



# **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.

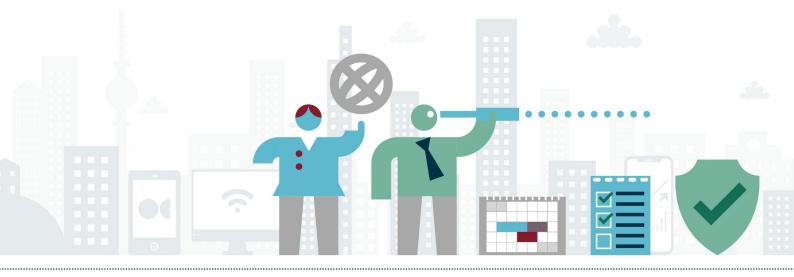
Key developments this month include:

- EU Commission publishes proposals for a new Green Claims Directive; reform of medicine and medical technologies regulation announced in the UK spring Budget; and right to repair proposals introduced by the EU.

March 2023

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Advertising and marketing

## Advertising and marketing

#### Greenwashing claims in the EU

The European Commission published its proposal for a <u>Directive on Green Claims</u>. The Commission's proposed legislation, known as the "Directive on substantiation and communication of explicit environmental claims", aims to regulate green claims specifically and protect consumers from greenwashing and misleading environmental claims.

For businesses the proposals, if implemented, will impose additional compliance obligations when making green claims including:

- Before making any environmental claim, traders will be obliged to undertake a life-cycle analysis based on widely
  recognised scientific evidence (if available). This life-cycle analysis will need to be made publicly available for
  consumers and for independent verification. Traders will be obligated to keep the life-cycle analysis under review
  and update when the science moves on or after five years.
- If the trader decides to make a mission statement claim about how they intend to improve the environmental credentials of their business, they will be obligated to provide a deadline for when they intend to complete their mission.
- The legislation codifies and expressly prohibits environmental claims which may be misleading in certain ways, for example because the environmental benefit is a result of a legal obligation or market standard for that product or service.

See our Insight for more.

The European Commission has opened a feedback period for the adopted proposal which closes on 18 May 2023.

### ASA discusses the ethics of automating regulation

The UK Advertising Standards Authority (ASA) has published an <u>article</u> on the ethics of automating regulation, which discusses the potential and the risks of artificial intelligence (AI) and machine learning in dealing with the challenges of digital advertising regulation.

The ASA's data science team already uses these technologies to help them identify claims about climate impact, and put them to experts for assessment. However, AI and machine learning pose certain risks, and the ASA acknowledges that the efficiency improvements gained from these tools cannot outweigh the risk of possible harm to consistency and transparency principles. The ASA notes that well-designed AI systems should be backed up by human oversight, and recognises that some processes cannot be automated at all (for example, responding to a complaint), and that AI should be used only where appropriate.

## The US warns companies to be cautious about advertising their AI products

The US Federal Trade Commission (FTC), responsible for antitrust law and consumer protection, has published a blog post: "Keep your Al claims in check", to address its concerns about the advertising of Al-powered products in the US.

It has highlighted some of the issues it is concerned about when companies advertise their Al products, and provided guidance around the following guiding questions, namely:

- Are claims regarding what the AI product can do exaggerated? The claim should not go beyond current AI capabilities, and claims should be scientifically substantiated.
- Does the company promise that an Al product can do something better than a non-Al product? Proof for a comparative claim is required.
- Is the company aware of any risks that the Al product could pose? It is important to evaluate risks before putting the product on the market.
- Does the product actually contain any AI technology? The FTC notes that using AI as part of the development process does not qualify as offering an AI-powered end product.

The FTC also highlighted its existing Al advertising quidance which provides more detail.

## Advertising and marketing

UK's Ofcom opens consultation on HFSS advertising restrictions

Please see Food law.

EU consumer group call for ban on food climate neutral claims

Please see Food law.



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Bribery, fraud and anti-money laundering

## Bribery, fraud and anti-money laundering

### Are you prepared for the UK Economic Crime Levy?

HM Treasury published draft <u>regulations</u>, together with an <u>explanatory memorandum</u>, on 28 February that will revise and make further provision for the assessment, payment, collection, and enforcement of the Economic Crime Levy (ECL).

The aim of the levy, which will be paid by the anti-money laundering (AML) regulated sector, is to raise £100m a year to help fund "new and uplifted" anti-money laundering and economic crime-tackling capabilities in line with the government's objectives under its 2019 Economic Crime Plan.

Our <u>Insight</u> considers which entities will be required to pay the ECL and the steps they will need to take to comply with the ECL process, based on the latest guidance from HMRC and the Financial Conduct Authority (FCA).

#### Updated guidance on SARs

The UK Financial Intelligence Unit (UKFIU), which is part of the National Crime Agency, has produced an updated Reporters Booklet, which contains a summary of feedback from law enforcement agencies on their use of suspicious activity reports (SARs).

These booklets are aimed at sharing and encouraging best practice among reporters, which include financial institutions, professionals such as solicitors, accountants and estate agents, or private individuals, where they have a suspicion or knowledge of money laundering or terrorist financing.

### **Economic Crime and Corporate Transparency Bill**

The <u>Economic Crime and Corporate Transparency Bill 2022</u>, which aims to help in identifying and preventing economic crime and reform the role of Companies House, is <u>progressing through the House of Lords</u>.

The bill is currently at the Committee stage, which is scheduled to take place on 27 March 2023. The bill's amendments currently include the introduction of a "failure to prevent" fraud, false accounting or money laundering offence. See our <a href="Insight">Insight</a> for further information on the bill.

### Government response to House of Lords Fraud Committee report

The House of Lords has published the <u>government's response</u> to the House of Lords Fraud Act 2006 and Digital Fraud Committee report "Fighting Fraud: Breaking the Chain", which was <u>published in November 2022</u>.

The government response addresses each of the committee's 65 recommendations, and in relation to tackling fraud, the government has reiterated its commitment to addressing the new for a new failure to prevent offence through the Economic Crime and Corporate Transparency Bill (about which, see above).

#### **Economic Crime Levy to be collected from July 2023**

A reminder that the government introduced an <u>economic crime levy</u> on anti-money laundering regulated businesses including credit institutions, independent legal professionals and estate agents, to fund the fight against economic crime.

The levy, which will be determined according to the businesses' UK revenue, will be paid annually to one of the following collection entities, HM Revenue and Customs, the Financial Conduct Authority, or the Gambling Commission. To ensure firms are charged the right amount, impacted firms must <u>submit</u> their data via a new Reg Data Report (FIN074) from 1 April. Failure to submit in time may result in a £250 administrative fee.



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## Competition

#### UK sustainability guidance

On 28 February 2023 the Competition and Markets Authority (CMA) published <u>draft guidance</u> on the application of competition law to agreements between competitors that pursue environmental sustainability objectives.

The CMA explains how to assess environmental sustainability and climate change agreements under competition law and discusses environmental sustainability agreements that are unlikely to infringe the rules.

Examples of environmental sustainability agreements unlikely to infringe competition law include:

- · agreements affecting the internal corporate affairs of businesses;
- campaigns to raise awareness of environmental issues within the industry;
- creating a database to collate the environmental credentials of suppliers and customers.

Any agreement that does not affect the way businesses compete with each other is likely to be permissible under competition law.

For an agreement to be permitted under competition law, the benefits of the agreement have to outweigh any associated harms. The CMA takes a more permissive approach towards defining these benefits in relation to "environmental sustainability agreements" and "climate change agreements". For these types of agreement, the scope of consumers is widened to include those on related markets in the case of "environmental sustainability agreements" and to wider society in the case of "climate change agreements". This more permissive approach should, in practice, enable more agreements to benefit from automatic exemption from competition law.

The CMA is consulting on this guidance until 11 April 2023. Read our <u>Insight</u> on this development, which examines the changes in greater detail. Please get in touch with one of our experts if you would like advice on considering how to respond to this consultation.

## NSIA - one year on

The <u>National Security and Investment Act</u> came into force on 4 January 2022. The NSIA has given the government the power to investigate and intervene in a wide range of transactions that would fall outside the scope of UK merger control.

It is estimated that there may have been over 1,000 mandatory notifications in 2022. We understand that around 95% of these notifications were cleared unconditionally, with around 50 being subject to in-depth scrutiny – following which the majority ultimately received unconditional approval.

Of the deals that were not cleared unconditionally, five ended up being blocked altogether and 14 deals permitted subject to conditions. The majority of these involved Chinese or Russian entities. The approval conditions included: requiring a UK government attendee to be present at board meetings; mandating external monitoring; requiring intellectual property to remain in the UK; and imposing obligations to continue to supply critical services in the UK, such as the Ministry of Defence (MoD) or the emergency services.

Over the last year, it has become apparent that the NSIA is very broad in scope. This is particularly notable as far as transactions in the energy, defence, artificial intelligence and data infrastructure sectors are concerned. These sectors can apply to acquisitions that, on first glance, would appear to fall outside the scope of the NSIA.

For example, the NSIA will apply to any acquisition of an entity which holds a generation licence even if it is not yet generating; any subcontractor in a chain of contractors where the customer is the MoD; or a contract which provides access to defence facilities even when the relevant entity does not provide goods or services with any obvious military applications (such as catering or cleaning).

As a result a number of M&A deals require careful consideration of whether notification under the NSIA is required. The need for consideration here includes corporate reorganisations, some asset transfers and properties near to defence locations.

## Competition

As a result it is recommended that companies consider the NSIA as soon as possible in the transaction process. This includes assessing NSIA risks when evaluating potential purchasers/investors and checking the overseas equivalents of NSIA if the target has non-UK revenues or activities.

Although the Investment Security Unit currently has an understanding approach to errors and omissions in notification forms, this approach is likely to change the longer that the NSIA is in force.

View our webinar.



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## Consumer law

#### EU Commission sets rules on supervisory fees under the DSA

On 2 March 2023, the <u>European Commission</u> adopted a <u>delegated regulation</u> to set rules on supervisory fees under the EU Digital Services Act (DSA).

Under the DSA, the EU Commission has powers to impose a fee on "very large online platforms" and "very large online search engines" (as defined) under its supervision, and the process is expected to begin in autumn 2023. The delegated regulation specifies detailed methodologies and procedures regarding the supervisory fees to be levied. This follows the Commission's consultation which closed on 19 January 2023.

Following the Commission's adoption of the delegated act, it has been passed to the EU Parliament and the Council, which have three months to scrutinise it. The scrutiny period can be extended by a further three months, at their request.

#### EDPB adopts guidelines on dark patterns

The European Data Protection Board (EDPB) has <u>published</u> three guidelines, including guidelines on dark patterns, following public consultation.

In particular, <u>Guidelines on deceptive design patterns in social media platform interfaces</u> provide specific examples of types of dark patterns and recommendations for designers and users of social media platforms on how to assess and avoid dark patterns that infringe the EU General Data Protection Regulation (GDPR).

Additionally, the guidelines describe best practices and recommendations for designers of social media interfaces on how to integrate the guidelines into the design thinking process. However, following public consultation the wording "dark patterns" was replaced by the term "deceptive design patterns".

Our dark patterns microsite covers more updates on the topic.

#### Ofcom consults on improving broadband information for customers

On 8 March 2023, the UK communications regulator, Ofcom, <u>launched a consultation</u> which aims to help consumers make more informed choices when they select broadband services.

Previously, Ofcom has conducted a consumer research to find out what information consumers find useful to know before choosing a broadband service. Its survey has shown that consumers are interested to know more about the complex underlying technology used to deliver their services. The current consultation explains Ofcom's view and outlines its proposals on how broadband service providers should make consumers aware of this information. The responses are welcomed by 3 May 2023.



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## **Cyber-security**

#### EU agencies warn of malicious cyber activity

On 15 February 2023, the European Union Agency for Cybersecurity (ENISA) and Computer Emergency Response Team (CERT-EU) issued a joint publication to alert organisations on sustained activity by particular threat actors.

The publication warns of Advanced Persistent Threats (APTs) – groups which gain unauthorised access to a computer network and are able to remain undetected for an extended period of time. Hacker groups APT27, APT30 and APT31, amongst others, were named as those targeting "business and governments in the Union", with a focus on information theft.

The ENISA and CERT-EU called for all public and private sector organisations within the EU to follow the listed cyber hygiene recommendations in order to improve their cyber resilience.

The NCSC has also published guidance to help large organisations and SMEs protect themselves online.

### Digital and cyber security regulation moves from DCMS to DSIT

On 7 February 2023, the government <u>announced</u> the creation of four new departments, including a new Department for Science, Innovation and Technology (DSIT).

Responsibility for digital and cyber security regulation has now moved across from the Department for Culture, Media and Sport to DSIT.

DSIT will continue to deliver the priorities set out by the <u>National Cyber Strategy 2022</u>, which aims to make the UK the safest place to live and work online.

#### NCSC issues guidance on supply chain mapping

The National Cyber Security Centre (NCSC) has issued <u>guidance</u> advising medium to large organisations who need to gain confidence or assurance that mitigation measures are in place for vulnerabilities associated with working with suppliers.

The guidance, which is recommended to be read in conjunction with NCSC guidance on <u>supply chain cyber security</u>, is aimed at the process of recording, storing and using information gathered from suppliers who are involved in a company's supply chain. The NCSC maintains that while it is not possible to completely eradicate supply chain attacks, an organisation's ability to respond rapidly to an attack will help limit the scope of damage to the organisation.

## Government response to Pro-Innovation Regulation of Technologies Review

On 15 March 2023, Sir Patrick Vallance's <u>Pro-Innovation Regulation of Technologies Review</u> was published, which looks at how pro-innovation regulation can support emerging digital technologies

The <u>government's response</u> accepts Sir Patrick's recommendation of amending the <u>Computer Misuse Act 1990</u> to include a statutory public interest defence, which would provide stronger legal protections for cyber security researchers and professionals, thereby enabling innovation in the sector. The government reiterated its commitment to ensuring the UK has the right legislative framework, powers and law enforcement capability to tackle the threat from cyber crime.

The Home Office has a live consultation and a forthcoming programme of work that will consider the merits and potential risks to reform.

The Information Commissioner's Office also issued a <u>statement</u> in response, welcoming future discussions of the recommendations in the report with Digital Regulation Cooperation Forum partners and the government.

## **FATF** report on Countering Ransomware Financing

On 14 March 2023, the Financial Action Task Force (FATF) issued a <u>report</u> analysing the methods that criminals use to carry out their ransomware attacks and how payments are made and laundered.

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The report lists a number of potential risk indicators that can help public and private sector entities identify suspicious activities related to ransomware, including:

- customers utilising virtual private networks (VPNs);
- transactions involving anonymity-enhancing cryptocurrencies;
- · use of encrypted networks; and
- sending of virtual assets to wallets linked to ransomware.



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## **Data protection**

### **EDPB concerns over EU-US Data Privacy Framework**

On 28 February 2023, the European Data Protection Board (EDPB) adopted its <u>opinion on the draft adequacy decision</u> regarding the EU-US Data Privacy Framework (DPF). The board welcomed the improvements in the draft decision over the EU/US Privacy Shield, which was invalidated by the CJEU in *Schrems II*, but expressed concerns over some elements of the DPF.

While the EDPB acknowledged significant improvements had been made with respect to government access to personal data, it raised concerns that relate to cornerstone elements of the General Data Protection Regulation (GDPR), including data subject rights and the availability of an appropriate redress mechanism.

It remains to be seen whether the next stage of the legislative process – an opinion from a committee of Member State representatives – will raise similar concerns.

## ICO approves fourth UK GDPR Certification Scheme

This month, the Information Commissioner's Office (ICO) approved <u>a certification scheme criteria for training and qualification service providers</u>, which follows three other schemes previously approved by the ICO.

The certification schemes are intended to help organisations demonstrate their compliance with data protection laws and are part of the ICO's 2025 strategy to provide services, tools and initiatives to help reduce the burden of compliance for organisations.

## UK government reignites data protection reform

Following much anticipation, the new Department for Science, Innovation and Technology has introduced the Data Protection and Digital Information (No.2) Bill. It is the second version of the bill and proposes wholesale changes to the UK's privacy framework.

Read our in-depth Insight on the bill.

### ICO publishes updated AI and data protection guidance

On 15 March 2023, the ICO updated its <u>guidance</u> on artificial intelligence (AI) and data protection in response to feedback from UK industry to clarify the requirements of fairness in this context. The updates are also part of the ICO's 2025 strategy to support innovation while safeguarding data privacy.

The updates includes new chapters on ensuring transparency, fairness and lawfulness in AI, and a new section on what organisations should assess in a data privacy impact assessment when using AI to process personal data.

The ICO anticipates making further updates to the guidance to reflect Al's continued development and also the upcoming UK government white paper on Al Regulation.

## EU Parliament gives green light to draft Data Act

Earlier this month, a substantial majority of the EU Parliament voted in favour of the draft Data Act, which is intended to establish common rules governing the sharing of data generated by the used of connected products.

The EU Parliament will now enter negotiations with the Council of the European Union to agree a final version of the draft Data Act.

For a deeper dive in to the key concepts of the draft Data Act, please see our previous Insight.

#### ICO agrees to reduce Easylife fine

The ICO has, following an appeal from Easylife, <u>agreed to reduce the £1.35m fine</u> which it had issued to Easylife in October 2022 for its breach of data protection laws. The fine has been reduced to £250,000.

The fine related to Easylife's use of customer personal data to predict an individual's medical condition and target them with specific health-related products.

## **Data protection**

The ICO has not explained the basis for the significant reduction, other than to state that it had considered the amount of the penalty again during the course of the litigation, in light of the issues raised by Easylife. Given this explanation, it appears that the ICO decided to take a pragmatic approach on the basis that the risks, and costs, of litigating the appeal were too great See our Insight for more.

## EDPB adopts guidelines on dark patterns

Please see Consumer law.



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**Employment and immigration** 

## **Employment and immigration**

#### Who is exempt from the immigration skills charge?

The Home Office has confirmed that a new immigration skills charge (ISC) exemption is now available for employers who use the global business mobility senior or specialist worker route for EU national workers from their overseas offices based in the EU.

The new exemption came into force on 1 January 2023 and the Immigration Skills Charge (Amendment) Regulations 2022 confirms that sponsors of the global business mobility senior or specialist route will be exempt from paying the ISC if all of the following apply:

- The certificate of sponsorship (CoS) was assigned on or after 1 January 2023
- The worker is a national of an EU country (does not include Iceland, Liechtenstein or Norway) or is a Latvian "non-citizen".
- The worker has been assigned to the UK by a business established in the EU, and which forms part of the same sponsor group.
- The end date of the assignment, as specified on the CoS, is no more than 36 months after the start date.

Read more, and https://www.osborneclarke.com/insights/who-exempt-immigration-skills-charge for further immigration developments, please see our latest Immigration Update.

#### Published advice for employers and recruiters

The Competition and Markets Authority (CMA) has <u>published advice for employers</u> on how to avoid anti-competitive behaviour, identifying three main types of such behaviours in labour markets:

- No-poaching agreements: These occur when two or more businesses agree not to approach or hire each other's
  employees (or not to do so without the other employer's consent). This can include where employers appoint
  recruiters who in turn have non-poaching agreements with certain key clients.
- Wage-fixing agreements: These occur when two or more businesses agree to fix employees' pay or other
  employee benefits or contractors' pay. This includes agreeing the same wage rates or setting maximum caps on
  pay.
- Information sharing: Sensitive information about terms and conditions that a business offers to employees might be shared between businesses. This in turn reduces competition between those in recruitment and retention.
- Using recruiters to help with the above: the advice covers using recruiters and so-called Recruitment Process Outsourcing and Managed Service Provider companies, who provide services to a number of competitors in a sector and who use their knowledge of client one to help client two know that client two does not need to pay more than x in terms of wage or contractor rates.

These are all stated to all be examples of business cartels. Not all agreements or practices that are anti-competitive will necessarily be in writing; they might instead take the form of informal practices (commonly referred to in this context as "gentlemen's agreements"), and might cover freelancers and contracted workers as well as permanent salaried staff. Read more in our <a href="Insight">Insight</a>. https://www.osborneclarke.com/insights/uk-employment-law-coffee-break

## Spring Budget 2023: what was in it for employers?

As had been widely anticipated, the <u>spring Budget 2023</u> set out the government's plans for "breaking down barriers that stop people working" following concerns laid out in the <u>autumn statement</u> over the rise in economically inactive individuals "seen particularly acutely within those aged over 50" following the Covid-19 pandemic.

The Budget sets out a comprehensive employment packaged focused on four groups: the long-term sick and disabled, welfare recipients and the unemployed, older workers and parents. The Office for Budget Responsibility expects this package to result in 110,000 more individuals in the labour market by the end of the forecast period. More detail can be found in our <u>Insight</u>.

#### Annual tribunal limit increase

The new annual tribunal limits have been announced for dismissals taking effect from 6 April 2023 as follows:

## **Employment and immigration**

A week's pay for the unfair dismissal basic award and statutory redundancy pay rises to £643 (from £571) and the unfair dismissal compensatory award rises to £105,707 (from £93,878), subject to the maximum cap of 52 weeks' pay.

The new statutory rates for family leave and national minimum wage rates have previously been announced which will also take effect in April 2023 – <u>view them here</u>.



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## **Environment**

### Water companies urged to share storm overflow improvement plans

Environment Secretary Thérèse Coffey recently <u>demanded</u> that water companies start sharing their assessment and action plans on storm overflow plans, as well as noting that they will face higher penalties that are quicker and easier to enforce (see our <u>earlier Regulatory Outlook</u> for more on this).

The government will be consulting in due course on measures to make it easier and quicker for penalties to be issued so polluters are made to pay immediately when damage is caused. The announcement further notes that on the upper limit of fines, all options – including £250 million – remain on the table and a public consultation will run in the spring to find an upper limit that is a "real and serious deterrent".

Coffey said: "Through the largest infrastructure programme in water company history we will tackle the problem at source, with more investment on projects like the new Thames Tideway super sewer. I am making sure that regulators have the powers they need to take action when companies don't follow the rules, including higher penalties that are quicker and easier to enforce. I am now demanding every company to come back to me with a clear plan for what they are doing on every storm overflow, prioritising those near sites where people swim and our most precious habitats."

More detail on the government's plans to deliver clean and plentiful water were also set out last month in its Environmental Improvement Plan 2023.

## UK government set to block Scotland's DRS rollout

It has recently been reported that the UK government is planning to block the launch of the Scottish deposit return scheme (DRS) in light of the impact on inflation, with the Scottish government and the DRS scheme administrators meeting with industry leaders to hold crisis talks to try and salvage the scheme.

UK environment minister, Lord Benyon, has also criticised Scotland's DRS: he confirmed that the UK government had not yet received an official request from Scottish ministers for the internal market exemption needed for the scheme to operate legally.

Additionally, two candidates for the Scottish National Party (SNP) leadership candidates have said they will delay the scheme if they win.

Judicial review proceedings on the Scottish DRS are also starting this month. The claim, brought by the former president of the Sottish Grocers Federation, challenges the legality of the retailer handling fees imposed by the scheme administrator, Circularity Scotland. The claim will proceed to the Court of Session on 30 March.

See our previous Regulatory Outlook for more on deposit return schemes in the UK.

#### Biodiversity net gain

The Environment Act 2021 will introduce mandatory requirements for biodiversity net gain (BNG) for new developments in England as part of the government's 25 year environment plan, with the objective of improving the natural environment (see our January issue of the Regulatory Outlook for more).

<u>Government guidance</u> has been eagerly awaited (given the expected implementation from November this year) and it has now been published, providing much needed further details of BNG. While it does not address every outstanding question, further guidance is expected to follow throughout the year.

Some key details are summarised below:

- **Timeline**: BNG requirements will begin from November 2023, although certain small sites have extra breathing space until April 2024 and it is expected that requirements for nationally significant infrastructure projects (NSIPS) will apply from 2025.
- The BNG requirement: Most new developments that require planning permission under the Town and Country Planning Act 1990 regime must provide a minimum 10% BNG compared to the condition of the development site prior to construction. There are also requirements for nationally significant infrastructure projects.
- **Exemptions**: The guidance sets out exemptions for developments that affect small habitats, householder applications, biodiversity gain sites, small scale self-build and custom housebuilding.

## **Environment**

- Onsite/offsite solutions: There is a preference that BNG obligations be satisfied onsite but with scope for
  flexible offsite solutions. There remains uncertainty as to how local planning authorities will approach this in
  practice.
- Unit market: The guidance discusses the market for biodiversity units. Developers that create biodiversity
  exceeding 10% will be able to sell excess units, subject to key requirements.
- Recording gains information: Onsite gains will be recorded by local planning authorities, while Natural England will manage the register for offsite banks.

## Consultation launched on carbon capture readiness requirements

On 13 March 2023, the Department for Energy Security and Net Zero published a <u>consultation</u> on its proposals for updated to the 2009 carbon capture readiness (CCR) requirements, which they are proposing to rename decarbonisation readiness (DR).

The government proposals to update the 2009 DR requirements include, among others:

- Moving the DR requirements from the planning consent process to the environmental permitting process. This
  should lead to overall simpler regulatory requirements and also allow the requirements to be amended more
  readily to respond to future market or technical developments. The Environment Agency would be responsible for
  the regulation of the requirements in England.
- Retaining the current CCR requirement for developers to undertake a light touch review of their plant's
  compliance with the DR requirements every two years, to ensure all regulated developers are regularly assessing
  their decarbonisation potential.
- Introducing a regular review to be undertaken by government of the DR requirements.

The consultation closes on 14 April 2023 and applies to England only. The Welsh government will publish a separate response and next steps in Wales.

## Carbon capture to receive £20bn in government investment over 20 years

In the spring 2023 <u>Budget</u>, it was announced that carbon capture, usage and storage (CCUS) would receive £20 billion of funding over 20 years. A shortlist of projects for the first phase of CCUS deployment will be announced later this month.

Further projects will be able to enter a selection process for Track 1 expansion launching this year, and two additional clusters will be selected through a Track 2 process, with details announced shortly.

#### Defra reminds businesses of their obligation as EPR reporting requirements come into force

Please see Products.



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Environmental, social and governance

## Environmental, social and governance

### FCA targets potential ESG 'harms' caused by UK asset management firms

The Financial Conduct Authority (FCA) has published its first "Dear CEO" letter since the launch of its new "integrated regulatory structure", which has meant that asset management is now supervised by the UK financial regulator's Buy-Side Directorate. The letter outlines the harms to consumers and markets most likely to arise from "asset manager" business models. Environmental, social and governance (ESG) investing is one of five risks of harm on which it focuses.

It encourages CEOs to consider whether the risks identified are present in their firms and recommends strategies are adopted to address them. It also provides developments to the ESG requirements and guidelines for asset management companies and the expectations on the design, delivery and disclosure of ESG and sustainable investment funds. See our <a href="Insight">Insight</a> for more.

## ESG reporting in Europe: Corporate Sustainability Reporting Directive obligations

As noted in our January issue of the <u>Regulatory Outlook</u>, the corporate sustainability due diligence directive will require qualifying companies to have a duty to undertake due diligence to identify actual and potential adverse impacts of their activities on human rights and the environment. For further analysis on this, please see our recent <u>Insight</u>.



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### FCA publishes its updated Perimeter Report

On 6 March 2023, the Financial Conduct Authority (FCA) published an <u>updated version</u> of its Perimeter Report. The report sets out what the FCA does and does not regulate, describes the specific issues that have been identified around the regulatory perimeter and action the FCA is taking in response. Where the regulator considers that bringing unregulated activities into its remit is likely to prevent harm and lead to better outcomes, it will work with the government to do so.

The FCA has made revisions to the previous version of the report, including:

- Appointed representatives. The FCA outlines the steps it is taking to tackle potential harm from the appointed
  representatives regime. Among other things, it has intensified supervision of firms that are providing regulatory
  hosting services and made changes to the authorisation process intended to identify risky business models and
  higher-risk principals.
- **ESG data and ratings providers**. The FCA notes that HM Treasury is preparing to consult on bringing ESG data and ratings providers within the FCA's regulatory perimeter. It highlights the work underway concerning the voluntary code of conduct for ESG data and ratings providers.
- **Funeral plans**. The FCA confirms that, if funeral plan providers are placed into administration, insolvency practitioners may carry out funeral plan contracts, but may not enter into new contracts.
- **Deferred payment credit (DPC).** The FCA confirms that it intends to consult on conduct standards for the DPC sector (that is, activities relating to buy now, pay later products) that will apply once the sector is brought within the regulatory perimeter. However, the extent of these rules will depend on HM Treasury's legislation covering the scope of firms and activities that will fall within the perimeter.
- Senior Managers and Certification Regime (SM&CR). The FCA notes that, although the Financial Services and
  Markets Bill 2022-23 enables the extension of the SM&CR to recognised investment exchanges, and credit rating
  agencies, it does not enable the regime's extension to payments and e-money firms. The FCA sees value in
  extending the SM&CR to these firms and is exploring possible options with HM Treasury.

#### Putting customers front and centre will help industry innovate

On 22 February 2023, the FCA published a speech by Sheldon Mills, its executive director for consumers and competition, given at the "Countdown to Implementation of the Consumer Duty" event, on how putting customers front and centre will help the industry innovate.

In his speech, Mr Mills reiterated the importance of the Consumer Duty and why the FCA embarked on it in the first place. He explained that it was designed to set and test higher standards and to reduce and prevent serious harm. As an outcomesbased approach, data and monitoring is key and it is hoped this will give firms the impetus to target their customers more accurately through new technologies and systems. The duty is also intended to reduce customer complaints, cut down costs down the line and boost competition.

The speech also reminded firms of some of the key deadlines, as well as practical steps that they need to take. The duty implementation deadline for open products and services is 31 July 2023, and 31 July 2024 for closed products.

To prepare, over the next five months, firms should share information with their commercial partners and make sure they are on board; this will include the firm's distribution network and wholesalers as well as retailers and any third parties. Mr Mills also advised firms to focus on the areas that will have the biggest impact on outcomes for customers.

Mr Mills flagged that the duty is not retrospective, so it will not mean organisations will be taken to the Financial Ombudsman Service for past actions or omissions so long as they are put right by July 2023 for products or services that are still on offer (or by July 2024 for those that have been withdrawn to new customers).

At every stage of the regulatory life cycle, the FCA will ask firms to demonstrate their business models, actions they have taken and how their culture is refocusing on good customer outcomes.

Finally, the speech highlighted the need, by the end of April, for manufacturers to complete all reviews necessary to meet the four outcome rules (which relate to the governance of products, price and value, consumer understanding and consumer support) and to share information with distributors to help them meet their obligations.

On 21 February 2023, the FCA sent a <u>letter</u> to all the payments firms that it supervises setting out its expectations on how these firms should embed the duty.

## FSB publishes G20 Roadmap for enhancing cross-border payments

On 23 February 2023, the Financial Stability Board (FSB) published a <u>report</u> on the G20 Roadmap for enhancing cross-border payments.

In October 2022, the FSB published a prioritisation plan and engagement model for taking the roadmap forward. The plan showed that the roadmap had reached an inflection point and needed to move to implementing practical projects to enhance cross-border payment arrangements to achieve the quantitative targets that had been established. Based on the current analyses and the stakeholders' feedback, the FSB, the Bank for International Settlements' Committee on Payments and Market Infrastructures (CPMI) and partner bodies have identified three key themes of focus for the next phase of the roadmap:

- Payment system interoperability and extension the CPMI will convene a forum to exchange information and
  experiences among interested central banks on developing or upgrading their payment systems. There will also be
  a G20 workshop on interlinking the faster payments service. The CPMI (in consultation with public and private
  sector stakeholders) will also finalise the requirements for service level agreements/schemes that stakeholders can
  use as a starting point when establishing agreements.
- Legal, regulatory and supervisory finalising frameworks an FSB working group on bank and non-bank supervision will develop recommendations, as needed, for strengthening consistency of the application of regulation and supervision to banks and non-banks providing cross-border payment services in a way that is proportional to their respective risks. The theme will also cover updating anti-money laundering rules and will include enhancing the Financial Action Task Force rules on wire transfers.
- Cross-border data exchange and message standards the FSB will develop recommendations for public consultation, for promoting alignment and interoperability across data frameworks applicable to cross-border payments. It will also cover finalising the ISO 20022 harmonisation requirements and promoting their real world implementation and improving application programming interface harmonisation for cross-border payments use.

This latest report details the specific actions that will be taken under the three priority themes to move the roadmap forward and achieve the targets by the 2027 target date.

### CPMI consults on proposed ISO 20022 harmonisation requirements

On 1 March 2023, the CPMI published a <u>consultative report</u> on the harmonisation of ISO 20022 requirements for cross-border payments.

It explains that the proposed harmonisation requirements provide overarching guidance for global and domestic market practices guidelines to ensure that the ISO 20022 messaging standard is consistently used to facilitate faster, cheaper, more accessible and more transparent cross-border payments.

The 15 proposed requirements are divided into three sections: Block A – fundamentals, Block B – transparency; and Block C – structured and coded data. They were developed by a joint task force established by the CPMI and the SWIFT Payments Market Practice Group.

The CPMI will revise its report in response to feedback received during the consultation and will deliver the final report to the Indian G20 Presidency by the end of 2023. It intends that the requirements should take effect in November 2025, which would align with SWIFT's scheduled date for removing the ability to send cross-border MT payment messages over its network.

The deadline for comments is 10 May 2023.

#### European Supervisory Authorities warn consumers on risks of cryptoassets

On 17 March 2022, the European Supervisory Authorities (ESAs) published a joint document warning consumers that many cryptoassets are highly risky and speculative, and are not suited for most retail customers to invest in or use as a means of payment or exchange.

The ESAs provide a list of questions consumers should ask themselves if they are considering buying cryptoassets or related products and services. They also provide brief explanations of what they perceive to be the key risks, which include:

- Extreme price movements
- Misleading marketing
- Absence of protection
- Product complexity
- Market manipulation, lack of price transparency and low liquidity
- Fraud

The ESAs note growing consumer activity and interest in cryptoassets, including virtual currencies and the emergence of new types of cryptoassets and related products that claim to generate high or fast returns (or both). These include non-fungible tokens, derivatives with cryptoassets as underlying, unit-linked life insurance policies with cryptoassets as underlying and decentralised finance (DeFi) applications.

They refer to the European Commission's proposed MiCA (Markets in Crypto-Assets regulation) regime, which provides a framework for the regulation and supervision of issuers and providers of services for cryptoassets. However, they remind consumers that the proposed regulation remains subject to the outcome of the co-legislative process, and consumers will not benefit from any of the safeguards in that proposal until it is adopted and applies.

## JMLSG publishes final revisions to its guidance

On 6 March 2023, the Joint Money Laundering Steering Group <u>published</u> final amendments to its guidance. The following revised parts of the guidance have been made available:

- Part II Sector 5 (Wealth management).
- Part II Sector 6 (Financial advisers, including financial planners).
- Part II Sector 11A (Consumer credit providers).
- Part II Sector 13 (Private Equity).
- Part II Sector 22 (Cryptoasset exchange providers and custodian wallet providers).
- Part I Chapter 6 Paragraphs 6.70 and 6.71 (on bringing a complaint to and handling it by the Financial Ombudsman Service).

These final revisions are now awaiting HM Treasury approval.

On 17 March 2023, the JMLSG published a <u>press release</u> announcing the publication of revisions to Part II of its anti-money laundering (AML) and counter-terrorist financing (CTF) guidance for the financial services sector.

The finalised revisions relate to chapters 8 (Non-life providers of investment fund products) and 9 (Discretionary and advisory investment management) of Part II of the guidance. The revised guidance has been submitted to HM Treasury for ministerial approval.



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## **Food law**

#### EU consumer group call for ban on food climate neutral claims

On 9 March the European Consumer Organisation <u>published</u> a report that misleading "carbon neutral" claims in the food sector are rife and subsequently should be banned. The reasoning behind their calls for an outright ban includes that the claims are scientifically inaccurate, they mislead consumers and there are no guarantees for "locking in" carbon for the future.

This report came ahead of the European Commission's proposal for a Directive on Green Claims which was published on 22 March. If implemented, the proposals will impose additional compliance obligations on businesses making green claims, see advertising and marketing for more.

### New US FDA guidance on labelling plant based milk alternatives

The US Food and Drug Administration (FDA) has recently published <u>draft guidance</u> on labelling plant-based products that are marketed and sold as alternatives to milk, such as plant-based milk alternatives (PBMA).

One of the main recommendations put forward by the FDA in its draft guidance is that PBMA products labelled with the term "milk" in their names, such as "soy milk", and which have a different nutrient composition to milk, should include a voluntary nutrient statement that outlines how the PBMA product compares with milk that is based on the USDA's Food and Nutrition Service's fluid milk-substitutes nutrient criteria.

The FDA has said that the aim of this new guidance is to provide consumers with more information on the nutritional differences between milk and PBMA products. Comments on the draft guidance must be submitted by 25 April 2023.

#### UK's Ofcom opens consultation on HFSS advertising restrictions

As detailed in our <u>Insight</u>, Ofcom has launched a consultation on its proposed approach to implementing new restrictions due to come into force in October 2025 on advertising for "less healthy" food and drink products that are high in fat, salt or sugar (HFSS).

The consultation provides insight into its view on the new rules, as well as being an opportunity to comment on its approach.

The Health and Care Act 2022 amended the Communications Act 2003 and prohibited TV services from including advertising and sponsorship for less healthy food and drink products between 5.30am and 9pm, as well as on-demand programme services (ODPS) from including advertising and sponsorship for less healthy food and drink products between 5.30am and 9pm. Paid-for advertisements for less-healthy food and drink products that are aimed at UK users are also prohibited from being placed online at any time.

The consultation on the draft regulations is open for <u>responses and comments</u> until 21 April 2023.

## UK food businesses call for government call for clearer rules on food labelling

As detailed in our January issue of the Regulatory Outlook, following recent cases it was expected that there would be an increase in allergen awareness and liability. This month a number of leading food businesses have written to the government calling for a more "rigorous" approach to precautionary allergen labelling. The two recommendations they set out in their letter are: 1) use of legal allergen threshold reference doses to inform precautionary allergy labelling for prepacked food; 2) creation of the new rapid reporting of food-related anaphylaxis cases in the UK.

With these calls from industry it will be interesting to see whether the government does take action to introduce legal thresholds rather than relying on "market standard" under the Food Industry Guide to the Voluntary Incidental Trace Allergen Labelling.

On 27 March, the Food Standards Agency (FSA) launched a <u>consultation</u> as part of a routine review and update of the Allergen Labelling Technical Guidance. It is seeking feedback on key guidance updates – standards for applying precautionary allergen labelling and best practice guidance that "No Gluten Containing Ingredients" statements should not be used. The consultation closes on 22 May, after which the FSA will consider the responses prior to amending and publishing the revised Technical Guidance in summer 2023.

#### **CBD** product validations

It has been reported that the FSA will soon make a decision on the validation of thousands of CBD (cannabidiol) products. While the FSA has not yet published anything publicly, media reports have confirmed that two CBD companies

## **Food law**

have received formal notification from the regulator to confirm the validation and that it will not move on to a risk assessment stage for further assessment.

## Alcoholic Beverages (Amendment) (England) Regulations 2023 (SI 2023/312)

The <u>Alcoholic Beverages (Amendment) (England) Regulations 2023</u> amend rules concerning the labelling of alcohol content and vine varieties on wines, and add flexibility on how the terms "alc"/"vol" can be shown in relation to the numerical alcohol content for all alcoholic drinks.

They come into force on 29 March 2023.

## Update on food hygiene ratings scheme alignment between three nations

The FSA has had a longstanding ambition to align England with Wales and Northern Ireland on the mandatory display of hygiene ratings. Following the then-prime minister's resignation in July 2022, the proposal for this was not included in the Department of Health and Social Care's Health Disparities White Paper.

In the latest <u>Chief Executive's Report</u> to the FSA Board, the FSA has now confirmed that it intends to put the case to the ministers again "*early in the term of the next government*".

## UK government's Genetic Technology (Precision Breeding) Act passes into law

The UK government's Genetic Technology (Precision Breeding) Act passed into law on 23 March 2023. This is a major development for England's ambition to become a world-leader in agri-food innovation, with opportunities to develop new crop varieties that are more resistant to factors such as pests and climate change.

The government says that the Act will introduce a new science-based and streamlined regulatory system which facilitates greater research opportunities and innovation in precision breeding through techniques such as gene-editing. A step-by-step approach will be used, with facilitation of precision breeding technologies used with plants first, followed by animals later. Stricter regulations remain in place for genetically modified organisms.

In parallel, the FSA has published its first report looking into what approvals and other labelling criteria should apply to such products. No firm decisions have been made and the matter will be kept under review. However, it is likely that many such products may require novel food approval and consideration will need to be given to labelling appropriately to ensure consumers are not misled.



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## **Health and Safety**

### New regulator takes major step forward in 'landmark moment for building safety'

The Health and Safety Executive (HSE) has <u>announced</u> that all high-rise residential buildings in England will have six months from this April to register with the new Building Safety Regulator, which will affect approximately 12,500 buildings.

Owners and managers of these buildings must register by October 2023 or may face prosecution. The HSE state that this new campaign aimed at owners and managers of high rise buildings will highlight their new legal duties and encourage those responsible for safety management of higher-risk residential buildings to prepare for this change in regulation.

### Amendment to OSB proposes criminal penalties for managers

An amendment has recently been proposed to the Online Safety Bill (OSB) in the House of Lords which creates a duty by Ofcom, working with the coroner, to require social media firms to hand over relevant content on "a timeframe that is fair to all parties". Those who fail to provide or preserve the content "without reasonable excuse" could face fines of up to 10 per cent of their firms' global turnover or a maximum one year's jail sentence, meaning that managers at tech companies could face imprisonment for failing to assist coroners.

The amendment, put forward by Baroness Kidron (founder of 5Rights, a charity campaigning for online safety), aims to provide bereaved parents with data to explain why their children died.

The OSB has completed its second reading in the House of Lords and the date of when it will be read at Committee Stage is to be announced.

#### 39 building developers agree to fix unsafe buildings

As detailed in our previous Regulatory Outlook, developers were asked by the government to sign the developer remediation contract, which requires them to take responsibility for all necessary work to address fire-safety defects arising from design and construction of buildings 11 metres and over in height that they developed or refurbished over the last 30 years in England.

On 14 March, it was <u>announced</u> that 39 building developers have since signed the remediation contract and are now committed to fix any unsafe buildings; their obligations start immediately.

This recent development will see at least £2 billion raised for remediation costs. Further information will be published in due course on "how developers will be prohibited from carrying out major development or from receiving building control approval unless they sign and adhere to the contract, using Building Safety Act 2022 powers".

### Artificial Intelligence and Digital Regulations Service launches

Please see Products.



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Modern slavery

## **Modern slavery**

#### Managing modern slavery risks within UK supermarket supply chains

This month it has been reported that a number of UK supermarkets have partnered up to form a task force which will fund independent audits on British farms, following calls from investors regarding worker exploitation within supply chains.

The action taken by some of the leading UK supermarkets follows on from reports that Asian agricultural workers were coming to work in the UK after paying fees to hiring agencies in their home countries. This left them to having to work to pay off these debts, known as debt bondage –which is recognised by the International Labour Organisation as an indicator of forced labour.

These recent developments provide pointers for other businesses looking at how to manage issues in their supply chains, including: action being taken collaboratively in a sector; the focus on actions to address specific identified issues (in the above case debt bondage); and a recognition that modern slavery is not just an issue that arises "somewhere else".







#### EU introduces proposal for right to repair

The European Commission has (on 22 March 2023) <u>published</u> its proposal for a <u>Directive on common rules promoting the repair of goods</u> which aims to increase the repair and reuse of defective products to promote sustainability.

Within the legal guarantee, the proposal makes a direct amendment to the Sale of Goods Directive for sellers to prioritise repair where it is cheaper than replacing the product. This means that consumers no longer have a choice about whether to repair or replace – rather a repair must be offered to consumers, unless this would be more expensive than a replacement.

Outside of this legal guarantee, the directive introduces the following measures to facilitate repair when the legal guarantee has expired:

- **Obligation to repair –** producers (that is, manufacturers) will be obligated to **repair goods**, upon a consumer's request, that fall outside the liability of the seller. This obligation does not arise for products that are impossible to repair. This obligation will apply to producers established both inside and outside the Union in relation to goods placed on the Union market.
- Information on obligation to report producers need to inform consumers of their obligation to repair products and provide information on the repair services in an easily accessible, clear and comprehensible manner (for example, through the online platform see below).
- Information needs to be provided to consumers to find suitable repairers in their area via an online repair platform. Each Member State will have to have at least one online platform.
- Introduction of a European Repair Information Form, which will help consumers compare different repair services based on key aspects, such as price, duration of repair or availability of a replacement product during repair. This form can be requested from the producers and also other repairers like the seller or independent repairers, or by searching via the online repair platform.

The directive will apply to consumer goods (any tangible movable item) and applies to any defect that may occur in those goods.

The proposal provides that Member States will have two years to implement the directive into national law, so while these changes will not be coming into force imminently, it is important for businesses to understand the direction of travel and start discussions about how this shift of focus to repair would be achieved.

The proposal will now be subject to the ordinary legislative procedure, which means they will be transmitted to the colegislators, the European Parliament and the Council for adoption.

#### MHRA publish proposals for new clinical trials regulatory framework

The government has published its <u>response</u> to the consultation on the regulation of clinical trials in the UK, setting out a number of reforms of the framework. The measures introduced are hoped to streamline and accelerate clinical trials in order to "find innovative ways to bring new treatments to patients faster and more effectively."

Among the measures proposed are a number to ensure transparency within clinical trials, with the new framework introducing a legal mandate to register the trial in a World Health Organization public register.

The legislation will also bring in a requirement to publish a summary of results within 12 months of the end of the trial and sharing trial findings with participants. Additionally, clinical trial applications will need to be completed within 30 days, in general, with a maximum 10 days for a decision to be granted once the MHRA has received any final information.

The Association of the British Pharmaceutical Industry has welcomed the new proposals and in its <u>response</u> Richard Torbett, ABPI Chief Executive, said: "It's great to see the MHRA taking forward these important changes to UK clinical trials regulation centred on patient safety and the benefits of participating in research. The reforms are a significant step forward for UK clinical trials and come at a crucial time for industry clinical research in the UK."

#### Spring Budget 2023 - UK chancellor announces a new regulatory model

In his recent spring <u>Budget</u>, chancellor Jeremy Hunt announced reform to the UK's regulation of medicines and medical technologies. In a bid to position the UK as a global hub for innovative products, the Medicines and Healthcare products

Regulatory Agency (MHRA) will get additional funding to accelerate access to new products and manufacturers will be able to leverage approvals from overseas regulators.

The chancellor has outlined how funding will change the role of the MHRA, stating that it will <u>receive</u> an extra £10 million over the next two years to put in place "the quickest, simplest, regulatory approval in the world for companies seeking rapid market access" for innovative medical products.

The rapid approval of medicines approved in other jurisdictions will also be introduced, with the Budget confirming that the MHRA is "exploring partnerships with trusted international agencies, such as in the US, Europe and Japan to provide simple, rapid approvals for medicines and technologies that have received their approval from 2024".

In the House of Commons, the chancellor went further, stating that the MHRA would move to a new model to allow "often near automatic sign-off for medicines and technologies" that have already been approved by regulators in jurisdictions such as the US, Europe and Japan.

In addition, from 2024, the MHRA will introduce a new approval process for the most "impactful" innovative medicines and devices, examples being cancer vaccines and AI therapeutics for mental health. This is hoped to accelerate patient access to treatments and build on the success associated with the UK's rapid approval of Covid-19 vaccinations. See our <a href="Insight">Insight</a> for more.

#### Call for evidence and inquiry launched on the Windsor Framework

On 17 March, the UK European Affairs Sub-Committee on the Protocol on Ireland/Northern Ireland published an <u>inquiry and call for written evidence</u> on the Windsor Framework (see our previous <u>Regulatory Outlook</u>). The Committee will examine the economic, political, legal and constitutional implications of the Framework and is seeking views on issues including: the customs procedures and movement of goods; the impact of the Windsor Framework on the application of EU rules in Northern Ireland; and whether issues around provision of medicines to Northern Ireland are resolved. The deadline to submissions is 4pm on Tuesday 2 May 2023 and you can respond <u>here.</u> The committee will also hear oral evidence from 22 March.

#### **EU PFAS restriction proposal**

The European Chemicals Agency (ECHA) last month <u>announced</u> details of a <u>proposal</u> which would restrict around 10,000 per- and polyfluoroalkyl substances (PFASs). The restriction will be on the manufacture, placing on the market and use of PFASs.

Most recently, on 22 March the ECHA launched a six month open consultation on the proposal for those who wish to provide their views. Comments are to be made by 25 September 2023, you can respond <u>here</u>.

An online information session is also being run on 5 April 2023 to explain the restriction process and to help those interested in participating in the consultation. More details on this can be found here.

This proposed restriction on PFASs is set to be one of the largest ever on chemical substances in the EU and so it is important your business follows this for further developments. Whilst the European Commission is not expected to make a decision on the PFAS ban until 2025, it is important that your business is familiarises itself with the proposal as actions may need to be taken further down the line, such as reducing PFAS and looking for alternatives.

In the UK, PFAS have been in the <u>media recently</u>. The Health and Safety executive (HSE) is looking to whether and to what extent the UK should phase out and eventually ban the use of PFAS. The HSE is expected to publish its recommendations this spring and we expect the review to conclude that restrictions on the use of PFAS is necessary and could come in during the course of 2024, subject to relevant grace periods.

### European Council adopts regulation extending transitional periods for certification of medical devices

On 7 March, the European Council <u>adopted</u> the proposal to extend the transitional provisions put forward by the European Commission on medical devices (MDR) and Regulation (EU) 2017/746 in vitro diagnostic medical devices (IVDR) to extend the transitional provisions for certain medical devices.

This amending legislation will extend the MDR transition periods, delaying the full implementation of the MDR and IVDR, and removes the sell-off date provision in MDR and IVDR in an attempt to avoid device shortages.

For producers of medical devices this means they have until 31 December 2027 for higher risk devices and until 31 December 2028 for medium and lower risk devices to meet the legal requirements.

The regulation came into force on 20 March.

The UK government has <u>announced</u> that the MHRA is looking at what the implications of these revisions are for acceptance of CE marked medical devices on the GB market. That would include certificates valid under the latest EU's revised transitional arrangements, if they are adopted as proposed. As announced in October 2022, there are plans to extend acceptance of the CE marking in GB which will be put into law in the coming months and the government will be publishing guidance on this as soon as possible (see our <u>Insight</u> for more). However, as it stands, until the legislation is updated the standstill period during which CE marking is accepted in GB ends on 30 June 2023. Industry will be hoping that the government formalises the extension to the period in which CE marking is accepted as soon as possible.

#### **Artificial Intelligence and Digital Regulations Service launches**

The NHS Health Research Authority has launched the <u>Artificial Intelligence and Digital Regulations Service website</u>. The service is a partnership between the Health Research Authority, National Institute for Health and Care Excellence, Care Quality Commission, and the MHRA. The website aims to clearly set out the information and guidance that developers and adopters need to follow to develop safe, innovative technologies in health and social care. This includes advice on legal requirements, best practice guidance for the development and adoption of AI and digital technologies.

The platform helpfully indicates which regulatory requirements are mandatory and which are best practice, bringing greater clarity to what is required of developers of medical and non-medical devices. The guidance for developers is all publicly accessible. To access regulations for adopters, you will need to sign up and create an account with the site.

#### MHRA recall and withdraw medicines containing cough suppressant pholcodine in the UK

Following a review conducted by the Commission on Human Medicines (CHM), the MHRA has, as a precaution, <u>recalled</u> and <u>withdrawn</u> all pholoodine-containing medicines.

The CHM review found that pholocodine-containing medicines may increase the risk of the very rare event of anaphylaxis, in particular when exposed to neuromuscular blocking agents (NMBA). NMBAs are used to relax the muscles during general anaesthesia for some surgical procedures.

The MHRA has instructed healthcare professionals to stop supplying the product immediately and to quarantine remaining stock. It also notes that patients should check through medicines to see whether pholocodine is a listed ingredient and if patients undergo general anaesthesia in the next 12 months, they should notify their anaesthetist that they have taken pholocodine-containing products before they have surgery.

#### My safety: toys and electrical products

The Office for Product Safety and Standards is leading a <u>new campaign</u> to raise awareness about potential hazards to adults and children associated with toys and electrical products. The campaign posters, which will be on social media platforms such as Facebook, Instagram and Twitter, concentrate on three main messages:

- 1. Consumers should be aware that not everything advertised on an online platform is sold by that platform.
- 2. They should search 'product recalls' on GOV.UK to see if any problems have been identified with a potential purchase.
- 3. And if they think they have bought an unsafe product they should report it

This new campaign aims to encourage consumers to be wary of where they are purchasing their products from, ensuring they are buying them from safe reliable sources. So whilst aimed at consumers, this campaign provides businesses placing toys on the market with a timely reminder that the safety standards of toys must be met.

#### Defra reminds businesses of their obligation as EPR reporting requirements come into force

On 28 February, the extended producer responsibility (EPR) reporting requirements, as set out in the <u>Packaging Waste</u> (<u>Data Reporting</u>) (<u>England</u>) Regulations 2023 (SI 2023/219) came into force.

Alongside these, the Department for Environment, Food & Rural Affairs (Defra) published a <u>reminder</u> to businesses that supply household packaging and meet the required threshold of their obligations to collect information on the amount and type of packaging they have supplied during 2023. The first reports must be submitted from 1 October 2023.

The requirements applies to producers with an annual turnover of £2 million that handle more than 50 tonnes of packaging each year and requires them to report twice a year, starting on 1 October 2023, with data on the amount and type of packaging they supply.

The Producer Responsibility Obligations (Packaging and Packaging Waste) Regulations 2023 will be introduced to establish the packaging EPR regime in full later in 2023. They will revoke and replace the 2023 data regulations by including equivalent data collection provisions.

New government guidance has also recently been published on how to structure packaging data submissions, and includes information about the different types of data that needs to be submitted and the codes that need to be used.



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Regulated procurement

## Regulated procurement

#### Procurement Bill 'go-live' delayed until early 2024 at the earliest

In their latest Transforming Public Procurement programme update email, the Cabinet Office provided us with an update on the timeline of the Procurement Bill:

- the bill has now completed its passage through the Committee Stage and moves to its penultimate stage, the Report Stage, in the House of Commons;
- it is expected to become law later this spring;
- after becoming law, draft secondary legislation will be prepared and the government will run a public consultation on this before it is made; and
- the expected "go-live" date of the new procurement regime is early 2024 at the earliest.

The Transforming Public Procurement government webpage has been amended to reflect these changes.

The date when the bill will reach the Report Stage is still to be announced. Almost all of the amendments made by the House of Lords were rejected in the Commons and the bill is still subject to further amendment. We may therefore see the bill "ping-pong" between House of Commons and the House of Lords if they cannot agree on the final form of the bill (meaning it will go back and forth between the houses to try and resolve disagreements regarding changes to it).

While the "go-live" date has been pushed back once again, those subject to the procurement regime should be using this time to understand the new procurement regime and how the regulations will work.

#### PPN 03/23: Standard Selection Questionnaire

The Cabinet Office has published an updated Standard Selection Questionnaire (SQ). The new SQ and accompanying statutory guidance is set out in <a href="PPN 03/23">PPN 03/23</a>, published on 9 March. The amendments are based on feedback from buyers and suppliers to improve the supplier selection process, and reflect changes to policy.

Changes include, among others:

- clarity on changes contracting authorities can make to the wording of questions (Annex A, paragraphs 9, 13, 42, and 43);
- introduction of supply chain questions (Annex A, paragraphs 66-67);
- introduction of additional requirements for modern slavery and clarity on handling responses to questions on the Modern Slavery Act (Annex A, paragraph 78); and
- introduction of questions related to reducing carbon emissions (Annex A, paragraph 76).

The revised SQ is to be in use at the latest by 1 April 2023, but can be used immediately. This timescale is to allow for the time needed to incorporate the revised SQ into procurement processes and for the amendment of e-procurement tools.

Despite the forthcoming changes to be made by the Procurement Bill, this PPN applies to procurements under the Public Contract Regulations 2015, so those contracting authorities to whom to whom these Regulations apply and suppliers who bid for opportunities under them should familiarise themselves with these changes.



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## Regulated procurement



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**Sanctions and Export Control** 

## **Sanctions and Export Control**

#### OFSI updates maritime services and oil price cap guidance

On 8 March 2023, the Office for Financial Sanctions (OFSI) updated its <u>guidance</u> on maritime services and the oil price cap exception.

The guidance now reflects the <u>price cap on Russian refined oil products</u>, and the introduction of the wind-down period for oil products loaded on ships before 5 February 2023.

#### UK amends guidance on licensing for Russian sanctions

The UK's statutory <u>guidance</u> on Russian sanctions has been amended in relation to licences for various services (that is, accounting, advertising, architectural, auditing, business and management consulting, engineering, IT consultancy and design and public relations services to a person connected with Russia): a licence may now be granted "*if it is necessary for ensuring critical energy supply to any country*".

#### Update to OFSI enforcement guidance

On 16 March 2023, OFSI updated its <u>Enforcement and Monetary Penalty guidance</u> to include details on its approach to assessing breaches of financial sanctions where breaches involve an incorrect assessment of ownership and control of an entity.

#### Updated sanctions review request form

On 28 February 2023, the Foreign, Commonwealth and Development Office (FCDO) <u>updated</u> its sanctions review request form, for use by designated persons, UN listed persons, or persons acting on their behalf, to request a review of their designation or UN listing.

The form now specifies that the following information should also be submitted concurrently:

- proof of identity of the designated person;
- confirmation of your authority to act on behalf of the requester (where applicable); and
- evidence supporting the request.

#### Government announces £50m economic deterrence initiative

On 13 March 2023, the government announced the launch of a new <u>UK Integrated Security Fund (UKISF)</u>, as part of the <u>Integrated Review Refresh 2023</u>, which updates the government's national security and international policies.

The UKISF will replace the existing Conflict, Stability and Security Fund (CSSF) and support the work of the new Economic Deterrence Initiative, which will tackle sanctions evasion across the UK's trade, transport and financial sanctions.

According to the government, £50 million in funding will be provided to improve the enforcement of the country's sanctions regime, in addition to working with the private sector to maximise the effect of sanctions against hostile actors.

### Global Advisory issued by the REPO task force

The Russian Elites, Proxies and Oligarchs (REPO) task force, which is made up of representatives from many countries, including the UK, issued a global <u>advisory</u> on Russian sanctions evasion. The advisory identifies tactics such as the use of family members and close associates and the use of real estate as a vehicle to launder money.

Recommendations for regulated entities in the advisory include ensuring that their compliance programmes implement relevant anti-money laundering/combating the financing of terrorism (AML/CFT) laws and regulations and are regularly reviewed.

REPO members also reported that they had discovered trust arrangements that may have been designed to thwart sanctions enforcement.

Separately, on 21 March 2023, the FCDO announced that all persons designated under the Russian financial sanctions regime had also been designated for the purpose of trust services sanctions.

# **Sanctions and Export Control**



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### **Telecoms**

#### Ofcom consults improving broadband information for customers

Ofcom is proposing new guidance <u>through consultation</u> to ensure that broadband providers give clear information to customers on the technology used in their broadband connections.

Ofcom research found that less than half of customers who reported being on a full-fibre broadband service lived in areas where it was actually available. Just over a quarter of customers lacked confidence in understanding the terms used by broadband providers. The research also suggested that the majority of customers would find it useful to be provided with a description of the underlying technology used to deliver their services.

The consultation sets out the regulator's proposals to help customers make more informed choices when it comes to broadband products and services. Broadband providers can only use the terms "fibre" and "full-fibre" on their websites and in contracts if their network uses fibre-optic cables all the way from the exchange to the home. Customers will be given a concise and clear description of the type of broadband network technology they are signing up to.

The consultation is due to close on 3 May 2023 and Ofcom aims to publish its findings later this year.

#### Key dates for diary

Date	Description	Summary
March 2023	Ofcom Plan of Work	Ofcom plans to publish its finalised "Plan of Work" for 2023/24 setting out the areas of focus for the next financial year.
Spring 2023	Ofcom consultation into digital content gateways and online communications services to be published	
3 April 2023	General Conditions updates	Updates to General Conditions – changes to B3, C1, C7 and Definitions to implement the European Electronic Communications Code and introduce a new process for switching landline and broadband services with effect from 3 April 2023
Autumn 2023	Ofcom responses to cloud services market and net neutrality reviews to be published	
31 March 2024	Telecoms Security Rules	"Tier 1" telecoms providers will now be expected to implement the most straightforward and least resource intensive measures (for example, maintaining accurate records of all externally-facing systems) by 31 March 2024.

## **Telecoms**



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