MASON HAYES & CURRAN

Products & Consumer Protection Mid-Year Review 2024

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Welcome to Mason Hayes & Curran's Product & Consumer Protection Mid-Year Review 2024

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In the six months since the publication of our 2023 Annual Review, there have been significant changes in the EU product and consumer protection law landscape. We review some of the key developments during the year to date and look ahead to future reform.

In this Review, we will consider key issues such as:

- An update on the proposed revised Product Liability Directive and its potential impact for consumer products stakeholders
- Recent developments under Irish law regarding the regulation of single use plastics and cap/lid tethering obligations
- Potential liability considerations arising from 'hallucinations' by customer service chatbots
- An update on the recently enacted EU Data Act and its impact for connected products and cloud services
- An overview of the implementation of the European Accessibility Act into Irish Law

We discuss these issues and much more and hope you enjoy the fifth edition of our Mid-Year Product & Consumer Protection Review.

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Michaela is Head of our Products practice and Head of Life Sciences. She advises clients in the pharmaceutical, healthcare, medical device, digital health, cosmetic, software and general consumer product sectors on various regulatory compliance matters. She frequently advises clients on the applicable regulatory framework, regulatory approval, labelling, packaging, traceability, safety and liability issues. Michaela also represents manufacturers in product liability claims and enforcement action by regulators.

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As part of its holistic approach to AI policy, the European Commission has proposed a package of reforms. These reforms aim to adapt EU product liability rules to the digital age and AI, including through a revision of the Product Liability Directive[1] (the PLD). The revised Directive is intended to be complementary in nature to current EU product safety frameworks. These include:

- The General Product Safety Directive[2] (GPSD)
- Its successor, the General Product Safety Regulation[3] (GPSR), which will apply from December 2024, and
- The recently adopted AI Act

These interlinked frameworks give rise to a complex new legislative environment that consumer product stakeholders must navigate with care. We highlight some important connections between these frameworks that developers of AI-enabled products and services should be mindful of.

Broader scope of the PLD

The PLD seeks to update the EU's strict liability regime applicable to products, including software and by extension, AI systems. Accordingly, claims for damage allegedly caused by AI-enabled consumer products and services will fall within the scope of the PLD. This is because the PLD expands the definition of a 'product' to include software:

"*'product' means all movables, even if integrated into, or inter-connected with, another movable or an immovable; it includes electricity, digital manufacturing files, raw materials and software*".

While the term 'software' is not defined in the PLD, the recitals to the PLD make clear that it applies to software of all kinds, including:

- Operating systems
- Firmware
- Computer programmes
- Applications, and
- AI systems

It also acknowledges that software is capable of being placed on the market as a standalone product and may subsequently be integrated into other products as a component. Accordingly, software will be a product for the purposes of applying no-fault liability under the PLD. This applies irrespective of:

- The mode of its supply or usage, and
- Whether it is stored on a device or accessed through a communication network, cloud technologies or supplied through a software-as-a-service model

1. *Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products*
2. *Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety*
3. *Regulation (EU) 2023/988 of the European Parliament and of the Council of 10 May 2023 on general product safety*

Insofar as an AI system qualifies as a 'product' and 'software', it is proposed to fall within the scope of the PLD. At a high-level, this will mean that the PLD will apply to most, if not all, consumer or public-facing systems. It will also apply to systems that are components of hardware that qualify as a physical 'product'. Accordingly, consumer products and services delivered using AI-enabled technologies such as wearable devices, chatbots and smart assistant apps will be affected.

Two noteworthy exclusions regarding the scope of the PLD are as follows:

1. The new product liability rules contained in the PLD will apply to products placed on the market or put into service 24 months after its entry into force. The current Product Liability Directive will be repealed with effect from 24 months after the PLD's entry into force. However, it will continue to apply to products placed on the market or put into service before that date.
2. The PLD will not apply to pure information, such as the content of digital files or the mere source code of software. It will also not "*apply to free and open-source software that is developed or supplied outside the course of a commercial activity*". However, if such software is subsequently integrated by a manufacturer as a component into a product in the course of a commercial activity, the PLD will apply.

Defectiveness

Under the PLD, the criteria for determining the defectiveness of a product, including an AI system, will be expanded. Some of these additional criteria, which are non-exhaustive in nature, are particularly relevant to AI systems and link back to AI Act requirements:

- In the first instance, the PLD provides that a product will be considered defective "*if it does not provide the safety that a person is entitled to expect or that is required under Union or national law*". Consequently, an AI system may be deemed defective for the purposes of a product liability claim by virtue of being non-compliant with requirements under the GPSD / GPSR and/ or the AI Act.
- Additional defectiveness criteria specified under the PLD include a product's interconnectedness, self-learning functionality and safety-relevant cybersecurity requirements.
- In reflecting the relevance of product safety and market surveillance legislation for determining the level of safety that a person is entitled to expect, the PLD also provides that, in assessing defectiveness, interventions by competent authorities should also be taken into account. This includes "*any recall of the product or any other relevant intervention by a competent authority or by an economic operator as referred to in Article 8 relating to product safety*".

Accordingly, when considering the defectiveness or otherwise of an AI system, its compliance with requirements under the GPSD / GPSR and/or the AI Act will be taken into account. Interventions by competent authorities will also be taken into account.

Rebuttable presumption - defectiveness

Under the PLD, the burden remains on a claimant to prove:

- The defectiveness of the product
- The damage suffered
- The causal link between the injury or damage sustained, and the allegedly defective product

These elements must be proven in accordance with the standard of proof applicable under national law in the relevant Member State(s). The PLD acknowledges, however, that injured parties are often at a disadvantage compared to manufacturers in terms of accessing and understanding information about how a product was produced and how it operates. This is particularly true in cases involving technical or scientific complexity.

Accordingly, the PLD introduces a rebuttable presumption of defectiveness where:

- The claimant demonstrates that the product does not comply with mandatory product safety requirements laid down in Union law or national law
- The claimant demonstrates that the damage was caused by an "*obvious malfunction*" of the product during "*reasonably foreseeable*" use or under ordinary circumstances
- A defendant fails to comply with a court order to disclose relevant evidence at its disposal

In the context of AI systems, the rebuttable presumption of defectiveness triggered under the PLD can arise from a product's non-compliance with mandatory product safety requirements laid down in Union law or national law. This presumption could therefore be triggered by an act of non-compliance with requirements under the GPSD / GPSR and/or the AI Act.

Rebuttable presumption - causation

The PLD also provides for the presumption of a causal link between a product's alleged defectiveness and the damage suffered. This presumption applies where it has been established that the product is defective, and the damage caused is of a kind typically consistent with the defect in question.

A rebuttable presumption will arise where a national court must presume a product's defectiveness or the causal link between its defectiveness and the damage suffered, or both, where, despite the disclosure of evidence by a manufacturer, and taking all relevant circumstances into account:

- The claimant faces excessive difficulties, in particular due to technical or scientific complexity, in proving the product's defectiveness or the causal link between its defectiveness and the damage, or both, and
- The claimant demonstrates that it is likely that the product is defective or that there is a causal link between the defectiveness, the damage, or both.

On the interpretation of '*excessive difficulties*', Recital 48 of the PLD refers to AI systems specifically. It provides that in determining technical or scientific complexity, national courts must do this on a case-by-case basis, taking into account various factors, including:

- The complex nature of the technology used, such as machine learning.
- The complex nature of the causal link such as a link that, in order to be proven, would require the claimant to explain the inner workings of an AI system.

It further provides that, in the assessment of excessive difficulties, while a claimant should provide arguments to demonstrate excessive difficulties, proof of these difficulties should not be required. For example, in a claim concerning an AI system, the claimant should neither be required to explain the AI system's specific characteristics nor how those characteristics make it harder to establish the causal link.

Manufacturer's control

The PLD introduces various new provisions that recognise that, in the case of technologically sophisticated products, a manufacturer's responsibilities do not necessarily crystallise at the factory gates. This is particularly significant for connected consumer products, where the hardware manufacturer retains the ability to supply software updates or upgrades to the hardware by itself or via a third party.

The PLD provides that the developer or producer of software, including an AI system provider, should be treated as a manufacturer. While the 'provider of a related service' is recognised as an economic operator under the PLD, related services and other components, including software updates and upgrades, are considered within the manufacturer's control when they are integrated, inter-connected or supplied by the manufacturer. It also applies where the manufacturer authorises or consents to their supply by a third party.

A 'related service' is defined in the PLD as "*a digital service that is integrated into, or inter-connected with, a product in such a way that its absence would prevent the product from performing one or more of its functions*". For example, where a manufacturer consents to the provision by a third party of software updates for its product or where it presents a related service or component as part of its product even though it is supplied by a third party. However, a manufacturer isn't considered to have consented to the integration or interconnection of software with its product merely by providing for the technical possibility to do so. Similarly, a manufacturer isn't considered to have consented by recommending a certain brand or by not prohibiting potential related services or components. Additionally, once a product has been placed on the market, it is considered within the manufacturer's control insofar as it retains the technical ability to supply software updates or upgrades itself or via a third party.

This means that manufacturers of products with digital elements may be liable for damage arising from changes to those digital elements that occur after the physical product is placed on the market. This is a significant shift to more of a 'lifecycle' approach. The consequence for manufacturers of AI-enabled products is that greater attention will need to be paid to:

- The degree of control it exercises over its products once placed on the market.
- Where its products remain within its control, the extent to which changes like software updates and upgrades impact on not just safety but also product liability exposure.
- What 'related services' form part of its products and the level of control exerted over these 'related services'. This includes the nature of the relationship with any third-party providers of related services and the potential consequences from a product liability perspective.

Substantial modification

The PLD maintains the general limitation period of 3 years for the initiation of proceedings for the recovery of damages. This limitation period runs from the day on which the injured person became aware, or should reasonably have become aware, of all of the following:

- The damage
- The defectiveness, and
- The identity of the relevant economic operator that can be held liable for the damage.

The PLD contains two modifications to the current 10-year longstop provision in the existing Product Liability Directive:

1. An extension to 25 years in certain cases involving latent personal injuries unless the injured person has, in the meantime, initiated proceedings against a potentially liable economic operator.
2. Where a product has been 'substantially modified', the calculation of time runs from the date that the substantially modified product has been placed on the market or put into service.

The PLD defines 'substantial modification' as the modification of a product after it has been placed on the market or put into service:

- That is considered substantial under relevant Union or national rules on product safety, or
- Where relevant Union or national rules do not provide such a threshold, that:
    - Changes the product's original performance, purpose or type without being foreseen in the manufacturer's initial risk assessment, and
    - Changes the nature of the hazard, creates a new hazard, or increases the level of risk.

What amounts to a 'substantial modification' can be quite case specific. However, the reference in the definition to modifications that are "*considered substantial under relevant Union or national rules on product safety*" engages the AI Act. This is because it contains references to substantial modification in the context of 'high-risk AI systems'.

An AI system will be considered 'high risk' where it is:

1. Intended to be used as a safety component of a product, or is itself a product, covered by the Union harmonisation legislation listed in Annex I to the AI Act.
2. Required to undergo a third-party conformity assessment before being placed on the market or put into service in the EU in accordance with the applicable Union harmonisation legislation listed in Annex I to the AI Act.

Examples of possible high-risk AI systems in a consumer product context include toys, cars and AI systems that continue to learn after being placed on the market or put into service.

Where no thresholds are provided under the relevant Union or national rules on product safety, the threshold is assessed by the extent to which the modification changes the product's original intended functions or affects its compliance with applicable safety requirements or changes its risk profile. For example, in cases involving regulated AI systems that are not high-risk under the AI Act. We expect that the practical application of these concepts in the context of AI systems will require complex and case-specific analyses on liability exposure and mitigation.

Irrespective of which threshold criteria is applicable to a specific AI-enabled product, AI system providers and providers of products with AI components, will need to carefully track how relevant AI systems are changing and the legal consequences of those changes.

Conclusion

The move to bring the EU product liability regime up to speed with updated product safety legislation is likely to give rise to increased litigation risks that will require careful management. This is particularly the case for liability exposure related to software as a 'product' for the purposes of product liability claims. To prepare for these incoming changes, stakeholders with consumer products on the EU market should carefully consider their potential liability exposure under the PLD.

We would recommend that they carefully analyse their existing product portfolio to:

- Identify what products would fall within the scope of the PLD, including a review of third-party software and 'related services', i.e. digital services embedded in their hardware products.
- Review the warnings and disclaimers provided to users relating to risks or potential harm associated with using their products and related services, particularly having regard to the extended definition of damage.
- Incorporate the necessary screens and protocols into their product roadmaps in order to identify and mitigate EU product liability exposure.

Consumer product stakeholders should also review their:

- Product liability insurance to ensure, amongst other things, that their coverage includes all damage envisaged under the PLD. Specifically, they should ensure that coverage extends to destruction or corruption of data and medically recognised damage to psychological health and to ensure that related services are also covered.
- Contractual arrangements with other economic operators to ensure there are adequate liability and indemnity provisions in place. This is particularly important given the new provisions in the PLD around service providers and what is considered to be within the manufacturer's control – even if a third party is carrying out certain tasks or services on their behalf.

‘Tethering’ Obligations and the Deposit Return Scheme Takes Off

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The Circular Economy Act 2022 was signed into law in August 2022. It places the Government’s circular economy strategy and Waste Action Plan for a Circular Economy on a statutory footing. Both policies are intended to give effect to the EU’s circular economy action plan. Some of the initiatives under this package of measures by the Irish Government have now been put in place, with others due to come into force soon.

There is an upcoming deadline this summer as the cap/lid ‘tethering’ obligations kick in from 3 July 2024. In addition, there are further duties on the horizon.

The Deposit Return Scheme has recently launched, with producers, retailers, consumers and the newly established Re-turn, the administrative body for the Scheme, now navigating the initial teething problems.

Single-use plastics and cap/lid ‘tethering’

The Government gave effect to the EU’s Single Use Plastics Directive[1] by the introduction of the Single Use Plastics Regulations[2] (SUP Regulations) in 2021.

The SUP Regulations take a phased approach to the introduction of obligations. The next one on the agenda is the introduction of the cap/lid tethering obligations.

From **3 July 2024**, all single use plastic beverage containers sold in Ireland for the first time that have a capacity of up to three litres and a cap or lid, must be manufactured so that the cap or lid remains attached to the container during the container’s intended use stage.

This obligation applies to all “producers” that place such products on the market in Ireland for the first time which may include manufacturers, sellers and importers.

Glass or metal containers are excluded, even where they have caps and lids made from plastic. There is a similar exemption available for containers of food in liquid form that is used for special medical purposes. It is also important to note that the obligation applies only to beverage containers and not to beverage cups. Cups and containers are treated as different product categories for the purpose of the SUP regime. The European Commission guidance[3] explains that one of the key elements for distinguishing between these is their shape.

Failure to comply with the tethering obligation is an offence. Persons who commit such an offence may be liable for a fine and/or imprisonment. This is the case for many of the obligations in the SUP Regulations.

1. *Directive (EU) 2019/904*
2. *SI 516/2021 - European Union (Single Use Plastics) (No2) Regulations 2021*
3. *Commission guidelines (2021/C 216/01) on single-use plastic products in accordance with Directive (EU) 2019/904*
4. *SI No 33/2024 - Separate Collection Deposit Return Scheme) Regulations 2024*

Deposit Return Scheme

The Deposit Return Scheme (DRS) was launched on 1 February 2024 by the DRS Regulations 2024. The DRS requires producers and retailers of PET beverage bottles and aluminium or steel beverage containers with a capacity between 150ml – 3 litres to charge a levy to purchasers. This levy is returned to the customers upon return of the products to a recycling facility. Producers and retailers must also register with Re-turn. They must also comply with other obligations to ensure customers are aware of the scheme such as product labelling, itemising deposits, and the take-back options.

There are some exemptions available to retailers:

- An automatic exemption from the scheme for retailers where the product is intended to be consumed on the premises
- Exemptions from the need to provide take-back options, subject to the approval of Re-turn, are for:
    - Retail stores 250m^2 or less in size
    - Purchases made online or through a vending machine
    - Products sold by a hotel, restaurant, pub or similar premises where food and drink is consumed

The availability of functioning deposit return facilities and the application of the exemptions seems to be giving rise to some initial teething problems within the DRS. This is particularly the case in hotel/restaurant settings where the premises can elect whether or not to charge the deposit depending on whether they are predominantly catering for onsite or offsite consumption. If the deposit is charged, then the container should be provided to the purchaser. This applies even where they consumed the beverage on the premises so that the customer, rather than the hotel/restaurant, collects the deposit[5].

What else is on the horizon?

The transition to a truly circular economy represents a huge change. The legal framework supporting this transition is constantly evolving, and there are many more circular economy measures on the horizon, including:

- Minimum targets for recycled content of certain single use plastic bottles, where the main component is PET, of 25% by **1 January 2025**. This is calculated as an average for all PET bottles placed on the market in Ireland. This will increase to 30% by **1 January 2030** under the SUP Regulations
- Due diligence obligations on certain coffee, cocoa, soya, cattle, oil palm, rubber, and wood products to ensure they are 'deforestation free' and comply with certain legislation. These obligations are due to come into effect from **30 December 2024**. For more information, see our previous article.
- A proposed Regulation on Packaging and Packaging Waste is being considered at EU level. This legislation would impose additional sustainability requirements for packaging, such as recyclability, reusability and compostability targets

Conclusion

The introduction of the Deposit Return Scheme and the single use plastic cap/lid 'tethering' obligations are the most recent measures in Ireland's drive to establish a circular economy. However, there are more on the horizon.

All retailers, hotel/restaurant/bar operators, producers and manufacturers will need to familiarise themselves with the existing and future obligations. In particular, it is time to ensure that you're ready to comply with the cap/lid 'tethering' obligations kicking in from 3 July 2024.

5. *Re-turn Hospitality Summary Information Guide*

Potential Liability for Chatbot Hallucinations?

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Chatbots are often the first point of contact with a company that a customer has on a website when they have a query. The recent adoption of the EU's AI Act has attracted most attention for the regulation of chatbots. However, a recent small claims tribunal decision from Canada is a cautionary reminder that other areas of law will also apply to a chatbot.

Background

The case saw a chatbot give inaccurate information to a consumer who raised a query about an airline's bereavement fare policy. This was despite the relevant webpage of the website correctly stating the airline's bereavement fare policy. Relying on the chatbot's "*hallucination*", the consumer bought two full-price fares to attend their grandmother's funeral. When the consumer submitted an application for a partial refund, the airline was directed by the small claims tribunal to comply and provide the partial refund.

The tribunal decision found that the airline had made a negligent misrepresentation as it had not taken reasonable care to ensure its chatbot was accurate. As a result, the airline was forced to honour the partial refund. While the airline argued that it was not responsible for information provided by its agents, servants or representatives, including a chatbot, the tribunal decided that this argument did not apply in this situation. This was due to the fact that the chatbot was not a separate legal entity. It was instead deemed to be a source of information on the airline's website.

The airline also argued that its terms and conditions excluded its liability for the chatbot but did not provide a copy of the relevant terms and conditions in the response. Therefore, the tribunal did not substantively consider the argument. In addition, while the chatbot's response had included a link to the relevant webpage, the tribunal found that the consumer was entitled to rely on the information provided by the chatbot without double checking it against the information at the webpage.

Application in Irish law

Under Irish law, it is possible that a court would reach a similar conclusion, particularly in a consumer dispute. It is unlikely that a court would find that a chatbot was a separate entity from the chatbot's operator. Therefore, it would find that the chatbot constituted information on the company's website.

Irish law also prohibits misleading commercial practices. This includes the provision of false or misleading information that would cause an average consumer to make a transactional decision that they would not otherwise make. The provision of false information by a chatbot which results in a consumer making a purchase on the trader's website could therefore be deemed a misleading commercial practice in an Irish court.

While the point was not fully considered in the Canadian decision, a contractual clause which excludes the liability of a company for hallucinations by its chatbot in similar circumstances may not be enforceable in Ireland. Under Irish law, contract terms which are unfair are not enforceable against a consumer. While terms which exclude a company's liability for chatbots are not uncommon, the fairness of a term such as this, particularly where the consumer has made a purchase from the company relying on the information provided by the chatbot, would be questionable.

Key takeaways

While chatbots are a useful tool for companies to interact with their customers, companies should be aware of the legal risks which arise through their use. While it is unlikely that this single tribunal decision from Canada will make companies liable for all chatbot hallucinations, it is a reminder that their use can lead to unexpected liability for the company operating the chatbot. The risk is starker in a B2C setting as EU consumer law will generally not allow organisations to make consumers responsible for risks associated with poor product performance.

Companies will also have to consider their potential liability for chatbot hallucinations under the European Commission's proposed revised Product Liability Directive. The revised Directive will enter into force in 2024. The new rules will apply to products placed on the market 24 months after its entry into force. The revised Directive will significantly modernise the EU's product liability regime. This includes by expanding the definition of a 'product' to include software, including standalone software, and digital manufacturing files.

Under the new rules, software will be a product for the purposes of applying no-fault liability. This is irrespective of the mode of its supply or usage and whether it is stored on a device or accessed through a communication network, cloud technologies or supplied through a software-as-a-service model.

The revised Directive also seeks to expand the scope of liability beyond when a product was put into circulation to possibly include the time after circulation. This proposed expanded scope may apply after a product has been placed on the market if a manufacturer retains control of the product, for example, through software updates and upgrades. Manufacturers may also be held liable for software updates and upgrades supplied by a third party where the manufacturer authorises or consents to their supply. For example, where a manufacturer consents to the provision by a third party of software updates or where it presents a related service, an integrated or inter-connected digital service, or component as part of its software even though it is supplied by a third party.

Organisations should also be mindful of the EU's proposed Artificial Intelligence Liability Directive, which is closely linked to and complimented by the revised Product Liability Directive. The proposed AI Liability Directive seeks to harmonise certain aspects of national fault-based civil liability rules for damage caused by AI systems. This includes high-risk AI systems, as defined under the AI Act. The AI Act has now been formally adopted and will come into force 20 days after its publication in the Official Journal of the EU (OJEU). Member States will, however, have two years from its entry into force to transpose the legislation into their national law.

Next steps

To reduce potential liability from chatbots, companies should regularly review the performance of their chatbots. In particular, the following could form part of the regular review:

1. Assessing the output of chatbots to ensure that the information they provide aligns with the company's advertising and sales practices
2. Promptly investigating any customer-reported issues associated with their chatbots

When the chatbot has been provided by a third party, ideally organisations should ensure that the contract with the third party affords it sufficient protection. Acceptable protection would include:

- Clearly outlining which party bears the liability for misleading/false information, and
- Having appropriate obligations in place for the third party to make corrections to the chatbot in a timely manner.

However, chatbot providers will resist very strongly any risk sharing which means organisations need to be vigilant about managing this risk in a practical manner. This includes by ensuring that related services are covered under their product liability insurance. So, when deploying chatbots with consumers, even for basic apparently benign use cases, thoroughly examine the risks associated with hallucinations and incorrect responses. If those responses cannot be fixed, consider another option or put in place a robust remedy process for your customers.

Sustainability Requirements for Products under New Ecodesign Regulation

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The eco-friendly design of goods is of crucial importance to the EU's environmental goals. The European Council recently approved the new Ecodesign for Sustainable Products Regulation (the Ecodesign Regulation). This means it will soon become law with the first product requirements expected to apply from 2027/2028.

The Ecodesign Regulation applies to nearly all goods that are placed on the EU market. This is a much broader scope than the Ecodesign Directive 2009 which is limited in scope to energy related products.

At its core, the Ecodesign Regulation:

- Sets environmental sustainability requirements for goods placed on the EU market
- Establishes a digital product passport to provide information about a product's environmental footprint, and
- Prohibits the destruction of certain unsold consumer goods

Scope

The Ecodesign Regulation applies to "any physical goods" placed on the EU market. It applies to goods produced both inside and outside of the EU. Some exemptions apply to goods such as food, medicinal products and plants.

The Regulation does not specify sustainability requirements for certain products. Rather, it creates a framework for the European Commission to specify what these requirements are. The requirements may include the following:

- Product durability, reusability, upgradability and reparability
- Presence of substances that inhibit circularity
- Energy and resource efficiency
- Recycled content
- Remanufacturing and recycling, and
- Carbon and environmental footprint

Certain resource-intensive product groups will be prioritised by the European Commission. These include:

- Iron and steel
- Aluminum
- Textiles
- Information and communications technology, and
- Electronics

The European Commission has already commenced preparatory work on textile requirements. It will continue to outline priority products every three years in a dedicated work plan.

Digital product passport

The Ecodesign Regulation establishes a single, digital entry point to access information about the environmental sustainability of products (Digital Product Passport). This information will be easily accessible by scanning a data carrier. It will include details on a product's durability, reparability, recycled content as well as the availability of spare parts. The Digital Product Passport aims to help consumers and businesses make informed choices when purchasing products. It also seeks to facilitate repairs and recycling. Additionally, it aims to improve transparency about a product's impact on the environment. The Digital Product Passport will also help enforcement authorities to perform checks and controls on products.

Ban on destruction of textiles

The destruction of unsold textiles and footwear will be prohibited under the new Regulation. There will be a temporary exemption from this for small and medium enterprises. The European Commission will be empowered to introduce similar measures for other goods in the future.

Disclosure on unsold products

Where economic operators discard unsold goods, they will be required to disclose this prominently as a notice on their website. The notice will have to include:

- The quantity and weight of unsold products
- The reasons for their disposal, and
- The measures put in place to prevent this going forward

Penalties

It is anticipated that national market surveillance authorities will play a prominent role in enforcing the Regulation. Member States will have to introduce penalties for non-compliance through national legislation. These will include fines and time-limited exclusions from public procurement procedures, amongst others.

Conclusion

The Ecodesign Regulation is a substantial development for the EU market. It is a key step towards a circular economy. Although the requirements will not be in place until 2027 at the earliest, stakeholders should familiarise themselves with the direction of travel under the Regulation. Sustainability requirements will be prescribed for specific products in accordance with the new framework. Organisations, along the product supply chains, will need to ensure they then put processes in place with sufficient time to achieve compliance.

New EU Rules for Connected Products and Cloud Services

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The EU Data Act introduces new requirements for:

- Access to data
- Switching cloud service providers, and
- Interoperability requirements in the EU

The purpose of the Data Act (Regulation (EU) 2023/2854[1]) is to:

- Unlock potential for data innovation in the EU
- Help create value from data, and
- Ensure greater balance between the different players in the market

The Data Act is part of the European strategy for data. It complements the Data Governance Act which applies since September 2023. The Data Act has considerable significance for a range of actors, including manufacturers, providers and users of connected devices and related services, and for providers and customers of cloud services.

Data sharing

The Data Act will have a significant impact for data sharing within the EU.

1. Access to data of connected products

The Data Act introduces rules enabling users of connected products access to product data and related service data from those products. This includes metadata which is required to interpret this data. Products must be designed and manufactured in a way which makes it possible, where relevant, for this data to be provided:

- By default
- Easily
- Securely
- Free of charge, and
- In a comprehensive, structured, commonly used and machine-readable format

There are also pre-contractual information requirements such as providing information to the user of the type, format and estimated volume of product data that the connected product is capable of generating.

The Data Act also contains rules permitting users to share this data with third parties subject to conditions, such as using the data only for the purposes agreed with the user and to erase the data once it is no longer needed. Users, in this context, include both businesses and consumers. However, micro and small companies are not subject to these obligations.

2. Obligation to share data with the public sector

The Data Act introduces requirements for data holders to make data available to public sector bodies and EU institutions where they can demonstrate an "*exceptional need*" to use the data requested. This will arise in situations where it is necessary to respond to a public emergency, where necessary to mitigate a public emergency, and to fulfil specific tasks in the public interest explicitly provided by law.

The Data Act also provides for a compensation scheme to cover the technical and organisational costs incurred to comply with the request in certain circumstances.

3. Unfair contract terms

The Data Act will introduce the concept of unfair contract terms in a business-to-business context for data sharing agreements. A contractual term is unfair if it is "*of such a nature that its use grossly deviates from good commercial practice in data access and use, contrary to good faith and fair dealing*". A black list of terms is provided which will always be unfair if unilaterally imposed by one enterprise on another, while a grey list of terms is provided which are presumed to be unfair when unilaterally imposed by one enterprise on another. This will be a departure from existing Irish law which mostly only regulates unfair contract terms in a business-to-consumer context.

Cloud switching

The Data Act will make the process of switching between cloud and edge computing services easier. This includes a prohibition on commercial, technical and organisational obstacles which prevent customers of such services from switching.

1. Contract terms

The Data Act requires the rights and obligations as regards switching to be included in a written contract and requires certain contract terms to be included such as:

- A requirement for the switch to occur on request from the customer without undue delay and, in any event, within 30 days
- An obligation of the cloud service provider to support the customer's exit strategy relevant to the contracted services
- The contract will be terminated (a) where applicable, upon successful completion of the switching process, or (b) at the end of the maximum period for initiation of the switching process where the customer does not wish to switch but to erase its exportable data and digital assets upon service termination, and
- A maximum notice period for initiating the switching process not to exceed 2 months

These mandatory contract clauses will have significant implications for providers' commercial models, contract duration and termination provisions, particularly for pricing of longer term services contracts.

2. Switching charges

The Data Act also provides for the gradual withdrawal of switching charges. Switching charges will be abolished from 12 January 2027. Since 11 January 2024, switching charges must be limited to the costs directly arising from the switching process. Cloud service providers must provide the prospective customer with clear information on standard service fees and early termination penalties that might be imposed. They must also provide clear information on the reduced switching charges that might be imposed up to 12 January 2027. Given that this obligation has applied from 11 January 2024, cloud service providers should immediately review their switching charges and contracting process if they have not already done so.

3. Obligation of good faith

Interestingly, the Data Act includes a requirement for all parties, including the incoming cloud service provider, to cooperate in good faith to make the switching process effective and to enable the timely transfer of data and maintain the continuity of the service.

4. Technical aspects of switching

Cloud service providers are also required to provide assistance services to switching users to facilitate the process and to take "*all reasonable measures in their power*" to achieve "*functional equivalence*". This includes:

- Providing capabilities
- Adequate information
- Documentation
- Technical support, and
- Where appropriate, the necessary tools

5. Exception for certain cloud services

Most of the requirements do not apply to cloud services which are custom built or services provided as a non-production version for testing and evaluation purposes for a limited period of time. However, where this is the case, the cloud service provider must inform the prospective customer that these obligations do not apply prior to the conclusion of a contract.

Next steps

The Data Act came into force on 11 January 2024, and most of its provisions will apply from 12 September 2025. Given that significant changes may be required by connected products and cloud service businesses, it is advisable to assess the effect the Data Act will have on your business. Considerable changes to contracts and technical measures may be required. Cloud service providers will also need to be aware of the new requirements regarding switching charges. They must implement this into their contracting process without delay, if they have not already done so, as this obligation has applied from 11 January 2024.

1. *Regulation (EU) 2023/2854 harmonised rules on fair access and use of data*

European Accessibility Act Implemented into Irish Law

Overview of the Irish implementing measures

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In an important development, the European Accessibility Act (EAA) has been implemented into Irish law through the European Union (Accessibility Requirements of Products and Services) Regulations 2023. The EAA is significant for a number of consumer-facing businesses and industries including e-commerce, telecoms, banking, transport and for companies in the technology products space. It will apply from 28 June 2025 and will introduce accessibility requirements for in-scope products and services.

At its core, the EAA is about ensuring products and services within its scope are accessible to persons with disabilities. It does this by setting baseline accessibility requirements for all in-scope products and services, with further, specialised requirements for specific products and services. These may require companies who supply in-scope products and services to make amendments to their products and services. It is therefore important for these companies to start planning for when the EAA becomes effective in 2025.

Clarity on the EAA in Ireland

The Regulations provide greater clarity on the effect of the EAA in Ireland. In particular, the Regulations confirm that the EAA will not be extended to the built environment for all in-scope services. Additionally, the Regulations confirm that Ireland will be implementing an exemption for self-service terminals, such as ATMs and payment terminals, which are lawfully used by service providers for the provision of services before the Regulations come into force. Service providers may continue to use these until the end of their economically useful life, up to a maximum of 20 years after their entry into force.

Market surveillance authority and compliance authorities

The Regulations clarify who the relevant authorities are for ensuring compliance with the accessibility requirements. The Competition and Consumer Protection Commission (CCPC) is the market surveillance authority for all products which are subject to the EAA.

The compliance authorities for services covered under the EAA are more diverse as follows:

Services	Authority
In-scope electronic communications services	Commission for Communications Regulation
Services providing access to audiovisual media services	Coimisiún na Meán
In-scope elements of air passenger transport services	Irish Aviation Authority
In-scope elements of bus, rail and waterborne passenger transport services	National Transport Authority
Consumer banking services	Central Bank of Ireland
E-books and dedicated software and e-commerce services	CCPC
Answering emergency communications to the single European emergency number '112'	Commission for Communications Regulation

The National Disability Authority is also given a special status under the Regulations to advise the relevant authorities on the accessibility requirements under the EAA and the Irish Regulations.

Enforcement and penalties

The Regulations give enforcement powers to the market surveillance authority and compliance authorities. These include the power to issue directions to businesses to comply with its provisions. In addition, they outline a procedure for individual consumers to take an action against businesses in the Irish courts where the consumer believes that the business is not complying with the Regulations. They also provide for public bodies and private associations, organisations or other legal entities with a legitimate interest to support these consumer actions with their approval. This is a particularly noteworthy development as it means private individuals, perhaps backed by interest groups, can bring court proceedings directly.

The Regulations also provide for penalties for breaches of its requirements as follows:

- On summary conviction, a class A fine (€5,000) or imprisonment of up to 6 months, or both
- On conviction on indictment, a fine of up to €60,000 or imprisonment of up to 18 months, or both.

Both companies and their directors, managers, secretaries and other officers can be found guilty of an offence under the Regulations. It will be a defence for a person, including a company, charged with an offence if they can prove that they exercised due diligence and took all reasonable precautions to avoid the commission of the offence.

Harmonised standards

Under Article 15(1) of the EAA, products and services which conform with harmonised standards published in the Official Journal of the European Union are presumed to conform with the accessibility requirements of the EAA, where the standards or parts of the standards cover those requirements. The European Commission has formally requested the drafting of standards in support of the EAA. This request provides for the following existing standards to be revised:

- EN 301 549 Accessibility requirements for ICT products and services
- EN 17161:2019 Design for All - Accessibility following a Design for All approach in products, goods and services - Extending the range of users
- EN 17210 Accessibility and usability of the built environment - functional requirements

The Regulations confirm that products and services which comply with these standards will be presumed to be in conformity with the Regulations. Therefore, those standards may be useful for businesses to consider relating to their compliance with the EAA.

Conclusion

While Ireland missed the deadline of 28 June 2022 for implementing the EAA, the implementation of the Regulations is a very welcome development. They provide greater certainty to businesses as to the impact the EAA will have on their businesses in Ireland. With only about 12 months left before the Regulations apply in Ireland, businesses should use the lead-in time to assess its effect on their business, including preparing for the compliance steps that they will have to take in advance of June 2025.

Recent MHC Events, Articles & Publications

Events & Webinars

- Webinar: Commercial Contracts: What's Market 2024?
- Seminar: The Future of Food

Publications

- Mondaq in Association with Mason Hayes & Curran | Product Liability Comparitive Guide 2024
- Product Liability Law in Ireland (Lexology Getting the Deal Through Series)
- 2024 WWL Life Sciences Rankings
- Supporting the 2024 AI Awards
- Managing IP EMEA Awards 2024 - MHC Wins Three National Awards
- IP Protection and Enforcement – Key Emerging Issues in 2024
- The AI Act is Adopted: Compliance Obligations on the Horizon
- Food, Agriculture & Beverage Sector Update - In Brief Series

About us

Mason Hayes & Curran is a business law firm with 120 partners and offices in Dublin, London, New York and San Francisco.

We have significant expertise in product, privacy and commercial law, which are sectors at the forefront of Digital Health law. We help our clients devise practical and commercially driven solutions for products regulated under complex and ever changing EU health and technology regulatory frameworks.

Our approach has been honed through years of experience advising a wide range of clients in diverse sectors.

We offer an in-depth understanding of the Digital Health regulatory landscape, with a strong industry focus. We ensure to give our clients clear explanations of complex issues, robustly defend their interests and devise practical value-adding solutions for them whenever possible.

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Chambers & Partners, 2024

Our Privacy & Data Security Team

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Chambers & Partners, 2024

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Legal 500, 2024

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