was also 17 October. So far, only Belgium and Italy have notified the Commission of full transposition while Croatia, Latvia and Lithuania have partially transposed the directive into national laws.

The Commission urges the remaining Member States to "*implement these rules at national level as fast as possible to ensure that the services which are critical for our societies and economies are cyber secure*".

For more detail about what steps businesses can take to ensure compliance, see our [Insight](#) and track the directive on our [Digital Regulatory Timeline](#).

## Cyber Resilience Act formally adopted by EU Council

Please see Products section.

## Counter Ransomware Initiative Summit

During the fourth Counter Ransomware Initiative (CRI) Summit in October 2024, the UK and 38 other countries issued [new guidance](#) alongside insurance bodies, with the aim of supporting organisations during ransomware incidents.

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As a general approach, the CRI strongly discourages organisations from paying ransom. Instead, companies are encouraged to prepare ahead, as part of their business continuity plan, and to develop policies, procedures, frameworks and communication plans to minimise the overall impact of a ransomware incident.

Read the [CRI joint statement](#) and [press release](#).

### **G7 Cyber Expert Group guidance for financial sector on planning for quantum computing**

The G7 Cyber Expert Group, a working group that coordinates cyber security policy and strategy across the G7 jurisdictions, published a [statement](#) highlighting the potential cyber security risks associated with developments in quantum computing.

The guidance contains recommended steps for financial authorities and institutions to take to develop a better understanding of the issue, as well as strategies for protecting sensitive financial data, including customer information.

Read the HM Treasury [press release](#).

### **UK and US cyber agencies warn of Russian foreign intelligence global cyber campaign**

The NCSC and partner agencies in the US published an [advisory](#) sharing the latest tactics being used by Russia's Foreign Intelligence Service (SVR) as part of a continued cyber campaign targeting organisations including technology companies and financial institutions around the world.

Organisations are encouraged to deploy patches and prioritise software updates to prevent systems from being accessed by SVR cyber actors.

Read the [full advisory](#).

### **UK and US issue alert over Iranian state-backed phishing attacks**

The UK and the US issued a [joint advisory](#) warning about the ongoing threat to various sectors worldwide from attackers working on behalf of Iran's Islamic Revolutionary Guard Corps (IRGC).

IRGC has been observed using social engineering techniques to gain access to the personal and business accounts of individuals involved in Iranian and Middle Eastern affairs.

Read the [joint cybersecurity advisory](#).

### **NCSC and allies issue advice over China-linked campaign targeting internet-connected devices**

The NCSC and its international partners in the US, Australia, Canada and New Zealand issued an [advisory](#) warning of a botnet (a network of internet-connected devices that are infected with malware) operated by a China-linked company being used to conduct cyber attacks.

The compromised devices affect Internet of Things devices including routers, webcams and CCTV cameras. Individuals and organisations are advised to follow the mitigation advice to protect themselves against malicious activity.

Read the [full advisory](#).



**Charlie Wedin, Partner**  
T: +44 117 917 4290  
[charlie.wedin@osborneclarke.com](mailto:charlie.wedin@osborneclarke.com)



**Ashley Hurst, Partner**  
T: +44 20 7105 7302  
[ashley.hurst@osborneclarke.com](mailto:ashley.hurst@osborneclarke.com)

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**Philip Tansley, Partner**  
T: +44 20 7105 7041  
[philip.tansley@osborneclarke.com](mailto:philip.tansley@osborneclarke.com)



**Nina Lazic, Associate Director**  
T: +44 20 7105 7400  
[nina.lazic@osborneclarke.com](mailto:nina.lazic@osborneclarke.com)





# Data law

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## UK government publishes Data (Use and Access) Bill

The UK government has published its much-anticipated draft data legislation, the Data (Use and Access) Bill. The bill is about a lot more than data protection, standardising information sharing across the NHS or (potentially) removing (some) barriers to the implementation of AI systems. It encourages data use across sectors, including for example by creating a framework for smart data schemes, introducing a certification framework for digital identity verification systems; and by changes to UK data protection laws.

See our [Insight](#) which provides an overview of the key provisions of the bill.

## Updates from the European Data Protection Board

During its latest plenary in October 2024, the European Data Protection Board (EDPB) adopted its work programme for 2024-2025 alongside a number of other documents – we provide an overview below.

### EDPB work programme 2024-2025

The EDPB's [work programme](#) is structured under four pillars: enhancing harmonisation and promoting compliance; reinforcing a common enforcement culture and effective cooperation; safeguarding data protection in the developing digital and cross-regulatory landscape; and contributing to the global dialogue on data protection.

#### *Enhancing harmonisation and promoting compliance*

Key actions include:

- the development of further guidance on key issues and concepts, including anonymisation, pseudonymisation, legitimate interest, children's data, "consent or pay" models, processing of data for scientific research purposes, data subject right of access under the Law Enforcement Directive, passenger names records, and age verification criteria; and
- supporting the development and implementation of compliance measures for controllers and processors, including issuing *opinions* on: accreditation requirements for monitoring bodies of codes of conduct and for certification bodies, codes of conduct and on certification criteria, including the European Data Protection Seal.

#### *Reinforcing a common enforcement culture and effective cooperation*

The EDPB will further strengthen efforts to ensure effective enforcement of the GDPR and cooperation between the members of the EDPB.

#### *Safeguarding data protection in the developing digital and cross-regulatory landscape*

The EDPB plans to create **common positions and guidance in the cross-regulatory landscape**, including:

- separate guidelines on the interplays between EU data protection law and the EU AI Act, the Digital Services Act and the Digital Markets Act;
- a position paper on the interplay between EU data protection and competition law;
- guidelines on processing to target or deliver political advertisements,
- guidelines on transfers of personal data in the context of transfers of crypto assets; and
- a document on anti-money laundering and countering financing of terrorism requirements.

It also plans to monitor and assess **new technologies, with the development of guidance** to promote a human-centric approach to topics, including:

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- guidelines on generative AI (data scraping), telemetry and diagnostic data, blockchain and the use of social media by public bodies; and
- a document on mandatory user accounts on online shopping websites.

### *Contributing to the global dialogue on data protection*

This includes the work on the GDPR and LED data transfer mechanisms and their practical implementation, as well as strengthening cooperation between EDPB members and non-EU data authorities.

### **EDPB adopts opinion on aspects of the relationship between controllers and their processors/sub-processors**

The EDPB has adopted an [opinion](#) on the interpretation of certain obligations of controllers that rely on processors and sub-processors, arising in particular from article 28 of the GDPR, as well as the wording of controller-processor contracts. It addresses processing in the European Economic Area (EEA), as well as processing following a transfer to a third country.

It concludes, among other things, that:

- A controller should have the information on the identity (that is, name, address, contact person) of all processors and sub-processors readily available at all times.
- A controller has always to verify whether its processors and sub-processors have given "*sufficient guarantees*" that the processing is compliant, and this applies regardless of the level of risk. However the extent of verification varies with the level of risk.
- The decision on whether to engage a specific sub-processor and the responsibility for them, including with respect to verifying the guarantees, remains with the controller, but it is not mandatory for the controller to itself see copies of the chain of sub-processor contracts; it depends on the risk level.
- In relation to the wording of controller-processor contracts, article 28(3)(a) of the GDPR states that a processor can process personal data only on the controller's "*documented instructions*" unless the processor is "*required to [process] by Union or Member State law to which the processor is subject*". The opinion states that it is not mandatory to include this latter carve out wording (or something very similar), but it is highly recommended. The EDPB goes on to say that the generic alternative wording (also frequently used in practice): "*unless required to do so by law or binding order of a governmental body*", which could be interpreted to include non-EEA local law (especially where the processor is based outside the EEA) is acceptable where the processor is based within the EEA but may be problematic where personal data is processed outside the EEA – see below.
- For personal data transferred outside of the EEA, the EDPB considers that the addition of the above carve out wording is, in itself, unlikely to comply with article 28(3)(a). Instead the contract should distinguish between the third country law(s) which would undermine the level of protection guaranteed by the GDPR and those that would not. Additional measures should apply in each case and the contract should specify that third country law does not release the processor from its obligations under the GDPR.

For controllers looking to encourage their processors to take more seriously the obligation to disclose and keep up to date their list of sub-processors (which can be an onerous obligation and one that processors often seek to dilute), this opinion may provide additional ammunition. However, the more detailed analysis and recommendations around article 28(3)(a) are less likely to be impactful in the short term.

### **EDPB consults on guidelines for processing on legitimate interest basis**

The EDPB has [published](#) for consultation draft guidelines on processing of personal data based on article 6(1)(f) of the GDPR (legitimate interest).

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These guidelines analyse the criteria in article 6(1)(f) of the GDPR that controllers must meet to lawfully engage in the processing of personal data based on the legitimate interests of the controller or a third party. The draft guidelines provide a detailed analysis of how these criteria are to be met and the challenges encountered in practice, including how to determine whether the processing is "necessary", what kinds of legitimate interest are applicable, and how to conduct the legitimate interests balancing test.

The guidelines also explain the relationship between the legitimate interests ground and a number of data subject rights under the GDPR.

The deadline for comments is 20 November 2024.

### **EDPB statement on the draft regulation laying down additional procedural rules for the enforcement of the GDPR**

The EDPB has published a [statement](#) on the recent legislative developments on the [draft regulation](#) laying down additional procedural rules for the enforcement of the GDPR (see this [Regulatory Outlook](#) for background).

In its statement, the EDPB sets out, among other things, recommendations to streamline cooperation and improve enforcement of the GDPR.

In addition, the EDPB highlights that including many references to national law in the new regulation would not be in the spirit of increased harmonisation and should therefore be avoided.

### **EDPB announces topic for 2025 coordinated action**

The EDPB has [chosen](#) the topic for its fourth coordinated enforcement action (CEA), which is the implementation of the right to erasure (right to be forgotten) by controllers. The action will be launched in the first quarter of 2025. This means that the EDPB will prioritise the right of erasure as a specific topic for data protection authorities to work on at national level, including by analysing and comparing the processes put in place by different controllers, in order to identify the most important compliance issues and get an overview of best practice. (In 2024, the EDPB's CEA is focusing on the implementation of the right of access (see this [Regulatory Outlook](#))).

### **EDPB publishes guidelines on technical scope of Article 5(3) of ePrivacy Directive**

The EDPB has adopted and published the final version of its [Guidelines 2/2023](#) on the technical scope of Article 5(3) of the ePrivacy Directive, following a consultation launched last year. It notes that "*the technical landscape has been evolving during the last decade [since the EDPB's [Opinion on device fingerprinting was issued](#)], with the increasing use of identifiers embedded in operating systems, as well as the creation of new tools allowing the storage of information in terminal equipment*".

The guidelines address the broader range of tracking tools (that is, beyond cookies) to which Article 5(3) applies. They aim to clarify which technologies are within scope of this provision.

The guidelines identify the three key elements for the applicability of Article 5(3): information (whether or not such information amounts to personal data); terminal equipment of a subscriber or user; and gaining access and storage of information and stored information, and provide a detailed analysis of each element, applying it to a non-exhaustive list of use cases, such as:

- URL and pixel tracking;
- local processing;
- tracking based on IP address only;
- intermittent and mediated Internet of Things reporting; and
- unique/persistent identifiers.

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### EU Commission publishes first review of the EU-US Data Privacy Framework

The European Commission has published a [report](#) on the first anniversary of the adequacy decision on the [EU-US Data Privacy Framework](#). It concludes that the US authorities have put in place the necessary structures and procedures to ensure the effective performance of the framework. This includes the implementation of safeguards to limit access to personal data by US intelligence authorities to what is necessary and proportionate to protect national security, and the establishment of an independent and impartial redress mechanism.

The Commission will continue to closely monitor relevant developments, paying particular attention to:

- the upcoming reports of the Privacy and Civil Liberties Oversight Board on the implementation of the Executive Order 14086 on Enhancing Safeguards for United States Signals Intelligence (EO 14086) and the functioning of the signals' intelligence redress mechanism, in particular the Data Protection Review Court; and
- possible further amendments to section 702 of the Foreign Intelligence Surveillance Act (FISA), relating to the conditions and limitations applicable to signals intelligence.

The Commission considers it important for the EU and US data protection authorities to develop common guidelines on key requirements under the framework's principles, for example on HR data and onward transfers. It proposes to carry out the next review in three years.

### ICO launches audit framework to help organisations assess their data protection compliance

The UK Information Commissioner's Office (ICO) has [launched](#) a new audit framework to help organisations assess their compliance with key requirements under data protection law. It describes it as a "*starting point*" for the evaluation of how an entity handles and protects personal information.

There are nine toolkits: accountability, records management, information and cyber security, training and awareness, data sharing, requests for data, personal data breach management, AI and age-appropriate design. Each toolkit has a data protection audit tracker that will help organisations identify and track actions in areas needing improvement.

This is not the first framework the ICO has developed to assist businesses assess their compliance with data protection law (for example, the ICO's very detailed [accountability framework](#), which was not widely adopted) and it will be interesting to see if businesses are more receptive to this framework.

### ICO's report on quantum technologies

The ICO has published a [report](#) on its early-stage thinking on the intersection of quantum technologies and data protection. The report looks at "*what a quantum-enabled future could look like, through a data protection and information rights lens.*"

It covers a broad range of quantum technologies, from quantum sensing, timing and imaging to quantum computing and quantum communications, and considers use cases in various sectors, such as medicine, finance, communications and law enforcement and explores when they may develop.

The ICO highlights the possibility that quantum computers could one day break the widely used cryptographic algorithms that protect data. The report warns that larger organisations, such as digital service providers or financial service providers, should start to prepare for the transition to post-quantum cryptography, including by identifying high risk information, critical systems and at-risk cryptography.

The ICO reminds organisations considering quantum use cases which involve personal data that they can apply to be part of its [Regulatory Sandbox programme](#).

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**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, Partner**  
T: +44 117 917 3556  
georgina.graham@osborneclarke.com



**Jonathan McDonald, Partner**  
T: +44 20 7105 7580  
jonathan.mcdonald@osborneclarke.com



**Daisy Jones, Associate Director**  
T: +44 20 7105 7092  
daisy.jones@osborneclarke.com



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

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## Digital regulation

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## UK updates

### Ofcom states that duties to comply with illegal content safety requirements should come into force in March 2025

Ofcom has published an [updated roadmap](#), setting out its progress in implementing the [Online Safety Act 2023](#) (OSA) since it became law a year ago and presenting its plans for next year.

Ofcom expects the illegal content safety provisions to come into force in March 2025, but says that publication of the register of categorised services will be delayed. See our recent [Insight](#) for more details.

### Sharing of non-consensual intimate images to be made a 'priority offence' under the OSA

The UK government has [announced](#) that the offence of sharing intimate images without consent will be made a "priority offence" under the OSA.

The amendment is set out in a draft statutory instrument, [The Online Safety Act 2023 \(Priority Offences\) \(Amendment\) Regulations 2024](#). This will amend Schedule 7 of the OSA (priority offences) by adding an offence under section 66B of the Sexual Offences Act 2003 (SOA) (sharing or threatening to share intimate photograph or film), which offence was introduced by the OSA and added to the SOA in January 2024.

The "priority offences" relate to the most serious forms of illegal content. Regulated services will be obliged to proactively remove this material when they become aware of it on their platforms, as well as take measures to prevent it from appearing in the first place. For more information on the OSA see our [Insight](#).

### Update on repeal of VSP regime by the OSA

Under the OSA, the UK government is obliged to give six months' [notice](#) of its intention to repeal the current video-sharing platforms (VSPs) regime.

On 22 May 2024, [the Online Safety Act 2023 \(Pre-existing Part 4B Services Assessment Start Day\) Regulations](#) came into force, setting the "assessment start date" as 2 September 2024. This date marks the commencement of the six months' notice for repeal of the VSP regime. This is also the date from which providers of pre-existing VSP services will need to carry out risk assessments of their services in line with their obligations under the OSA.

The final date of repeal will be decided by the government in secondary legislation. Ofcom anticipates this will be after its codes of practice for the protection of children come into force, which it expects will be around July 2025 (see above). The date of repeal will mark the end of the current transition period and the date when pre-existing VSPs will become fully subject to the OSA. Now is therefore the time to prepare.

### Ofcom launches consultation on fees and penalties regime under the OSA

Under the OSA, Ofcom's costs for its work in relation to the online safety regime are to be covered by providers of regulated services under a fees and penalties regime to be implemented by Ofcom working with the secretary of state (the government has previously published its guidance to Ofcom on determining the fees – see this [Regulatory Outlook](#)). Ofcom has launched a [consultation](#) on draft secondary legislation to define "qualifying worldwide revenue", which will be used to calculate both the fees and the maximum penalty that Ofcom will be able to levy against providers for breaches of the OSA.

Ofcom is proposing to define qualifying worldwide revenue as the total revenue of a provider referable to the provision of regulated services anywhere in the world. Where the provider is found liable together with one or more of its group undertakings, it will be calculated on the entire group and will be the worldwide revenues generated by the group in the most recent accounting period of those found liable, whether the revenues relate to regulated services or not.



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Providers of regulated services will have to pay fees if their qualifying worldwide revenue meets or exceeds a certain threshold to be set by the secretary of state based on Ofcom's advice, which the regulator expects to submit in April 2025. Ofcom proposes a £250m threshold and suggests exempting providers with UK referable revenue under £10m.

The consultation closes on **9 January 2025**. According to its updated roadmap, Ofcom expects the fees regime to be implemented by the 2026/27 financial year.

### **UK government requests Ofcom to prepare report on designation of Tier 1 services under Media Act 2024**

See Consumer section.

## **EU updates**

### **Council of the EU adopts position on measures to facilitate dispute resolution in digital age**

The Council of the EU has [adopted](#) its negotiating mandate on a proposal for a directive to adapt the alternative dispute resolution (ADR) framework to the challenges of the digital world. The proposal was made by the European Commission in October 2023 (see this [Regulatory Outlook](#) for background).

The Council's mandate:

- Limits the scope of the ADR directive to disputes arising under contract, including the stages before a contract is concluded (for example, advertising, information provision) and after the end of a contract (for example, use of digital content).
- Allows member states to decide on the application of ADR procedures to disputes with third-country traders.
- Makes ADR accessible in both digital and non-digital format and ensures that companies would have to inform consumers in advance when non-high-risk automated systems (bots or AI) are used in decision-making processes, as is the case for high-risk systems covered by the [EU AI Act](#).
- Extends the period for businesses to reply to an ADR request from 20 to 40 working days in complex disputes or in exceptional circumstances.
- Gives the Commission three months, once the directive has entered into force, to develop a new digital interactive tool to replace the current online dispute resolution platform.
- Gives member states an extra year to put the necessary legislation in place.

The negotiating mandate formalises the Council's position, meaning that it can now commence negotiations with the European Parliament.

### **EU Commission publishes outcome of its digital fairness fitness check of EU consumer law**

See Consumer section.

### **Council of the EU adopts position on measures to facilitate dispute resolution in digital age**

See Consumer section.

### **Council of the EU adopts the new Product Liability Directive**

See Products section.

### **Council of the EU adopts Cyber Resilience Act**

See Products section.

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# Digital regulation

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## International updates

### UK and US governments sign online safety pact

The UK and US governments have signed a [joint statement](#) on online safety, calling for platforms to go "*further and faster*" to protect children online by taking "*immediate action*" and continually using the resources available to them to develop innovative solutions, while ensuring there are appropriate safeguards for user privacy and freedom of expression. Vital to achieving this goal are, according to the statement, age-appropriate safeguards, including protections from content and interactions that harm children's health and safety.

The signatories commit to setting up a new joint government working group on children's online safety, which will work on key areas, including promoting better transparency from platforms. It will also consider researchers' access to privacy-preserving data on social media to assist in understanding the impacts and risks of the digital world on young people, including generative AI.

### OECD committee on consumer policy adopts declaration on protecting and empowering consumers in the digital and green transitions

See Consumer section



**John Davidson-Kelly, Partner**  
T: +44 20 7105 7024  
john.davidson-kelly@osborneclarke.com



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



**Ben Dunham, Partner**  
T: +44 20 7105 7554  
ben.dunham@osborneclarke.com



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



**Tom Harding, Partner**  
T: +44 117 917 3060  
tom.harding@osborneclarke.com



# Employment and immigration

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## **New statutory duty to prevent sexual harassment**

The new statutory duty to take reasonable steps to prevent sexual harassment comes into force on 26 October 2024. The Equality and Human Rights Commission (EHRC) has now published its updated guidance reflecting observations raised during the consultation and setting out helpful and detailed considerations and actions for employers towards compliance. It has also published a short guide for employers on preventing sexual harassment at work. The guidance comments that employers are unlikely to be able to comply with the preventative duty unless they carry out a risk assessment, so this is something that will need consideration.

The Employment Right Bill announced by the government (see below) provides that the new duty on employers to take reasonable steps to prevent sexual harassment will be amended to provide for an employer to have to take "all" reasonable steps. It also introduces liability for third-party harassment extending to all the protected characteristics currently covered by harassment (age, disability, gender reassignment, race, religion or belief, sex, and sexual orientation) in the course of employment, unless an employer has taken all reasonable steps to prevent the third party from harassing them.

Regulations may also be introduced specifying what may be "reasonable steps" for these purposes including, among others, carrying out assessments of a specified description; publishing plans or policies of a specified description; steps relating to the reporting of sexual harassment; steps relating to the handling of complaints.

The bill also amends the existing statutory provisions on whistleblowing to explicitly include sexual harassment as a relevant failure in relation to disclosures qualifying for protection.

## **UK government announces new Employment Rights Bill: what does this mean for employers?**

This month the government "*unveiled*" its Employment Rights Bill, as it looks to deliver "*economic security and growth to businesses, workers and communities across the UK*".

Many of the proposed reforms had been heavily trailed in Labour's Make Work Pay plan and in the media after the government's election, but there was increasing speculation as to what may or may not be included in this bill, the form the proposals will take and what measures will be immediate or subject to consultation and secondary regulations.

Indications are that some reforms are unlikely to have an impact in practice for some time, with the government expressly stating that the proposals around unfair dismissal and probationary periods will not come into force until autumn 2026.

The bill was presented before Parliament on 10 October and is stated to bring forward 28 individual employment reforms which cover a broad range of employment reforms. We explore these in our [Insight](#).

Four government consultations have already been published on statutory sick pay reforms, collective redundancies and fire and re-hire, the application of zero-hours contracts measures to agency workers and creating a modern framework for industrial relations.

## **Employment Rights Bill sets out major change for UK staffing companies and platforms and users of contingent workforces**

The new Employment Rights Bill covers a broad range of general changes in employment law, as well as fire and rehire, flexible working, union law, sick pay and other benefits.

The proposals that relate to day-one rights, zero-hours workers and a new enforcement agency could have a huge impact on many current non-standard workforce arrangements and contingent working generally. While the bill aims to enhance workers' rights, it also poses challenges for employers, especially those using non-standard workforce arrangements, see our [Insight](#) for more on these challenges.

## **EU Platform Workers Directive formally adopted**

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## Employment and immigration

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The employment status of those working in the gig economy remains a significant risk area for platform operators (and users of platform workers). While many individuals enjoy the benefits self-employment can offer, recent years have seen increasing claims for employment status and the legal rights and entitlements that brings. This has attracted significant media attention. And the status of those workers for employment law purposes may have significant employment tax, social security and VAT cost consequences for the platforms via which they find work, so this topic is central to the ability of the platforms to operate competitively.

The Platform Workers Directive (PWD) seeks to provide rights for platform workers across EU Member States, including a presumption of employment status in certain circumstances and proposed new rights for platform workers.

The PWD has now been formally adopted by the European Parliament and Council. Member States have two years to implement the directive into national legislation (though many will do so more quickly, with some already having laws covering most of what it covers). It will be interesting to see whether non-EU countries such as the UK (perhaps under a new Labour government, which is considering introducing a statutory definition of self-employment) adopt similar measures. Read our [Insight](#) for more.



**Julian Hemming, Partner**

T: +44 117 917 3582

[julian.hemming@osborneclarke.com](mailto:julian.hemming@osborneclarke.com)



**Kevin Barrow, Partner**

T: +44 20 7105 7030

[kevin.barrow@osborneclarke.com](mailto:kevin.barrow@osborneclarke.com)



**Gavin Jones, Head of Immigration**

T: +44 20 7105 7626

[gavin.jones@osborneclarke.com](mailto:gavin.jones@osborneclarke.com)



**Catherine Shepherd, Knowledge Lawyer  
Director**

T: +44 117 917 3644

[catherine.shepherd@osborneclarke.com](mailto:catherine.shepherd@osborneclarke.com)



**Helga Butler, Immigration Manager**

T: +44 117 917 3786

[helga.butler@osborneclarke.com](mailto:helga.butler@osborneclarke.com)



**Kath Sadler-Smith, Knowledge Lawyer  
Director**

T: +44 118 925 2078

[kath.sadler-smith@osborneclarke.com](mailto:kath.sadler-smith@osborneclarke.com)



# Environment

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# Environment

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## UK ETS publishes consultation on aligning free emissions proposal with UK CBAM in 2027

On 26 September 2024, the Department for Energy Security and Net Zero (DESNEZ) and the devolved administrations of the UK Emissions Trading Scheme (UK ETS) released a [further consultation](#). This follows the initial consultation published in December 2023, which focused on the free allocation review of emissions allowances under UK ETS. The goal is to better identify those most at risk of carbon leakage and ensure fair distribution of free allocations.

This further consultation, which closed on 11 October, proposed shifting the start of the second allocation period from 2026 to 2027. In response to feedback from the original consultation, the aim is to align changes to free allocation with the introduction of the UK Carbon Border Adjustment Mechanism (CBAM) in 2027.

The effect of the proposal would be as follows:

- baseline data reporting exercise will continue as planned from 1 April to 30 June 2025;
- applications for the second free allocation period will be made in 2026;
- updated lists of installations with hospital or small emitter (HSE) and ultra-small emitter (USE) status will come into effect from 2026, with the application window for inclusion on these lists open from 1 April to 30 June 2025; and
- changes to the current rules regarding the electricity generator classification will come into effect in 2026.

## Further amendments on monitoring and reporting greenhouse gas emissions

On 27 September 2024, [Commission Implementing Regulation \(EU\) 2024/2493](#) was published in the Official Journal of the European Union. The further regulation amends Implementing Regulation (EU) 2018/2066, which governs the monitoring and reporting of greenhouse gas emission (GHG) emissions under the EU Emissions Trading System (EU ETS). The regulation applies retrospectively from 1 January 2024, with many provisions taking effect from 1 July 2024 and 1 January 2025.

The regulation introduces amendments regarding:

- Monitoring and reporting GHG emissions from: biomass fuels, renewable fuels of non-biological origin (RFNBOs), recycled carbon fuels (RCFs) and synthetic low-carbon fuels; activities including oil refining, production of iron, alumina and hydrogen, and the transport of carbon dioxide (CO<sub>2</sub>) other than by pipeline for geological storage (these activities were included in the scope of the EU ETS by the EU ETS Amending Directive 2023); activities within the scope of the EU Emissions Trading System: fuel for heating buildings, road transport and non-EU ETS industry.
- The non-CO<sub>2</sub> effects of aviation.
- Emissions of GHGs that are not directly released into the atmosphere.

## ESMA publishes its first annual report on EU Carbon Markets

The European Securities and Markets Authority (ESMA) has published its inaugural annual report, ["EU carbon markets 2024"](#).

Key findings:

- Prices in the carbon market have been volatile, with a decline observed since the beginning of 2023.
- Financial intermediaries purchase the majority of emission allowances at auctions.
- Most secondary trading occurs through derivatives.

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The ESMA will publish a new report annually.

## **Draft Persistent Organic Pollutants (Amendment) Regulations 2024 laid before Parliament**

The [regulations](#) amend the retained GB Persistent Organic Pollutants (POPs) Regulation (EU) 2019/1021, which prohibits the manufacturing, placing on the market or use of chemicals listed in Annex 1.

The amendments to the regulations include implementing certain changes from the Stockholm POPs Convention and updates reflecting scientific and technical progress.

## **Natural England publishes a State of Natural Capital Report for England 2024**

On 9 October 2024, Natural England published a [report](#) examining the state of natural capital in England. The report uses evidence to evaluate the condition of ecosystems, the associated risks, and the implications for humanity, which relies on the benefits provided by nature.

In a government [press release](#), Tony Juniper, chair of Natural England, spoke at an event to launch the report. He highlighted the critical connection between the health of our ecosystems and the well-being of society and the economy. Tony stated that *"nature is the national wealth service"* and emphasised that *"you cannot grow the economy if we don't grow nature"*.

To support this nature-focused approach, the report outlines actions and opportunities for ecosystem restoration. These include implementing nature-related disclosure requirements for companies and promoting nature-related investments.

## **ESMA publishes an updated sustainable finance implementation timeline**

The European Securities and Markets Authority (ESMA) published an updated sustainable finance implementation [timeline](#). This timeline outlines key regulatory developments in sustainable finance, such as the Corporate Sustainability Reporting Directive (CSRD).

The update highlights two areas:

- The dates by which non-financial and financial undertakings must disclose key performance indicators under the Taxonomy Regulation.
- The potential publication of content related to the European Commission's review of sustainability-related disclosures in the financial services sector (SFDR) in mid-2025.

## **The Council of the EU formally adopts a directive supporting air quality**

On 14 October 2024, the Council of the European Union formally adopted a [directive](#) aimed at enhancing air quality standards across the EU. This directive supports the EU's net-zero objectives and prioritises the health of EU citizens by establishing air quality targets for 2030.

By 2030, the European Commission will review the air quality standards underpinning this directive to ensure they align with the latest scientific evidence.

## **UK government publishes a response to its carbon capture (decarbonisation) readiness**

In 2023, the government published a consultation on its proposals to expand the carbon capture readiness (CCR) requirements. On 15 October 2024, the Department for Energy and Security and Net Zero (DESNZ), published the [government response](#) to this consultation. This response applies to England only, the Welsh government will issue a separate response detailing actions for Wales.



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## Environment

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The proposal renames CCR as decarbonisation readiness (DR), ensuring that all new-build combustion power plants have a path to decarbonisation. The DR requirements will be moved from the planning consent process to the Environmental Permitting regime for applications submitted after 28 February 2026.

### UK government publishes a response to its new Climate Change Agreements scheme

On 16 October 2024, the government [responded](#) to its 2023 consultation on a new climate change agreements (CCAs) scheme. CCAs are voluntary agreements that aim to increase energy efficiency, allowing sector associations to receive a reduced rate climate change levy.

The consultation proposed a new CCA scheme to begin 1 January 2025, setting three new target periods running from 2025 to 2030, with three certification periods running to March 2033. It also addressed which elements of the current scheme would be retained and provided further proposals for the future.

DESNZ responded to the consultation and concluded that the scheme would last for five years instead of six, beginning on 1 January 2026. It has confirmed that it will set targets to the end of 2030 and provide a climate change levy until March 2033. The response clarified that, while retaining some aspects of the old scheme, the new CCA scheme will be separate to encourage compliance with the climate targets.



**Matthew Germain, Partner**

T: +44 117 917 3662

[matthew.germain@osborneclarke.com](mailto:matthew.germain@osborneclarke.com)



**Arthur Hopkinson, Associate**

T: +44 117 917 3860

[arthur.hopkinson@osborneclarke.com](mailto:arthur.hopkinson@osborneclarke.com)



**Julian Wolfgramm-King, Senior Associate  
(Australian Qualified)**

T: +44 20 7105 7335

[julian.wolfgramm-king@osborneclarke.com](mailto:julian.wolfgramm-king@osborneclarke.com)



**Caroline Bush, Associate Director**

T: +44 117 917 4412

[Caroline.bush@osborneclarke.com](mailto:Caroline.bush@osborneclarke.com)



**Lauren Gardner, Associate**

T: +44 117 917 3215

[lauren.gardner@osborneclarke.com](mailto:lauren.gardner@osborneclarke.com)



## Environmental, social and governance

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# Environmental, social and governance

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## Commission proposes 12 month delay to EU Deforestation Regulation

On 2 October, the European Commission put forward a [proposal](#) to delay the implementation of the EU Deforestation Regulation (EUDR) by 12 months. Key points from the announcement are as follows:

- Extra 12 months – the proposal would mean the EUDR applies from **30 December 2025** for large companies and 30 June 2026 for micro- and small enterprises. The intention is that the extra 12 months can serve as a phasing-in period to ensure proper and effective implementation. The Commission has invited the Parliament and Council to adopt this proposal by the end of the year.
- New guidance and FAQs – the proposal is accompanied by a new [set of guidance](#) and [FAQ document](#).
- Risk classification to countries – the proposal confirms that the Commission is looking to speed up the classification process of countries to "low", "standard" and "high" risk. Apparently, a large majority of countries worldwide will be classified as "low risk".
- EUDR IT System will be ready for business – the European Commission confirms that the IT System used for submitting due diligence statements will be available from November and fully operational from December 2024. This will allow EUDR affected businesses to start registering/submitting DD statements before the law takes effect in December 2025.

The Council of the EU, on 16 October, agreed to postponing the date of EUDR application by 12 months. Notably the Council's [press release](#) explains that "*the targeted amendment will not affect the substance of the already existing rules.*"

The Council will now inform the European Parliament of its position in view of the Parliament taking a decision on its position, with the aim that the proposal be formally adopted by both the Council and Parliament and published in the Official Journal of the EU so it can enter into force by the end of the year.

## Where next for UK green consumer finance?

The potential of green finance is clear, but the growth of the sector is hampered by a range of practical and regulatory challenges. What solutions is the industry leaning towards, and what measures might the government take to boost green finance? See our [Insight](#) series for more.

## Guidelines to take effect on the use of ESG or sustainability-related terms in fund names

The [final guidelines](#) on the use of ESG or sustainability-related terms in the names of funds will come into force on 21 November.

The guidelines aim to unambiguously regulate the use of words or acronyms that are indicative – or merely allusive – of sustainability-oriented investment strategies within the names of investment funds.

They include substantive provisions that will have a direct impact on how to manage in-scope fund portfolios, including a minimum 80% net asset value investment requirement.

In addition to EEA AIFMs, UK managers using the services of host AIFMs from Luxembourg or Ireland, for example, will also need to consider the implications of these guidelines.

## Select committee publishes report on the impact of the Modern Slavery Act 2015

Please see Modern Slavery.

## European Parliament approves Regulation on forced labour products

Please see Modern Slavery.

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## Environmental, social and governance

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### The Transition Finance Market Review (TFMR) publishes its report on Scaling Transition Finance

In October, the Transition Finance Market Review (TFMR) published its [report](#) and findings on "Scaling Transition Finance". The report describes transition finance as encompassing "*the financial flows, products and services that facilitate an economy-wide transition to net zero*".

The report identifies three areas for scaling the transition finance market:

- "Establishing clarity and credibility", to define the scope and objectives of this type of finance;
- "Scaling finance for transition activities", to ensure that solutions are commercially viable;
- "Scaling finance for transitioning entities", by prioritising transition strategy in financing decisions.

### FCA announces the publication of Climate Financial Risk Forum guides on key climate risks

The Climate Financial Risk Forum (CFRF) is a financial services industry forum jointly established by the Financial Conduct Authority (FCA) and the Prudential Regulation Authority (PRA). On 10 October 2024, the CFRF [published guides](#) designed to assist the financial sector in addressing climate-related financial risks and opportunities.

The guides cover three key areas:

- Nature-related Risk: Handbook for Financial Institutions, which frames nature as a financial risk.
- Short-term Scenarios, to provide further guidance to firms.
- Mobilising Adaption Finance to Build Resilience, to help facilitate increased levels of investment into the climate response.

### European Parliament approves regulation on ESG rating activities

This month the European Parliament [approved](#) the final text of the regulation on the transparency and integrity of ESG rating activities. Under the regulation, EU ESG ratings providers will have to apply for authorisation from ESMA (the EU's financial markets regulator and supervisor). Non-EU ESG rating providers will be able to provide ESG ratings in the EU in limited circumstances. ESG ratings providers will be subject to ongoing supervision by ESMA.

The Council is expected to formally adopt the regulation at an upcoming meeting, after which it will be published in the Official Journal of the EU and enter into force.

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



**Chris Wrigley, Partner**  
T: +44 117 917 4322  
[chris.wrigley@osborneclarke.com](mailto:chris.wrigley@osborneclarke.com)



**Matthew Germain, Partner**  
T: +44 117 917 3662  
[matthew.germain@osborneclarke.com](mailto:matthew.germain@osborneclarke.com)



**Katie Vickery, Partner**  
T: +44 20 7105 7250  
[Katie.vickery@osborneclarke.com](mailto:Katie.vickery@osborneclarke.com)



## **Fintech, digital assets, payments and consumer credit**

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# Fintech, digital assets, payments and consumer credit

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## Updates on authorised push payment fraud

### PSR confirms £85,000 maximum reimbursement limit for APP fraud

On 25 September 2024, the Payment Systems Regulator (PSR) published a [press release](#) confirming its decision on the maximum reimbursement limit for victims of Faster Payments authorised push payment (APP) fraud, setting the new maximum limit at £85,000.

As previously reported (see last month's [Regulatory Outlook](#) for background), this is a significant change from the previously proposed limit of £415,000. The PSR considers that this decision:

- strikes an appropriate balance having regard to its innovation and competition objectives;
- provides world-leading protections to those falling victim to scams, given that over 99% of APP claims will be covered by the maximum limit; and
- gives firms strong financial incentives to continue to make improvements to their fraud prevention controls.

The Bank of England (BoE), as the operator of Clearing House Automated Payment System (CHAPS), has similarly decided that the maximum reimbursement for CHAPS will be £85,000, recognising the benefits to both industry and consumers in having a consistent limit across the two payment systems.

The new maximum limits came into effect on 7 October 2024. Both the PSR and BoE will closely monitor their impact and are expected to perform an evaluation of effectiveness after 12 months of operation.

### PSR guidance on APP scams reimbursement requirement

On 23 September 2024, the PSR published [guidance](#) to support payment service providers (PSPs) in assessing whether an APP scam claim raised by a consumer is reimbursable under the Faster Payments scheme and CHAPS reimbursement rules, following a consultation period (reported in this [Regulatory Outlook](#)). If deemed instead to be a private civil dispute, such a claim will not be reimbursable.

The guidance sets out high-level factors that PSPs should consider when making a determination:

- communication and relationship between the consumer and the alleged scammer;
- trading status of the alleged scammer;
- alleged scammer's capability to deliver the goods and services related to the claim;
- extent to which the alleged scammer deceived the consumer as to the purpose of the payment; and
- information held by the receiving PSP(s) about the relevant account(s).

### FCA 'Dear CEO' letters on APP fraud reimbursement

On 7 October 2024, the Financial Conduct Authority (FCA) published two "Dear CEO" letters setting out its expectations relating to the new APP fraud reimbursement measures, one to [banks and building societies](#) and the other to [payment and e-money institutions](#) (collectively PSPs), including:

- **Anti-fraud systems and control.** PSPs should: have effective governance arrangements, controls and data to detect, manage and prevent fraud, and regularly review their effectiveness; maintain appropriate customer due diligence controls, both at onboarding stage and on an ongoing basis to identify and prevent accounts being used to receive proceeds of fraud or financial crime.

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# Fintech, digital assets, payments and consumer credit

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- **Consumer duty:** under the consumer duty, PSPs must avoid causing foreseeable harm (which would include a consumer falling victim to a scam relating to a firm's financial products due to the PSP's inadequate systems); and
- **"On us" APP fraud reimbursement:** if PSPs plan to use internal book transfers (also called "on us" or intra-firm payments, where both the sending and receiving payment accounts are held with the same firm or group), consumers may be more exposed to APP fraud – as such, the relevant PSP should discuss this in advance with the FCA.

## Other UK updates

### UK Finance work on new payment and settlement capabilities in banking sector

On 17 September 2024, UK Finance (UKF) published a [press release](#) regarding its "*regulated liability network (RLN) experimentation phase*", on which it has been working with eleven of its members.

Described as a new type of financial market infrastructure that can deliver new capabilities for payments and settlement, including tokenisation and programmability, UKF highlighted a number of potential benefits including reducing fraud, improving efficiency in the home buying process, and reducing the cost of failed payments in the UK.

In particular, the UKF suggests that an RLN could be of use in relation to the BoE's approach to innovation in money and payments, as set out in the BoE's July 2024 discussion paper.

### Payment Services (Amendment) Regulations 2024 published

On 9 October 2024, the [Payment Services \(Amendment\) Regulations 2004 \(SI 2024/1013\)](#) were published and will come into effect on 30 October 2024.

The amendment regulations amend the Payment Services Regulations 2017 (which require PSPs to execute payment transactions within maximum time limits), so that a payer's PSP can delay the crediting of the payee's PSP's account for certain in-scope payments from D+1 by up to a further 72 hours, (that is, D+4). The payer's PSP can delay where, within a specified time, the PSP establishes reasonable grounds to suspect the order has been made subsequent to fraud or dishonesty perpetrated by a third party (which may include the payee).

The delay should be used to enable the PSP to determine whether the order should be executed and must not exceed a specified time limit.

### PSR updates powers and procedures guidance

On 20 September 2024, the PSR published an [updated version](#) of its powers and procedures guidance, which was originally published in 2015 and last updated in 2020. The updated guidance – which was a result of a consultation period reflecting changes to the PSR's management structure – includes the PSR's:

- role and ways of working; and
- powers to take regulatory action under the Financial Services (Banking Reform) Act 2013, including its decision-making process and the process for appeals.

### Individual pleads guilty to illegally operating crypto ATMs

On 30 September 2024, the FCA published a [press release](#) announcing that an individual has pleaded guilty to five offences relating to illegally operating crypto ATMs (which allow individuals to buy or convert funds into cryptoassets), the first UK conviction of its kind. Sentencing will take place in due course.

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## Fintech, digital assets, payments and consumer credit

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Businesses seeking to provide cryptoasset services falling within the scope of the Money Laundering, Terrorist Financing and Transfer of Funds (Information on the Payer) Regulations 2017 must be registered with the FCA. Currently, there are no legal crypto ATM operators in the UK.

### Approach to implementing and operating Digital Securities Sandbox confirmed

On 30 September 2024, the BoE and the FCA published a [joint policy statement](#) (PS24/12), final guidance and other materials setting out their approach to implementing and operating the Digital Securities Sandbox, the first financial market infrastructure sandbox to be established under powers granted by the Financial Services and Markets Act 2023.

The sandbox (that will allow firms to use developing technology, such as distributed ledger technology, in the issuance, trading and settlement of securities), is now open to applications.

### BoE response to discussion on longer RTGS and CHAPS operating hours

On 3 October 2024, the BoE published a [response paper](#) regarding a possible extension to Real-Time Gross Settlement (RTGS) and CHAPS operating hours. Although the BoE expresses a preference for a first-stage extension of 4.5 hours in the morning (with settlement starting at 1.30 am), no extension is expected before 2027.

The BoE now plans to work with industry to shape future RTGS and CHAPS settlement hours, and to publish a consultation paper in 2025 setting out a more detailed proposal.

### EU updates

#### European Commission adopts delegated regulations under MiCA on complaints handling

On 30 September 2024, the European Commission adopted a delegated regulation [specifying](#) the requirements, templates and procedures for the handling of complaints relating to asset referenced tokens under the Markets in Crypto-Assets Regulation (MiCA).

On 1 October 2024, it adopted a delegated regulation [specifying](#) the requirements, templates and procedures for the handling of complaints by cryptoasset services providers under MiCA.



**Nikki Worden, Partner**

T: +44 20 7105 7290

[nikki.worden@osborneclarke.com](mailto:nikki.worden@osborneclarke.com)



**Paul Anning, Partner**

T: +44 20 7105 7446

[paul.anning@osborneclarke.com](mailto:paul.anning@osborneclarke.com)



**Paul Harris, Partner**

T: +44 20 7105 7441

[paul.harris@osborneclarke.com](mailto:paul.harris@osborneclarke.com)



**Seirian Thomas, Senior Knowledge Lawyer**

T: +44 20 7105 7337

[seirian.thomas@osborneclarke.com](mailto:seirian.thomas@osborneclarke.com)





# Food law

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# Food law

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## New Regulatory Innovation Office

The UK government has launched the Regulatory Innovation Office (RIO) to streamline regulatory processes and support the swift market entry of innovative products and services.

One of the four initial areas of focus for the RIO is on engineering biology, which can create new products such as cultivated meats. This initiative is part of a broader strategy to attract investment and improve regulatory collaboration. Read our [Insight](#) for more.

## Regulatory sandbox for cell-cultivated products

The government announced that a £1.6 million award has been given to the Food Standards Agency (FSA) to create a [regulatory sandbox](#) for cell-cultivated products (CCPs).

The sandbox will offer pre-application support to CCP companies and answer key questions that must be addressed before they can enter the market; for example, around labelling. It will allow businesses to test new developments under regulatory supervision and, with the newly-launched RIO facilitating product approval, it is hoped this will reduce the time and cost of applying for regulatory approval helping get products to market quicker.

The announcements of the RIO and sandbox underscores the government's commitment to bringing innovative foods, such as alternative proteins and novel foods, to market.

## Government to introduce regulations under Precision Breeding Act

At the World Agri-Tech Innovation Summit on 30 September, minister for food security and rural affairs, Daniel Zeichner, [announced](#) that the government will introduce secondary legislation under the Precision Breeding Act as soon as parliamentary time allows.

The press release states that the legislation will simplify the authorisation process for bringing new products to market, to make "*things fairer for SMEs and boosting investment*", and will allow precision-bred products to be rolled out across the country. It also adds that measures will be introduced to reduce the use of pesticides.

This announcement, alongside the establishment of the RIO, could lead to an advancement in the development of precision-bred products in the near future, and businesses should stay informed about progress in this field.

## FSA issues guidance on caffeine in food supplements

The Food Standards Agency (FSA) and Food Standards Scotland (FSS) have issued [guidance](#) on caffeine in supplements following an incident where a man died after miscalculating the amount of caffeine powder he was meant to use.

The [guidance for businesses](#) sets out the legislation and registration requirements as well as advice for food business operators. This includes providing clear dosage guidance, complying with labelling requirements, and ensuring for those products sold on online platforms, the information is accurate. Businesses placing supplements containing caffeine on the market should refer to this guidance to ensure they are compliant.

## Government not to proceed with GB wide 'not for EU' labelling

The government [announced](#) on 30 September that it will **not** be proceeding with the introduction of "not for EU" labelling across Great Britain from 1 October 2024. The update does however outline that it "*will develop legislation to apply 'not for EU' labelling in Great Britain in the future in a targeted way, if there is evidence of need.*"

As previously [reported](#), the "Not for EU" label still needs to be affixed to those in-scope agri-food products which are being placed on the Northern Ireland market via the Northern Ireland Retail Scheme ("the green lane"). Phase 2 of those products required to be labelled came into force on 1 October 2024.

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# Food law

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This means that from 1 October 2024, all prepacked meat, prepacked meat products, meat packed and dairy products needs to be labelled with "Not for EU" if they are being moved between GB to Northern Ireland via the [Northern Ireland Retail Movement Scheme](#).

## Consultation on best practice guidance - allergen information for non-prepacked foods

The Food Standards Agency (FSA) has launched a [consultation](#) to develop a consistent approach to allergen labelling for food business operators providing non-prepacked food. Currently businesses are required to tell customers if the food they are serving contains any of the 14 mandatory allergens, choosing how to provide this information whether it be written or verbal.

The FSA is now proposing to update its [best practice guidance](#) to state that **written** allergen information is to be made readily available and presented, **and** ensure staff can support this with a conversation. This written allergen information should be easy to use, clear, comprehensive and accurate.

In regards to presenting this information, the guidance states that businesses can choose whether to provide the information using words or symbols with accompanying words. If symbols are used, the name of the allergen should form part of it (for example, be written underneath). However, if the allergen name does not make up part of the symbol, a legend or key with the allergen name in written form, clearly defining which allergen each symbol represents, must be present allowing easy cross-referencing for consumers.

In addition, the guidance emphasises the importance of conversations, including encouraging consumers to make businesses aware about allergen requirements and ensuring staff are asking about any requirements. The guidance adds that when allergen requirements arise, businesses should decide who is best place to deal with them. Further, food businesses should ensure staff are trained to have a conversation about allergens, as well as deciding if additional safeguards should be used, such as messages on a sign, for example, *"Please talk to us if you have a food allergy, intolerance or coeliac disease. We want to cater safely for everyone"*.

The consultation closes on 27 November 2024 and businesses should consider whether they wish to respond. The FSA will collate the responses they receive and aim to publish the updated guidance in early 2025.

## Committee calls on government to develop new strategy to fix food system

The House of Lords Food, Diet and Obesity Committee has published a [report](#) calling on the government to develop a long-term new strategy to fix our food system which it describes as "*broken*". The committee outlines this strategy should be accompanied by a new legislative framework which gives the FSA "*independent oversight of the food system and responsibility for reporting to Parliament on progress against targets to reduce sales of less healthy food and associated health outcomes*." As well as this, the report sets out a number of further recommendations for the government, including to:

- introduce mandatory front-of-pack nutrition labelling that clearly distinguishes healthier and less healthy products;
- ban location and price promotions of HFSS (high in fat, salt and sugar) food and drink by out-of-home businesses with more than 50 employees, and for smaller out-of-home businesses and franchise premises if practicable;
- make large food businesses (those with more than 250 employees) report on the healthiness of their food sales; and
- ban the advertising of less healthy food across all physical and digital media by the end of this parliament.

The government should aim to, if possible, respond to the report within the next two months.

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## Food law

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



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



**Anna Lundy, Associate Director**  
T: +44 20 7105 7075  
anna.lundy@osborneclarke.com



## Health and Safety

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# Health and Safety

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## World Mental Health Day

On 10 October, it was World Mental Health Day. In light of this, the Health and Safety Executive (HSE) [reminded](#) employers of their legal duty to prevent work-related stress and support good mental health in the workplace by conducting risk assessments and implementing necessary measures.

The HSE has a number of resources to assist businesses including its [Working Minds campaign](#) and its [risk assessment template](#). Businesses should ensure that mental health is managed properly within the workplace as well as influencing and promoting positive mental health outside of work.

## Terrorism (Protection of Premises) Bill: next stages

The bill has received its second reading in the House of Commons and will now move to the Public Bills Committee. The first sitting of the Public Bill Committee is [expected](#) to be on Tuesday 29 October. Views on the bill are [invited](#) in a call for evidence.

The deadline for submitting responses is currently expected to be 19 November but may be earlier if the committee concludes its consideration of the bill before then.

Anyone with submissions to make to the Public Bill Committee about the current form of the bill, is strongly advised to submit written evidence as soon as possible.

If you missed our recent Eating Compliance for Breakfast webinar on the bill, you can [see the slides](#) and [view the recording](#).

## Health and Safety at Work etc. Act 1974 (Amendment) Bill 2024-25

A [private members' bill](#) has been introduced in the House of Commons to amend the Health and Safety at Work etc. Act 1974 to place a requirement on employers to take proactive measures to prevent violence and harassment in the workplace; to make provision for protections for women and girls in the workplace; and to require the Health and Safety Executive to publish a Health and Safety Framework on violence and harassment in the workplace, including violence against women and girls in the workplace.

The first reading in the House of Commons was on 21 October, and the second reading is scheduled for 29 November 2024. Private members' bills rarely become law, but even if they do not, they can be politically influential on particular issues and affect legislation indirectly.



**Mary Lawrence, Partner**  
T: +44 117 917 3512  
[mary.lawrence@osborneclarke.com](mailto:mary.lawrence@osborneclarke.com)



**Matthew Vernon, Senior Associate**  
T: +44 117 917 4294  
[matthew.vernon@osborneclarke.com](mailto:matthew.vernon@osborneclarke.com)



**Reshma Adkin, Associate Director**  
T: +44 117 917 3334  
[reshma.adkin@osborneclarke.com](mailto:reshma.adkin@osborneclarke.com)



**Georgia Lythgoe, Senior Associate**  
T: +44 117 917 3287  
[Georgia.lythgoe@osborneclarke.com](mailto:Georgia.lythgoe@osborneclarke.com)



**Alice Babington, Associate**  
T: +44 117 917 3918  
[alice.babington@osborneclarke.com](mailto:alice.babington@osborneclarke.com)



# Modern slavery

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# Modern slavery

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## Modern Slavery Act 2015: UK select committee calls for urgent reforms

A House of Lords select committee has published a [report evaluating the impact and effectiveness of the Modern Slavery Act \(MSA\)](#) 2015 following the UK Parliament's request for a review.

The committee's report, "The Modern Slavery Act 2015: becoming world-leading again", published on 16 October is generally critical of the existing legislation, with the committee stating that the UK's response to modern slavery "*has not kept up with the advances of other nations*".

The House of Lords Select Committee on the Modern Slavery Act 2015 has highlighted areas where the UK has fallen behind in its approach to tackling modern slavery and offers a series of recommendations for improvement. Read more in our [Insight](#).

## European Parliament approves Regulation on forced labour products

The European Parliament has [approved](#) the final text of the [Regulation on forced labour products](#) which will prohibit products made with forced labour going on the EU market. The Council is expected to formally adopt the text without further amendments.

After this, the regulation will be published in the Official Journal of the European Union and will enter into force on the day following its publication. The regulation will apply three years after its date of entry into force.



**Chris Wrigley, Associate Director**  
T: +44 117 917 4322  
[chris.wrigley@osborneclarke.com](mailto:chris.wrigley@osborneclarke.com)



**Alice Babington, Associate**  
T: +44 117 917 3918  
[alice.babington@osborneclarke.com](mailto:alice.babington@osborneclarke.com)





# Products

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# Products

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Jump to: [General / digital products](#) | [Product sustainability](#) | [Life Sciences and healthcare](#)

## General / digital products

### UK

#### Regulatory Innovation Office

The UK government has launched the Regulatory Innovation Office (RIO) to streamline regulatory processes and support the swift market entry of innovative products and services. Initially focusing on engineering biology, AI and digital healthcare, connected and autonomous technology, and the space sector, the RIO aims to reduce regulatory barriers and enhance the UK's competitive edge in innovation. This initiative is part of a broader strategy to attract investment and improve regulatory collaboration and will affect businesses looking to place innovative products on the market. Read our [Insight](#) for more.

#### Call for evidence on common charger for electrical devices

The EU has adopted the "Common Charger Directive" which requires the use of USB-C based charges for mobile phones and other portable electronic devices placed on the EU market from December 2024. The Office for Product Safety and Standards (OPSS) is currently [seeking views](#) from manufacturers, importers, distributors and trade associations as to whether the UK should also adopt this initiative.

The OPSS recognises that manufacturers are likely to adopt a similar approach to the EU Common Charger Directive on a voluntary basis in order to avoid supply chain complexity and therefore expect it to become industry standard. As such, the government is looking for comments as to whether it is beneficial to implement this change by amending the Radio Equipment Regulations 2017 using the new powers given under the Product Regulation and Metrology Bill, which is currently making its way through Parliament.

The call for evidence closes on 2 December 2024.

#### Consultation launched on PAS 7055:2025 Button and coin batteries

BSI has published PAS 7055:2025 on button and coin batteries. This PAS specifies safety requirements for button and coin batteries up to 32 mm in diameter to mitigate the risk of ingestion and defines the safety requirements for manufacturers and producers. This PAS is also relevant for retailers and distributors of these products and can be [downloaded for free](#). A four-week consultation on this is currently running and comments are to be made by 28 October 2024.

Businesses whose products contain button and coin batteries should review the PAS and decide whether they wish to submit any comments.

#### Product Regulation and Metrology Bill has second reading

On 8 October, the Product Regulation and Metrology Bill had its [second reading](#) in the House of Lords and was broadly welcomed by the House. However, a key theme coming from the debate is that the bill lacks detail and without seeing the draft statutory instruments which will provide this detail, there is little for the Lords to scrutinise. Many members called on the government to bring forward draft regulations, as well as the government's response to the product safety review consultation, before committee stage.

Certain lords also welcomed the bill addressing products being sold online, noting that there is a need for clear and enforceable duties on online marketplaces to ensure product safety. Lithium-ion batteries were also discussed by a number of lords noting the increasing safety risk and calling for third-party safety certification and better regulation.

Other points raised by the Lords included the need for clarity on interaction with devolved competencies and the Windsor Framework; concerns about the adequacy of resources for enforcement authorities; and the importance of consulting stakeholders and ensuring parliamentary oversight of secondary legislation.

The committee stage is scheduled for 4 November 2024.

The Delegated Powers and Regulatory Reform Committee published a [report](#) scrutinising the bill. The committee criticised the bill for being "*skeleton legislation*," meaning it lacks substantive detail and instead grants broad powers to ministers. Additionally, the committee highlighted that the bill does not require consultation or set criteria for the exercise

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of these powers, reducing transparency and accountability. The committee stated that this is a departure from existing regulatory practices that often include consultation requirements. These findings will be fed back to the House of Lords.

The bill has also been [criticised](#) by the Lords Select Committee on the Constitution, which reiterated the concerns over the bill being skeleton legislation and the broad scope of powers it gives ministers, which it says inhibits parliamentary scrutiny.

### EU

#### Council formally adopt the new Product Liability Directive

On 10 October, the Council of the European Union [adopted](#) the new Product Liability Directive.

The new directive updates civil liability rules to reflect the digital and circular economy. Key elements include:

- Digital products: extending the definition of a "product" to include digital files and software - this includes software-as-a-service and AI.
- Circular economy: shifting liability when products are repaired by third parties outside the original manufacturer's control.
- Disclosure of evidence: easier access to evidence for consumers.
- Non-EU manufacturers: liability for damages from non-EU products.
- Burden of proof: potential to reverse the burden of proof under certain conditions.

The directive will be published in the Official Journal of the European Union in the coming weeks and will enter into force 20 days following its publication. Once in force, Member States of the EU have until two years to transpose the new directive into national law.

You can track the directive on our [Digital Regulatory Timeline](#).

#### Council formally adopts Cyber Resilience Act

The Council of the EU [adopted](#) the [Cyber Resilience Act](#) on 10 October. This new horizontal regulation introduces stringent cybersecurity requirements for products with digital elements, such as connected home devices. Key elements include:

- EU-wide cybersecurity standards for hardware and software.
- CE marking to indicate compliance.
- Application to all connected products, with some exceptions.

The directive will be published in the Official Journal of the European Union in the coming weeks and will enter into force 20 days following its publication. Once in force, the full regulation will apply in around 36 months, with some provisions taking effect earlier.

You can track the regulation on our [Digital Regulatory Timeline](#).

#### European Parliament approves Regulation on forced labour products

Please see Modern slavery.

### Product sustainability

### UK

#### Government to ban single-use vapes from 1 June 2025

The government has laid [legislation](#) which will ban the sale of single-use vapes from 1 June 2025. Businesses will have until this date to sell any remaining stock ahead of the ban coming into force. The government explains that this ban will not only protect the environment by reducing waste and pushing towards a circular economy, but also reduce appeal to

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young people. A single-use vape is one which is not refillable and/or rechargeable. The ban will be enforced by Trading Standards within each local area, using civil penalties.

The Scottish, Welsh and Northern Irish governments will also be introducing equivalent legislation, with the same implementation date of 1 June 2025, with [Wales](#) already confirming its intention to do so.

### Draft EPR regulations laid before Parliament

The draft [Producer Responsibility Obligations \(Packaging and Packaging Waste\) Regulations](#) 2024 have been laid before parliament. The regulations implement the extended producer responsibility (EPR) scheme for packaging waste.

The key change from the previous draft of the regulations (see this earlier [Regulatory Outlook](#)) is that the provision on mandatory recyclability labelling has been removed. The government is delaying the implementation of this requirement as they want to see what the EU will do under the Packaging and Packaging Waste Regulation to ensure a consistent approach to minimise costs and complexity for businesses. They will introduce the recycling labelling requirements via amending regulations when ready to do so.

### Design for Life Roadmap: Building a circular economy for medical technology

Please see the Lifesciences and healthcare section.

## EU

### FAQs on Ecodesign for Sustainable Products Regulation

The European Commission has published [FAQs](#) on the Ecodesign for Sustainable Products Regulation (ESPR) which covers, among other things: scope of the regulation; interplay with others regulations, including the Packaging and Packaging Waste Regulation, the Right to Repair Directive, and the Corporate Sustainability Reporting Directive; questions around the Digital Product Passport (DPP), including a provisional timeline, noting they expect the first DPP provisions in mid-2027; details on the ecodesign forum, including who can join the forum which includes non-EU based parties; and preparation of the delegated acts and working pan.

This document will be helpful for businesses in understanding the ESPR and how it will affect them and their products.

### FAQs on EU PFAS restriction

The European Environmental Bureau has published [FAQs](#) on the proposal restricting the use of PFAS presented to the European Chemicals Agency (ECHA) in February 2023. The aim of this document is to clarify misinterpreted information that has disseminated since the proposal was put forward. As a reminder, the ECHA is still yet to publish further information following its consultation on the proposal (see this earlier [Regulatory Outlook](#) for more). While they await this consultation response, businesses should use this FAQ document to remind themselves of the proposal on restricting PFAS and how it will affect them.

### Commission restricts use of a sub-group of PFAS chemicals

The European Commission has [adopted](#) new measures under REACH to restrict the use of undecafluorohexanoic acid (PFHxA) and PFHxA -related substances. These are sub-groups of PFAS.

The restriction will ban the sale and use of PFHxA in consumer textiles, such as rain jackets; food packaging, like pizza boxes; consumer mixtures such as waterproofing sprays; cosmetics; and in some firefighting foam applications. It does not affect other applications of PFHxA, for example in semiconductors, batteries or fuel cells for green hydrogen.

The announcement outlines that this restriction is distinct from the [potential restriction on the entire PFAS group](#) which the European Chemicals Agency (ECHA) is assessing following a 2023 proposal by five European governments.

From 10 October 2026 the restriction will apply to: textiles, leather, furs and hides in clothing and related accessories for the general public; footwear for the general public; paper and cardboard used as food contact materials; mixtures for the general public; cosmetic products. The concentration limits are 25 ppb for PFHxA and its salts, 1,000 ppb for PFHxA-related substances. This will then apply to textiles, leather, furs, and hides (other than those in clothing and related accessories for the general public) from 10 October 2027.

From 10 April 2026 restrictions will come into place for firefighting foams and concentrates for training and testing (except functional testing with contained releases) and firefighting foams and concentrates for public fire services (with exceptions

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for industrial fires at establishments covered by Directive 2012/18/EU). The concentration limits are 25 ppb for PFHxA and its salts, 1,000 ppb for PFHxA-related substances. From 10 October 2029 restrictions for firefighting foams and concentrates for civil aviation (including civilian airports) will come into effect.

### Life Sciences and healthcare

#### UK

#### MHRA launches 2024/25 business plan focusing on harnessing new technology

The Medicines and Healthcare products Regulatory Agency (MHRA) has published its [2024/25 business plan](#) which has a particular focus on innovation and harnessing medical technology. Within the plan, the MHRA sets out its four priorities for the coming year which are to:

- Maintain public trust through transparency and proactive communication, including working to address health inequalities.
- Enable healthcare access to safe and effective medical products.
- Deliver scientific and regulatory excellence through strategic partnerships.
- Become an agency where people flourish alongside a responsive customer service culture.

The plan also provides initiatives that the MHRA will be introducing, which includes, among others:

- Boost how the it handles enquiries by end Q3 (which could give businesses some extra practical support, particularly for innovative products).
- Review the International Recognition Procedure by Q3 to make sure it is working as intended (which could improve routes to market in the UK for pharmaceutical manufacturers).
- Deliver the 2024/25 milestones for medical devices international recognition (which could speed up authorisation for medical devices and health-tech already approved in other jurisdictions).
- Prepare legislation to deliver a new UK clinical trials regulatory framework by end Q4 (which would finally see action following the O'Shaughnessy Review of 2023 into clinical trials).
- Keep to the road map on delivering new UK medical devices regulations in 2025.

The MHRA's focus on innovation is expected to be facilitated by the creation of the new RIO - which will initially be focusing on digital healthcare - and so we expect to see further developments in this space and it will be interesting to see how the RIO supports the MHRA in delivering its priorities.

#### UK government invest £118 million investment into new research hubs for medical technology

The government has this month announced a [£118 million investment into five new research and partnership hubs](#) to develop new medical technologies, such as AI models that can detect cancer. This investment, alongside the RIO, underlines the government's commitment to advancing technology in the healthcare sector.

#### MHRA's AI Airlock regulatory sandbox for AIaMD now open

The AI Airlock is a regulatory sandbox for AI as a medical device (AIaMD) (previously covered [here](#)). The MHRA is now [calling](#) for applications from manufacturers and developers of AI medical devices to join the regulatory sandbox. The project is intended to help the MHRA identify and address challenges in regulating AI medical devices to help cut down the time to bring AI medical devices safely to market. Businesses that manufacture and develop AIaMD should decide whether they wish to apply to the sandbox.

#### Post-market surveillance regulations laid in Parliament

The [draft Post-Market Surveillance \(PMS\) amending regulations](#) were laid in Parliament on 22 October 2024. These draft regulations amend the Medical Devices Regulations 2002 to insert new post-market surveillance requirements to bring the UK regulatory framework closer in line with international best practice.

The key changes include:

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- **PMS system:** manufacturers are required to have a PMS system for each device, proportionate to the risk posed by the device.
- **Investigation and reporting of serious incidents:** enhanced serious incident reporting obligations for manufacturers requiring them to report any serious incidents involving their devices to the secretary of state and investigate serious incidents and submit a final report to the secretary of state.
- **Field safety corrective actions (FSCA) and field safety notices (FSN):** clearer obligations on manufacturers to consider conducting a FSCA to prevent or reduce the risk of a further serious incident. Accompanied by detailed requirements relating to FSN to better target patients and users at risk.
- **Periodic safety update reports:** more stringent requirements for manufacturers to conduct periodic reviews of their PMS data in a bid to support manufacturers in earlier detection of trends/signals that may have an impact on the safety of a medical device.

The draft PMS SI will be debated in Parliament and is expected to come into force in the summer of 2025 following a six-month implementation period. Manufacturers should start to familiarise themselves with the new regulations to understand the changes and what their new obligations will be.

### **New regulations laid for medicines manufactured at the 'point of care' and modular manufacturing**

The draft [Human Medicines \(Amendment\) \(Modular Manufacture and Point of Care\) Regulations 2024](#) have been laid to amend the Human Medicines Regulations 2012 and the Medicines for Human Use (Clinical Trials) Regulations 2004 to provide a new regulatory framework for medicines manufactured at the "point of care" (POC), and modular manufacturing (MM), where products are manufactured in modular, relocatable units.

There is currently no legislative provisions for POC and MM of medicines and the current regulations are designed for medicines produced at a few sites and distributed globally, which is not suitable for products manufactured at POC and MM. These products often have short shelf-lives or are highly personalised, necessitating manufacturing at or near the point of care.

Therefore the amending regulations will allow for medicines to be manufactured and supplied at the POC and support MM. They come into force six months after the date they are made. Detailed guidance on the new framework will be published by the MHRA in advance of the regulations coming into force.

### **Unlocking the potential of UK healthtech**

The Office for Life Sciences commissioned KPMG to identify and systematically map out manufacturing and research and development activity across the UK healthtech sector. The report, titled "[Unlocking the potential of UK HealthTech](#)", has been published and highlights the significant opportunities for the UK to become a global leader in healthtech innovation. The report found, among other things, that UK healthtech businesses are committed to manufacturing in the UK, but found that the current regulatory landscape is a barrier to innovation, affecting R&D and manufacturing. Other challenges include that NHS procurement is focused on cost optimisation and as such procurement policies suppress innovation adoption.

The report sets out a number of recommendations including streamlining regulation and embracing value-based procurement so the NHS prioritises long-term innovation and healthcare benefits over cost considerations.

With the life sciences sector being one of the government's growth-driving sectors, as set out in its recently published [Industrial Strategy](#), we anticipate that these findings will assist the government in driving reform within the sector.

### **Changes proposed to the statutory scheme to control the cost of branded health service medicines**

The government has published its consultation [response](#) on proposals to amend the statutory scheme to control the cost of branded health service medicines, alongside an impact assessment. This scheme sits alongside the 2024 voluntary scheme for branded medicines pricing, access and growth (VPAG), that control the costs of branded medicines to the NHS. Following the responses received, the following changes will be implemented:

- Adjusting baseline sales in the statutory scheme by £150 million in 2025, £330 million in 2026, and £380 million in 2027.
- Implementing a differentiated approach to setting payment percentages for newer and older medicines.

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- Setting the headline payment percentage for newer medicines at 15.5% in 2025, 17.9% in 2026, and 20.1% in 2027.
- Establishing the basic payment percentage for older medicines at 10.6% in 2025, 11% in 2026, and 10.9% in 2027, with a top-up payment percentage for older medicines ranging from 1% to 25%, if applicable, based on the level of observed price erosion from a reference price.
- Introducing exemptions to the top-up payment percentage for relevant plasma-derived medicinal products and company sales totalling less than £1.5 million of a health service medicine in a specific virtual therapeutic moiety each year.
- Raising the exemption threshold from scheme payments for small companies, from sales below £5 million to sales of less than £6 million.

### **Design for Life roadmap: building a circular economy for medical technology**

The Department of Health and Social Care has launched a [Design for Life](#) roadmap to reduce the amount of single-use medtech used in the NHS and reduce reliance on products imported from foreign countries. Ensuring circularity in these products will mean looking at designing, procuring and the process of medical products that allows them to be re-used, re-manufactured or recycled. This roadmap feeds into the government's wider aim of moving towards a circular economy.

The roadmap is divided into six problem statements which are to be addressed by 30 actions to deliver a 2045 vision. The six problem statements are as follows, with some of the actions highlighted as well:

**Leadership and alignment:** unclear direction and misaligned strategies across the value chain lead to inconsistencies, inefficiencies and inertia, hindering meaningful, coordinated progress.

- **Actions include:** presenting a full ecosystem roadmap (2024-2027); develop circular key performance indicators (KPIs) and standardised metrics (priority action) (2027-2029)

**Behavioural change:** the medtech landscape is one in which linear products are the default choice, maintained by a lack of value placed on circular systems and limited support for change.

- **Actions include:** develop training and skills framework (2027-2029); develop behavioural change plan (2029-2031)

**Commercial incentivisation:** stakeholders are insufficiently incentivised, or in some instances are disincentivised to choose and deliver circular solutions.

- **Actions include:** circularity of medtech embedded in engagements and strategies (2024-2027); deliver value-based procurement for circularity of medtech products (2027-2029)

**Regulations and standards:** UK regulatory regimes and technical standards predate circularity and have potential to further enable the medtech sector to recognise opportunities and align internationally.

- **Actions include:** Develop and maintain circular standards (including vocabulary); align regulatory environment for circular medtech with global counterparts; establish medtech as a core sector within UK circular economy work (2029-2031)

**Physical and digital infrastructure:** the existing physical and digital infrastructure and supporting services hold back the scaling of circular solutions, both locally and nationally.

- **Actions include:** develop a decontamination infrastructure framework; establish a materials recovery and recycling framework (2029-2031)

**Transformative innovation:** the innovation ecosystem is not tailored to circular objectives, impeding development of solutions.

- **Actions include:** Establish a medtech innovation centre (2027-2029) and identify areas where circular design research is needed (2029-2031)

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Immediate actions include establishing governance structures, engaging with relevant strategies, precommercial collaboration, surveying stakeholders, and exploring opportunities for a medtech innovation centre. Priority research areas will focus on performance indicators, decontamination service models, regulatory barriers, and pilot projects for demonstrator products and services.

Businesses in this sector should keep abreast of developments with the roadmap and engage in any stakeholder consultations where relevant.



**Katie Vickery, Partner**

T: +44 20 7105 7250

[katie.vickery@osborneclarke.com](mailto:katie.vickery@osborneclarke.com)



**Peter Rudd-Clarke, Partner**

T: +44 20 7105 7315

[peter.ruddclarke@osborneclarke.com](mailto:peter.ruddclarke@osborneclarke.com)



**Veronica Webster Celda, Senior Associate**

T: +44 20 7105 7630

[veronica.webster@osborneclarke.com](mailto:veronica.webster@osborneclarke.com)



**Thomas Stables, Senior Associate**

T: +44 20 7105 7928

[thomas.stables@osborneclarke.com](mailto:thomas.stables@osborneclarke.com)





## Regulated procurement

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# Regulated procurement

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## Procurement Act: Litigation timing change

The Cabinet Office updated its guidance on [remedies](#) under the new Procurement Act 2023. Within this there are two timing changes to be aware of when contemplating procurement litigation under the Act:

1. The claim form must be served within four months of the date the claim form is issued.

This is a change from the requirement under the current regulations to serve it within seven days of being issued.

A contracting authority can serve a notice on the claimant requiring (1) service of the claim form within a set deadline or (2) discontinuance of the claim.

2. The claimant has 14 days to serve the Particulars of Claim **following service** of the claim form.

This has also changed from seven days **from issue** of the claim form under the current regulations. The time limits for service for any claims to procurements still covered by the current regulations will remain unchanged. Claims will continue to be under the existing regulations in relation to any procurements commenced before the Act comes into force on 24 February 2025 or call offs from any frameworks in place before that date.

REMEMBER: For the automatic suspension to be put in place, the contracting authority needs to be notified that a claim has been issued within the standstill period – however, the guidance has made it clear that this notification does not need to take the form of service of the claim form. (*"While it is expected that a claimant will serve the claim form on the contracting authority at the same time as notifying it of the commencement of proceedings where it wishes the automatic suspension to apply, as required by section 101 of the Act, this is not strictly required"*).

## Guidance published on the Central Digital Platform

The Cabinet Office has published [guidance](#) and a [factsheet](#) on the central digital platform (CDP) under the Procurement Act. The CDP will be where all UK contracting authorities publish information relating to procurements, including procurement notices, and will also be used to store core supplier information.

Once registered, suppliers will input their commonly used information and may then choose to share this with authorities they wish to bid to. Over time, the CDP will be the go-to place to find not only opportunities to bid for, but also for information on contracts that have been let, how the awarded supplier is performing and how contracts are being changed.

Suppliers only need to register at the point that they want to bid for a contract after the law comes into force on 24 February 2025, but we recommend this is done in good time before the first bid submission is due.

Suppliers and authorities should review both the guidance and factsheet to familiarise themselves with the CDP and what it will require of them.

## Survey on the National Procurement Policy Statement

The Government Commercial Function has opened a stakeholder [survey](#) inviting comments on the development of the new National Procurement Policy Statement (NPPS). This follows on from the government announcing the delay of the implementation of the new procurement regime as it wanted to withdraw and re-write the NPPS.

The survey closes at midday on 4 November 2024.

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## Regulated procurement

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**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, Associate Director**  
T: +44 117 917 3151  
kate.davies@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



**Gabrielle Li, Associate**  
T: +44 117 917 3233  
gabrielle.li@osborneclarke.com



# Sanctions and Export Control

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# Sanctions and Export Control

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## Office of Trade Sanctions Implementation launch

As [previously reported](#), the Office of Trade Sanctions Implementation (OTSI) officially launched on 10 October 2024.

The new unit, which sits within the Department for Business and Trade, will be responsible for the civil enforcement of certain trade sanctions relating to UK services and trade of sanctioned goods outside the UK. Applications may now be made to OTSI for licences for the provision of standalone services, including professional business services.

The following guidance pages have been updated to reflect OTSI's launch:

- [Providing professional and business services to a person connected with Russia.](#)
- [Applying for a licence to provide sanctioned trade services.](#)
- [Mandatory reporting for suspected breaches of trade sanctions.](#)
- [Reporting a suspected breach of trade sanctions.](#)

For further information on OTSI's new powers, see our [Insight](#).

## G7 issues guidance for industry on preventing Russian export controls and sanctions evasion

The UK, US, Canada, France, Germany, Italy and Japan (the G7) [published](#) guidance for industry on preventing Russian evasion of export controls and sanctions.

The guidance aims to help industry in identifying Russian evasion practices and to comply with Global Export Control Coalition (GECC) controls.

The joint guidance outlines the following areas:

- a list of items which pose a heightened risk of being diverted to Russia (the common high priority list);
- updated red flag indicators of potential export control and sanctions evasion;
- best practices for industry to address these red flags; and
- screening tools and resources to assist industry in conducting enhanced due diligence.

## OFSI issues monetary penalty for breach of Russia sanctions

The Office of Financial Sanctions Implementation (OFSI) [issued](#) a monetary penalty to Integral Concierge Services (ICSL) for breaches of the Russia sanctions regime.

This is only the second penalty issued by OFSI in relation to the sanctions implemented in the UK against Russia following its 2022 invasion of Ukraine.

ICSL was given a penalty of £15,000 for services provided to a designated person subject to an asset freeze. Between 2022 and 2023, ICSL made or received 26 payments amounting to £15,487.30 in connection with the services it was providing to the designated person, despite knowing or having reasonable cause to suspect these were in breach of financial sanctions in the UK.

This case was classified as "serious". Aggravating factors included the cumulative amount of the payments (although the majority were of lower value) and their repeated nature. While it did co-operate with the investigation and OFSI considered this to be a mitigating factor, this did not entitle it to a reduction in the penalty since ICSL had not make a voluntary disclosure.

OFSI stated that the case emphasises the importance of voluntarily disclosing breaches of the regulations to OFSI. Of the ten monetary penalties OFSI has imposed, five of these did not originate from voluntary disclosures.

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# Sanctions and Export Control

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See the full [penalty report](#). For further reading, see our [Insight](#) on the first monetary penalty issued by OFSI in 2019.

## OFSI general licences

- OFSI published general licence [INT/2024/5294388](#), which allows persons to make and facilitate payments in respect of UK government debt, including all securities issued by or on behalf of HM government. The licence, which takes effect from 14 October 2024, applies to all UK autonomous sanctions regulations, and is of indefinite duration.
- OFSI amended general licence [INT/2023/3179120](#), which allows UK designated persons to make permitted payments to water companies from a frozen UK bank account. The definitions for UK designated persons and return payments under the licence have been updated. The licence took effect from 21 September 2023 and is of indefinite duration.

## Update on Russia sanctions licensing for intra-corporate services

The Export Control Joint Unit within the Department for Business and Trade [announced](#) that from 31 October 2024, the provision of intra-corporate services will no longer be considered as grounds for licensing under [Russia \(Sanctions\) \(EU Exit\) Regulations 2019](#) (Russia sanctions regulations).

Following a review of the professional and business services sanctions under [Regulation 54C](#) of the Russia sanctions regulations, the UK government decided to remove the licensing consideration relating to the provision of such services from UK parent companies and their UK subsidiaries to their Russian subsidiaries.

Companies that still wish to provide intra-corporate services to their Russian subsidiary may seek a licence from the secretary of state under [Regulation 65 of the Russia sanctions regulations](#), provided they are able to demonstrate how the provision of services aligns with the overarching goals of the sanctions regime.

Licensing applications submitted before 31 October 2024 will not be affected.



**Greg Fullelove, Partner**

T: +44 20 7105 7564

[greg.fullelove@osborneclarke.com](mailto:greg.fullelove@osborneclarke.com)



**Kristian Assirati, Senior Associate**

T: +44 20 7105 7847

[kristian.assirati@osborneclarke.com](mailto:kristian.assirati@osborneclarke.com)



**Jon Round, Associate Director**

T: +44 20 7105 7798

[jon.round@osborneclarke.com](mailto:jon.round@osborneclarke.com)



**Chris Wrigley, Associate Director**

T: +44 117 917 4322

[chris.wrigley@osborneclarke.com](mailto:chris.wrigley@osborneclarke.com)



**Galina Borshevskaya, Senior Associate**

T: +44 20 7105 7355

[galina.borshevskaya@osborneclarke.com](mailto:galina.borshevskaya@osborneclarke.com)



**Carolina Toscano, Associate**

T: +44 20 7105 7086

[carolina.toscano@osborneclarke.com](mailto:carolina.toscano@osborneclarke.com)



**Telecoms**

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## Telecoms

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Nothing to report this month.



**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



**Matt Suter, Senior Associate**

T: +44 20 7105 7447

matt.suter@osborneclarke.com



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