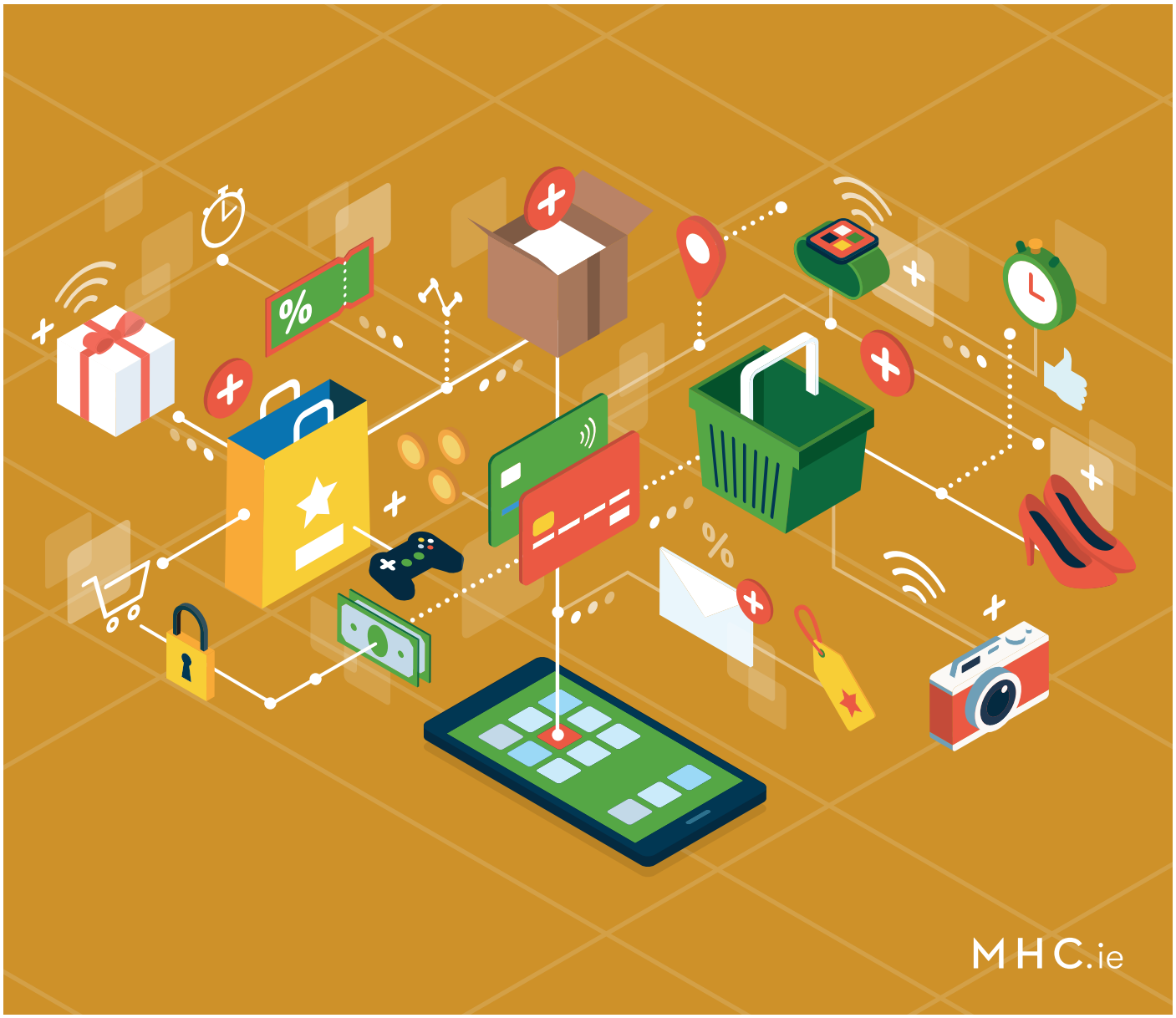
MASON HAYES & CURRAN

Mid-Year Product & Consumer Protection Review

ISSUE 1 – JULY 2020



Introduction

The consumer products industry has been growing exponentially over the past number of years. In particular, one area which has shown significant growth is the fitness software market in Ireland with current revenue of €31.82 million and an expected increase in growth of 3.84% by 2024. The largest segment of this market is wearables with a market volume of €24.54 million in 2020.

The product and consumer protection law landscape in the EU is also rapidly changing and is a highly regulated sector. 2020 has seen a significant number of changes to the consumer protection and product landscape in the EU.

With regard to Brexit, given the prevalence of EU derived legislation in the consumer and product spheres, the impact of a no-deal Brexit could be significant for the industry. Companies may be affected in a broad range of areas, from product development, to market approval, to the selling of products on the EU market.

Further, manufacturers seeking to assist and develop new products to curb the spread of COVID-19 have been faced with novel regulatory considerations. It is crucial that manufacturers and retailers ensure that their goods and services comply with the impending and recent legislation in this area.

We understand the impact for businesses where there is a failure to comply with legislation, both from a legal and reputational perspective.

Our experienced team is dedicated to providing pragmatic and clear advice, robustly defending our client's interests and devising practical, commercially focused solutions to help businesses adapt to the ever changing consumer and product regulatory landscape.

In this Review, we will deep dive into some themes, from consumer protection during COVID-19 to the enhancement of producer responsibility. It will focus on upcoming EU legislation applicable to the manufacture and sale of consumer products, including:

- New Deal for Consumers
- The Goods Package
- The Consumer Protection Cooperation Regulation
- The Single-Use Plastics Directive
- The Accessibility Directive
- The New Safety Standard IEC 62368-1 for ICT and AV Equipment
- New Measures Under the Ecodesign Directive

These pieces of legislation are due to take effect over the next few years, while the Single-Use Plastics Directive came into force in July 2019.

It is important that those in the product and consumer sectors familiarise themselves with the upcoming and recent legislation to ensure compliance with the legislation.

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Michaela is a Regulatory Partner who advises clients in the pharmaceutical, healthcare, medical device, digital health, cosmetic, video game, 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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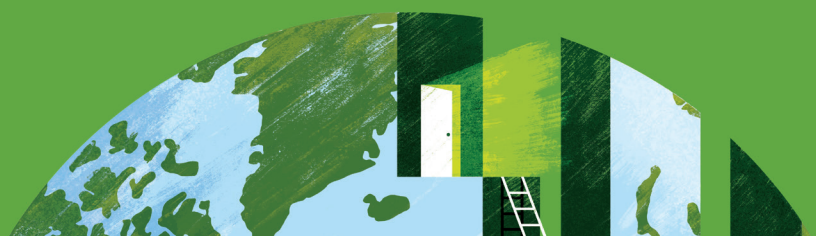
Wendy is a Partner in our Commercial team and her practice also includes EU law, sponsorship and advertising, consumer law, logistics and procurement contracts, and an expertise in the food and beverage sector. She works closely with clients on outsourcing contracts, technology agreements, privacy and data security, distribution and sales solutions and on all contracts for establishing and growing a business.



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Consumer Protection Issues During COVID-19

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The COVID-19 pandemic has completely transformed the way in which traders operate globally as business moved online during the strict lockdown periods which has led to an increased focus on the robustness of consumer protection law throughout the EU. Media coverage has widely reported the increase in consumer scams and illegal marketing practices from online selling. In addition, cancellation of services, travel and events has led to a ramp up of enquiries at Consumer Support Centres throughout the EU as consumers want to seek redress for their cancelled services while heavily affected industries have lobbied for changes to refund rules.

We look at some of the consumer protection issues that have become particularly relevant during the COVID-19 pandemic and review the recent guidance published by the Irish Competition and Consumer Protection Commission (CCPC). In addition, we review recent enforcement action taken by the Consumer Protection Cooperation Network (CPCN).

Amending consumer terms and conditions

The Unfair Contract Terms Directive, as implemented in Ireland by SI 27/1995 Unfair Terms in Consumer Contracts Regulations(Unfair Contract Terms Regulations) is one of the most significant aspects of consumer legislation as it provides that consumers will not be bound by a contract term if it is deemed to be unfair to them. This will typically apply where the term is contrary to the requirement of good faith or if it causes a significant imbalance of the parties' rights and obligations under the contract, to the detriment of the consumer.

Schedule 3 to the Unfair Contract Terms Regulations provides a non-exhaustive 'grey list' of contract terms which may be found to be unfair. However, there has previously been some confusion as to other types of provisions that might constitute unfair terms. This has been an area of particular focus since the start of the COVID-19 crisis as many businesses are in a position where they are unable to provide their goods/services and are seeking to rely on protections in their terms and conditions, e.g. by providing vouchers instead of refunds.

On 15 June 2020, the CCPC published guidelines for businesses to ensure that consumers are adequately protected and are not bound by unfair terms in consumer contracts. It provides additional details around the types of circumstances where unfair terms may arise in contracts and some additional clarity for both businesses and consumers around the scope of what is and is not permissible during the current crisis.

Guidance on producing and selling face coverings in Ireland

On 2 June 2020, the CCPC published guidelines to assist traders in placing safe and legally compliant consumer face coverings on the market. This guidance explains the difference between PPE masks and face coverings and seeks to clarify some of the confusion which has arisen. Current advice by the Irish Government recommends that members of the public should wear a face covering in public where it is difficult to maintain a social distance of at least 2 metres, such as on public transport and in retail shops. PPE face masks are intended primarily for use in the healthcare sector.

The National Standards Authority of Ireland (NSAI) has set out the minimum requirements for the design, manufacture, packaging, marking and labelling of face coverings to be worn by consumers. Producers should be aware that face coverings should not be either explicitly or implicitly sold as PPE or medical devices. In relation to the marketing communications that accompany face coverings, the NSAI Guidance clearly states that the face coverings' packaging, labelling or advertising must not contain claims that they protect, or are intended to protect the consumer from contracting COVID-19 as these claims are likely to mislead consumers and will be regarded as a misleading commercial practice under consumer protection law.

Consumer protection 'common position' during COVID-19

The Consumer Protection Cooperation Regulation 2017/2394 (CPC Regulation) came into effect in January 2020 and provides national authorities with stronger enforcement powers against traders and improves mechanisms for cooperation.

The CPC Regulation sets out the enforcement powers which every EU member state must give to their consumer protection authority, including:

- The ability to carry out test purchases and act as a 'mystery shopper'
- Request information from domain registrars and banks
- Order online platforms to delist traders or search engines to delete entire websites or remove online scams
- Assist consumers in obtaining compensation from traders

Alongside the growth in online shopping, the Commission has recently encountered an increase in deceptive marketing techniques. In March 2020, the Commission issued the CPC Common Position on COVID-19 in consultation with consumer protection authorities, which outlines the most common scams, fraudulent claims and misleading commercial practices. The main issues identified include:

- Pressure selling techniques by using phrases such as "selling out fast" or are in "limited supply" in order to convince consumers to buy more and/or paying a higher price for products
- Misleading advertising relating to unsubstantiated claims being made that a product offers a consumer protection and or health benefits against contracting COVID-19
- Excessive pricing on products as consumer demand surges

The Unfair Commercial Practices Directive, which was transposed into Irish law by the Consumer Protection Act 2007, prohibits commercial practices which deceive consumers about the benefits or the results to be expected from the use of a product. For example, this would apply where a trader claims that a product can cure COVID-19 when this is unsubstantiated by evidence or where it is claimed that the product is only available for a very limited of time when this is not true.

The Commission aims to identify illegal practices, remove them and prevent similar ones from reappearing. On 23 March 2020, the Commissioner for Justice and Consumers, Didier Reynders, wrote to a number of online platforms and social media organisations to require their cooperation in taking down scams from their platforms. In response, these platforms and marketplaces have agreed to measures in collaboration with national authorities. The scale of these issues has been significant. For example, one online platform was required to remove more than 15 million listings.

Enforcement action taken by the CPCN

The CPCN have carried out online investigations or general 'sweeps' of online platforms/websites in a coordinated manner to identify breaches of consumer law across EU member states. The aim of these sweeps is to assess conformity of online listings, identify issues and to prevent future violations of EU consumer law. Recent examples highlighted prices and discounts in online shopping, delivery conditions and withdrawal rights. At the conclusion of the general sweep, each website is informed of consumer law issues and told to make corrections. The effectiveness of these sweeps cannot be overstated. For example, in 2018, the CPCN carried out a sweep on price transparency and drip pricing. Before the sweep, 45% of swept websites were compliant with EU consumer law and after the sweep 78% of companies complied with consumer law.

For cross-border online sales, the CPC Regulation introduced at the start of 2020 has stepped up the powers of national authorities in cross-border situations. Authorities will be able to request information from banks to detect fraud, carry out test purchases to check geographical discrimination or withdrawal rights and to order the removal of online content hosting systems.

Conclusion

Since the outset of the COVID-19 pandemic, consumer protection issues have come into much sharper focus as the regulators step up efforts to ensure consumers are not subjected to exploitative marketing efforts and are protected from sub-standard or dangerous products. The reform of consumer law has been one of the key pillars of the EU's Digital Single Market reforms and the legislative reforms coming on-track over the next 18 months will have a transformative effect in this area.

Even without the enhanced legislative rules being in place, it is clear from the COVID-19 pandemic that EU consumer protection authorities will not tolerate opportunistic and exploitative conduct by traders. The increased focus on enforcement in the CPC Regulation will help strengthen coordinated enforcement across the EU member states. The CCPC has also responded to marketing and advertising practices and indicated that it is very alert to illegal commercial practices which may harm consumers, especially vulnerable consumers.

EU Adopts New Regulation to Strengthen Market Surveillance

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The EU's new Regulation on market surveillance and compliance of products[1] (the Regulation) seeks to improve market surveillance of specific products covered by EU harmonisation legislation.[2] If specific market surveillance rules are currently in force for a particular product that the Regulation also deals with, then these rules will still apply.

In addition, products imported into the EU will also be governed by the Regulation. Examples of products and chemicals covered include: medical devices, machinery, batteries, toys, fertilisers, detergents and cosmetics, amongst many others.

The role of the economic operator

One of the most significant elements of the Regulation is the role attributed to 'economic operators'. The Regulation prohibits a number of products to be placed on the market unless an economic operator established in the EU is identified.

The economic operator must ensure the availability of the product's technical and conformity documentation. They are also responsible for cooperating with market surveillance authorities in cases of non-compliance and informing authorities when they believe a product presents a risk. For the purposes of the Regulation, an economic operator can be:

- the manufacturer
- the importer, in instances where the manufacturer is not established in the EU
- an authorised representative who has a written mandate from the manufacturer, or
- a fulfilment service provider, when none of the above are established in the EU. A fulfilment service provider is a person or company offering at least two of the following services: warehousing, packaging, addressing and dispatching, without having ownership of the products involved. Postal and parcel delivery companies are specifically excluded.

1. *Regulation (EU) 2019/1020*
2. *Harmonisation rules aim to create a common set of standards across the EU.*

Know your obligations

The Regulation sets out a specific obligation for all economic operators of cooperation with market surveillance authorities. Companies placing relevant products on the EU market, who have not yet identified a responsible person established in the EU or who have an economic operator in the United Kingdom, should consider their obligations and take steps now to ensure compliance with the Regulation.

This requirement will also impact e-commerce businesses in particular as it requires non-EU suppliers who ship directly to end users in the EU to establish a representative in the EU, and makes the fulfilment service provider responsible when there is no such representative.

Enhanced powers for market surveillance authorities

The Regulation obliges Member States to designate one or more market surveillance authorities in its territory and enhances the authorities' powers to ensure an effective level of market surveillance for products sold offline and online. Market surveillance authorities must ensure that economic operators take corrective action when instructed and the authorities must act when they fail to do so. They must also conduct appropriate checks of products, including physical and laboratory checks, where appropriate.

Their powers under the Regulation include the following, amongst others:

- the power to require economic operators to provide relevant documents such as technical specifications and data or information on compliance
- the power to carry out unannounced on-site inspections and physical checks of products
- the power to enter any premises that the economic operator uses
- the power to require economic operators to take the appropriate corrective action in the event of non-compliance, including the power to prohibit the making available of a product on the market and the power to order that the product be withdrawn or recalled
- the power to impose penalties
- the power to acquire samples
- the power to remove content from, or restrict access to, an online interface

Manufacturers should be aware that products deemed non-compliant by a market surveillance authority in one Member State will be presumed to be non-compliant in other Member States unless a relevant market surveillance authority in another Member State concluded the contrary on the basis of its own investigation.

Specific rules for imported products

The Regulation also introduces specific rules which apply to imported products. EU countries must designate authorities with powers to check imports and market surveillance authorities must provide them with information on products and economic operators where a high risk of non-compliance has been identified.

Conclusion

The implications of the Regulation will not become fully clear until July 2021. Economic operators placing products and chemicals subject to the Regulation on the EU market, including distance sellers, should take action now to understand and prepare for the impact of this Regulation. In particular, an EU-based economic operator should be lined up now to take responsibility.

In terms of the impact of Brexit, UK companies will need to consider the appointment of an economic operator in the EU once the transition period comes to an end.

Consultation on EU Consumer Agenda Roadmap

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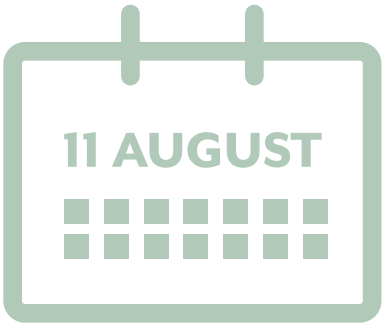
The EU has issued a Consultation on its new consumer agenda roadmap. The current Consumer Agenda expires in 2020, and the new agenda will aim to update EU consumer policy to tackle new challenges brought about by digitalisation, the rising importance of environmental issues, and to take account of learnings from the COVID-19 crisis and its aftermath.

It proposes to build on the experiences drawn from the immediate measures taken by Member States and the European Commission, outlined on page 4, in response to COVID-19 related problems. This includes cancellation of travel and events, rogue trading practices such as selling products with false health claims, unsafe products and increasing household debt.

The proposed agenda also refers to encouraging consumers' purchasing decisions towards sustainable options, and revising the General Product Safety Directive, in light of risks brought by new technologies and online selling.

Interested parties can submit feedback on the roadmap up to 11 August 2020.



Top 5 EU and Irish Guidance Documents Recently Published

1. CCPC Guide to Identifying and Avoiding the Use of Unfair Terms in Consumer Contracts (15 June 2020)

2. CCPC - new product safety guidance for COVID-19 consumer face masks (2 June 2020).

3. EU Commission Guide - How to verify that medical devices and personal protective equipment can be lawfully placed on the EU market and thus purchased and used – also in the COVID-19 context (May 2020)

4. European Commission Consultation on a new Consumer Agenda Roadmap - submissions by 11 August 2020

5. Proposal/Inception Impact Assessment FOR A DIRECTIVE on Consumer policy – strengthening the role of consumers in the green transition (also called "Empowering the consumer for the green transition") – feedback before 1 September 2020

Overview of Key Product and Consumer Law Legislation

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New Deal for Consumers

The "New Deal for Consumers" is an EU proposal to strengthen consumer rights. The New Deal comprises of two proposed EU Directives on:

- better Enforcement and Modernisation of EU consumer protection rules; and
- representative actions for the protection of the collective interests of consumers.

Some of the key effects of the New Deal for Consumers will be to:

- strengthen consumer rights online;
- give consumers the tools to enforce their rights and get compensation;
- clarify that national authorities can address misleading commercial practice of dual quality consumer products; and
- introduce effective penalties for violations of EU consumer law.

The Enforcement and Modernisation Directive 2019/2161 (Omnibus Directive) will make substantive amendments to four existing pieces of consumer protection legislation:

- the Unfair Commercial Practices Directive (2005/29/EC);
- the Consumer Rights Directive (2011/83/EU);
- the Unfair Contract Terms Directive (93/13/EEC); and
- the Price Indications Directive (1998/6/EU).

The main focus of the changes is to improve transparency and outcomes for consumers as they buy goods and services online. Different protections will apply depending on whether the consumer purchases from a seller who is operating as a trader or a private seller. The Omnibus Directive also seeks to identify and regulate fake customer reviews and hidden paid-for advertising.

The most significant feature of the Omnibus Directive is the increased enforcement for breaches of consumer law. The Omnibus Directive seeks to impose fines of not less than 4% of the trader's annual turnover, or at least €2 million when information on turnover cannot be obtained.

The criteria for determining the appropriate level of fines is similar to that under the GDPR and focuses on:

- the nature, gravity, scale and duration of the infringement;
- whether there has been any action to mitigate damage;
- any financial gains or losses by the seller from infringements of consumer law; and
- whether the trader has any previous allegations made against them.

The Directives are due to be applied from 1 January 2022 and EU Member States will have a two-year period to transpose the requirements into national law. The deadline for the publication of national measures is 28 November 2021. The provisions will apply in each member state from 22 May 2022.

The Goods Package

The "Goods Package" will make it easier to sell a product in another EU Member State and will strengthen the controls by national authorities to ensure that products are safe and comply with EU rules. The Goods Package is comprised of the following regulations:

- Regulation on the Mutual Recognition of Goods (EU) 2019/515

This Regulation is applicable since 19 April 2020.

The objective of this Regulation is to improve the application of the principle of mutual recognition, and therefore ensure that goods lawfully marketed in one EU Member State can be sold in any other EU Member State, as long as they are safe and respect the public interest.

- Regulation on Market Surveillance and Compliance of Products (EU) 2019/1020

One of the core obligations of the new Regulation provides that a product may be placed on the EU market only if there is an economic operator established in the EU who has certain responsibilities under the Regulation.

The implications for non-EU based sellers are two-fold:

- For non-EU based sellers, the full rigours of EU Product Safety rules will apply; and
- For non-EU based sellers who operate as a platform or online interface, there will be obligations to respond to market surveillance authorities' requests to remove content on the platform.

The Regulation is applicable from 16 July 2021 for the most part, with Articles 29, 30, 31, 32, 33 and 36, establishing the Union Product Compliance Network, to take effect from 1 January 2021.

The Consumer Protection Cooperation Regulation

The Consumer Protection Cooperation Regulation (EU) 2017/2394 came into effect on 17 January 2020. The Regulation aims to provide more stringent policing of cross-border infringements by national consumer protection authorities tasked with ensuring compliance with consumer protection law. The enhanced enforcement powers of the consumer authorities will lead to a coordinated approach across the European Union, which may impact the way in which online traders respond to consumer law infringements.

Some of the key elements are:

- Traders can be required to provide the consumer authorities with access to documents, supply information and have the consumer authorities carry out on-site inspections;
- The consumer authorities will have a new investigatory power to purchase goods or services as a test purchase under the guise of a mystery shopper;

- A competent authority in one EU Member State can request that an authority in another EU Member State take enforcement measures; and
- Member States are obliged to provide mutual assistance and greater powers are given to national authorities for the coordination of cross-border enforcement action.

The Single-Use Plastics Directive

The Single-Use Plastics Directive (EU) 2019/904 bans certain single-use plastic products as well as imposing measures to reduce consumption, extend producer responsibility and design requirements for beverage containers. Some of the key elements of the Single-Use Plastics Directive are:

- Certain prohibited products for which alternatives are available
- Measures to reduce consumption
- Labelling requirements
- Separate recycling collections for single-use plastic bottles
- Extended producer responsibility for supplementary costs associated with certain single-use plastic products

EU Member States must bring laws, regulations, and administrative provisions necessary to comply with this Directive into force by 3 July 2021. This timeframe may be extended to 3 July 2024 for the adoption of measures for certain single-use beverage containers that have caps and lids made of plastic, that they may only be placed on the market if the caps and lids remain attached to the containers during the products' intended use storage.

The Accessibility Directive

The Accessibility Requirements for Products and Services Directive (EU) 2019/882 introduces accessibility requirements for specific products and services such as phones, computers, payment terminals, banking services and e-commerce services. The key requirements include:

- Consumer products must be capable of being operated by persons with disabilities and have packaging, installation instructions and other product information that is accessible
- Manufacturers of products must demonstrate compliance with the applicable accessibility requirements by drawing up an EU declaration of conformity and affixing a CE mark
- Websites and apps must be easily operable and understandable for persons with disabilities and include accessibility information made available by more than one sensory channel

EU Member States must bring laws, regulations, and administrative provisions necessary to comply with this Directive into force by 28 June 2025.

New Measures Under the Ecodesign Directive

In October 2019, the European Commission adopted new legislative measures under the Ecodesign Directive (2009/125/EC) for energy-related products such as refrigerators, washing machines, dishwashers and televisions. These measures have the aim of increasing the lifecycle of products.

Manufacturers, importers and authorised representatives of these types of products will have various responsibilities under these new measures including the repairability of products, access to repair and maintenance information for certain appliances and the availability of spare parts. The legislation also regulates, for the first time, welding equipment and fridges with a direct sales function.

Digital Content Directive

This Directive will update consumer law for the sale of digital services and digital content.

It will apply to the provision of digital content by a trader for which the consumer pays a price, which could be in the form of providing personal data where it goes beyond the amount of personal data necessary to provide the services.

The concept of digital content captures games, e-books, software applications and films, and digital services which includes streaming and social media services. Goods with digital elements such as smart fridges and electronic will not be within the scope of the Digital Content Directive, and will instead be within the scope of the new Sale of Goods Directive.

Some other notable exclusions include translation services, healthcare, but not healthcare apps, and gambling.

The digital content/service being provided must comply with both subjective criteria, e.g. description and quality in accordance with the contract, and objective criteria, e.g. the good must be fit for the purpose for which it would ordinarily be used.

The Directive is due to come into effect from 1 January 2022.

Sale of Goods Directive

The Sale of Goods Directive (EU) 2019/771 will operate in parallel with the Digital Content Directive, to ensure that there is no gap in consumer law protection where a product has digital elements. The Sale of Goods Directive applies to all contracts for the sale of goods apart from those that fall within the scope of the Digital Content Directive.

As with the Digital Content Directive, the Sale of Goods Directive sets out both subjective and objective criteria for conformity, which must be complied with.

A key feature of the Directive is the remedies available to the consumer. In the event of a lack of conformity, consumers are entitled to a repair, replacement, price reduction or even termination of the contract in certain circumstances.

The consumer also has a two-year guarantee to remedy any defects in goods which are discovered after delivery, though Member States are free to introduce longer liability periods, or indeed shorter periods in the case of second-hand goods.

The deadline for Member States to implement this Directive is 1 July 2021, and the rules will apply to all relevant contracts from 1 January 2022.

Online Platform Regulation

The Online Platform Regulation 2019/1150 (the P2B Regulation) came into effect on 12 July 2020 and will apply in a business-to-business context relating to online platforms and traders. However, this Regulation aims to protect traders that sell online to consumers.

The broad definition attributed to 'online intermediation services' means that many e-commerce market places, auction websites, App stores, social media sites etc will be within the scope of the P2B Regulation. It imposes a set of obligations on online platforms for providing updates on changes to terms and conditions in clear language to business users that are easily accessible on a durable medium. It bans certain unfair practices, such as making changes to terms and conditions without good reason or notice, and requires online platforms to fulfil transparency obligations in relation to the parameters for the ranking of search results. In the case where an online platform decides to suspend or terminate an account, it must provide the business user with a statement of reasons within the timeframe specified. The platform will also be required to publish information on its internal complaint handling process and to display details of at least two independent mediators and be willing to engage in mediation in the event of a dispute with a business user.

The P2B Regulation will apply to those which have their place of establishment or residence within the EU and that, through their platform, offers goods or services to customers that are located within the EU. It does not apply where sellers are not established in the EU or where the platform is used to offer goods exclusively to customers located outside of the EU, or to persons who are not consumers.

The Regulation of Hand Sanitizers During COVID-19

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COVID-19 has left many manufacturers with surplus stock; as a result, many are now attempting to reconfigure their lines of production to both remain in business and also assist in the battle against COVID-19. This is essential for not only the health crisis and meeting demand for critical products such as hand sanitizer, but also to preserve the economy. However, any products that are produced need to fully conform to the relevant regulations. Manufacturers looking to produce hand sanitizer therefore need to be cognisant of these in order for their product to be placed on the Irish market.

Biocides

A biocidal product, or 'biocide', is defined as 'any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism'.

Products that fall within this definition include disinfectants, hand sanitizers, preservatives, insect repellents, etc. One noteworthy point is that hand sanitizers looking to be classified as a biocidal product must only make general claims relating to their antibacterial action or the killing of germs. They must not, however, make any medicinal claims or contain medicinal substances.

Legal considerations

Regulatory

A biocidal product must be authorised before it can be made available on the market or used within the EU. This takes place by way of two consecutive steps. Firstly, the active substance (AS) is evaluated at a European Union level and provided relevant criteria are fulfilled it is approved for use in a specified product-type (PT). Secondly, authorisation of each biocidal product is assessed at national level.

In order for national authorities to make a suitable assessment of the exposure and risk to human health and the environment, the EU has developed different product types within the category of biocides. Annex V of the Biocidal Products Regulation (EU) 528/2018 (BPR) classifies biocidal products into 22 specific product types.

National authorities are required to assess the active substances contained in the biocide against the specific product type's intended use. Therefore, products will be approved for some uses but not others, depending on the risks associated with the use of the active substances. For example, if supplying hand sanitizer, the active substances contained in the biocidal product must be approved for the purpose of disinfecting the skin, falling into the relevant product type PT-1: human hygiene.

Additionally, the AS/PT combination can only be supplied from a supplier listed within the European Chemicals Agency (ECHA) register as per Article 95 of the BPR. Further pre-market authorisation requirements are laid down under Articles 17 and 19 of the BPR.

Furthermore, a product label is mandatory and must be accompanied by its authorisation number (PCS number – provided after submission of application) to complete an application to place a biocidal product on the Irish market. The Pesticide Control Division (PCD) of the Department of Agriculture, Food and the Marine (DAFM) are obliged to approve it in its final format for each pack size in which the product will be marketed before it can be placed on the Irish market. Label requirements have been reduced during COVID-19 and the new requirements can be found from the PCD guidance which is available here.

Products may only be marketed in Ireland with the labels as received and accepted by the PCD.

Consumer protection

As well as regulatory considerations, consumer protections must be considered before attempting to produce hand sanitizer during COVID-19. Whilst businesses face unprecedented pressure at present, consumer law regulators have issued guidance to remind businesses that consumer laws continue to apply. In the current climate there is a high demand for hygiene products, such as hand sanitizer. Despite this, the Competition and Consumer Protection Commission (CCPC) are keeping vigilant with regards to the sale of such products in order to protect consumers.

Manufacturers are advised to avoid misleading statements, for example, false representations that a product is capable of curing an illness when it cannot or other prohibited health claims. Aggressive commercial practices or pressurised sales tactics such as 'price gouging' towards consumers and unfair contract terms such as attempting to limit consumers' legal rights directly or indirectly are also impermissible.

Marketing claims

Another legal consideration with regard to producing PPE during COVID-19 is that marketing claims must be supported by robust evidence. The Advertising Standards Authority for Ireland (ASAI) has reminded businesses that any claims being made for products referring to COVID-19 should be adequately substantiated. The ASAI have stated that advertisers are required to avoid claims which undermine public health or exploit consumer's anxieties. Under the ASAI Code, members must adhere to the ASAI's Code of Standards for Advertising and Marketing Communications in Ireland. As stated under this Code, any marketing communications should not mislead, or be likely to mislead, by inaccuracy, ambiguity, exaggeration, omission or otherwise. The advertiser must be in a position to support all claims, expressed or implied, that the advert or statement conveys to reasonable customers through vigorous evidence.

COVID-19 exemptions

Article 55 of the BPR permits Member States to set aside the aforementioned regulatory requirements for market authorisation in the interests of public health emergency situations. National competent authorities are required to notify the European Commission and other competent authorities of any derogation that they have applied within their territory. National derogations from the normal authorisation procedure cannot exceed 180 days, but may be extended on submission of a reasoned request, for a further 550 days by the European Commission.

The PCD has implemented derogations in light of COVID-19. PT-1 applications are now their main priority and pre-market authorisation requirements have been temporarily set aside. Where a biocidal product contains an active substance not yet approved and still under review of the ECHA, for example ethanol, manufacturers are permitted to submit a market application to the PCD.[1]

The PCD aim to respond within one working day and provide a decision on foot of any application within 10 days. They have also implemented a fast track procedure for market authorisation by way of Article 55(1); where seeking to use an already approved active substance but which its date of approval has lapsed, manufacturers can deviate from the rules laid down by Articles 17 and 19. This is relevant for active substances such as isopropyl alcohol (propan-1-ol or propan-2-ol).

Additionally, the ECHA are permitting manufacturers who want to use new sources of propan-1-ol or propan-2-ol to submit a request for technical equivalence (TE). Lastly, the ECHA has reduced information requirements and has implemented a modified, temporary procedure to assess these applications.

1. *The Pesticide Control Division (PCD) 'Derogation based market access for disinfectant/sanitising products for protection of human health due to COVID-19', (30 March 2020)*

Conclusion

The response to COVID-19 is a necessarily fast-moving field, especially now as we move to lift restrictions. Ordinarily the process for market authorisation of a biocidal product such as hand sanitizer is time consuming. However, Member States have accommodated for the shortage of such necessary products by implementing a number of derogations under the BPR in light of public health emergency situations. Manufacturers may be permitted to use ethanol as an active substance under the Review Programme, labelling requirements have been reduced and a fast track procedure for market authorisation is now available. Additionally, alternative sources for already approved active substances may be permitted by the ECHA. As a result, manufacturers such as distillers can now enter a new line of production.

Despite these temporary market authorisation derogations implemented in light of COVID-19, a large range of legal considerations remain for those seeking to produce PPE such as hand sanitizer. Manufacturers should obtain legal advice where they are unsure of the risks involved before attempting to manufacture hand sanitizer.

Report on Liability for Artificial Intelligence and Other Emerging Digital Technologies – 10 Key Findings

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The European Commission published a Report on Liability for Artificial Intelligence and other emerging digital technologies which details the findings of an Expert Group on Liability and New Technologies – New Technologies Formation on 21 November 2019.

The Group considered "whether and to what extent existing liability schemes are adapted to the emerging market realities following the development of new technologies such as artificial intelligence, advanced robotics, the internet of things and cyber security issues". The Group also analysed the current liability regimes across the Member States and assessed their suitability and adequacy to deal with damage resulting from the use of emerging digital technologies.

In summary, they found that while the laws of the Member States do ensure basic protection of rights, also referred to as primarily damages in tort and contract, these laws are not specifically applicable to this dynamic, complex and fast developing area. This is as a result of more technical issues which arise with this technology such as complexity, modification through updates, self-learning during operation, limited predictability and vulnerability to cybersecurity threats.

The Group made the following key findings on how liability regimes should be designed and, where necessary, changed to adapt to this evolving area of digital technology:

1.

A person operating a permissible technology that nevertheless carries an increased risk of harm to others, for example AI-driven robots in public spaces, should be subject to strict liability for damage resulting from its operation.

2.

In situations where a service provider ensuring the necessary technical framework has a higher degree of control than the owner or user of an actual product or service equipped with AI, this should be taken into account in determining who primarily operates the technology.

3.

A person using a technology that does not pose an increased risk of harm to others should still be required to abide by duties to properly select, operate, monitor and maintain the technology in use and, failing that should be liable for breach of these duties if at fault.

4.

A person using a technology which has a certain degree of autonomy should not be less accountable for ensuing harm than if said harm had been caused by a human auxiliary.

5.

Manufacturers of products or digital content incorporating emerging digital technology should be liable for damage caused by defects in their products, even if the defect was caused by changes made to the product under the producer's control after it had been placed on the market.

6.

For situations exposing third parties to an increased risk of harm, compulsory liability insurance could give victims better access to compensation and protect potential wrongdoers against the risk of liability.

7.

Where a particular technology increases the difficulties of proving the existence of an element of liability beyond what can be reasonably expected, victims should be entitled to facilitation of proof.

8.

Emerging digital technologies should come with logging features, where appropriate in the circumstances, and failure to log, or to provide reasonable access to logged data, should result in a reversal of the burden of proof so as not to adversely affect the victim.

9.

The destruction of the victim's data should be regarded as damage, compensable under specific conditions.

10.

It is not necessary to give devices or autonomous systems a legal personality, as the harm these may cause can, and should, be attributable to existing persons or bodies.

EU Consumers Obtain Access to Collective Redress

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A draft directive has been approved by the European Parliament and the Croatian presidency of the EU, regarding representative actions for the protection of the collective interests of consumers.

The new rules aim to give consumers effective judicial protection collectively when breach of EU law by traders deprives them of their rights. The directive covers actions for both injunctions and redress measures.

The directive will enable designated entities to seek injunctions and/or redress, including compensation or replacement, on behalf of a group of consumers that have been harmed by a trader who has infringed one of the EU legal acts listed in the annex of the Directive. These legal acts include areas such as financial services, health, tourism and data protection, amongst others.

The directive provides clear rules on the allocation of judicial costs in a representative action for redress based on the 'loser pays' principle. Furthermore, with a view to avoiding conflicts of interest, it imposes on qualified entities a number of transparency requirements, in particular as regards their funding by third parties.

The directive will apply to representative actions brought on or after the date of its application.

Next steps

The Council will adopt its position at first reading. The European Parliament will then approve the Council's position at first reading and the directive will be deemed to have been adopted.

Manufacturing Medical Devices and PPE for COVID-19 – 5 Key Considerations

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As the spread of COVID-19 continues to have a significant impact on all industries and sectors worldwide, many manufacturers are looking to assist and to develop new products during this emergency. Despite the rush to help, there are a number of regulatory considerations that manufacturers should be aware of.

Medical devices

HPRA approval

Under normal circumstances, medical devices cannot be placed on the market without a CE mark. Obtaining regulatory approval and certification for medical devices before placing the product on the market can take a number of months. The Irish regulatory authority for medical devices, the Health Products Regulatory Authority (HPRA), has however introduced a relaxation of the rules to permit certain non-CE marked medical devices relevant to the COVID-19 emergency to be supplied in certain circumstances. The process involves an urgent assessment of an application to place devices on that market that could help during these unprecedented times.

The HPRA will assess the device to determine whether its provision is in the interest of protection of health, despite the fact it is not yet CE marked. This process is unique to regulatory exemptions and is specifically for the management of the COVID-19 pandemic only.

Separately, the HPRA has also advised that manufacturers and distributors of In-Vitro Diagnostic Test Kits for COVID-19[1] should contact the HPRA prior to supplying the testing kits to the Irish market. The HPRA has stated that it can advise if a particular test is in line with the national strategy for COVID-19 testing in Ireland at a particular/given point in time.

Revised European harmonised standards for medical devices

The European Commission has also reached a decision on harmonised standards for medical devices to respond to the urgent need for high performing devices to be placed on the European market. The agreed standards allow medical device manufacturers to show conformity to the relevant medical device regulations and will make it easier for companies to gain direct access to the internal market for their products, while also ensuring a high degree of safety for users and consumers.

Examples of some of the devices covered include:

- Medical face masks
- Surgical drapes, gowns and suits
- Washer-disinfectors
- Sterilisation

To ensure a quick response to the increased demand for medical devices and PPE generated by COVID-19, the European Commission has agreed with the European standardisation organisation that 14 standards can now be accessed for free and will be fully available by the national standardisation bodies.

Personal protective equipment (PPE)

According to current estimations by the World Health Organisation "PPE supplies across the world need to be increased by 40%". The urgent requirement for PPE has resulted in a number of companies adapting their businesses to help in this crisis in remarkable ways.

Manufacturers should, however, be mindful of certain regulatory issues once PPE production begins.

Face masks and gloves – PPE or medical devices?

Face masks and gloves are just two of the essential products that are designed to ensure protection against COVID-19 for frontline workers. But how are these products regulated?

Face masks and gloves may be considered as PPE or medical devices and sometimes, they can be classified as both if they have a dual purpose. Their regulation will differ depending on the type of product and the manufacturer's intended purpose for the product. If the product is intended to have a dual purpose it will fall within the scope of both the PPE Regulation[2] and the Medical Device Directive (MDD)[3] or the Medical Device Regulation (MDR).[4]

The product must comply with the legal requirements of the MDD or MDR and relevant basic health and safety requirements of the PPE legislation. Manufacturers are encouraged to assess on a case-by-case basis the intended purpose of their device and to determine what specific safety requirements will apply.

CE marks for PPE

In the context of COVID-19, the European Commission has issued guidance to facilitate the uptake of new PPE products on the EU market. As part of this guidance, the Commission has urged all notified bodies, including third party testing bodies, to prioritise any new requests submitted by manufacturers for COVID-19 related products.

The Commission has also provided for certain scenarios in which products may be placed on the market even if the conformity assessment procedures have not yet been finalised or, in certain circumstances, have not even commenced.

Firstly, if national market surveillance authorities find that the equipment ensures an adequate level of health and safety in accordance with the essential requirements set out in EU law, they may authorise these products on the EU market, even though the conformity assessment procedures, including the affixing of CE marking, have not been fully finalised.

Secondly, in exceptional circumstances, products can be placed on the market even if the certification procedures have not been initiated and no CE marking has been affixed upon them, if the following cumulative conditions are fulfilled:

- The products are manufactured in accordance with one of the EN standards or in accordance with any of the other standards referred to in the WHO guidelines or a technical solution ensuring an adequate level of safety
- The products are part of a purchase organised by the relevant Member State authorities
- The products are only made available for the healthcare workers

- The products are only made available for the duration of the current health crisis, and
- The products are not entering the regular distribution channels and made available to other users

Liability considerations

Finally, manufacturers should be aware of the risks involved when placing unregulated products on the Irish market. The supply of unregulated products not authorised to be on the market may result in enforcement action taken by the HPRA and withdrawal of the product from the market given the health and safety risks involved for members of the public. In addition, manufacturers should be mindful that under Irish product liability law, there is a risk they may be found liable for damages where a product is considered to be defective. Therefore manufacturers must remember their obligation to provide safe products to the public.

Conclusion

A number of Irish manufacturers across the country have been adapting and modifying their businesses over the past few weeks to assist healthcare frontline workers in the fight against COVID-19 by developing new innovative products. From an early stage in production, companies should identify whether the product they are manufacturing is, in fact, a medical device or PPE, or both. Manufacturers should have a clear understanding of the regulatory path the product must follow and what derogations are permitted.

Product liability issues are also something that businesses should think about before deciding if they want to commence production of medical devices or PPE.

Webinars & Recent Publications

Webinars

- Commercial Contracts – What's Market? (14 July 2020)
- The EU Regulation of Wearables – A Changing Landscape (7 July 2020)
- Regulatory Investigations & Prosecutions Update (17 June 2020)
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- Getting Ireland Back to Work: Employment Law and Health & Safety Issues (6 May 2020)
- Selling Online – Consumer Protection Overhaul (26 May 2020)
- Getting Ireland Back to Work - GDPR Issues (12 May 2020)
- Commercial Contracts During COVID-19: Onboarding, Managing and Exiting (15 April 2020)

Publications

- Product Liability and Safety in Ireland: Overview – Thomson Reuters, 2019
- Getting the Deal Through: Product Liability in Ireland 2019
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- On Your Bike: Pedalling Your Way to Copyright Protection (30 June 2020)
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- Public, Regulatory & Investigations Update: Not So Generic Challenges to Marketing Authorisations of Generic Products (1 May 2020)
- Manufacturing Medical Devices and PPE for COVID-19 – 5 Key Considerations (22 April 2020)
- Product Regulation: Cleaning House – Ireland Bans Microbeads in Certain Products (10 March 2020)
- Product Liability Update: Liability for Digital Technologies and Artificial Intelligence (3 February 2020)
- Manufacturers and Developers – Are You Regulation-Ready for 2020? (6 January 2020)

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