Hogan Lovells

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Introduction

Our Global Products Law practice

Our Global Products Law practice is internationally renowned for its work in product litigation, safety, and compliance. We act for clients around the world covering all product sectors, including pharmaceuticals and medical devices, cars, tobacco, mobile phones, cosmetics, electrical and electronic products, chemicals and hazardous substances, toys and children's products, food and beverages, sporting goods, aircraft and machinery. Our product litigation and product safety lawyers are supported by an in-house Science Unit and a Project Management Unit.

About International Products Law Review (IPLR)

Our International Products Law Review is our longstanding publication dedicated to reporting on product liability and product safety developments for international product suppliers, and others interested in international product issues. You can access previous content from IPLR **here** too.

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Batteries Regulation

New Sustainable Batteries Regulation: Reflections from our Global Products Law team

Following the closure of the European Commission's recent consultation period, the European Parliament and Council are set to consider a proposed new Sustainable Batteries Regulation in the coming months (the "Proposed Regulation"). Read on for a summary of some of the key issues for further consideration.

Background

The Commission's initiative to update the legislative framework for batteries in the EU builds on the Circular Economy Action Plan to make the EU's economy more sustainable. The new law in the shape of a Proposed Regulation includes requirements on sustainability, safety and labelling, as well as requirements for the collection, treatment and recycling of waste batteries.

Our perspective

We work closely with many of the world's leading technology, telecoms and consumer product manufacturers based in the EU and around the world. We help to ensure their compliance obligations are met and managed effectively, both as end-users of batteries and suppliers of products containing batteries.

We routinely receive queries about how the current Directive 2006/66/EC (the "Batteries Directive") applies to product companies' operations, what some of the technical terminology used in means in practice, how the Batteries Directive and its national implementing legislation should be interpreted and how the existing regulatory framework for batteries applies to products and the supply chain. The Proposed Regulation provides an opportunity for clarity. We contributed to the recent consultation on the Proposed Regulation in early 2021 and highlight below some of the significant changes the new Batteries law will introduce across the EU for products companies.

Battery Passports: Impact on commercially sensitive information?

The Proposed Regulation includes the concept of "battery passports", in order to help economic operators to make informed decisions and strategically plan their battery needs.

The aim is to increase transparency and improve traceability of batteries. That said, the information laid down in Annex XIII of the Proposed Regulation is wide-reaching. Much of that information may be considered commercially sensitive in some business sectors. Potentially, a more limited data disclosure could also fulfil the aim of moving towards the sustainability goal, while better reflecting important commercial realities for business.

Batteries Regulation

End of life arrangements

Under the Proposed Regulation, the Commission aims to target and re-enforce producer responsibilities. The underlying message is a laser focus on transparency in the chain of disposal at end of life. The Proposed Regulation discusses the establishment of a network of collection points for different battery categories, with costs to be borne by producers. Alternative financing arrangements are expressly permitted under the current Batteries Directive for industrial batteries, whilst the position is silent for portable batteries. We have seen this lead to a varied landscape across the EU, with some regulators interpreting the Directive (and their national implementing legislation) so as to permit such arrangements to cover portable batteries, and others not. The position is more nuanced under the Proposed Regulation. Whilst it may be premature to signal the end of "AFAs" as we know them, the strong message is that the Commission wishes to increase transparency in the battery supply chain, and the conclusion of private agreements could be viewed as contrary to this purpose. We monitor any updates in this space with interest.

Increased responsibilities for portable batteries

The Commission seeks to improve collection and recycling of all batteries across the EU, but for now notably for portable batteries. Where a consumer goods manufacturer supplies batteries to consumers for the first time (this could be in the appliance or separately in the box), under this new law they could become a portable battery producer. This brings a raft of 'producer' obligations at end of life.

Under the Proposed Regulation, manufacturers will also need to ensure that any batteries incorporated into their appliances are "readily replaceable" which means that a battery can, after its removal, be substituted for a similar battery without the appliance functionality being affected. This could require considerable design changes for many manufacturers placing small electronic goods on the market, notably at lower price points, where we see batteries either completely sealed or not possible to safely replace.

Button cells (coin batteries) are commonly incorporated into small appliances, and do not appear to be exempted from these new portable battery requirements. Indeed, the ubiquity of these small batteries could be viewed as one reason why the Proposed Regulation is intended to capture them.

By strengthening requirements around portable batteries, the Commission hopes that far fewer will end up in landfill.

Batteries Regulation

Where next?

We have picked out some of the potential key impacts of the Proposed Regulation. At present there is no "fixed date" for an updated draft of the Proposed Regulation. Further amendments will not be made by the European Commission but by the European Parliament and Council. Although the Proposed Regulation could be implemented by the start of 2022, based on average legislative proposal timescales this appears to be ambitious, and it may not be implemented until the end of 2022. However, we know that sustainability-related measures are EU priorities (in order for the EU to meet its ambitious targets in this area), and so this legislation may progress faster than the usual timeframe. We will keep you up to date – look out for a more detailed analysis of the Batteries Regulation once the draft law is finalised!


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Digital Accessibility

Products and accessibility. Non-negotiable.

Accessibility: What brings change?

Accessibility is crucial for those with disabilities to enable independence, opportunities, and the fulfilment of fundamental rights. Society is increasingly mindful of the importance of this in the "physical world" around us (e.g. buildings, infrastructure, and transportation). But this same focus on adaption and accommodation needs to apply to the accessibility of physical products, and, more than that: it needs to apply to digital products and services.

The impact and benefits of accessibility can be felt across society. In the same way that "curb cuts" (lowered sections on pavements) enables wheel-chair riders as well as helping those with buggies, suitcases, and delivery carts, greater accessibility of products and services enhances the experience for us all. Where would we be without voice-activated home devices? The software powering those devices was devised to enable accessibility for the disabled community.

Partner Valerie Kenyon recently attended a global conference focusing on product safety and compliance: ICPHSO 2021. There was fascinating coverage of accessibility issues from the FCC and a leading tech corporate. Through lively panel debate, product accessibility was looked at from various angles, including the view of regulators (via the US FCC perspective) and product safety professionals. The panel looked at how accessibility can be positioned across major corporations in terms of compliance suggestions and general buy-in.

Below, Valerie and her team reflect on how accessibility issues are currently shaping the legislative agenda: and impacting on their daily product counselling work.

Putting accessibility front and centre: what can companies do?

First, when creating a product or developing a service, it's critical that the right people are involved, including those with disabilities, so that the starting point is accessible design across the product lifecycle. Put simply: product companies can do more by continuing to hire from as diverse a talent pool as possible.

Second, product companies can collaborate more and seek out (or even come to expect) the input of government to drive the accessibility agenda. "Soft government" has not worked in relation to accessibility to date: the speed of progress has been too slow.

Third, it's important to involve the right stakeholders. There are many opportunities for companies to reach out to stakeholder groups for advice and input – for example, the European Disability Forum (an umbrella organisation of persons with disabilities that defends the interests of over 100 million persons with disabilities in Europe).

Digital Accessibility

Accessibility in the EU: how has it developed [to] apply to products?

All EU countries have ratified the relevant UN Convention on the Rights of Persons with Disabilities, which clarifies and qualifies how all categories of rights apply to persons with disabilities and identifies areas where adaptation has to be made for persons with disabilities to effectively exercise their rights and where protection of rights must be reinforced.

There have been aligned efforts in the EU to move accessibility for products towards a common approach which would benefit industries working globally. There are technical standards in the EU for ICT relating to accessibility which, although currently only technically applicable to public sector website and mobile applications, demonstrate best practice for private entities.

EU legislation has been patchy, covering specific areas as electronic communications , and audio media services , or limited to public sector products, which created a compelling case for further EU-level legislation to cover all aspects of accessibility across EU member states: the EU Accessibility Act is set to fill the gap.

The European Accessibility Act

The European Accessibility Act is key to the advancement of accessibility rights for disabled persons in the EU. It is a directive that aims to improve the functioning of the internal market for accessible products and services by removing barriers created by divergent rules in Member States. The European Accessibility Act covers products and services that have been identified as being most important for persons with disabilities, while being most likely to have diverging accessibility requirements across EU countries. This includes computers and operating systems, ATMs, banking services, e-books, e-commerce, and smart phones (it is a much wider list than this). Member States have until 2022 to implement the Directive, making its terms part of their respective national legislation.

The EAA focuses on digital products and services with a view to improving accessibility of technologies and technology products for persons with disabilities or functional limitations. It sets out a number of examples for both products and services, such as making sure information is available through more than one sensory channel, or providing assistive devices alongside a product that might, for example, providing text on a screen rather than aurally.

The European Accessibility Act means that EU member states are able to introduce accessibility legislation based on the Directive and to go beyond the European act, as is recommended by the European Commission, to broaden accessibility requirements. It is market access legislation so companies cannot sell products and services in the EU single market if products do not comply with the accessibility requirements in the European Accessibility Act.

The accessibility requirements apply unless the requirements would change the very nature of the product/service or if the requirements would impose a disproportionate financial or administrative burden. Where this is the case, entities would be required to comply with the accessibility requirements to the extent possible and then justify where they cannot due to such a disproportionate burden in an accessibility statement, that details their compliance with the accessibility requirements applicable to them under national law. The “disproportionate burden exemption” would largely apply to micro-organizations with less than 20 employees.

Digital Accessibility

- Obligations across the supply chain – the EAA outlines specific obligations for manufacturers, importers and service providers.
- The enforcement mechanism proposed by the EU Accessibility Act is quite strong. It requires member states to ensure that adequate and effective means of enforcement exist, with the possibility to issue penalties and also to withdraw products from the market. Furthermore, disability organisations can take the economic operator to court for infringements of the Act.
- The EAA provides for a presumption for conformity, where products are in conformity with relevant harmonized standards as published in the Official Journal of the \ European Union. Products in conformance with the EAA should be CE marked and a Declaration of Conformity should be prepared.
- A Transitionary period is underway and EU member states are currently adopting and writing national laws, with a deadline of 28 June 2022. Later this year we will know more about the development of technical harmonised standards that flow from the European Accessibility Act.
- Alongside the required enforcement authority, consumer organisations will likely be playing a pivotal role in policing requirements in future.

Where next?

Our Global Products Law team has been focusing on supporting products companies with how to adapt their products and processes to take account of current and incoming accessibility legislation. There is a great deal to monitor that's happening around the world, and the USA, for example, has differing state laws, but compliance with European standards should cover most bases for product companies operating globally.

Product companies need to be thinking about:

- Staying on top of country-specific requirements in this rapidly developing area of law.
- The provision of information, instructions and warnings on their products or services.
- Providing alternative sensory channels for use of their products or services.
- Ensuring electronic information is perceivable, operable, understandable and robust.
- Providing adequate support services, assistive technologies or alternative means of access to information.

Watch this space for more from our Global Products Law team.


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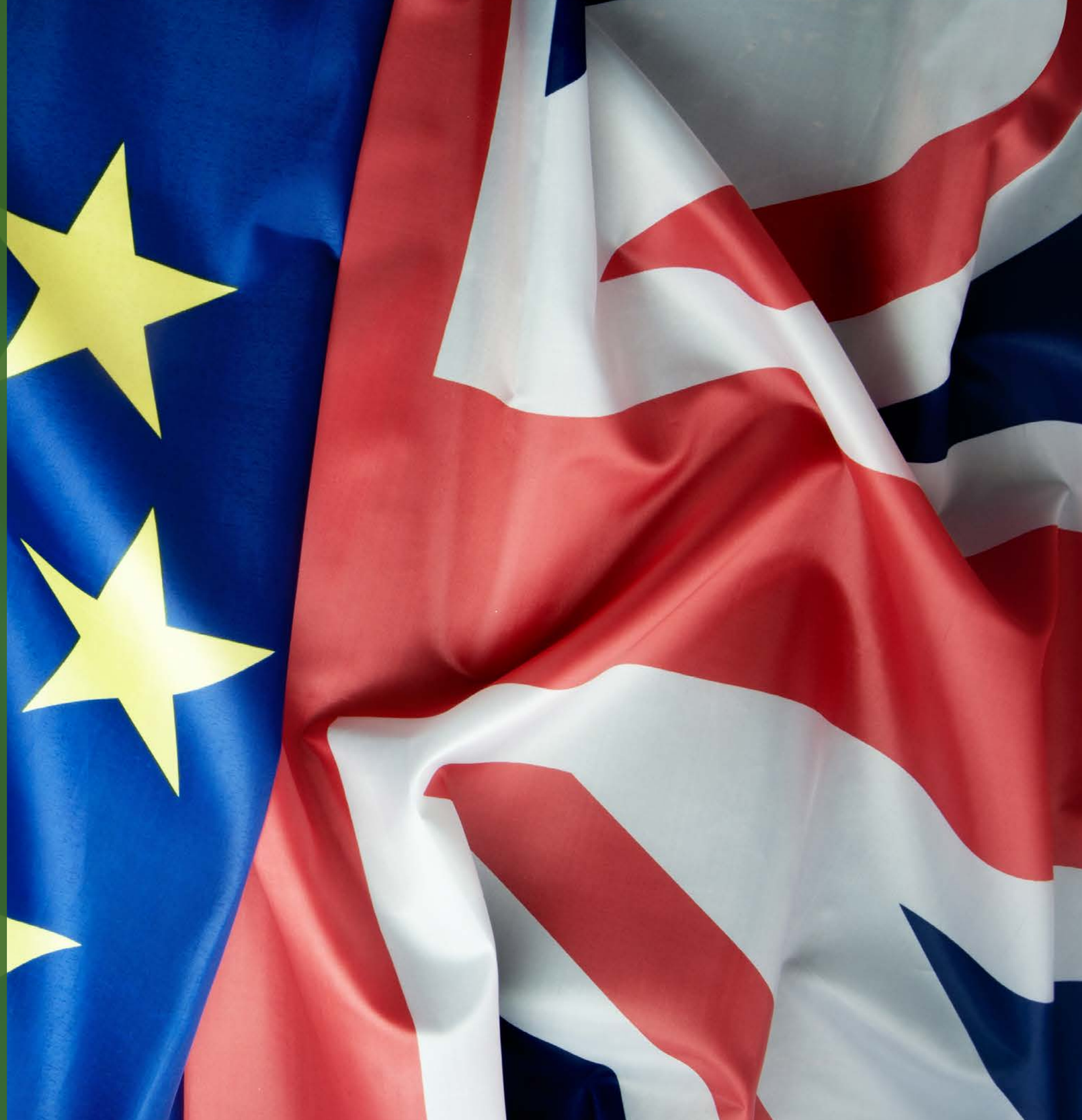
Brexit



Brexit: a snapshot – key changes to product compliance requirements

March 2021

On 31 January 2020 at 11pm (UK time), the UK formally left the EU after over 40 years of membership and on 31 December 2020 the temporary transitional period came to an end. The UK's relationship with the EU is now no longer governed by EU treaties, but instead by the terms of the EU-UK Trade and Cooperation Agreement, which was agreed on 24 December 2020 and contains new rules governing how the UK and EU will trade together from 1 January 2021.

Furthermore, the European Union (Withdrawal) Act 2018 came into effect on 31 January 2020 at 11pm (UK time) and retains EU-derived legislation, including product safety laws, in domestic UK law. The Product Safety and Metrology Regulations amend the retained EU product-related law to address deficiencies arising from the UK's withdrawal from the EU and provide for some specific provisions applicable in the Great Britain and Northern Ireland market from 1 January 2021.

What does this mean for companies launching their products in both the EU and UK markets after 1 January 2021? In short, their goods must now comply with both UK and EU regimes and adhere to the respective labelling and certification obligations to retain access to both markets.

In addition, the mechanism for moving goods between the UK and EU has changed following Brexit and this has had an impact on the status of economic operators within the supply chain. Some businesses that previously had a UK-based "distributor" may find this distributor now becoming an importer into the UK following Brexit, and so should make sure that this entity meets the relevant obligations.

We provide a snapshot of some of the key product compliance changes below.

UKCA mark

From 1 January 2021 a new mark, the UKCA (UK Conformity Assessed) mark, must be provided on products placed on the market in Great Britain, i.e., England, Scotland, and Wales. To allow businesses time to adjust, the CE mark will continue to be accepted in the UK until 1 January 2022 for certain products. The UKCA mark will, however, not be recognised in the EU.

When considering the UK as a market, Northern Ireland acquires a dual status and, for the purpose of product compliance, is considered part of both the UK and EU markets. Therefore products placed on the market in Northern Ireland can still follow EU rules and continue to apply the CE mark unless they were manufactured specifically to new UK rules or a mandatory third-party conformity assessment was carried out by a UK notified body, in which case a new Northern Ireland specific UK (NI) mark must apply.

Brexit

UK importer's details

From 1 January 2021, in addition to manufacturer's details, UK importer details must be provided on goods placed on the UK market. Until 31 December 2022, the UK importer details can be provided "on the accompanying documentation" rather than on the product itself. Accompanying documentation may take the form of any document that stays with the product until it reaches its end user and there are a number of possible solutions according to guidance issued by the UK Office for Product Safety & Standards, e.g., providing the importer details on a shipping document, on an invoice, or on a label on the outer packaging in which the goods are packed.

Conformity assessment

For goods placed on the EU market after 1 January 2021, any mandatory third-party conformity assessment will need to be carried out by an EU-recognised conformity assessment body, and it will no longer be possible for UK conformity assessment bodies to carry out such conformity assessments for products placed on the EU market.

For goods placed on the market in Great Britain, any mandatory third-party conformity assessment will need to be carried out by a UK-recognised approved body.

How to prepare?

Manufacturers should anticipate regulatory changes in the products sector. Companies should keep an eye on any amended UK regulations applicable to specific product categories and consider whether changes need to be made to the supply chain or product SKU codes in order to simplify logistics and keep costs down.

Significance for other markets

The effects of Brexit also have more far-reaching consequences, for example, in the Italian and German markets. Although Brexit isn't "new" per se, and companies in both Italy and Germany have been starting to prepare for the UK's departure from the EU over the last couple of years, it is only now that the EU and UK have concluded their negotiations with a trade agreement that daily business between the EU and UK has fundamentally changed. Customs declarations for goods, health checks for agricultural products, and other formalities make business more challenging, for importers and traders of goods that are now imported into Europe from the UK as a third country.

There are also new challenges for companies that wish to retain access to the UK market. For example, from an Italian perspective, the UK market represents a large share of the Italian exports of agri-food products. As a result of Brexit, Italian companies that previously enjoyed a high level of protection in the UK for their protected designation of origin (PDO) and protected geographical indication (PGI) products may no longer benefit from such protection, and may face increased competition. It will therefore be necessary for Italian companies to conclude new agreements in order to ensure their products are well protected from competition on the UK market.

For further information and resources on Brexit, please contact our authors or visit the Hogan Lovells Brexit Hub: https://www.hoganlovellsbrexit.com/

Brexit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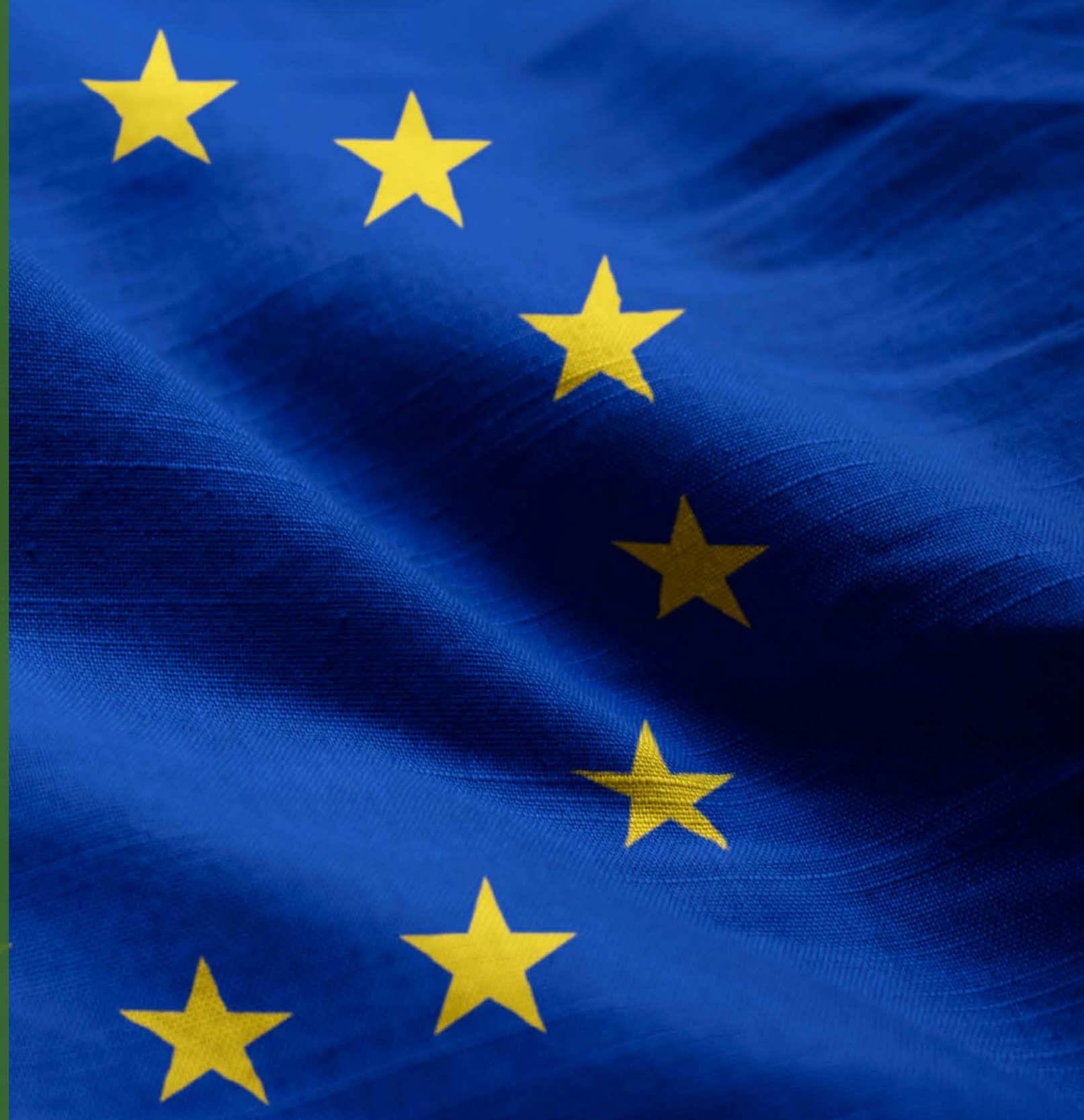

EU litigation landscape reshaped by new class action system

March 2021

In the European Union (EU), we can legitimately expect a significant increase of collective actions in the coming years for two mains reasons: the quick introduction of new connected products on the market in the context of the pandemic, and the new European collective actions legislation.

On 24 November 2020, the European Parliament endorsed the new European collective actions legislation, Directive 2020/1828 on representative actions for the protection of the collective interests of consumers (the 'Directive'). It will take until 2023 for the new procedures to be actually implemented: Member States are required to adopt implementing measures by 25 December 2022 and the measures will apply from 25 June 2023.

Regulating the development of collective redress mechanisms has been in the European Union's line of sight for a while. The adoption of the Directive therefore marks the conclusion of one of the European Commission long-standing objectives.

Interaction with the existing or future national mechanisms for collective redress

Member States do not have a uniform approach when it comes to collective redress. Compensatory collective redress is available in a majority of Member States, but in some of them, it is limited to specific sectors. And some Member States still do not provide for any possibility to collectively claim compensation in mass harm situations.

The new Directive imposes an EU class action system and sets minimum requirements below which Member States must not fall.

The Directive does not require Member States to scrap their existing mechanisms : 'This Directive does not prevent Member States from adopting or retaining in force procedural means for the protection of the collective interests of consumers at national level' (Article 1(2)).

Consequently, some Member States will have to introduce at least one representative action procedure for injunction and redress measures, while others will amend their existing procedural mechanisms, allowing for some optional choices.

However, doubts remain about how this European collective redress mechanism will interact with the existing or future national mechanisms, for instance, the data class actions created by the General Data Protection Regulation.

New procedural mechanism

The Directive enables representative actions against infringements by traders of a variety of EU directives and regulations, including the General Product Safety Directive, the Product Liability Directive, the General Data Protection Regulation, the General Food Law Regulation, the Sale of Goods Directive, the Regulations on medicinal products for human use, and the Medical Devices Regulations.

Collective Actions

The Injunctions Directive (2009/22/EC), which is to be repealed by the new Directive, already provided for certain injunction measures. The mandatory redress measures Member States should have in place is thus the real game changer.

These are the main features of the EU class action system:

- Actions can be brought only by 'qualified entities' designated by a Member State.
- 'Qualified entities' have to meet standardized criteria to have standing to sue.
- Certain 'Qualified entities' designated for cross-border representative actions can act as plaintiffs across Member States' borders.
- Several 'qualified entities' from different Member States are allowed to jointly bring a single representative action in one Member State where the alleged infringement affects or is likely to affect consumers from different Member States.
- 'Qualified entities' may choose to apply for an injunction or to seek compensation (redress measures).
- Redress measures may include compensation, repair, replacement, price reduction, contract termination, or reimbursement of the price paid.
- Member States can decide whether to establish an 'opt-in' system or an 'opt-out' system.
- Consumers can opt to be bound by the outcome of an action for redress.
- An 'opt-in' system is required for any consumer living outside the relevant Member State to join the action.
- Final decisions have cross-border effects.

Safeguards

In a 2 February 2012 Resolution, the European Parliament took a position on the use of collective redress mechanisms for the protection of European protected rights and recalled that "safeguards must be put in place within the horizontal instrument in order to avoid unmeritorious claims and misuse of collective redress, so as to guarantee fair court proceedings". The European Parliament stressed that "Europe must refrain from introducing a US-style class action system or any system which does not respect European legal traditions".

The Directive notably sets the following safeguards to avoid abusive lawsuits:

- Strict rules on the designation and funding of 'qualified entities' to prevent misuse of representative actions.
- The unsuccessful party pays the proceeding's costs for the winning party (loser-pays principle).
- Third parties may fund representative actions in accordance with national law and subject to measures ensuring that no conflict of interests or undue influence exists.
- Prohibition of punitive damages.

What's next?

Member States have latitude when implementing certain features of the Directive. The next 24 months will therefore be decisive for the shape of the collective proceedings in the Member States and some jurisdictions may emerge as enabling these representative actions with fewer options than others.

Given the possibility of cross-border representative actions, we may see some venues becoming (even) more popular for collective redress. While the Directive promises safeguards against abusive lawsuits, it will be crucial that defendants' rights and fairness of procedure will be maintained in practice.

What you should do to prepare

The Directive raises the risks of actions seeking collective redress in the EU. Here are a few things to keep in mind:

1. Without delay, anticipate increased cross-border litigation in the EU with stronger consumer participation.
2. Monitor local consumer regulations for inclusion in the scope of the Directive.
3. Anticipate that potential plaintiffs will shop around to find the 'best' forum, or national courts, to launch collective actions if you have multiple establishments and subsidiaries.

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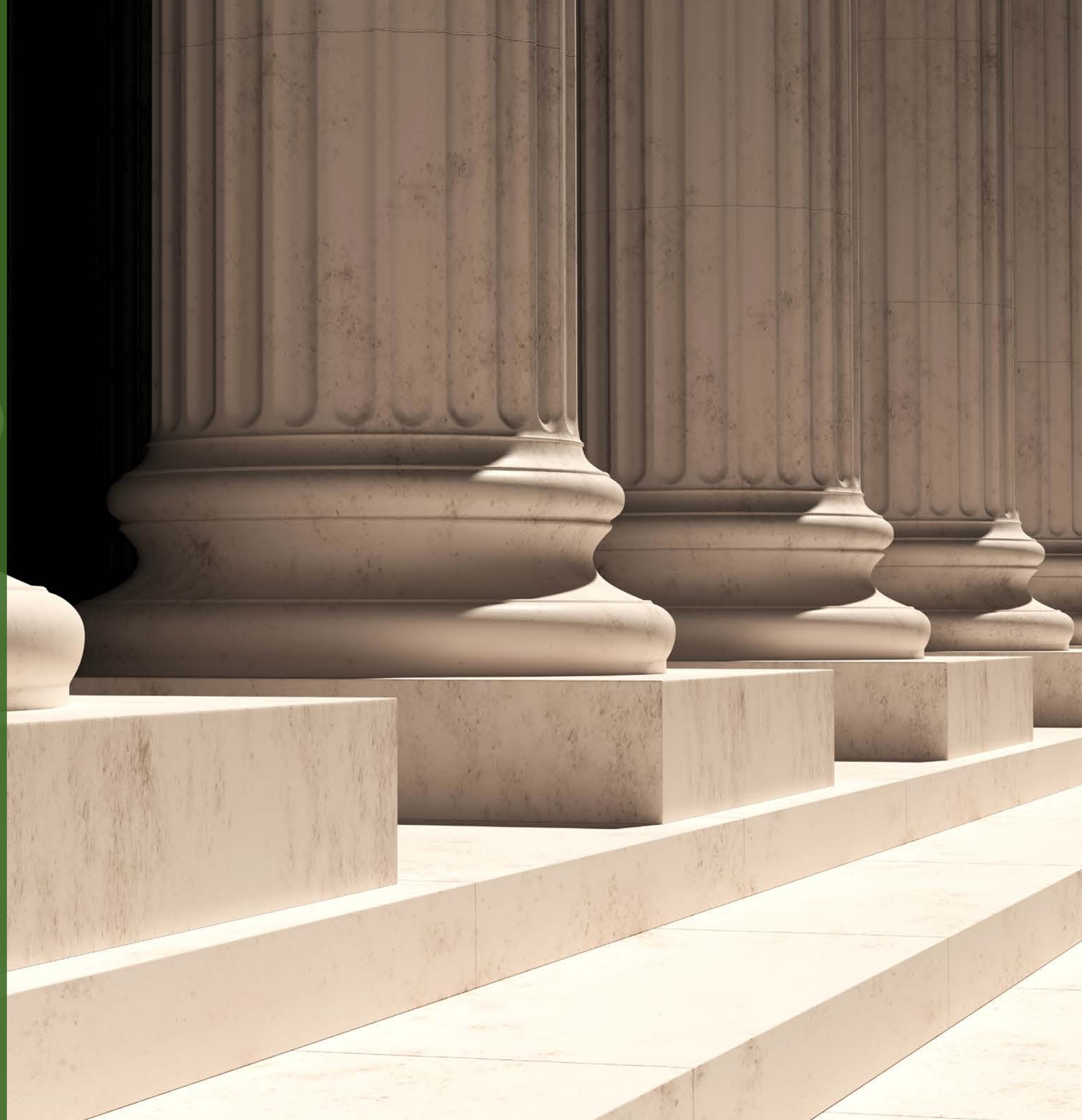
US PREP Act



U.S. courts continue to apply narrower view of PREP Act immunity

During the past 12 months, we've published several articles on the March 10, 2020, Public Readiness and Emergency Preparedness Act (PREP Act) Declaration (the "Declaration") related to COVID-19 as well as covering the five amendments to the PREP Act since then. You can read our prior publications providing key background on the Declaration here.

We also wrote an article on the earliest jurisprudence involving consideration of PREP Act immunity in the context of removal. As we commented there, the New Jersey and Kansas federal courts' decisions in those cases – remanding for lack of federal question jurisdiciton upon finding PREP Act protections inapplicable to allegations of negligent failure to use COVID-19 countermeasures and that the PREP Act applies only to acts, not failures to act, relating to covered countermeasures – hinted at the start of a possible trend among the judiciary to take a narrower reading of the scope of PREP Act immunity than what would otherwise seem to be fairly broad-sweeping coverage conferred under the plain language of the PREP Act.

Since then, HHS has, in no uncertain terms, rebuked these early courts' narrowed interpretations of PREP Act immunity head on. Indeed, within days of our piece discussing these initial court decisions, HHS issued its Fourth Amendment to the PREP Act Declaration (the "Fourth Amendment") in which it added explicit language stating that there can be situations where not administering a covered countermeasure to a particular individual such as where public health authorities determine that certain categories of persons like first responders should have priority to receive a vaccine – can fall within the PREP Act and the Declaration's liability protections. This language in the Fourth Amendment seemed to leave no doubt as to the Secretary's intention for a broad application of the PREP Act. Just over a month later, the Secretary then doubled down on this position by way of its Fifth Advisory Opinion 21-01 ("Advisory Opinion 21-01") issued on January 8, 2021. This advisory opinion appears to be aimed squarely at the judiciary and seems to evince the Secretary's frustration with these recent federal courts' interpretations of the PREP Act. Most notably:

- Advisory Opinion 21-01 expands on the language of the amended Declaration to clarify that the PREP Act provides complete preemptive federal jurisdiction for cases in which it is a defense. The Secretary further commented that, even in the case of plaintiffs seeking to avoid federal jurisdiction through artful pleading, "federal courts are free to entertain discovery to ascertain, for jurisdictional purposes, the facts underlying the complaint."
- Also in Advisory Opinion 21-01, the Secretary reiterated HHS' position that PREP Act protections apply in cases where the complainant alleges harm from the defendant's complete failure

or even refusal – to use covered countermeasures, particularly in those cases where such a failure arises from the conscious allocation of scarce resources among potential countermeasure recipients. In other words, the "decision-making that leads to the non-use of covered countermeasures by certain individuals is the grist of program planning [as defined in PREP Act], and is expressly covered by the PREP Act."

- Referring to the recent court decisions finding that the PREP Act cannot be read to apply to the non-administration or non-use of a covered countermeasure, the Advisory Opinion states, "[T]his 'black and white' view clashes with the plain language of the PREP Act, which extends immunity to anything 'relating to' the administration of a covered countermeasure."
- Finally, Advisory Opinion 21-0 clarifies that pursuant to Grable & Sons Metal Products, Inc. v. Darue Engineering & Mfg., 545 U.S. 308 (2005) – which recognized that a case involving interpretation of a federal statute constitues a substantial question of federal law and therefore belongs in federal court – "ordaining the metes and bounds of PREP Act protection in the context of a national health emergency necessarily means that the case belongs in federal court."

This and other commentary from HHS thus seems to repeatedly emphasize its intention that courts take a broad intepretation of PREP Act coverage and immunity. Yet, as indicated by another more recent court decision discussed below, the judiciary appears poised to continue applying a narrower reading of the PREP Act where possible.

Another federal court sets further implied limits on PREP Act immunity

In Avicolli v. BJ's Wholesale Club, Inc., the U.S. District Court for the Eastern District of Pennsylvania considered whether a distributor of hand sanitizer was immune from tort liability under the PREP Act. 2021 WL 1293397 (D.N.J. April 7, 2021). Although the court ultimately found that a substantive analysis of immunity was premature, the case provides further insight into how courts are interpreting the scope of liability under the PREP Act and related guidance.

In May 2020, Plaintiffs Dennis and Nadine Avicolli purchased a seventeen-ounce bottle of hand sanitizer from Defendant BJ's Wholesale Club ("BJ's"). Unbeknownst to the Avicollis, the manufacturer subsequently recalled all 17-ounce bottles two months later because they contained methanol or wood alcohol. Nadine Avicolli ingested some of the hand sanitizer in August 2020, suffering weakness of one side of her body and substantial loss of vision, among other things.

The plaintiffs brought product liability claims against the retailer, manufacturer, and distributor of the hand sanitizer, alleging negligence, strict liability, breach of warranty, and violations of Pennsylvania's consumer protection statute. Defendant retailer BJ's moved to dismiss the complaint, asserting immunity under the PREP Act as a "covered person" distributing a "covered countermeasure. " Specifically, BJ's argued that it was immune from liability under the Declaration because: (i) it is a "covered person" as a "distributor"; (ii) hand sanitizer is a "covered countermeasure" because it is a "qualified pandemic or epidemic product";

and (iii) the claims arose from the "administration or use" of the hand sanitizer.

The court denied the defendant's motion to dismiss, finding that the facts alleged in the complaint were insufficient to afford defendants immunity under the PREP Act. Focusing on the method of distribution to define the limits of PREP Act immunity, the court noted that neither plaintiffs nor the defendant provided a basis for inferring that BJ's obtained the hand sanitizer through one of the two means of distribution specified by the Secretary of Health and Human Services. Citing an advisory opinion issued by the Office of General Counsel for the Department of Health and Human Services, the court concluded that BJ's did not qualify for PREP Act immunity because it neither obtained the hand sanitizer under agreement with the federal government nor in response to the COVID-19 pandemic.

While the court declined to reach the merits of whether BJ's sale of hand sanitizer fit within the PREP Act's coverage, it distinguished the facts of the case from those that would allow an inference that the hand sanitizer was obtained through qualifying channels sufficient to be immune from liability: " [F]or example, a distillery which began obtaining and selling hand sanitizer as part of a coordinated effort to mitigate the spread of COVID-19. "

In other words, BJ's sale of hand sanitizer was consistent with its standard business operations rather than a response specifically tailored to combat the pandemic.

Comment

At bottom, Avicolli suggests that a retailer obtaining hand sanitizer for re-sale before the pandemic would presumably be excluded from immunity under the PREP Act, unlike a retailer that obtained a product after the start of the pandemic to specifically assist in mitigating the spread of COVID-19. Although the court simplistically focuses on whether a retailer obtains a product before or after the start of the pandemic, Avicolli does not consider a third option: a retailer who obtains a covered countermeasure before the start of the pandemic but sells the product as part of a response to the pandemic. Thus more generally, the case serves as yet another signal that the judiciary is likely to continue reading implied limitations into the scope of the coverage conferred under the PREP Act Declaration, notwithstanding HHS' guidance to the contrary. It's ultimately unclear whether other courts will find pre-pandemic purchasing and immunity under the PREP Act as mutually exclusive. Regardless, establishing a timeline of such purchases may be important to a PREP Act immunity defense and may, at least in some courts, determine whether a defendant can limit its liability for COVID-19-related claims.

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New Market Surveillance

Batteries Regulation

Digital Accessibility

Brexit

Collective Actions

US PREP Act

New Market Surveillance

Enforcement! What the (new) Market Surveillance Regulation brings to product safety and compliance

The basics

Market Surveillance Regulation 765/2008 sets out the requirements for accreditation and market surveillance relating to the marketing of products in the EU, and it took effect on 1 January 2010. It reinforces the provisions for market surveillance outlined in the "New Approach Directives". It complements and supplements the existing market surveillance provisions in the New Approach Directives on product supply. These New Approach Directives set out the essential requirements (on health and safety, for example) that must be met before products can be sold in the European Community. The Directives explain how manufacturers should conform with the essential requirements: products that meet the requirements should display CE marking, meaning that they can be sold anywhere in the Community/EEA. However, Market Surveillance Regulation 765/2008 will shortly be replaced by the "new" Market Surveillance Regulation.

Read on for a summary of key items in relation to the new Market Surveillance Regulation: we expect change is on the horizon.

The new Market Surveillance Regulation

Market Surveillance Regulation 2019/1020 applies to any products (sold online and/or in stores) which are subject to at least one of the 70 EU product Regulations and Directives listed under Annex I, unless that legislation contains more specific, equivalent provisions regulating market surveillance and enforcement. The list of "Annex I products" includes medical devices and in vitro diagnostic medical devices, cosmetics, hazardous substances, electronic and electrical equipment, construction products, toys, and machinery. You can read about the full scope of the new regulation here.

The goal of the new Market Surveillance Regulation can be broadly described as to further enhance and broaden existing market surveillance powers and activities, to reinforce trust in the EU single market, to further protect citizens in relation to the safety and compliance of products, and to improve coordination and collaboration between regulators. The recitals of the new regulation are certainly worth a read in the eyes of the authors of this article: they are comprehensive in explaining that "there's a new sheriff in town" when it comes to the enforcement of product laws in the EU.

In a nutshell, the new regulation aims to:

- improve compliance by business operators up front.
- strengthen market surveillance cooperation and effectiveness.
- clearly define obligations for economic operators, Member States, and market surveillance authorities.
- modernise the framework to cover new supply chains and address online sales.

When does the new Market Surveillance Regulation come into force?

Broadly speaking, the key date for product companies to have on their radar is 16 July 2021.

Companies should be prepared to feel the impact of the new regulation, in particular in relation to their interactions with regulators, who have increased surveillance and control powers, as well as the increased potential to be coordinated and to have access to resources.

How might the new Market Surveillance Regulation have the most impact?

It is too soon to tell which aspects of the new Market Surveillance Regulation will "make their presence known" first. Our Global Products Law team has summarised below some of our expectations:

1. The significant expansion in market surveillance powers will likely lead to greater market surveillance activity in the future, which is likely to have a significant impact when it comes to e.g. product compliance audits, test purchases, and other proactive enquiries from market surveillance authorities.
2. Although the focus of market surveillance should be on safety, the new wide-ranging powers to investigate and enforce may result in greater administrative and compliance costs on companies, especially from the investigatory powers to request information, make unannounced visits, conduct system audits, and, in some cases, reverse engineer products and embedded software.
3. We anticipate that all products companies will benefit from ensuring that all compliance and product information is easily available, up-to-date, accessible in all the EU languages where their products are sold, and the marking and labelling and packaging is compliant.
4. The impact of the new database for national market surveillance authorities to share compliance data with each other, allowing authorities across member states to work in unison, could well lead to an increasingly coordinated and joined-up approach between member states. This means, for example, that a carefully mapped out strategy in relation to potential safety issues and non-compliances will become even more important in future where products have been sold in multiple jurisdictions.
5. There is a particular focus on products sold online and ensuring that they are compliant with product laws in the EU. This will require some considerable changes to the current expectations of some companies who supply products to the EU via online sales channels.
6. Economic operators" in the supply chain are subject to compliance obligations contained in the new regulation. The definition of this is broad, namely: "the manufacturer, the authorised representative, the importer, the distributor, the fulfilment service provider or any other natural or legal

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person who is subject to obligations in relation to the manufacture of products, making them available on the market or putting them into service in accordance with the relevant Union harmonisation legislation". This broad definition will have a significant impact in terms of the diligence to be applied in future when it comes to ensuring compliance with EU product laws.

7. While the new regulation was adopted before the end of the Brexit transition period, most of the relevant provisions do not come into force until 16 July 2021. How the regulation might impact on the United Kingdom remains an open question. However, we anticipate that the UK market surveillance authorities will continue to show a proactive, coordinated, well-resourced approach and will be keen to keep pace (or move ahead of) other market surveillance regulators in the European Union and around the world.

Final word

Our team works across all EU member states and the United Kingdom to help global products companies to navigate product laws, safety, and compliance. We have close links with regulators and will keep you updated as trends develop.


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