# International Products Law Review

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# Global Products Law Practice

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. Hogan Lovells product litigation and product safety lawyers are supported by an in-house Science Unit and a Project Management Unit.

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## About *International Products Law Review*

In December 2000, Lovells (as it then was) launched its quarterly European Product Liability Review, the only regular publication dedicated to reporting on product liability and product safety developments in Europe for international product suppliers, and others interested in international product issues. Over the next ten years, this unique publication featured hundreds of articles, from authors across our network, covering issues in Europe and, increasingly, further afield. Reflecting the growing globalisation of product risks, and following the creation of Hogan Lovells through the combination of Lovells with Hogan & Hartson in May 2010, the publication was renamed International Product Liability Review in March 2011.

Hogan Lovells International Products Law Review continues to be the only regular publication dedicated to reporting on global developments in product litigation and product regulation. It is distributed worldwide free of charge to our clients and others interested in international product issues.

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*See Leopold's article, "Drones in German skies: new EU regulations take flight" on page 14.*

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*See Mahsa's article, "Multi-component products: expiry period for damages claims" on page 20.*

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### COVID-19: A quick recap of key considerations for products companies

The rapid spread of COVID-19 and the responses to it worldwide are significantly impacting how we do business. While the exact length and severity of the crisis is uncertain and impossible to model accurately at this point, companies are preparing for considerable commercial disruption. Products companies are hit particularly hard on a number of fronts. Valerie Kenyon and Jamie Rogers (London) and Christelle Coslin (Paris) discuss the operational challenges faced by products companies globally and consider what steps companies can take to mitigate the challenges.

### HHS Issues Advisory Opinion Encouraging Broad Reading of its PREP Act Declaration

As the coronavirus (COVID-19) pandemic evolves, the United States faces unprecedented needs, which are quickly creating challenges for manufacturers, distributors and health care providers, among others. Lauren Colton (Baltimore) has written an article titled, "HHS Issues Advisory Opinion Encouraging Broad Reading of its PREP Act Declaration" that we wanted to share with you.

## Feature

### Promoting the circular economy: France adopts anti-waste law

At the start of February 2020, a new law was adopted which is set to have a significant impact on product manufacturers selling products in France. Pauline Faron and Sarah de Magalhaes (Paris) summarise key elements of this legislation – known as the Anti-waste Law – which contains around 100 new measures aimed at fundamentally changing companies' production methods, as well as consumer behaviours.

## Europe – Germany

### Drones in German skies: new EU regulations take flight

After years of regulatory uncertainty and patchwork national approaches, the introduction of new EU legislation provides the foundation for an EU-wide harmonised framework for unmanned aircraft systems (drones). However, as Leopold Borst, Marc-Philipp Wiesenberg and Franziska von Hesler (Munich) explain, while the European legislator has taken into account general product safety and product compliance law, as well as issues unique to the civil aviation sector, there are likely to be numerous unresolved legal issues when the new regulations come into force. These could present challenges for both manufacturers and operators of drones in Germany.

## Europe – Netherlands

### Multi-component products: expiry period for damages

Noor Hogerzeil and Mahsa Amiri Bavandpour (Amsterdam) report on a recent case before the Court of Appeal of Arnhem-Leeuwarden, which examined the expiry period for a claim relating to an alleged defective product containing multiple components. In its judgment, the Court of Appeal specifically stated that its decision achieved a balance between the interests of the consumer and the manufacturer in this case. Accordingly, it will be interesting to see what happens if the case reaches the Supreme Court and if not, how it is applied subsequently.

## Europe – Poland

### Sugar and alcohol: new taxes coming soon

Agnieszka Majka, Celina Bujalska and Anna Wiktorow (Warsaw) report on a new bill adopted by the Polish parliament which will impose extra charges on sales of some alcoholic and soft drinks. As the new Bill comes into force at the start of July 2020, there is limited time for preparation and companies should move now to adjust their pricing policies. However, it is yet unknown whether the outbreak of COVID-19 will postpone the enforcement.

## Europe - UK

### Multi-addressee communications: when are they privileged?

Zen Cho (London) reports on a recent decision in the Court of Appeal that examined important questions on legal advice privilege, including the proper approach for determining the privileged status of emails sent to multiple recipients.

### Consumer smart-device security: moving towards increased regulation

Following the consultation process in 2019, it was announced in February that the UK government would be drawing up new legislation aiming to ensure that all consumer smart devices sold in the UK adhere to new rigorous security requirements to prevent cyber security breaches and protect consumers. Lucy Ward and Eshana Subherwal (London) run through the background to this new legislation and identify the three key security requirements that manufacturers need to know about.

## Asia Pacific – Japan

### Small claims procedure: a user-friendly route to damages

Manufacturers placing products on the Japanese market should be aware of the small claims procedure – a popular procedure through which consumers can seek low level damages. Dr. Eva-Marie Koenig and Mitsuhiro Yoshimura (Tokyo) explain the origins of this procedure, its objectives and how it is used by consumers to bring straightforward warranty claims, claims for breach of contract as well as claims for defective products.

London-based Senior Scientist, Dr. Marion Palmer, has helped create COVID-19 airways procedures boxes to act as a protective screen against the droplets generated during airway procedures, which contain high levels of the virus.

Support Dr. Palmer's crowdfunding campaign here:

https://www.crowdfunder.co.uk/protect-our-nhs-specialists-from-covid-19

# COVID-19: A quick recap of key considerations for products companies

## Introduction

The rapid spread of COVID-19 and the responses to it worldwide are significantly impacting how we do business. While the exact length and severity of the crisis is uncertain and impossible to model accurately at this point, companies are preparing for considerable commercial disruption. Products companies are hit particularly hard on a number of fronts.

Longer lead times for sourcing components, delays when moving goods and issues posed by an increasingly non-centralized workforce are just a few of the operational challenges faced by products companies globally. Not to mention, in some jurisdictions, the requests for manufacturers to change their production lines to start to produce vital medical equipment.

## What businesses should consider

With so much change underfoot, below is a short overview of key issues for products companies to keep in mind.

- **Keep your eye on product safety:** This could be a more challenging time to focus on information in the supply chain about product safety and related issues, but cutting corners creates risk. It's important to emphasize within the business the need to be vigilant to potential product safety issues in the usual way: even if the approach to dealing with those issues may need some creative thinking in the current climate. Placing unsafe products on the market can lead to regulatory action and possible fines, litigation risk, criminal sanctions and reputational harm that is hard to fix.
- **Take care with new suppliers:** There are likely to be difficulties within the supply chain and it may be necessary to switch suppliers. Take the time to conduct appropriate due diligence on anyone you plan to work with. If you wouldn't have worked with the supplier before COVID-19, make sure you're working with the supplier for all the right reasons now.
- **Take care with new products:** Is your business considering manufacturing or selling a new product range for the first time, or into new markets? At this stage in time, the usual product due diligence and safety standards apply – as do the potential product liability risks. If your business is considering changing its Personal Protective Equipment (PPE) manufacturing to develop face masks (for example) – have you checked all of the laws and relevant standards that apply, and is your marketing team familiar with this product and able to promote it appropriately? If your business wants to start to describe products as having potential health benefits: have you taken appropriate advice with regards to medical device and health care rules which could apply?
- **Repairs and replacements:** Disrupted supply chains may impact your ability to meet statutory and contractual obligations to consumers and other end-users. Consider how you plan to meet this challenge and whether suitable alternatives can be put in place: do scripts with service centres need to be updated; could relevant FAQs be placed on your website to help consumers know what to expect, and when?

Visit our COVID-19 topic center for answers.

https://www.hoganlovells.com/en/knowledge/topic-centers/covid-19/

- **Be pragmatic:** This may be the time for tough, but mutually beneficial, conversations. Review your supply chain contracts to assess the level of risk. If a commercial relationship is under strain, open a constructive dialogue about how to manage the situation.
- **Review your force majeure clauses:** This is an area that has kept many businesses busy recently. Force majeure clauses offer relief to a party should an event occur which is out of the party's reasonable control and which prevents the party from performing its contractual obligations. Check your clause for relevant references, such as to 'disease' or 'pandemic', or for generic sweeper language. A force majeure clause will be judged on its terms and the specific context it becomes applicable to COVID-19 or its ramifications may qualify.[1]
- **Review your insurance policies:** You may have different insurance policies that could respond to losses related to the pandemic, or you may suffer loss through business interruption. Business interruption policies typically only cover disruption caused by physical property damage, but you may have purchased enhanced or specific coverage that could apply (for example, standalone cover or cover for disruption to critical contingent sites or resulting from denial of access). You may also suffer losses stemming from liabilities resulting from the situation: for example, businesses should also consider whether their liability policies (such as D&O insurance or employers or public liability policies) will cover future claims arising from their response to the crisis. You may also have credit insurance in support of transactions that have been disrupted or cancelled – again, this may provide protection. Finally, work travel may be disrupted and again your company's travel or event cancellation insurance may allow for the recovery of lost cost associated with that. In all cases, the cover provided will be driven by the precise wording of the policy, so it is important to get a handle on these contracts now.
- **Be prepared for potential litigation risks down the road:** in times of crisis thinking ahead is challenging, yet with deteriorated market conditions, one can expect a surge in both supply chain and product litigation. Do your best efforts to maintain best practices in terms of document retention, keeping a good track record of chain of events and decision making trees as this evidence may become useful later. Your usual practices to prevent and mitigate litigations risks may need to be adapted in a world where a number of employees are working from home.

The issues raised here are far from exhaustive, this is an evolving area that requires businesses and their lawyers to be adaptable. We know that this is a difficult time. Whatever your business needs, whatever challenges you face, we're here to help.

Get in touch with our leading Global Products Law Practice for more information and to navigate litigation and regulatory risks.

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1 For further information, see https://www.hoganlovells.com/en/publications/coronavirus-as-a-contractual-force-majeure-event-a-simple-checklist

# COVID-19: HHS Issues Advisory Opinion Encouraging Broad Reading of its PREP Act Declaration

## Introduction

As the coronavirus (COVID-19) pandemic evolves, the United States faces unprecedented needs, which are quickly creating challenges for manufacturers, distributors and health care providers, among others. We have written an article titled, "HHS Issues Advisory Opinion Encouraging Broad Reading of its PREP Act Declaration" that we wanted to share with you.

## Brief summary underscoring key highlights

On April 14, 2020, the Department of Health and Human Services (HHS) General Counsel issued an advisory opinion ("the Opinion") on the March 10, 2020 Public Readiness and Emergency Preparedness Act ("PREP Act") Declaration ("the Declaration") related to COVID-19, in response to numerous requests for guidance from manufacturers, distributors, and health care providers. Although the Opinion is not binding law and does not answer every question about the Declaration, it does provide insight into the intended scope of the Declaration.

By way of background, the PREP Act confers a significant benefit to manufacturers, distributors, and providers of certain products by providing an affirmative defense to product liability lawsuits with respect to use of those products to respond to a declared emergency. The PREP Act provides immunity "from suit and liability under federal and state law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or use by an individual of a covered countermeasure if a Declaration has been issued with respect to such countermeasure."2 There are three key elements necessary to obtain PREP Act immunity, all of which are addressed in the Opinion and discussed in our article.

To read the full article please click here.

We also authored previous content that may be useful please click here.

To access all Hogan Lovells COVID-19 content please see our COVID-19 information hub.

If you have any questions, please feel free to reach out and I'd be happy to address them.

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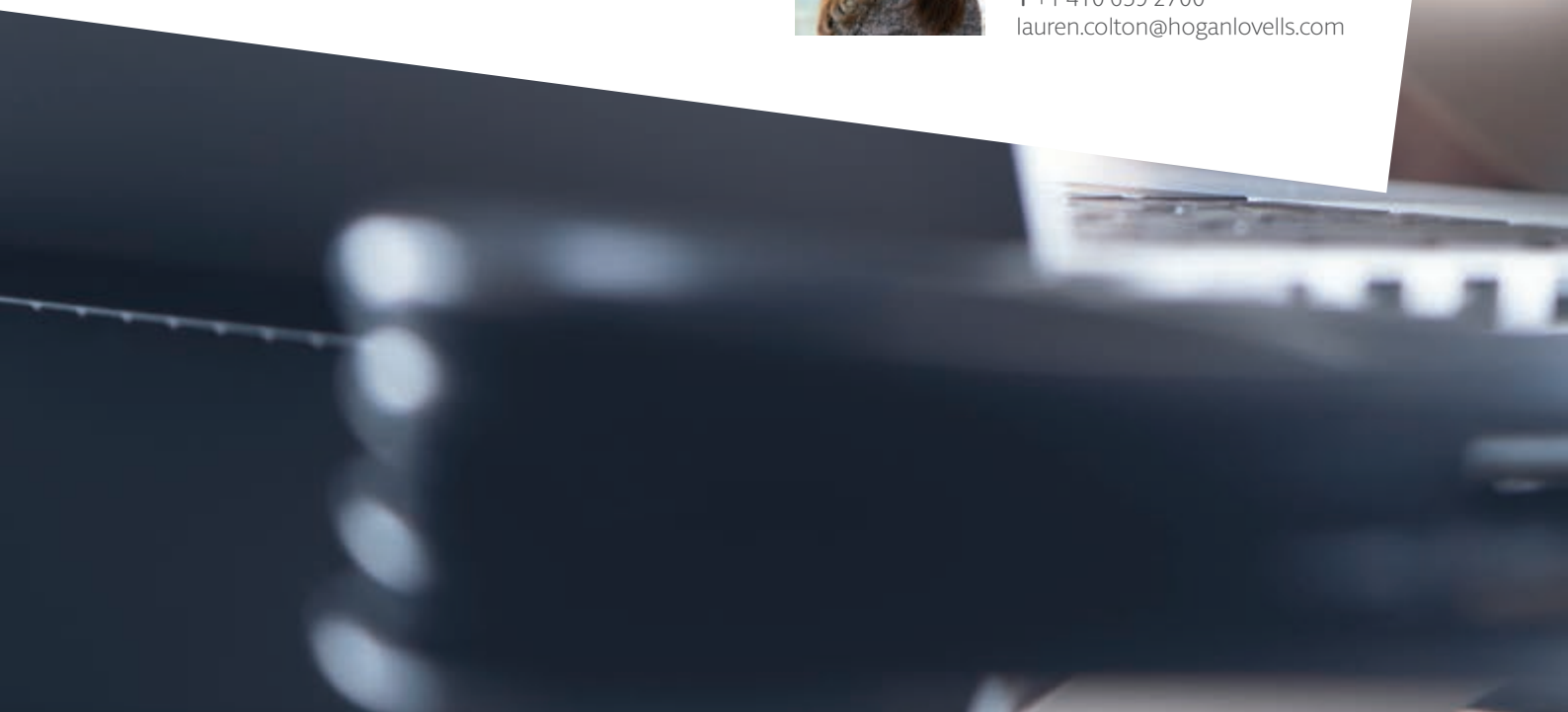

Feature

# Promoting the circular economy: French Anti-waste law adopted

## Introduction

On 10 February 2020, law no 2020-105 on the fight against waste and for a circular economy (the "Anti-waste Law") was officially promulgated in France. Adopted after a broad consultation with stakeholders (including companies, NGOs and local authorities) which started in 2017, this law contains around 100 new measures. These are aimed at fundamentally changing companies' production methods and consumer behaviours – seeking to preserve natural resources and biodiversity by reducing waste, and encouraging repair and reuse of products.

This ecological transformation relies on the concept of the "circular economy" throughout a product's lifespan. Manufacturers - and producers more broadly[1] - will have to adapt their manufacturing processes to produce "eco-friendly" products, ensure that products can be repaired easily, inform consumers appropriately about the durability of their products and ensure that products can be recycled to reduce waste.

The Anti-waste Law introduces a wide variety of new measures. These range from setting a goal of achieving zero disposable plastic across France by 2040, a prohibition on the destruction of non-food unsold products, and the possibility for medications to be sold in pharmacies by the unit (when their pharmaceutical form allows it), to the mandatory requirement for information on the length of time operating software updates for computers, mobile phones and/or tablets will support "normal" use of the device.

This article focuses on some of the Anti-waste Law's most important measures.

## Increased consumer information

Various new mandatory requirements have been introduced for producers to provide more detailed product information.

- New information on a product's "environmental qualities and characteristics" will have to be provided to consumers by any appropriate means (marking, packaging, label etc). This should cover product information such as whether the product is made of recycled material, the use of renewable resources, the product's reparability, reusability, recyclability, the presence of dangerous substances etc. An implementing decree should be adopted by the French government to specify the scope of this obligation and practical implications.
- Better information on sorting rules will be provided by extending the use of the "Triman" logo (pictured below). Currently, the Triman logo must be affixed on the product, its packaging and the inbox materials (provided they are recyclable).Going forwards this logo will need to be accompanied by information on the applicable sorting process for each type of product. An implementing decree should also be adopted in this regard, but this measure should come into force in 2022.

1 Under Article L. 421-1 of French Consumer Code, the definition of "producer" is broader than the definition of "manufacturer" as it covers (a) manufacturer of the product (when it is established in the European Union) and any persons who present themselves as manufacturers by affixing their names, trademarks or other distinctive signs on the product, or any repairer of the product, (b) manufacturer's representative (when the manufacturer is not established in the European Union) or the importer of the product (in the absence of a representative established in the European Union), and (c) any other professionals in the marketing chain, in so far as their activities may affect the safety characteristics of a product.

## Fight against planned obsolescence

### New reparability and durability index

A new "reparability index" will be introduced, to be replaced by a "durability index" in 2024. The reparability index will be a simple, visual tool displaying a score out of 10. Its purpose is to let consumers know how easily their electronic equipment can be repaired (if at all). This information will be communicated by producers, importers, distributors, or any other person placing electrical and electronic equipment ("EEE") on the French market, to sellers of their products and to any other person who requests this information. Then, sellers of EEE as well as those using a website or an online distribution platform will in turn communicate the "reparability index" to consumers at the point of sale by any appropriate means (markings, labels, packaging etc.). The new measure will apply to both bricks and mortar and e-commerce sales, and will come into force on 1 January 2021. An implementing decree will be adopted specifying the criteria to be taken into account when calculating the index.

From 1 January 2024, the reparability index will be completed/replaced by the durability index, which will include new product criteria such as reliability and robustness. An implementing decree will be adopted in due course to establish the list of products and equipment covered by the durability index, as well as how it should be calculated.

### Spare parts availability

Manufacturers are currently under no obligation to inform consumers if spare parts are not available for their product. However, if spare parts are available, they are subject to an obligation to inform consumers about the period during which spare parts that are absolutely necessary for the functioning of a product will remain available.

This will now change, and manufacturers will have to inform consumers at the time of purchase that spare parts are not available (should this be the case). This measure will apply to all movable goods, such as EEE and furnishings, household appliances, small computer and telecommunications equipment, screens and monitors. If spare parts are available, the period within which the spare parts must be supplied by the manufacturer to the seller or repairer will be reduced to 15 working days, instead of two months (the current limit).

A further implementing decree will also have to be adopted and these measures will come into force on 1 January 2022.

### Better information on statutory conformity warranties

The billing document (receipt or invoice) delivered to the consumer at the time of product purchase will now have to indicate the existence and the duration of the statutory conformity warranty. An implementing decree will be adopted to define the list of products subject to this new obligation.

Additionally, a six-month extension to the duration of the statutory conformity warranty will be applied to any product repaired under that warranty. In other words, the warranty will be extended to two and a half years (instead of two years) where a product repair is involved. This measure will come into force on 1 January 2022.

## New EPR streams

In France, on the basis of Extended Producer Responsibility ("EPR"), producers and distributors have to finance the management of their waste through a financial contribution to a Producer's Responsibility Organisation ("PRO"), which takes charge of managing that waste on their behalf. Also known as the "Polluter Pays Principle", it means that the more polluting a product is, the higher the end-of-life costs for the producers.

Currently, there are 14 EPR streams that organise waste prevention and management of the same categories of products (such as batteries, EEE, end-of-life vehicles and boats, household packaging, unused medicines, tyres, graphic paper, textiles and footwear, chemicals, furniture, gas bottles etc).

## Extension of "polluter pays" principle

Eleven new EPR streams have been created by the Anti-waste Law. Covering categories including tobacco products, toys, sports and leisure goods, gardening products, chewing gum and sanitary textiles.

The specific timetable for application will vary between 2021 and 2023, depending on the sectors involved.

## Bonus-malus system for "eco-friendly" products

Manufacturers that design products on the basis of environmental performance criteria (such as the quantity of material used, incorporation of recycled material, use of renewable resources, durability, reparability, potential for reuse, recyclability, absence of eco-toxicity or dangerous substances) will benefit from a bonus on the contribution they pay to the PRO for the management and treatment of their products' end-of-life. Conversely, should they fail to do so, their contribution will be increased by way of a malus.

This measure, which aims to reduce over-production and over-packaging of products, as well as the need to transform entire production and consumption models, will come into force on 1 January 2021.

## Comment

Through the publication of several implementing decrees, most of the new measures created by the Anti-waste Law will be applicable from 2021 onwards. Manufacturers should make the most of the intervening period to prepare in order to be ready when these obligations later come into force. In subsequent editions of IPLR we'll be reporting on the practical implementations of these new obligations, so stay tuned!

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Europe *Germany*

# Drones in German skies: new EU regulations take flight

## Introduction

Unmanned Aircraft Systems (UAS) – more commonly known as drones – have been in use for many years. For a long time, they were only used for experimental and military purposes. But as smaller, inexpensive devices have become more available, they've found a wider range of applications and potential users. Although mainly used by private individuals as cameras, drones are used by public institutions and private companies for transport and research, among many other applications.

In logistics, drones can provide a flexible, on-demand shipping method. Scientific institutions, meanwhile, may profit from new possibilities like airborne observation of wildlife behaviour. In their capacity as cameras, drones can be used for plant surveillance or intelligence reconnaissance. As such, they can also provide technical assistance in maintaining dangerous machines or reaching hard-to-access places. In agriculture, drones are already gradually replacing time-consuming human work such as monitoring the condition of fields and applying pest controllers.[1]

As a consequence, there is – and will be even more – traffic in the sky. The number of private drones operating in the public space is soaring. Already in 2016, the European Drones Outlook Study estimated that the sector will see an annual turnover of €10 billion by 2035 and more than €15 billion by 2050.[2]

This trend has prompted activity and increased focus by legislators in Germany and the EU. Within a few years, both have created legal regimes to (further) define regulations for manufacturers, distributors and operators of drones. While manufacturers and distributors need to be particularly aware of updated product safety, product monitoring and notification obligations, operators will have to be prepared to accommodate updated requirements and obligations for the registration and use of UAS.

This article provides a high-level overview of the current and upcoming legislative framework, focusing particularly on two recent EU Regulations released in 2019.[3]

1 *Cf. SESAR JU, European Drones Outlook Study (November 2016), p52-70*

2 *Cf. SESAR JU, European Drones Outlook Study (November 2016), p3.*

3 Please note that this article will concentrate on UAS intended for commercial and private purposes. For military, police, disaster protection and further areas of UAS usage, diverging regulations may apply.

## Resolving a hotchpotch of German and European rules

Historically, EU laws did not cover the production, distribution and operation of UAS in EU member states. That explains why – as the number of UAS used for commercial and private purposes continued to grow – several national legislators started developing their own national frameworks. For example, the German Air Traffic Act (*Luftverkehrsgesetz* or "LuftVG"), the German Air Traffic Regulation (*Luftverkehrs-Ordnung* or "LuftVO") and some subordinate regulations cover discrete areas of UAS operation and use in Germany.

The resulting patchwork of laws had significant weaknesses, particularly with regard to cross-border operations and the coordination of UAS operations with EU civil manned aviation.

Realising these shortcomings, the EU legislator took the opportunity to revise its rules on civil aviation and simultaneously introduce an EU-wide, harmonised framework on the design, production, maintenance and operation of UAS.[4] As such, Regulation (EU) No 2018/1139, which introduces common rules in the field of civil aviation and establishes a European Union Aviation Safety Agency[5] ("EASA-BR"), serves as the regulatory basis for all major UAS matters in the EU.

Based on EASA-BR, the European Commission recently adopted two regulations on UAS in the civil aviation sector: Delegated Regulation No 2019/945 on unmanned aircraft systems and third-country operators of unmanned aircraft systems[6] ("EASA-DR") and Implementing Regulation No 2019/947 on rules and procedures for the operation of unmanned aircraft[7] ("EASA-IR"). Both regulations are intended to further develop a uniform legislative framework for UAS and will gradually become applicable, fully entering into force by 2022.[8]

4 https://ec.europa.eu/transport/modes/air/uas_en, last visited 7 February 2020

5 Amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91, OJ L 212, 22.8.2018, p1.

6 OJ L 152, 11.6.2019, p1.

7 OJ L 152, 11.6.2019, p45.

8 *See Art 20 et seqq EASA-IR*

While EASA-DR differentiates between three categories of UAS operations, depending on the potential safety and security hazards involved, and defines respective operating requirements, EASA-IR provides for specific requirements on the production and distribution of UAS, starting with the "lightest" category.

## UAS Operations: open, specific or certified?

The division of UAS operations into three categories may have the most far-reaching implications for UAS operators:

- **"Open" drone operations** generally cover operations believed to involve low safety and security risks. "Open" operations do not generally require prior authorisation or operational declaration prior to use.[9]
- **"Specific" drone operations** generally cover operations believed to involve higher safety or security risks. "Specific" operations generally require either prior authorisation by the competent authority[10] or a declaration by the operator to remain within limits of specified standard scenarios with their operation.[11]
- **"Certified" drone operations** generally cover operations believed to involve significant safety or security risks. "Certified" operations must therefore conform to a multitude of additional requirements, including operator certification and, potentially, the licensing of remote pilots.[12]

As well as taking into account the design of an UAS (i.e. its mass and measurements), the categories defined by the legislator also cover potential safety and security hazards presented by its intended use (e.g. flight altitude, proximity to assemblies of people, transport of dangerous goods or people, and operation within or beyond visual lines of sight).

9 See Art 3a and 4 EASA-IR

10 In Germany, the competent authority is generally the German Federal Aviation Authority (Luftfahrt-Bundesamt) and/or a subordinate state authority.

11 See Art 3b and 5 EASA-IR

12 See Art 3c and 6 EASA-IR

## This graphic below provides an overview of the main criteria:

| | Open | Specific | Certified |
|---|---|---|---|
| **Requirements for respective category** | | | |
| MTOM* | < 25 kg | n/a | n/a |
| Measurements | n/a | < 1m or < 3m, depending on operation | > 3m |
| VLOS** or BVLOS*** | VLOS | VLOS or BVLOS, depending on operation | VLOS or BVLOS |
| Carriage of dangerous goods | not possible | not possible | possible |
| Carriage of people | not possible | not possible | possible |
| Operation above assemblies of people | not possible | depending on operation | possible |
| Maximum flight altitude | < 120m | n/a | n/a |
| **Requirements for operation** | | | |
| Prior authorisation or declaration required? | no | depending on operation | authorisation |
| Certification of the pilot | (Online) theoretical knowledge examination + potentially self-practical training | Training as identified by the operational authorisation or by respective standard scenario | High requirements – comparable to pilot licence in manned aviation |

* Maximum Take-Off Mass; ** Within Visual Line Of Sight;
*** Beyond Visual Line Of Sight.

## The devil is in the details

The current German operating laws generally regulate the operation of UAS in a similar way.[13] However, the categorisation of drone operations differs from the categorisation introduced by the EU Regulations. The main similarities and differences are:

- drone operations without prior authorisation are generally allowed for drones that have a MTOM of less than 5kg;
- unlike under European laws, operating drones with a MTOM of more than 5kg but less than 25kg will usually be subject to a reservation of authorisation;
- as under European laws, operating drones with a MTOM of more than 25kg generally require prior authorisation;
- as under European laws, BVLOS operations and operation above assemblies of people generally require prior authorisation;
- unlike the situation under European laws, operations without prior authorisation are generally limited to a flight altitude of 100m above the ground (instead of 120m).

German and EU law provisions are already quite similar. However, the new EU regulations entering into force will introduce some specific changes to UAS operations in Germany. From a compliance perspective and in order to mitigate against unnecessary risks, operators should carefully consider the upcoming changes and make sure they revise their internal guidelines and procedures – preparing for new authorisation processes where needed.

## Manufacturers: product safety and product compliance

UAS manufacturers already have to follow general EU product safety requirements (e.g. under the General Product Safety Directive 2001/95/EC[14], the Machinery Directive 2006/42/EC[15], the EMC Directive 2014/30/EU[16], the Toy Safety Directive 2009/48/EC[17], and the Radio Equipment Directive 2015/53/EU[18]).

But with the new regulations coming into force, UAS will for the first time be subject to a legal regime that corresponds to the already established general principles of European product safety and product compliance legislation.

Key impacts of the main provisions include:

- when EASA-DR comes into force, certain UAS will be subject to product-specific conformity assessment requirements, including CE marking requirements, and numerous technical requirements depending on the respective UAS construction category (C0-C4)[19];
- in case of risks to the health or safety of persons or to certain other aspects of public interest, the so-called "economic operator" (i.e. the manufacturer, the authorised representative, the importer and/or the distributor) may be subject to certain corrective actions and/or notification obligations[20];

13 *See Sec 21a et seqq LuftVO.*

14 *Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety, OJ L 11, 15.01.2002, p4.*

15 Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (recast), OJ L 157, 09.06.2006, p24.

16 Directive 2014/30/EU of the European Parliament and of the Council 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (recast), OJ L 96, 29.03.2014, p79.

17 Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys, OJ L 170, 30.06.2009, p1.

18 Directive 2015/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC, OJ L 153, 22.05.2014, p62.

19 See Art 4 EASA-DR and the Annex to the EASA-DR

20 See Art 36 and 38 EASA-DR.

- some cases of (merely) formal non-compliance may also lead to corrective action and/or notification obligations.[21] For example, missing/improper CE markings, missing manufacturer's or importer's name, missing serial number, missing sound power level indication and manual/instruction issues may require corrective actions to be carried out. If non-compliance persists, the competent authority may even issue a (EU-wide) sales stop and/or a recall order.

## Comment

After a period of regulatory uncertainty and patchwork national approaches, EASA-BR, EASA-IR and EASA-DR have set the foundation for an EU-wide harmonised UAS framework. In laying down this framework, the European legislator has taken into account not only decades-long experience of general product safety and product compliance law-making, but also issues unique to the civil aviation sector.

Even so, we anticipate numerous unresolved issues when EASA-IR and EASA-DR come into force. These could present legal and business challenges for both manufacturers and operators. Hogan Lovells will continue to actively monitor the upcoming implementation processes as well as ongoing legislative proceedings and will be happy to coordinate closely with all stakeholders involved.

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21 *See Art 39 EASA-DR.*


PHANTOM

Europe *Netherlands*

# Multi-component products: expiry period for damages claims

## Introduction

On 17 December 2019, the Court of Appeal of Arnhem-Leeuwarden (the "**Court of Appeal**") handed down an interesting judgment on the expiry period applicable to the right to claim for damages in a matter involving an alleged defective product. In this case, the product consisted of four components that had been put into circulation on different dates by the same manufacturer.

## Facts

On 24 September 2004, a patient underwent surgery during which an orthopaedic surgeon inserted a hip prosthesis into his body. The hip prosthesis consisted of four separate components; (i) a cup placed in the pelvis, (ii) a head that rotates in that cup, (iii) a taper adaptor, and (iv) a stem.

Each component was manufactured and delivered to the hospital on different dates. The head, taper adaptor and cup together are called the hip system. The hip system together with the hip stem forms the hip prosthesis.

Following various health complaints, the patient underwent a blood test and on 27 February 2012, the results showed an increase in cobalt and chromium values. As the pain continued, a hip revision surgery took place on 20 July 2012 during which the hip system of the prosthesis was replaced but the stem was not removed.

After the hip revision surgery, the cobalt and chromium values in the patient's blood decreased significantly. However, the patient's complaints of persistent pain continued. As a result, the patient was seen by a rehabilitation doctor on 18 April 2013. The doctor diagnosed the patient with a pelvic misalignment and a difference in leg length. On 27 September 2013, a second hip revision took place.

The patient claimed that the manufacturer of the hip prosthesis should be held liable for the damages allegedly suffered (along with future damages) as a result of the implantation of the hip prosthesis. The patient therefore issued a writ of summons on 19 May 2014.

## Interim judgment at first instance

Under Article 6:191(2) of the Dutch Civil Code ("**DCC**"), an injured person's right to damages against a manufacturer as per Article 6:185, paragraph 1 DCC, is extinguished at the end of the expiry period. The expiry period is currently 10 years, beginning on the day after the date that the manufacturer put the product that caused the alleged damage into circulation, unless the injured person has begun proceedings against the producer in the meantime. This provision implements Article 11 of the Product Liability Directive ("**PLD**").[1]

At first instance, the manufacturer argued that the head had been put into circulation on 5 May 2004 (the date it was delivered to the importer) and that the claimant's right to claim damages in relation to the head had therefore expired on 5 May 2014. On that basis, according to the manufacturer, the claimant's right to claim alleged damages for the hip system as a whole had also expired.

According to the claimant, the damage could not have been caused by the components individually. Instead, damage resulted when the components came together as an end-product (i.e. the cup and head had functioned defectively together).

The claimant therefore argued that the expiry period only started to run the day after the operation, given that the components of the prosthesis were not actually assembled into an end-product – the hip prosthesis – until the operation took place.

The District Court agreed with the claimant: the product could only be considered to be a product that could cause damage when its four different components were combined into one single product (the hip prosthesis).

The District Court therefore ruled that the claimant's right to claim damages had not ended 10 years after the head had been put into circulation. This was because the other three components' periods had not expired on the day the writ of summons was issued.

The manufacturer appealed the decision to the Court of Appeal.

1 Directive 85/374/EEC

## Court of appeal judgment

The manufacturer appealed, arguing that the expiry period started separately for each component, depending when they were put into circulation. The head was the first component put into circulation on 11 February 2004.[2] Accordingly, the manufacturer argued that the expiry period began on 12 February 2004. That meant the claimant's right to claim damages had expired 10 years later (on 11 February 2014).

The manufacturer also argued that (i) it could not qualify as the manufacturer of the hip prosthesis, (ii) it did not put the end-product into circulation and (iii) it was not involved in the implantation of the end-product into the claimant's body.

The Court of Appeal's deliberations and decisions are interesting, both in relation to the interpretation of the terms "manufacturer" and "date of putting into circulation" (as defined in the DCC/PLD), and in regards to the question of whether the expiry period of one component impacts the expiry period of the end-product as a whole.

## "Manufacturer" and "date of putting into circulation"

The Court of Appeal ruled that the date of the claimant's operation could not be considered to be the date on which the components were put into circulation. This would run contrary to the 2006 ruling of the Court of Justice of the EU ("**ECJ**") in *O'Byrne/Sanofi*[3] and the ECJ ruling of *Centre hospitalier/Dutrueux* on 21 December 2011.[4]

In O'Byrne/Sanofi, the ECJ ruled the following with regard to the date of putting into circulation:

> "27. In light of those considerations, a product must be considered as having been put into circulation, within the meaning of Article 11 of the Directive, when it leaves the production process operated by the producer and enters a marketing process in the form in which it is offered to the public in order to be used or consumed. 28. Generally, it is not important in that regard that the product is sold directly by the producer to the user or to the consumer or that that sale is carried out as part of a distribution process involving one or more operators, such as that envisaged in Article 3(3) of the Directive."

In *Centre hospitalier/Dutrueux*, where a patient had suffered from burns caused by a defective mattress in a hospital, the ECJ ruled:

> "In the present case, the liability that may be incurred by a user which, like Besançon CHU, employs, in the course of providing treatment to a patient, a product or equipment that it has previously acquired, such as a heated mattress, is not among the matters regulated by Directive 85/374 and hence does not fall within the directive's scope."

In the case at hand, the Court of Appeal ruled – without any further clarification – that the hospital where the hip prosthesis was inserted into the patient could not be regarded as the manufacturer (or importer or supplier) within the meaning of Article 6:187 DCC.

Therefore, according to the Court of Appeal, the expiry period under Article 6:191(2) DCC did not start at the date of surgery (as the start of the expiry period is explicitly linked to the moment at which the manufacturer puts the product into circulation). The Court of Appeal ruled that the "date of putting into circulation" was in fact the date when the components were received by the importer, because this was the moment when the components left the production process operated by the manufacturer and entered a marketing process in the form in which they were offered to the public for use or consumption.

2 In first instance, the manufacturer had stated that this was 5 May 2004, but this was corrected on appeal.

3 European Court of Justice 9 February 2006, C-127/04, *NJ* 2006/401 *(O'Byrne/Sanofi)*.

4 European Court of Justice 21 December 2011, C-495/10, ECLI:EU:C:2011:869 *(Centre hospitalier/Dutreux)*.

## Expiry period prolonged

On the question of receipt of the four components by the importer, the Court of Appeal noted that the first date of receipt (of the head) was 11 February 2004 and the last date of receipt (of the taper adapter) was 18 August 2004.

Accordingly, there was a difference of six months between the dates of receipt of the four components. The key question to be answered by the Court of Appeal was whether expiration of the expiry period of the first component put into circulation also meant that the expiry periods of the other three components had also expired.

The Court of Appeal observed that this specific question had not previously been addressed in the case law of the ECJ or of the Dutch Supreme Court. It therefore quoted the Opinion of Advocate General Trstenjak in the *Aventis/O'Byrne* case.[5] Trstenjak had argued that each of the components of an end-product put into circulation by different manufacturers has its "own" expiry period, stating:

> "106. If several producers or suppliers to be classified as producers form part of a chain of value creation, the time when the limitation period starts running must be ascertained separately for each producer. If, then, proceedings brought against one producer or supplier to be classified as a producer interrupted the expiry period in relation to all the other producers and suppliers to be classified as producers involved, regardless of whether they were ever made parties to the proceedings or even became aware of them, that could scarcely be reconciled with the approach followed in O'Byrne of examining the particular individual case."

As the Court of Appeal observed, if one followed this line of reasoning, it would also apply to the expiry periods of components of an end-product, even if those components had been manufactured by the same manufacturer. That would mean that the expiry period for each component ran separately and, as a result, the patient's claim in this case should have been rejected.

In this case, however, it had not been stated or shown that one of the components of the prosthesis was defective. Rather, it has been claimed that the alleged defectiveness of the hip prosthesis (as an end-product) was caused by friction between the head and cup. Accordingly, the conclusion arrived at in *Aventis/O'Byrne* would be unworkable in practice and would lead to an undesirable result. The Court of Appeal therefore decided that because the case before it concerned an end-product consisting of several components (the hip prosthesis), each of which had been put into circulation by the same manufacturer but on different dates, and given that the alleged defectiveness was caused by the combination of two of those components (the head and cup), the expiry period of the end-product began when the last of those two components (the cup) was put into circulation (7 August 2004).

Following this reasoning, the Court of Appeal stated that it had achieved a balance between protecting the consumer, who has an interest in bringing the defect caused by a combination of components before a court of law, and the manufacturer, who has an interest in a clear end date of the expiry period (and of its liability).

The Court of Appeal therefore concluded that at the time the writ of summons was issued (19 May 2014), the expiry period of the hip prosthesis had not yet expired.

## Comment

It is questionable whether the decision that the hospital/surgeon does not qualify as the manufacturer of the hip prosthesis would be upheld on appeal in cassation. The only substantiation given by the Court of Appeal on this point was its reference to the ECJ's ruling in *Centre hospitalier/Dutreux*.

In that case, the product (a defective mattress) was already an end-product when it was delivered to the hospital. However, in the case before the Court of Appeal, the end-product hip prosthesis) had been formed when the hospital/surgeon combined the four separate components.

5 European Court of Justice 2 December 2009, C-358/08, ECLI:EU:C:2009:744 (Aventis/O'Byrne).

Additionally, it seems arbitrary to decide that the expiry period for the end-product began when the last component of the two components causing the alleged defectiveness (the cup and stem) was put into circulation (the cup). It appears that this decision was inspired by the Court of Appeal's apparent desire to achieve a claimant-friendly result.

Contrary to what the Court of Appeal stated, this outcome is not in the interest of legal certainty (a clear end-date for the expiry period) for the manufacturer. In some cases, it could, in fact, lead to expiry periods much longer than the 10 years stipulated in the PLD (and the DCC).

By way of example, say one of the components of the hip prosthesis was replaced several years later by a new component (which has been put into circulation at a much later date than the other components). That new component, together with one of the other, much older, not-replaced components, then causes the alleged defectiveness. Following the Court of Appeal's judgment, this would mean that the expiry period for the other components was prolonged by years – as opposed to days or months like in the current case. Perhaps it is for this reason that the Court of Appeal specifically stated that its decision achieved a balance between the interests of the consumer and the manufacturer in this case.

The manufacturer has three months from the date of this judgment to lodge an appeal with the Supreme Court of the Netherlands.

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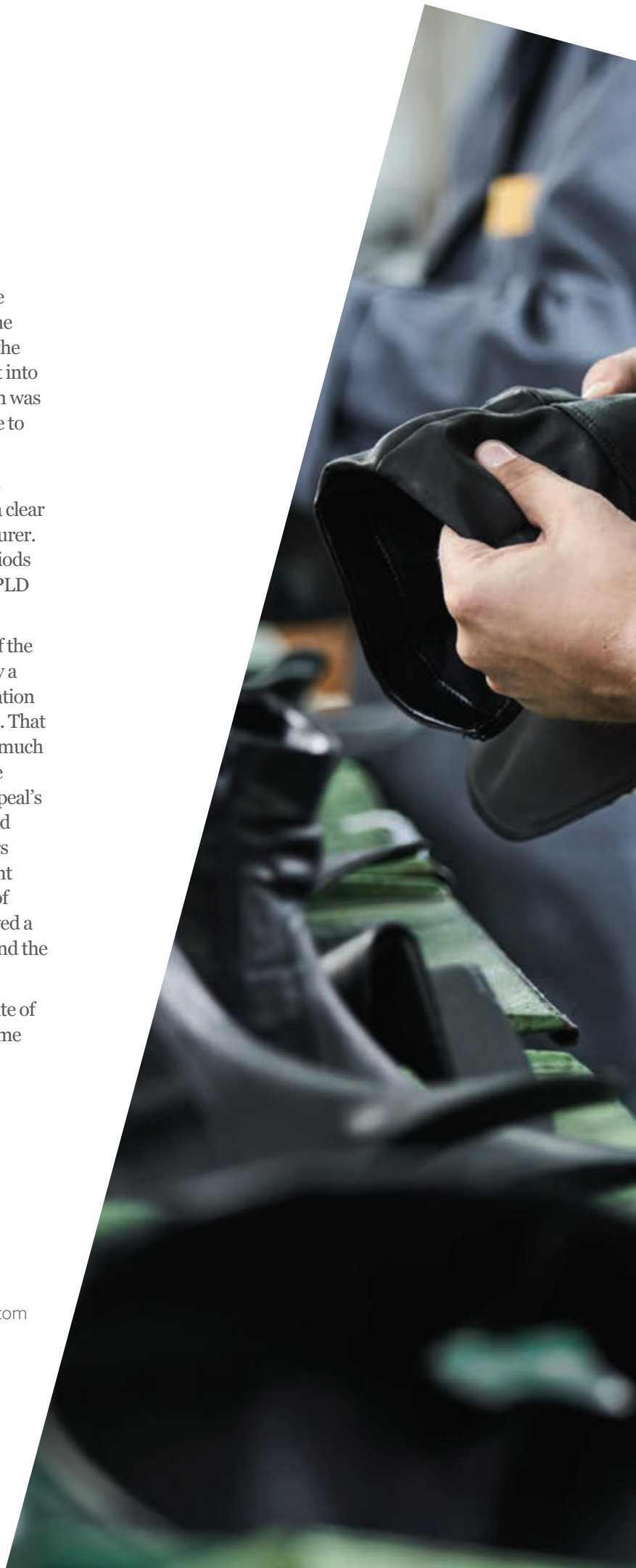

Europe *Poland*

# Sugar and alcohol: new taxes coming soon

## Introduction

The Polish parliament recently adopted a bill "amending certain acts in connection with the promotion of pro-health consumer choices" (the "Bill"). The Bill, which enters into force on 1 July 2020, imposes additional charges on alcohol sold in packaging smaller than 300 ml and soft drinks containing sugar.

The government's aim is to counter obesity and alcohol addictions. Under the Bill, almost all of the sums raised will be redistributed to the National Health Fund and municipalities to fund education, prevention, psychiatric care and addiction treatments.

Although it's commonly referred to as a "sugar tax", the Bill imposes charges through an administrative fee. It will apply to the distribution of:

- alcoholic beverages – an additional fee for **wholesale permit** and;
- sweetened beverages – a fee for **introduction into the national market**.

*Charge amounts*

<table>
<tr><th colspan="2">Alcoholic beverages</th><th colspan="3">Sweetened beverages</th></tr>
<tr><td rowspan="3">PLN 25</td><td rowspan="3">for every litre of 100% pure alcohol sold in packaging with volumes of up to 300 ml</td><td rowspan="3">Fixed fee</td><td>PLN 0.5</td><td>for every litre of beverage with added sugar or sweeteners within the meaning of Regulation (EC) no 1333/2008 of the European Parliament and of the Council</td></tr>
<tr><td>PLN 0.5</td><td>for every litre of beverage with the addition of an active substance (caffeine or taurine)</td></tr>
<tr><td>Variable fee</td><td>PLN 0.5</td><td>for every gram of sugar above 5g/100ml per litre of beverage</td></tr>
</table>

Fees will be charged at the moment of sale to retail outlets.

*Exemptions*

The following beverages are exempt from the new charges:

- medical devices;
- dietary supplements;
- foods for special medical purposes, infant formulae and follow-on formulae within the meaning of Regulation (EC) no 609/2013 of the European Parliament and of the Council;
- excise goods and;
- beverages whose primary ingredient is milk (or related products).

Additionally, beverages that contain at least 20% of fruit, vegetable or fruit-vegetable juice, as well as carbohydrate-electrolyte solutions within the meaning of Regulation (EC) No 432/2012, will be **exempted from the fixed fee**.

## Comment

The Polish government based its proposal on similar taxes and charges that have already been introduced in other countries. The Bill was submitted to Parliament in February 2020 and will enter into force on 1 July 2020. Preparation time is therefore extremely limited and companies should take immediate steps to adjust their pricing policies.

Initially, this new legislation was also supposed to cover dietary supplements (and their advertising). However, the government eventually decided to exclude them from the Bill's scope. According to the Vice Minister for Health, these issues will be covered by a separate, larger amendment of laws concerning dietary supplements. As no draft bill has been published at this point, its details remain unknown. We will monitor government progress and inform on any new developments.

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Europe *UK*

# Multi-addressee communications: when are they privileged?

## Introduction

In *The Civil Aviation Authority v Jet2.Com Ltd*[1] the English Court of Appeal considered two important questions on legal advice privilege

1. Is it necessary for a communication to have the dominant purpose of seeking or receiving legal advice in order for it to attract legal advice privilege?
2. What is the proper approach for determining the privileged status of emails between multiple parties where one of the senders or recipients is a lawyer?

## Background

Jet2.Com Ltd ("Jet2") is a UK budget airline that had refused to participate in an alternative dispute resolution (ADR) scheme for consumer complaints promoted by the UK aviation industry regulator, the Civil Aviation Authority (the "CAA"). Having issued a press release criticising Jet2 for its refusal to participate in the scheme, the CAA subsequently provided its correspondence with Jet2 to the Daily Mail newspaper. This resulted in negative publicity for Jet2.

Jet2 issued a judicial review claim, arguing that the CAA's decisions to issue the press release and publish its correspondence were unlawful. As part of the claim, Jet2 applied for disclosure of all drafts of a letter the CAA had sent Jet2 on 1 February 2018 in response to Jet2's complaints about the CAA's press release (the "CAA Letter"), as well as all records of any discussions of those drafts.

The CAA argued that the drafts of the CAA Letter and the records of discussions of the drafts, which included internal CAA emails sent to both lawyer and non-lawyer CAA personnel, were subject to legal advice privilege. This is a category of legal professional privilege that protects from disclosure confidential communications between a client and a lawyer (including in-house lawyers) for the purpose of giving or receiving legal advice, whether or not litigation is ongoing or contemplated.[2]

## First instance decision

At first instance, the judge concluded that the documents sought by Jet2 should be disclosed. The judge held that where a draft of the CAA Letter was sent in one email to both in-house lawyers and other non-lawyer CAA personnel, insofar as it was sent to a non-lawyer for their commercial views, neither the email nor the non-lawyer's response was protected by legal advice privilege. That would apply even if the email was privileged insofar as it was sent to the in-house lawyer. This was because the dominant purpose of the email, as addressed to the non-lawyer, was not the giving or receiving of legal advice.

The exception to this was if the content of the email, or the non-lawyer's response, disclosed or was likely to disclose the nature and content of legal advice. If so, the email/response would be privileged.

The CAA appealed against the order for disclosure.

## Court of Appeal decision

It was uncontroversial that the "dominant purpose" test applied to litigation privilege, so that only communications generated for the dominant purpose of litigation were covered. However, it was unclear whether the test applied to legal advice privilege, which is restricted to communications between lawyer and client for the purpose of giving or obtaining legal advice. Indeed, in a recent case preceding *CAA v Jet2*, the Court of Appeal had concluded that the dominant purpose test did not apply to legal advice privilege (although these comments were *obiter*).[3]

1 [2020] EWCA Civ 35 (28 January 2020)

2 Litigation privilege, the other main category of legal professional privilege, covers confidential communications between a client and a lawyer, or between either of them and a third party, where the communication was made for the dominant purpose of existing or contemplated litigation.

3 Director of the Serious Fraud Office v Eurasian Natural Resources Corporation Limited [2018] EWCA Civ 2006

In this latest case, however, the Court of Appeal (the "Court") ruled that the dominant purpose test did apply to legal advice privilege, on the grounds that

- the preponderance of authorities supported the inclusion of a "dominant purpose" criterion for legal advice privilege;
- though they have different characteristics, litigation privilege and legal advice privilege are limbs of the same privilege and there was no compelling reason for differentiating between them in this context and;
- the common law in other jurisdictions, such as Australia, Singapore and Hong Kong, had incorporated a dominant purpose test for legal advice privilege as well as litigation privilege;[4] this suggested that such a test could work in practice and that it was a legal area where there could be advantage in the common law adopting similar principles.

The Court also assessed the privileged status of emails that had been sent to multiple recipients, including in-house lawyers and non-lawyers,[5] and set out the following principles regarding the proper approach for considering such communications

- the purpose of the communication needs to be identified. If the **dominant** purpose is to obtain the commercial views of non-lawyer recipients, the communication will not be privileged, **even if** a secondary purpose is to obtain legal advice from the lawyer recipients;
- the response from the lawyer, if it contains legal advice, is almost certainly privileged, even if it is copied to more than one recipient;
- an email sent to multiple recipients should be considered as separate communications between the sender and each recipient. Where there is a multi-addressee email seeking both legal advice and non-legal (eg commercial) input, the communications to and from the lawyer will be privileged. The communications to and from non-lawyers will not be privileged, unless the dominant purpose of a specific email to/from non-lawyers is to instruct the lawyer;
- where there is a realistic possibility that a communication may disclose legal advice, that communication will be privileged in any event.

Accordingly, the Court found the relevant documents were not privileged. It upheld the judge's order for disclosure.

It also criticised the *Three Rivers (No 5)*[6] principle. This holds that legal advice privilege does not apply to all communications between a company's lawyers and its employees for the purpose of giving or obtaining legal advice, but only to communications with employees specifically tasked to seek and receive legal advice.

The Court considered that the decision was out of step with the approach adopted in other common law jurisdictions and had undesirable effects. It disadvantaged large corporations seeking legal advice (compared to smaller entities), for example. This was because in larger organisations the information on which legal advice was required was likely to be in the hands of employees who had not been tasked to seek and receive legal advice.

Even so, in this case the Court considered that it was bound by *Three Rivers (No 5)*.

4 The Court of Appeal cited Esso Australia Resources Limited v Commissioner of Taxation [1999] HCA 67 (Australia), Skandinaviska Enskilda Banken AB v Asia Pacific Breweries [2007] 2 SLR 367 (Singapore) and Citic Pacific Limited v Secretary of Justice [2016] 1 HKC 157 (Hong Kong).

5 The first instance judge had found as a matter of fact that the in-house lawyers in question had been acting qua lawyers, not as executives being consulted about largely commercial issues. If the in-house lawyers had in substance been acting as executives giving commercial advice, legal advice privilege would not apply to their communications.

6 Three Rivers District Council v Bank of England (No 5) [2003] QB 1556

## Comment

The chief takeaway of this case is summarised in Hickinbottom LJ's statement:

> "[Legal advice privilege] is a privilege, and those who wish to take advantage of it should be expected to take proper care."

The Court's decision is a salutary reminder that simply copying a lawyer on correspondence or having a lawyer take meeting minutes will not in itself render the correspondence or meeting minutes privileged from disclosure.

It must be proved that the dominant purpose of the correspondence or meeting was to give or obtain legal advice. Companies should review the guidance they give employees on email communications and how to deal with multi-addressee emails, to ensure the risk of losing privilege in privileged documents is managed appropriately.

The case also confirms that, for all its difficulties, Three Rivers (No 5) remains good law. If the principle restricting legal advice privilege only to communications with employees tasked with seeking and receiving legal advice is to be overturned, it will need to be done by the Supreme Court or Parliament.

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# Consumer smart-device security: moving towards increased regulation

## Introduction

Following the conclusion of a public consultation process in 2019, the Department for Digital, Culture, Media & Sport ("DCMS") announced in early February 2020 that the UK government intends to draw up legislation aimed at ensuring that all consumer smart devices sold in the UK adhere to rigorous security requirements for the Internet of Things (IoT).

Conscious of the increasing number of consumer internet connected devices available on the UK market, the government has made it clear that it plans to take action to protect consumers from cyber- attacks and security breaches. In doing so, they've considered whether it's necessary to develop a robust regulatory framework governing the cybersecurity of consumer IoT devices.

## A brief history

In March 2018, the DCMS published its "Secure by Design" report. This advocated the need for clear security guidelines and measures to be introduced to protect consumers, and for strong security features to be built into smart products at the product design stage. In particular, the report recommended a "fundamental shift in approach" by moving the burden away from consumers having to secure their IoT devices and placing it more squarely with manufacturers and others.

Following the report the DCMS published a voluntary "Code of Practice for Consumer IoT Security" in October 2018. This set out 13 outcome-focused "good practice" (but ultimately non-binding) guidelines for implementation by parties involved in the development and manufacture of consumer IoT to improve the cybersecurity of their devices.

In May 2019, the DCMS launched a public consultation advocating regulatory proposals for consumer IoT security. Stakeholders were invited to share their views on potential new mandatory industry requirements including a mandatory new labelling scheme for smart devices.

The result is the announcement of new legislation aimed at securing IoT devices from cyber-attacks, with manufacturers in particular required to apply various security controls to their devices.

The objectives of this legislation are to restore transparency within the UK market, ensure that manufacturers clearly communicate the security features of a device to consumers, and allow consumers to make more informed purchasing decisions. However a mandatory labelling scheme is not part of the current legislative proposals.

## What will the new legislation look like?

The government has indicated that the new legislation will focus on three key security requirements for the manufacture and sale of IoT devices.

1. An end to default passwords: All consumer IoT device **passwords must be unique** and not resettable to any universal factory setting. Many IoT devices are sold by manufacturers with default usernames and passwords (for example, the username might be "admin" and the password "123456 ") with the expectation that consumers will change these prior to use. In practice, this often doesn't happen and the government's concern is that this leaves devices vulnerable to cyber-threats.
2. Nominating a point of contact for consumers: Manufacturers of consumer IoT devices must provide a **public point of contact** so that anyone can report a flaw or vulnerability, and these reports must be acted on in a timely manner.
3. Length of time of software support: Manufacturers of consumer IoT devices must **explicitly state** at the point of sale the minimum length of time for which devices will receive security updates (both online and in stores). The need for updates must be made clear to consumers and the updates should be easy to implement.

These three measures, aim to set a new standard for best-practice requirements for companies that manufacture and sell consumer smart devices.

Matt Warman, Digital and Broadband Minister at the DCMS, has said that the new legislation will "hold firms manufacturing and selling internet-connected devices to account and stop hackers threatening people's privacy and safety". He has also said that "it will mean robust security standards are built in from the design stage and not bolted on as an afterthought".

## What does this mean for businesses?

It is currently expected that these requirements will apply to a wide range of consumer IoT devices, including:

- digital health products, smart watches and wearable health trackers;
- smart home assistants;
- connected home automation and safety products (eg smoke detectors, alarm systems and door locks);
- connected appliances (eg washing machines and fridges);
- connected children's toys and baby monitors and;
- smart cameras, TVs and speakers.

It's currently unclear how the three mandatory requirements are likely to be reflected in legislation, and when exactly the legislation will come into effect, but the UK government says it aims to deliver the legislation as soon as possible.

What is clear though is that, while the overarching aim of any new legislation will be to effectively protect consumers from the risks posed by cyber-threats, at the same time, this legislation will need to achieve a delicate balance between facilitating ease of implementation by businesses and supporting the long-term growth of IoT.

## What about new labelling scheme?

Given the mixed responses and concerns raised during the consultation, it's likely to come as a relief to a number of businesses that the government has decided against moving ahead with its proposed mandatory security labelling scheme at this time. The objective of such a scheme would have been to communicate important security information to consumers and help consumers make more informed decisions when purchasing connected devices.

The government has deferred this plan for now, recognising the complexity of supply chain management and potential disruption to businesses as a result of affixing a label to physical products. Instead, it plans to obtain more stakeholder feedback and carry out further policy development in order to refine the proposals and determine the most appropriate way to communicate important security information and regulatory compliance to consumers.

Notably, it intends to examine an alternative option to the labelling scheme through which retailers would be responsible for providing information to the consumer at the point of sale (both online and in stores).

## Comment

To ensure that it delivers a consistent, global approach to IoT security, the government has stated that it will:

- work with international partners and standards bodies, including the European Telecommunications Standards Institute (ETSI), in developing this legislation;
- encourage the adoption of the ETSI TS 103 645 standard, the first globally applicable industry standard on consumer IoT security, which establishes a security baseline for consumer smart devices and provides a basis for future IoT certification schemes;
- pursue a "staged approach" to regulation and, taking on board the responses received during the consultation, invite further stakeholder feedback to develop the regulatory proposals; it is hoped that this will provide businesses with reassurance and sufficient time to implement the proposals effectively and sustainably, and will enable regulation to keep pace with technological change and the cyber-threat landscape (importantly, this "staged approach" to regulation may involve the government mandating further security requirements for consumer IoT in the future, as and when appropriate) and;
- publish a final-stage regulatory impact assessment later in 2020, which we expect will shed further light on the government's regulatory proposals.

We are monitoring relevant developments in this area and encouraging manufacturers to keep an eye on further invitations from the government for stakeholder engagement, as their proposals take shape.

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Asia Pacific – *Japan*

# Small claims procedure: a user-friendly route to damages

## Introduction

Under EU product liability law, a manufacturer is only liable where its defective product caused 'harm' to the consumer. Harm in this context includes material damage (exceeding €500) to the consumer's personal property (other than the defective product itself).[1] By contrast, Japanese product liability legislation does not impose any such monetary threshold with monetary damages of ¥1 to ¥600,000 (approximately €4,900) being able to be claimed for using the small claims procedure.[2]

Similar to its European counterpart, the small claims procedure in Japan provides for the simple, speedy and affordable adjudication of low-value consumer and commercial claims. The procedure can therefore be used by consumers to bring small claims relating to product liability and it is important that manufacturers placing products on the Japanese market are aware of it.

## Background

The small claims procedure was introduced in 1998 as part of the reforms to the Japanese Code of Civil Procedure. The objective of the reforms was to introduce a more user-friendly civil procedure process which enabled easier access to the courts.[3] Initially, the maximum amount able to be claimed under the small claims procedure was ¥300,000 (approximately €2,400). The limit has since been increased (in 2004) to ¥600,000.

## How does it work?

Under the small claims procedure, a claimant is able to file a claim in the summary courts. The summary courts are the courts that generally handle less complex civil cases (normal or small claims) not exceeding ¥1.4 million. The summary courts appointed judges can be qualified jurists as well as people qualified by their experience in judicial practice or academia. Laypersons designated by the courts may attend the trial and render an opinion on the case. These so-called "judicial commissioners" often assist in small claims proceedings.[4]

Legal representation is not precluded, but the small claims procedure has been specifically designed to be used by parties who have not appointed attorneys. To facilitate filings, service counters at the summary courts provide forms for the most common types of claims.[5] Actions can also be filed orally.[6] In small claims proceedings, legal service is provided by the court clerks, who provide neutral advice and instruct consumers on how to complete the relevant forms for filing.[7]

Fees generally range between 1% and 2% of the claimed amount, making small claims proceedings much more affordable than ordinary civil proceedings.[8] However, only monetary claims can be litigated using the small claims procedure.[9] This excludes, for example, claims for redelivery of goods or transfer of title in cases involving a breach of contract.

1 Article 9 (b) Directive 85/374/EEC.

2 Articles 368 ff. Japanese Code of Civil Procedure. See for an overview Masayuki Yoshida, Japanese Small Claims Procedure: How Does It Work?, [2004] MurUEJL 15.

3 Kakiuchi, "Access to justice in Japan", JPLRes 1 (1 January 2007), 0.3.1.

4 See Court System of Japan, pp. 8 ff., available at http://www.courts.go.jp/english/vcms_lf/2018_Court_System_of_Japan.pdf.

5 Masayuki Yoshida, Japanese Small Claims Procedure: How Does It Work?, [2004] MurUEJL 15, para. 15.

6 Article 271 Japanese Code of Civil Procedure.

7 See Masayuki Yoshida, Japanese Small Claims Procedure: How Does It Work?, [2004] MurUEJL 15, para. 17.

8 Masayuki Yoshida, Japanese Small Claims Procedure: How Does It Work?, [2004] MurUEJL 15, para. 18.

9 Article 368 Japanese Code of Civil Procedure.

Small claims must not be lodged by the same claimant with the same summary court more than 10 times a year.[10] The claimant has to report the number of previously filed actions in the relevant year when lodging the claim.[11] If the number is reported is incorrect, a fine up to ¥100,000 may be imposed.[12] Such penalties illustrate the purpose behind the procedure; to be used as an easy do-it-yourself litigation tool designed for laypersons and – in a similar vein to the EU threshold of €500 (discussed above) – intended to avoid excessive litigation.[13]

Generally, the procedure requires that the trial should be concluded on the first day set for the oral hearing.[14] The parties are asked by the court to submit all evidence beforehand.[15] Such evidence may be limited to evidence that can be examined immediately, which makes obtaining expert opinions or requesting examinations out of court almost impossible.[16] For the oral hearing, the parties generally sit down at a round table where the dispute is settled on the spot.[17]

Small claims judgments cannot be appealed.[18] However, parties have two weeks following the hearing to lodge objections with the summary court who heard the claim.[19] Importantly, counter-claims are not permitted in small claims actions.[20]

10 Art. 368 (1) Japanese Code of Civil Procedure; Art. 223 Japanese Court Rules of Civil Procedure; Masayuki Yoshida, Japanese Small Claims Procedure: How Does It Work?, [2004] MurUEJL 15, para. 8.

11 Article 368 (3) Japanese Code of Civil Procedure.

12 Article 381 Japanese Code of Civil Procedure.

13 Masayuki Yoshida, Japanese Small Claims Procedure: How Does It Work?, [2004] MurUEJL 15, para. 8.

14 Article 370 (1) Japanese Code of Civil Procedure.

15 Article 370 (2) Japanese Code of Civil Procedure.

16 Article 371 Japanese Code of Civil Procedure.

17 See the photo above.

18 Article 377 Japanese Code of Civil Procedure.

19 Article 378 Japanese Code of Civil Procedure.

20 Article 369 Japanese Code of Civil Procedure.

## Comment

Following the introduction of the small claims procedure in 1998, the number of small claims filed more than doubled. In 2005 for example, 23,584 claims were lodged. However, since then, numbers have decreased with just 7,070 claims being brought in 2018.[21]

A reason for this may be that small claims have instead been diverted towards using alternative dispute resolution (ADR) or settled via one-to-one negotiations between consumers and company representations. ADR and consulting desks are provided by public organisations, such as the National Consumer Affairs Center of Japan (NCAC), the Association for Electric Home Appliances, and the Consumer Product Safety Association, which has established the Consumer Product PL Center.

Complex product liability litigation may not be handled in small claims proceedings due to the legal and technical issues that are likely to be involved. However, small warranty claims or claims for breach of contract relating to defective products tend to lend themselves as a suitable subject matter for the small claims process.

As just one example, the Yokosuka Summary Court recently ordered the seller of a collector's movie pamphlet to return an amount of ¥16,000 (approximately €130) to the consumer because it differed from the product description on the seller's website.[22]

As such, despite the drop in proceedings since 2005, there is still every indication that the small claims procedure remains an attractive tool for the speedy settlement of straightforward cases. More importantly, consumers in Japan are well aware of its availability. It is therefore important manufacturers placing products on the Japanese market are aware of it too.

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21 See report of the Case Law Committee of National Consumer Affairs Center of Japan at http://www.kokusen.go.jp/wko/pdf/wko-201912_16.pdf.

22 Yokosuka Summary Court, Judgment of July 18th, 2018, not listed, see report at http://www.kokusen.go.jp/wko/pdf/wko-201912_16.pdf.

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