Product & Operational Risk PG: 2014 Annual Review

BAKER & MCKENZIE

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In this Issue

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EU Product safety legislation overhaul

2014 has seen a raft of changes to EU product safety legislation and more are on the horizon. In this article we provide an update on the following:

- In March 2014 the European Commission (the "Commission") published 9 new Directives relating to the safety of products across a variety of industry sectors continuing the process of aligning pre-existing legislation to the new framework on sectoral product harmonisation in order to ensure greater consistency of the rules across Europe.

- Less progress was made on the proposals to revise the scope of the general product safety and market surveillance rules, but it is hoped that the presentation of new evidence on the controversial country of origin requirement in early 2015 will encourage the Commission and the European Parliament ("EP") to reach a compromise. That aside, the proposals maintain most of the existing product safety requirements, but also impose stricter documentation and notification obligations.

Proposal for a Consumer Product Safety Regulation ("CPSR")

The key points of the CPSR, as currently drafted, are as follows:

- The proposed CPSR would replace the General Product Safety Directive (2001/95/EC) ("**GPSD**").

- Like the GPSD, the CPSR would cover all non-food manufactured consumer products with the exception of a specific list of excluded products, such as medicines and antiques. The range of products covered by the proposal is extended beyond the scope of the GPSD to include products which consumers are exposed to in the course of services provided to them, but which consumers do not actually use themselves, e.g. teeth whitening products and sun beds as used by service providers on consumers.

- The CPSR aims to improve product traceability and associated documentation by requiring all products covered by it to be marked with a batch and lot number, the identity of the manufacturer and importer and, for the first time, the product's place of origin.

- The proposal involves using the non-preferential origin provisions in the EU Customs Code to determine the country of origin, the complexity of which will undoubtedly add to the

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burden on manufacturers should this provision survive the legislative process.

- Other obligations imposed on economic operators by the CPSR include a requirement for manufacturers to draw up technical documentation for their products, which includes undertaking risk analysis and risk management by showing what standards have been applied, what testing methods have been used and what the results were.

- Economic operators are obliged to take corrective measures if they have reason to believe that the product they have made available is not safe or not in conformity with the legislation. Corrective measures include withdrawing a product from the supply chain or recalling it from end users, even for formal non-conformities, such as having no signature on the CE form.

Proposal for a Market Surveillance of Products Regulation ("MSR")

A new MSR is planned to bring together the market surveillance rules currently found in Regulation 765/2008, the GPSD, and sector-specific pieces of EU legislation.

The aim of the MSR is to simplify the current regime and improve cross-border cooperation between Member States by codifying the powers of the market surveillance authorities into one regulation. It will increase the obligations on the authorities by setting out what checks should be made on products and the procedure they should follow in order to ensure surveillance is effective. For example, authorities will be able to act by blocking imports or ordering sales to be stopped, even where a product does not present a health and safety risk. Even formal non-conformities such as a failure to state the country of origin will require rectification, and if rectification is not possible, withdrawal from distribution channels may be necessary.

A new overarching guiding body of Member States' market surveillance authorities (the European Market Surveillance Forum) is proposed to coordinate information exchange, organise joint market surveillance and joint testing, and to establish best practice. The Information and Communication System for Market Surveillance will also be extended to all Member States. Finally, the RAPEX system will be moved from the GPSD to the MSR, and it is thought that the website may be used to report all risk types and levels rather than just significant risks to health and safety.

The result of these changes is that economic operators will likely notice an increase in market surveillance activities, including spot checks of products on shelves and at external borders.

Next Steps

The EP and the Commission have so far failed to reach common ground during their negotiations of the proposals, with the new country of origin requirement proving to be the main sticking point.

The disagreement reportedly stems from the fact that northern Member States (including the UK and Germany) consider the requirement to be overly burdensome for economic operators and disadvantageous to imported products which, as a result of global supply chains, are often

made in non-European jurisdictions. Other Member States argue that mandatory marking of origin will have a positive effect on consumer protection.

With the aim of progressing negotiations, the EP has invited the Commission to present further information and evidence on the benefits of the proposed mandatory marking of origin. The Commission is gathering evidence to present a technical study at the beginning of 2015. The current drafts of the CPSR and the MSR can be found here and here respectively.

The "Alignment Package" to the "New Legislative Framework" ("NFL")

The package of measures known as the NFL was adopted by Council Regulation 765/2008 in July 2008. This was complemented by Council Decision 768/2008/EC (on a common framework for the marketing of products) which sets out reference provisions and general principles to be incorporated into future product harmonisation legislation. Together, the statutory instruments form a consistent legal framework for the marketing of products.

With a view to bringing product harmonisation legislation into line with the NFL, the Commission adopted a package of proposals to accelerate the alignment of nine Directives, which would not have been revised in the near future, to Decision 768/2008 (the "**Alignment Package**"). The objective of the Alignment Package is to ensure better product safety by clarifying definitions, obligations of economic operators, traceability requirements, conformity assessment bodies and procedures, and CE marking.

Whilst the Pyrotechnic Articles Directive was aligned in 2013, on 29 March 2014 the following eight Directives were published in the Official Journal:

- Directive 2014/35/EU on the marketing of electrical equipment designed for use within certain voltage limits (known at the Low Voltage Directive);
- Directive 2014/30/EU on the harmonisation of the laws of Member States relating to electromagnetic compatibility (recast);
- Directive 2014/34/EU on the harmonisation of the laws of Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (known as the WMC Directive);
- Directive 2014/33/EU on the harmonisation of the laws of Member States relating to lifts and safety components for lifts;
- Directive 2014/29/EU on the harmonisation of the laws of Member States relating to the making available of simple pressure vessels
- Directive 2014/32/EU on the harmonisation of the laws of Member States relating to the making available on the market of measuring instruments (recast);
- Directive 2014/31/EU on the harmonisation of the laws of

Member States relating to the making available on the market of non-automatic weighing instruments; and

- Directive 2014/28/EU on the harmonisation of the laws of Member States relating to the making available on the market and supervision of explosives for civil uses (recast).

Comment

Whilst there is still disagreement over the country of origin requirement, the legislative timetable for when the CPSR and MSR will come into force remains unconfirmed. What is clear is that changes to the product safety rules remain a priority for the Commission. Manufacturers should be mindful that when a resolution is reached many of them will have to implement new technical information gathering and traceability requirements, which will require serious consideration.

For more details please contact Kate Corby or Amy Wong

Legislative Update - Product Regulation

In this article we report on key product-related EU legislation in the news in 2014, specifically: (1) the extended reach of the recast WEEE Directive; (2) increasing regulation of ecodesign and energy labelling; (3) new guidance on the batteries regime; (4) the EU's watered down conflict minerals proposal; and (5) a proposal to add four new substances to the RoHS Directive.

1. The recast Directive on waste electrical and electronic equipment (the "recast WEEE Directive")

EU Member States were supposed to transpose the recast WEEE Directive into their national laws by 14 February 2014. All but a small minority of Member States missed this deadline, with a number of Member States (including Germany and Spain) still not having adopted final legislation at the time of writing.

Like the original regime, the recast WEEE Directive aims to prevent the generation of waste electrical and electronic equipment ("**WEEE**") while also encouraging re-use, recycling and other forms of recovery to minimise amounts of WEEE disposal. Key changes include:

- expanding the scope of the WEEE regime from the current ten categories of EEE to cover all EEE, subject to certain exclusions (see further below);
- clarifying the definition of "producer" and the role of distance sellers supplying products to end-users from a third country;
- creating a new role for "authorised representatives" to discharge producer obligations;
- extending take-back requirements for very small EEE where distributors supply EEE from retail units with a sale area relating to EEE of at least 400m^2;
- setting higher, but more flexible, Member State targets on collection and recycling; and

- introducing shipping requirements for "used EEE" (see further comments below on "Shipments of 'used EEE'").

The EU Commission published guidance on the new law in the form of "Frequently Asked Questions on the recast WEEE Directive" ("**FAQ Guidance**") in April 2014 following the original publication of an earlier draft version of the guidance in 2013.

Set out below is an overview of some of the issues that have arisen under the recast WEEE Directive during the course of 2014.

Expanded scope and printer cartridges

From 15 August 2018, the scope of the WEEE regime widens from the current ten categories of electrical and electronic equipment ("**EEE**") to cover all EEE (subject to specific exclusions). One product type causing considerable uncertainty is printer cartridges. While it is generally accepted that printer cartridges containing electrical parts should be considered to be "EEE" under the recast WEEE Directive, stakeholders have disagreed as to when this should happen: from 14 February 2014 or 15 August 2018. Whereas the July 2013 draft of the Commission's WEEE guidance suggested printer cartridges would be in scope of the recast WEEE Directive from 14 February 2014 the final guidance does not deal with this point, leaving it open for different approaches by different Member States. The UK Government has publicly stated that it is not intending to treat printer cartridges as being in scope until 15 August 2018, but that other Member States may not necessarily follow the same approach.

Shipments of "used EEE"

The recast WEEE Directive contains important provisions for businesses involved in repair and refurbishment activities who ship used EEE in, out and around the EU.

Annex IV of the recast WEEE Directive sets out minimum requirements for international non-waste shipments of used EEE similar to those contained in the Revised Correspondents' Guidelines No 1, albeit with small differences. These requirements have been put into law to give competent authorities powers to presume suspect shipments are waste shipments unless proved otherwise, thereby supposedly helping them to tackle the growing number of e-waste crimes.

One scenario where used EEE may be shipped as non-waste under the WEEE Directive is where it is being sent back to a producer (or third party acting on its behalf) as defective for repair under warranty with the intention of re-use. The equivalent scenario in the Revised Correspondents' Guidelines No 1, however, only specified that the used EEE had to be sent "e.g. under warranty". This has caused speculation about the circumstances in which a product will be considered as "under warranty". The FAQ Guidance suggests that this term should be construed broadly as covering a wide range of service, maintenance and repair agreements, but the outer limits of this broad interpretation remain untested.

Large scale fixed installations ("LSFIs") and large scale stationary industrial tools ("LSSITs")

As a result of the expansion of the WEEE regime to cover all EEE from

15 August 2018, various new exemptions to the scope are provided in the recast WEEE Directive, including exemptions for LSFIs and LSSITs. While the 2013 draft version of the FAQ Guidance attempted to clarify the meaning of "large-scale" and other aspects of the exemptions, the final FAQ Guidance is considerably briefer and largely just cross-refers to the Commission's RoHS 2 FAQ Guidance Document. This leaves a number of potential areas of uncertainty in connection with the exemptions:

- what requirements must parts meet to be considered "specifically designed" as part of an excluded LSFI or LSSIT?
- when will LSFIs and LSSITs be considered "permanently" installed or used and does this prevent movement from one site to another?
- what are the minimum requirements for a tool to be considered "large-scale"? The 2013 draft version of the FAQ Guidance had included a "rule of thumb" for determining if a tool was large enough to be a LSSIT but this did not make it into the final version. Further, the RoHS 2 FAQ only provides minimum requirements for LSFIs and states that specific guidance metrics should be developed for LSSITs.

UK approach to "dual use" EEE

The UK Department for Business, Innovation & Skills (**"BIS"**) has recently announced that it will change its approach to "dual use" EEE (i.e. EEE that potentially could be used by both household and non-household end-users) to bring it into line with the approach of the EU Commission as set out in the Commission's FAQ Guidance. Historically, the UK took the view that "dual use" products did not have to be counted as household EEE when used by a non-household end user. However, BIS' new approach means that "dual use" EEE should be classified as "household EEE" if the product could be used in both households and business premises even if, in fact, it is only used in business premises. For example, a laptop could only be treated as a non-household product if it could be demonstrated that it had a different specification to one that could be purchased by a consumer. This new approach means that producers in the UK will have to report and account for all dual use EEE as household EEE.

2. Updates on the Ecodesign and Energy Labelling Regimes

The Ecodesign Regime's expanding scope and the need for guidance

The coverage of the EU's ecodesign regime has expanded with new energy efficiency requirements for computers applying from 1 July 2014 (under Regulation (EU) No 617/2013) and for vacuum cleaners applying from 1 September 2014 (under Regulation (EU) No 666/2013); as well as new "networked standby" power consumption requirements for "networked equipment" applying from 1 January 2015 (under Regulation (EU) No 801/2013).

These new measures are already causing challenges for manufacturers. For some products, the requirements and procedures for energy efficiency testing lack clarity or detail, and the approach of market surveillance authorities to their own conformity tests remains unclear.

This includes whether and when products sold with accessories should be combined for energy consumption tests (the question being whether the accessory is such an integral part of the main product that it does not have a separate identity for ecodesign purposes). There has been little guidance from the Commission on these points and, with the increasing scope of the ecodesign regime, further guidance would be very timely.

Tailoring the Energy Labelling Regime to internet sales

The EU's energy labelling regime was amended in 2014 to better address the different methods of disseminating energy information to end-users in distance (i.e. internet) and in-store sales scenarios.

Regulation (EU) No 518/2014 amends ten product-specific energy labelling Regulations, including those for white goods, refrigerators, washing machines and televisions, to introduce new labelling and information requirements tailored to distance sales. The new provisions require that dealers are provided with electronic versions of a product's energy label and product fiche and prescribe the manner in which these must be displayed electronically. These new requirements apply in respect of in-scope energy-related products placed on the market from 1 January 2015.

3. Updates to the Batteries Regime

There has been much focus in 2014 on the requirement under the EU Batteries Directive 2006/66/EC, as amended, ("**Directive**") for batteries incorporated into electrical or electronic equipment ("**EEE**") to be capable of being "readily removed". The European Commission's revised guidance on the interpretation of the revised Directive, published in May 2014, makes it clear that batteries must be removable without delay or difficulty, and at a reasonable cost, by either an end user or a qualified independent professional.

In addition, the revised Directive requires EEE that incorporates batteries to be accompanied by instructions on how the batteries can be removed, again either by the end user or an independently qualified professional. During the preparation of the of the Commission's revised guidance, there was much discussion between industry and the Commission as to whether this requirement should be interpreted as meaning removal instructions must accompany the EEE in all cases, irrespective of whether the battery was designed to be end-user removable or not. Industry's concern here related to the safety of providing end-users with removal instructions for batteries that should only be handled by qualified professionals (e.g. because of risks arising from improper handling of soft cell Lithium-ion batteries).

The revised Commission guidance does not, however, indicate that it would be sufficient for batteries that are not end-user removable simply to state that the battery should only ever be removed by a qualified professional. Instead, the guidance states that removal instructions should accompany all EEE containing batteries. The former approach did seem to be endorsed by the UK Government's guidance on battery removability, which until December 2014 stated that "*an alternative to instructions on how to remove a battery is providing information on who, in the view of the manufacturer, is the best person to do it.*" However, this text has been removed from the UK Government's guidance (see: https://www.gov.uk/placing-batteries-on-the-uk-market-producer-responsibilities#removability-requirements) and the guidance aligned

with the Commission's guidance. Any entities that have previously relied on the pre-December 2014 UK guidance will need to ensure that all of their EEE which incorporates batteries is now accompanied by instructions on how the batteries can be removed.

The guidance does not therefore directly address the safety concerns of industry. An approach endorsed by the UK Government, however, may go some way to mitigate these concerns. The UK Government guidance states that it would seem reasonable, as an alternative to full instructions being provided with the product, for a product to be accompanied instead by "*Simpler instructions*" which are both "*suitable to meet the base requirement of the [UK Batteries] regulation*" and "*supported by more detailed information on a free access website*". Although this guidance is only reflective of the UK Government's interpretation of the requirement, we consider it to be a pragmatic approach for companies concerned about enclosing detailed removal instructions with products whose batteries should only be removed by a professional.

4. Update on EU Conflict Minerals Proposal for Voluntary Regulation

EU manufacturers and importers seem likely to avoid mandatory supply chain due diligence for conflict minerals, contrary to expectations that the EU would follow the US Dodd-Frank Act and impose compulsory requirements. On 5 March 2014, the European Commission published a legislative proposal for a voluntary self-certification scheme for importers of tin, tungsten, tantalum and gold (and their ores). This proposal is now being considered by the European Parliament and Council, both of which need to approve the proposal before it can enter into force.

Why have conflict minerals laws?

The rationale for conflict minerals laws, such as the one proposed, is to address the immense hardship and suffering caused when mining revenues are captured by armed gangs to fund violence and human rights abuses in conflict-affected areas, such as the Great Lakes Region of Africa. Tin, tungsten, tantalum and gold (and their ores) are generally targeted by such laws because they are often sourced from conflict-affected countries. These minerals play a vital role in many different applications, including in the automotive, electronics, jewellery, aerospace, packaging, construction, lighting and industrial machinery and tooling sectors.

The EU Proposal

The EU proposal comprises a package of measures on conflict materials, including a proposal for a new regulation on the responsible sourcing of minerals.

Significantly, the proposed regulation is far weaker than forecast by earlier commentary on the expected form of the measures. Firstly, the proposal would only establish a voluntary self-certification system. Secondly, that system would only apply to importers into the EU of the relevant materials themselves (and their ores). This means that manufacturers and importers placing finished products on the EU market that contain the relevant minerals are not within the remit of the scheme, contrary to the expectations of some commentators. This approach appears to reflect business concerns that a mandatory due diligence requirement with a broader reach would be too onerous and costly.

As with the US Dodd-Frank Act, the list of minerals is a closed one. However, unlike the US approach, which only applies to minerals sourced from the Democratic Republic of Congo the (**"DRC"**) and neighbouring countries, the EU proposal applies to minerals sourced from all "conflict-affected and high-risk areas", a determination that importers will have to make themselves. The Commission is reportedly working on guidelines to assist companies in making this determination.

In order to self-certify that their supply chains are "conflict-free", companies will have to follow the steps in the OECD due diligence conflict materials framework. Responsibility for checking whether or not self-certified importers are compliant will lie with Member States authorities.

The EU will then publish annually a global list of responsible smelters and refiners, drawn up in cooperation with the OECD. "Responsible smelters and refiners" will be those in the supply chain of certified "responsible importers". The aim of the list is to increase accountability and encourage responsible sourcing, particularly from conflict-affected areas, and to allow downstream purchasers to easily identify responsible smelters and refiners. By this list the Commission is clearly trying to avoid criticism levelled at the US Dodd-Frank regime that it has created a de-facto embargo of minerals sourced from the DRC and surrounding areas. This unintended consequence has arisen because companies appear to find it easier simply to ban minerals originating in the region from their supply chain, leading to a decline in legal mining, a sharp fall in mineral prices, and increased mineral smuggling.

Other Measures

In addition to the proposed regulation, the Commission has published a Communication setting out further measures for conflict minerals. These include introducing into the Commission's own public procurement contracts requirements that any products supplied to it are "conflict-free", and financial support for small and medium enterprises that participate in the voluntary certification scheme.

Current Status

The proposal is now under consideration by the European Parliament and Council. Discussions in meetings of the EU Parliament's Committee on International Trade (INTA) in November and December 2014 show that the Parliament has several issues with the scope of the current proposal. On the other hand, Council working party meetings have reportedly been less contentious.

The Commission's view is that by targeting what it considers to be the "weak spot" in mapping mineral supply chains (i.e. focussing only on importers) with a voluntary self-certification scheme, it will do enough to break the link between mineral extraction and the financing of armed conflict (one of the Commission's stated objectives for the proposal). The Commission has stated that it thinks this approach will support compliance with existing conflict minerals initiatives (e.g. the OECD Due Diligence Framework and the US Dodd-Frank regime).

However, the INTA meetings have revealed that some still think that imposing voluntary obligations on the 400-500 EU importers of minerals does not go far enough. Separately, some NGOs have called for the

scope of the proposal to be broadened, e.g. so as to become mandatory and capture entities placing products containing conflict minerals on the market.

A further area of contention within the Parliament relates to the closed list of minerals covered by the proposal. Suggestions were made in the INTA meetings that this list should be expanded to capture additional materials, including copper, jade and coal, as these are often also sourced from conflict-affected areas.

With so many aspects of the proposal still under discussion, the Commission considers it unlikely that adoption of the regulation will occur until the end of 2015 at the earliest. Nevertheless it seems clear that, notwithstanding specific areas of contention, in principle the European Parliament very much supports the introduction of conflict minerals legislation.

5. Proposal to add four new substances to the RoHS Directive

In December 2014 the European Commission notified the World Trade Organization of its proposal to add four new substances to Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (the "RoHS Directive").

The new substances

The new substances consist of four phthalates which are primarily used as plasticizers in plastics, particularly PVC plastic. The four phthalates are: Bis(2-ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP) and Diisobutyl phthalate (DIBP). These substances will be restricted at 0.1% concentration by weight per homogenous material, in line with the thresholds of most existing RoHS restrictions (the exception being cadmium, which is restricted at 0.01%).

The brominated flame retardant hexabromocyclododecadane (HBCDD) is not included in the proposal despite being one of the "priority" substances for consideration for inclusion in the RoHS Directive. This substance was, however, added to the Stockholm Convention on Persistent Organic Pollutants in May 2013 and so a complete phase-out of HBCDD in electronics, whether imported or produced in the EU, will occur within the next few years in any event.

DIBP was not one of the original "priority" substances named for inclusion in RoHS and, although not currently used in traditional EEE, has been included in the proposal because of concerns that it would otherwise become a substitute for DBP and thereby require restriction at a later date.

Overlap with existing phthalates restrictions

Notably, the new RoHS restrictions for DEHP, BBP and DBP will not apply to toys because the presence of these substances in toys is already subject to restriction under entry 51 of Annex XVII of the REACH Regulation (1907/2006/EC). Entry 51 restricts DEHP, BBP and DBP in the plasticised materials within toys in concentrations greater than 0.1% by weight of the plasticised material, calculated for the three phthalates cumulatively.

It is also worth noting that the four phthalates have already been

included in the REACH Regulation Annex XIV "Authorisation List", prohibiting their use in EU-based manufacturing operations from February 2015 unless authorised. Annex XIV does not, however, apply to imported products manufactured outside of the EU and so, without the new RoHS restriction, these products would not currently be caught.

Timeframe

The proposal is in the form of a delegated directive so will not need to be approved by the European Parliament or Council. The Commission is expected to adopt the proposal formally in the first part of 2015, with Member States subject to a transposition deadline of 31 December 2016. The restrictions will then apply from 22 July 2019 for all EEE except for medical devices and monitoring and control instruments, which will only be caught from 22 July 2021. On this basis, EEE manufacturers and the global supply chain will have at least four and a half years to prepare for the new restrictions.

For more details please contact Graham Stuart, Rachel Barlow or Aurella Smith-Anthony

Blue Guide 2014 - Guidance on "Placing on the Market" and other concepts

In April 2014, the European Commission published the Blue Guide on the Implementation of EU Product Rules (the "2014 Blue Guide").

The 2014 Blue Guide updates the "Guide to the Implementation of Directives based on the New Approach and the Global Approach", published by the Commission in 2000 (the "2000 Blue Guide"). Though much of the guidance and core concepts from the 2000 Blue Guide remain unchanged by the 2014 Blue Guide, it contains somewhat overdue updates to account for legal developments (such as modifications introduced by the Lisbon Treaty in December 2009) and to ensure a common understanding on the implementation of the "New Legislative Framework" for the marketing of products. It includes several new chapters, covering issues such as the obligations of economic operators and accreditation, as well as several revised chapters on, for example, standardisation and market surveillance. In this article we summarise the key changes

Key Objectives

The key objectives of the 2014 Blue Guide are to explain the different elements of the New Legislative Framework and to facilitate a better overall understanding of the system so that relevant product legislation is implemented properly and effectively across different sectors throughout the Single Market.

The New Legislative Framework comprises a set of measures that were adopted by the European Council and Parliament on 9 July 2008. The measures are designed to enhance the functioning of the internal market for goods, and to strengthen and modernise the conditions for placing a wide range of industrial products on the EU market. Their aim is to improve market surveillance rules; increase the quality of conformity assessment of products; clarify the meaning of CE marking; and establish a common legal framework for industrial products.

Scope

The 2014 Blue Guide covers non-food and non-agricultural products referred to as industrial products or products for use by consumers or professionals. These products are subject to EU harmonisation legislation. The 2014 Blue Guide includes an updated list of harmonisation legislation falling within its scope.

Placing on the Market & Other Key Changes

According to the 2014 Blue Guide, harmonisation legislation applies when a product is first "placed on the market" or first "made available" in the EU. The question of when this occurs lies at the heart of many EU product laws but is complicated by today's dispersed production and distribution systems. One key development under the 2014 Blue Guide is a change to the point in time at which an imported product is considered to be "placed on the market" or first "made available" in the EU. Under the 2000 Blue Guide this took place at the point of import into the EU. The 2014 Blue Guide, however, states that placing on the market occurs when the importer on-supplies a product to a distributor or end-user. This shifts the decisive point in time for the application of Union harmonised legislation to slightly later in the supply chain and has implications for importers with respect to, in particular, the risk of warehoused products not being considered placed on the market ahead of transitional deadlines for new product standards.

Other key changes and clarifications under the 2014 Blue Guide that manufacturers, importers and distributors will need to factor into their supply chain logistics and due diligence considerations include the extension of the "intended use" of a product to that which is reasonably foreseeable; a first attempt at tackling e-commerce and other distance selling arrangements; and extended guidance on traceability requirements.

For more details please contact **Graham Stuart**, **Rachel Barlow** or **Aurella Smith-Anthony**

Consumer Product Safety - Increased Cross-Border Information Sharing

The increasing global trend towards the sharing of consumer product information across borders and between market participants and regulators continued in 2014. Corporations involved in any stage of the consumer product supply chain should be aware of the consequences and risks, as well as the potential benefits of these developments. In this article, we provide an update on recent developments with some of the key regional information exchanges.

US/EU/China TrilatVeral Summit

The 2014 trilateral summit attended by representatives of the product safety authorities from the EU, China and the US was the latest in a series of biennial discussions between these authorities with the aim of developing a coordinated response to consumer product safety challenges.

The importance of information exchange has been a recurring theme in these discussions. In the authorities' joint press statement following the

2014 summit, they asserted the importance of international regulatory cooperation and noted that discussions had covered how to make practical use of the concept of “seamless surveillance”, i.e. cooperation between product safety authorities in countries of origin and in countries of destination.

A number of other priorities were also discussed, including:

- exchanging information regularly, and as early as possible, on major safety issues and on new and prospective developments in consumer product surveillance systems;
- sharing ideas regarding cooperation to implement the concept of seamless surveillance; and
- exploring the possible convergence of safety requirements for consumer products.

OAS Network

The Organisation of American States (**OAS**), which comprises 35 states in North and South America, also promotes information exchange across borders. The OAS's Consumer Safety and Health Network (**CSHN**) is a tool that allows both consumers and authorities within the region to exchange and disseminate information on product safety issues, for example acting as a warning system in respect of products deemed unsafe by overseas markets.

On 23 October 2014, the Permanent Council of the OAS adopted the Operational Rules of the Consumer Safety and Health Fund, which aims to contribute to the strengthening of the CSHN by financing activities with regard to institution building, exchange of experiences, and the design and implementation of the Inter-American Rapid Product Safety Warning System, through which American countries will be able to share alerts on product safety and join global initiatives on this issue.

OECD Portal

The Organisation for Economic Cooperation and Development (**OECD**)'s Working Party on Consumer Product Safety launched a Global Recalls portal in 2012 to provide easy access via a single website to information on products recalled from the market in Australia, Canada, Europe and the United States. This addresses the first of a ten-point action plan developed by the OECD in this area. The Working Party is also developing a platform to hold data on reported product related injuries.

Currently, regulators from the US, the EU, Australia and Canada upload information to the portal (although Canada did not list any recalls in 2014). Other regulators are expected to use the portal in the future, including regulators in Brazil and Mexico who are partners of the project. 747 recalls were listed on the portal in 2014, of which 210 were listed by Australia, 207 by the US and 330 by EU members.

Comment

The increase in cross-border information sharing of this nature presents potential benefits to participants in the product supply chain, including enhanced regulator guidance and opportunities to conduct international business within a more consistent regulatory framework. However, this

also presents certain challenges. In addition to losing some control over the management of an evolving product safety issue, participants must also be prepared to deal with the increasing speed with which product information can be disseminated and the consequent potential for increased reputational damage should a regulator, or indeed a consumer, decide to share negative information in respect of a product. Being aware of the various information sharing networks, reviewing the accuracy of information shared and proactively managing relationships with users will prove critical if a company finds itself the subject of negative reporting.

For more details please contact Matthew Foster or Amy Smith

Collective Action - Updates from the EU

As reported in last year's newsletter the European Commission published a Recommendation on 11 June 2013 acknowledging that, while many Member States had collective redress procedures or planned to introduce such mechanisms, the Commission encouraged all Member States to adopt some form of collective redress by no later than 11 June 2015. The Commission explained in MEMO/13/530 that such mechanisms improve access to justice for citizens and for companies, but recommended that Member States use procedural safeguards so as to minimise the risk of abuse or the rise of a US-style claims culture. The recommended safeguards include not permitting contingency fees, prohibiting recovery of punitive damages and using an opt in rather than opt out structure.

The response from Member States, as summarised below and in last year's article, has been varied but does indicate a willingness to expand collective action rights for consumers across the EU. The Commission has committed to reassess the position in 2017 and has stated that it is prepared to issue a Directive requiring Member States to act if it remains dissatisfied with the scope of recovery available. In this article we highlight developments from 2014.

Latest Responses from the Member States:

England and Wales

Plans were afoot to introduce an opt-out collective model for use in competition damage cases prior to the publication of the Recommendation. This model is contained in schedule 8 of the Consumer Rights Bill, which had its third reading in the House of Lords on 8 December 2014. Draft rules on collective proceedings and collective settlements were published by the Competition Appeal Tribunal in March 2014 and can be found here.

England and Wales also has existing rules that allow group litigation in other circumstances. There remain no proposals to widen or adapt these rules for rights of action that are not related to competition law damage.

The Netherlands:

A form of class action exists in the Netherlands. An association (*vereniging*) or foundation (*stichting*) may start a collective action provided that: (i) the action serves to represent the similar interests of others; and (ii) it represent those interests pursuant to its articles of association. Both requirements are easy to satisfy. A draft legislative

proposal was published in July 2014 with a view to introducing a more formal mechanism for collective proceedings but the timeframe for implementation is not yet clear.

There is also a statutory mechanism by which multiple damages claims can be settled collectively, so providing a process that circumvents a host of individual damages actions by securing settlement between the defendant and an association or foundation that represents the interests of each of the individual claimants. Group members may opt out of this process and are then free to start or continue an individual action.

Germany:

The Green Party initiated an inquiry in the German Parliament on 10 June 2014 in response to the Recommendation. This inquiry will evaluate whether changes to existing collective redress mechanisms (for example the Capital Investors' Model Proceeding Law) are necessary. The German Parliament has sought views from other EU member states, German associations and lobbyists' organisations including the German Federal Bar Association (Bundesrechtsanwaltskammer).

France:

The French Parliament adopted a new consumer law on 17 March 2014 that includes a new opt in collective action procedure. Collective actions can be brought by fifteen authorised national consumer associations under this law in respect of harm caused in connection with a sale of goods, a provision of services, or an infringement to competition law. Compensation for physical injuries is excluded. Consumers within the scope of any claim have two to six months to opt-in and claim any damages awarded by the French courts.

Other forms of collective redress are also available in France, including representative actions in the fields of consumer, finance and environmental law and under Article 421-1 of the French Consumer.

Comment

There are some continuing developments in this area and reassessment of existing procedures by some Member States. However, there is still no sign of a sea change or move towards US-style class actions in the EU. The Commission does not propose to review the matter until 2017 and so it remains to be seen whether any formal legislative step requiring the implementation of collective redress mechanisms might follow.

For more details please contact Francesca Richmond

Third Parties (Rights against Insurers) Act 2010: Commencement & Insurance Bill provisions

The Government's Insurance Bill (the "Bill"), which makes various amendments to the Third Parties (Rights Against Insurers) Act 2010 (the "2010 Act"), was introduced to Parliament in August 2014. It is hoped that the Bill will speed up the entry into force of the 2010 Act which has been subject to long delays. The aim of the 2010 Act is to bring about significant reform in the way that third parties might pursue direct claims against insurers instead of against an insured that is, or is likely to become, insolvent.

Proposed changes under the 2010 Act

At the moment, under the Third Parties (Rights against Insurers Act) 1930, third parties are entitled to claim directly against the insurers of an insured insolvent company. However, the procedure to do this is both complicated and expensive. The most significant changes under the 2010 Act are as follows:

- A third party will be able to proceed directly against an insurer, rather than first having to establish liability in proceedings against the insured. This change will enable the claimant to resolve issues of liability and insurance coverage in the same proceedings, making claims easier to pursue and reducing costs for the claimant.

- The list of insolvency events to which the 2010 Act relates is much wider than before and includes situations where a company has been subject to an administration order, has had a receiver or provisional liquidator appointed, or has entered into a voluntary arrangement.

- The 2010 Act provides for third parties to have easier access to information in respect of the insurance position of an insolvent company. The 2010 Act makes clear that a potential claimant may request such information from *any* person (not just the insurers and insurance brokers).

- Whilst it will remain the case that an insurer will be able to benefit from any defence against the third party that it would otherwise have had against the insured, the scope of such defences has been curtailed. For instance, it will no longer be an acceptable defence to say that an insured did not satisfy a condition in its insurance policy, as long as the third party can itself meet the condition.

- It is also now clear that for the 2010 Act to apply, the insolvency event must occur in the UK. Prior to the 2010 Act, the jurisdictional scope of making a third party claim was unclear.

- The 2010 Act received Royal Assent in March 2010 and it was intended for the Act to come into force relatively quickly. This process was however subject to lengthy delays and in 2013 the Government announced that it was going to amend the 2010 Act to cover further insolvency scenarios. The Bill, in making a number of minor amendments to the 2010 Act, does just this. Furthermore, the Bill makes provisions for the Secretary of State to extend the range of insolvency events covered by the 2010 Act in the future.

Comment

When it is eventually in force, the new legislation will have a significant impact, and will likely lead to higher levels of litigation against insurance companies at an earlier stage. In particular, it will make pursuing the insurers of a distressed manufacturer or supplier a much less protracted, and much more cost effective, process. The 2010 Act is currently expected to come into force in October 2015.

For more details please contact Sarah West or Patrick Harte

RAPEX Report 2013: More of the Same

On 25 March 2014, the European Commission published its 10th Annual Report on RAPEX. RAPEX is the EU rapid alert system for dangerous products. Its purpose is to ensure the exchange of information on dangerous products withdrawn from the market and/or or recalled from consumers anywhere in Europe is promptly circulated between Member States and the Commission so that appropriate action can be taken. Details of the most significant developments in the system in 2013 are outlined below.

Key achievements

The key achievements of the RAPEX system in 2013, as reported by the Commission, were:

- **Earlier detection.**
- **More notifications on dangerous products.** In 2013, a total of 2,364 notifications on dangerous products were submitted through the RAPEX system (an increase of 3.8% from 2012). Hungary, Germany, Spain, Bulgaria, UK were the source of 48% of all RAPEX notifications on dangerous products in 2013. According to the Commission, this is likely to be linked to the size of those markets, greater import volumes and/or more experienced inspectors. It is not indicative of the quality of the products in those countries.
- **Better market surveillance and product safety enforcement by national authorities including through specific products.** The report notes that, with financial support coming from the Commission, the continued joint efforts of market surveillance authorities across the EU have led to improved coordination in enforcing product safety rules, and taking effective action against dangerous and non-compliant products.
- **Growth in the number of follow-up actions to RAPEX notifications.** According to the report, the number of follow-up actions taken by the Member States following receipt of a notification increased in 2013. The follow-up measures most frequently taken in relation to dangerous consumer products were: withdrawal from the market, sales bans, recall from consumers, imports rejected by customs authorities, and corrective actions.
- **Better risk assessment by authorities.**
- **Improved traceability (less products with an unknown origin).**
- **More focus on quality and usefulness of notifications.**
- **Growing cooperation with Customs Authorities.** The report notes that customs authorities are increasingly involved in product safety surveillance, and the number of measures initiated by the border controls and notified in RAPEX has risen steadily over the past few years.
- **Continued network building and training coordinated by the commission.**

Origin of Dangerous Products

The Commission reports that the majority of dangerous products notified through RAPEX came from outside the EU. China was the reported country of origin for 64% of the notifications. The report suggests that this could be the result of increased traceability (for example, items with an origin previously listed as "unknown", now being listed as originating from China) and goes on to state that the Commission and Member States have established a regular cooperation with the Chinese authorities to address product safety issues.

Comment

Although market surveillance targeting unsafe products is already a priority of the EU Commission, the focus on and extent of the work done by Member State authorities in this area is likely to increase once the proposed Market Surveillance Regulation comes into force (see further the article here).

For more details contact Kate Corby or Antonia Lish

Medical Innovation Bill Proposed

The Medical Innovation Bill (the "Bill") is making its way through the UK Parliament's legislative process. The intention of the Bill is to encourage the use by doctors of innovative treatments without fear of litigation. The Bill has provoked much controversy and divided opinion in the medical community, although it has recently received tentative backing from the General Medical Council. Its scope does not, however, extend to those companies who produce or supply medical devices and should the Bill be adopted in its current form this could lead to an imbalance in future litigation and medical development.

The proposal

Lord Saatchi proposed the Bill following the death of his wife from ovarian cancer. The Bill is principally aimed at protecting innovative treatment of relatively rare terminal cancers/other terminal conditions. However, the scope of the Bill has not been so restricted (other than to exclude cosmetic surgery). It can be reasonably expected that those treating patients in less extreme circumstances will seek this proposed statutory protection, but whether and to what extent the Courts will be willing to entertain such arguments is impossible to predict.

The Bill aims to allow doctors to use innovative treatments on patients without fear of being the subject of a negligence claim. In order to benefit from this statutory protection, which will sit alongside the common law *Bolam* test,[1] doctors will need to obtain the further views of one or more appropriately qualified doctors in relation to the proposed treatment, consider those views in the context of the risks and benefits associated with the proposed treatment and also obtain the patient's informed consent.

Why this Bill is relevant

Many product liability claims in the context of the medical devices industry also involve claims of medical negligence against doctors/NHS hospital trusts. Additional protection provided to doctors by virtue of the

Bill, especially in more complex areas of specialism where treatment options attract controversy, may have the effect of diverting claimants' attention towards pharmaceutical and medical device manufacturers and suppliers who will not benefit from the statutory protection offered by the Bill.

In addition, given the complexity of the cases potentially falling within the scope of the Bill, any analysis of whether a doctor's decision was responsible will inevitably involve highly technical and specialist medical issues in circumstances where the disease itself may not be sufficiently understood. There may also be a risk that the treatment in question may not be within the product's indication(s).

Continued spotlight on informed consent

The question of informed consent is typically a contentious one in litigation involving medical care and the proposed Bill does little to deflect this focus. However, one recent amendment to the Bill[2] requires that the details of the doctor's discussions in relation to the proposed treatment must be recorded in the patient's notes. It is hoped that this requirement is more than merely administrative and will encourage doctors to give more detailed information to patients when discussing the risk/benefit profile of proposed treatment options. Notwithstanding this, consent is likely to remain a focal point of litigation involving any aspect of medical negligence. For the reasons outlined above, it is also questionable whether pharmaceutical and medical device manufacturers should be consulted too in specific cases.

Comment

Under the current proposal, a doctor could benefit from the statutory protection in respect of a medical negligence claim by a patient, whereas in the same case the pharmaceutical or medical device manufacturer or supplier will not have such a defence to, for example, a claim under the Consumer Protection Act 1987. Whilst the encouragement of innovative treatment in a sensible and responsible way is something to be applauded, the potential exposure of product manufacturers or suppliers does not appear to have been sufficiently considered as part of the current debate. Without the investment of such companies into their research and development programmes, doctors may not have access to the necessary innovative treatments that this Bill would seek to protect.

We will continue to follow the development of the Bill with interest.

A copy of the draft Bill can be found here.

For more details please contact Louise Oakley or Will Jones

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[1] This affords a defence to a doctor who can demonstrate that he acted in accordance with a practice accepted as proper by responsible members of the profession, even if there are others who would not have taken the same view.

[2] In what is now section 1(5).

Consultation on New Sentencing Guidelines for Health & Safety Related Offences

The Sentencing Council, an independent body charged with developing sentencing guidelines for Courts, launched a consultation on 13 November 2014 to engage public opinion on the creation of new guidelines for sentencing in health and safety, food safety and hygiene and corporate manslaughter offences. The Consultation aims to provide consistency and proportionality across all sentencing guidelines for these offences. It also aims to ensure that fines will reflect the seriousness of the offence, and take into account the financial circumstances of the offender, as well as the extent to which the offender fell below the required standard. In short, although the proposals are likely to lead to a more consistent approach to sentencing, they are also likely to lead to an increase in the level of fines for larger organisations.

Why now?

The Sentencing Council's decision to launch this consultation was prompted and shaped by several recent developments:

- The 2014 Court of Appeal decision in *R v Sellafield and Network Rail* [1] highlighted the issue of fines in the context of health and safety and environmental offences. The judgment emphasised the importance of finding the right level of fine, taking into consideration the financial circumstances of the offender, while still maintaining the appropriate sentencing aims.

- The Council published guidelines in February 2014 for environmental safety offences, an area broadly related to health and safety, and food safety and hygiene. These guidelines put in place new rules which would result in higher fines for environmental offenders than for offenders of health and safety and food safety and hygiene. The Council is therefore seeking to improve the consistency and proportionality of sentencing across all similar offences.

- The Legal Aid, Sentencing and Punishment of Offenders Act 2012[2], although not yet in force, will give magistrates the power to impose unlimited fines for particular offences, including for offences relating to health and safety and food safety and hygiene. Once magistrates have these new sentencing powers, the Council intends that the new Sentencing Guidelines will assist the magistrates in concurrently applying fair and proportionate sentences.

Nature of the Proposals

The Council has determined that in areas of health and safety and food safety and hygiene there is very little guidance on sentencing and therefore there is inconsistency in how factors have been weighted and applied in reaching sentencing decisions across the country. The Council found that fines imposed on organisations for health and safety offences appeared too low in relation to the level of harm caused, and that there have been relatively few prosecutions for corporate manslaughter.

The approach taken by the Council is that fines must reflect the seriousness of the offence, and take into account the financial circumstances of the offender, as well as the extent to which the offender fell below the required standard. The fines should also meet the aims of punishment and deterrence in a fair and proportionate way: a penalty

must remove any economic gain derived from the offence, to ensure it is not cheaper to offend again than to take the necessary precautions. For organisations the fine should be sufficiently substantial to have a real economic impact, in order to ensure compliance.

In light of these objectives, the proposal in the consultation is that for each of the offences the Court will be required to consider the culpability of the offender and the harm caused, then to assess the appropriate level of the fine, primarily by reference to turnover.

The culpability and harm

- Health and Safety offences: the starting point for health and safety offences under these proposals is to consider: 1) the risk of harm created by the offence, including the seriousness of the harm and the likelihood of that harm arising; and 2) whether the offence exposed a significant number of people to the risk of harm and whether the offence was a significant cause of actual harm.

- Corporate Manslaughter: the Court will consider the extent of culpability and harm for corporate manslaughter by reference to a range of factors, including: the foreseeability of the injury; how far short of the appropriate standard the offender fell; whether the non-compliance was widespread; and the number of injuries/fatalities.

- Food safety and hygiene offences: under these proposals, the Court is required to consider the extent to which the offender has deliberately breached the law, or to what extent they have fallen short of acceptable standards.

The level of the fine

The Council has suggested that the turnover of an organisation is used as the starting point for assessing the level of a fine, and then the Court will consider aggravating and mitigating factors to make adjustments. The Court is also required to examine the financial circumstances of the offender in the round, including taking into account profit margins relative to turnover, any economic benefit derived from the offence, and whether the fine would put the offender out of business (although it indicated that in some cases this may be an acceptable consequence).

Comment

Practitioners in this area are likely to welcome the Council's attempts to unify sentencing across health and safety, food safety and hygiene and corporate manslaughter. The current lack of clarity around sentencing in these areas ought to be greatly improved by the draft guidelines, giving clients more certainty over likely penalties for offences. However, the proposed changes are likely to result in higher levels of fines for large organisations, given the extent to which the Court will be required to take into account the financial circumstances of the offender in setting the fine.

The Consultation is open until 18 February 2015 and can be accessed here

For more details please contact Sarah West or Sarah Abdelmalek

[1] *R v Sellafield and Network Rail* [2014] EWCA Crim 49

[2] Section 85, Legal Aid, Sentencing and Punishment of Offenders Act 2012

Case Law Update: Defect, causation, jurisdiction/applicable law and manufacturer's brochures

2014 saw a number of interesting case law developments in the product liability sphere. This update explains how recent cases have helped clarify:

- what constitutes a defective product;
- the liability of end suppliers for manufacturer brochures;
- jurisdiction and applicable law in product liability claims; and
- issues of causation.

What makes a product defective?

Buckley v Henkel Ltd, County Court (Liverpool) November 25 2013

Facts

Ms Buckley used a hair dye manufactured by Henkel. The hair dye contained PTD, a vital ingredient in permanent hair dyes, but one that is known to cause allergic reactions. Before using the dye, Ms Buckley said she had read the product instructions and carried out a “patch test” to check whether it would cause her to react. Ms Buckley said that her patch test was negative, but when she used the dye, she suffered a severe allergic reaction.

Ms Buckley made a claim against Henkel for damages for personal injury, arguing that the product was defective under the Consumer Protection Act 1987 (the "CPA"). She said the product's safety was not "*such as persons generally are entitled to expect*" (the definition of a defect in a product under s3(1) of the CPA), because:

(i) the presence of PTD within the product made it unsafe; and

(i) the patch test and instructions were defective in that they did not enable her to reliably ascertain whether she was allergic to the dye.

Decision

On the question of whether the presence of PTD in itself made the product defective, Deputy District Judge Ranson accepted that there were notable risks associated with PTD, but was persuaded by the argument that its use was permitted under EU law. He referred, by analogy, to "*other commonly available products which carry with them risks*", and said that "*persons generally would not be entitled to expect*

that certain products would be completely free from risk (particularly if those risks are highlighted)". In this case, he thought the number of explicit warnings and consequences highlighted in the instructions, including one that warned the consumer of the danger of a "severe" allergic reaction ("*hair colourants can cause allergic reactions which in rare instances can be severe*") sufficiently alerted the consumer to the risks associated with PTD.

On the question of whether the patch test was defective, the instructions were once again important, because they stated that the risk of an allergic reaction would be reduced but - crucially - not eliminated, following a successful test (*"the absence of a reaction to this test is no guarantee that an allergic reaction may not occur as a result of a future hair colouring process*"). Mr Ranson was unwilling to find that "*a procedure introduced into a product to improve its safety should then make the product itself defective because it is not 100% effective when it is does not purport to be*".

The claim was therefore rejected.

Comment

This case should offer some comfort to manufacturers of "*commonly available products which carry with them risks*", particularly where the particular product or ingredient is explicitly permitted by legislation. However, it also serves as a reminder of the importance of including clear warnings alongside products known to carry risk. In this case, the statements that the product could cause an allergic reaction, and that the patch test was not a guarantee of safety, were crucial to Henkel successfully defending the claim.

For more details, please contact Sarah King or Patrick Harte

Clinicians held responsible for the content of manufacturer brochures

Webster and ors v Liddington and ors [2014] EWCA Civ 560

Facts

IE Ltd ("IE") produced Isolagen, a cosmetic product designed to treat the signs of aging skin. The manufacturing process involved taking a sample of a patient's skin cells and placing them in foetal calf serum (FCS), a bovine product, to grow fibroblasts (skin cells that produce collagen). The fibroblasts were washed clean of FCS, and then injected into the patient. IE, along with certain clinics that offered the Isolagen treatment, drafted and published brochures explaining this process, which stated that Isolagen contained nothing other than the patient's own cells.

A number of patients who had undergone the Isolagen treatment discovered that it had contained traces of FCS. These patients sued the doctors and clinics who had provided them with the treatment, alleging that they had been misled by the brochures as to the purity of Isolagen. The Claimants did not pursue a product liability action against IE as the company was in administration.

The first instance judge found in favour of the Claimants, and held that,

by handing the brochures to the Claimants, the clinicians had made misrepresentations as to the purity of Isolagen. The clinicians appealed to the Court of Appeal arguing that:

(i) they were not responsible for the statements in the brochures; and

(ii) those statements were substantially correct.

Decision

In the leading judgment in the Court of Appeal, Lord Justice Jackson applied *IFE Fund SA v Goldman Sachs International*[1], considering the test of what a reasonable person would have inferred was being implicitly represented by the words and conduct in the context. The Court concluded that a reasonable person standing in the shoes of the Claimants would consider that the clinicians were adopting the contents of the brochure. The following factors were highlighted as important in reaching this conclusion:

(a) the imbalance in knowledge of the treatment between the patients and clinicians;

(b) the sale of Isolagen as a product, not just the treatment in general;

(c) the fact the patients did not ***need*** Isolagen, but chose it, relying on the brochures; and

(d) the lack of disclaimer by the clinicians about the information in the brochures.

Jackson LJ, in dismissing the Defendant's argument, held that it was material that there was FCS in the Isolagen, even in trace amounts, because of expert evidence that between 3 and 10 percent of the population have a propensity to suffer an allergic reaction to bovine products; and because the presence of FCS might have had impacted the patients' decision to have the treatment.

Comment

This case is a caution to providers of end products and services against giving their clients and customers material produced by manufacturers or other entities in the supply chain, without a disclaimer as to the accuracy of the material's content.

For more details, please contact Sarah King or Will Jones

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[1] [2006] EWHC 2887

Jurisdiction and applicable law in product liability cases

Kainz v Pantherwerke AG (C-45/13, 16 January 2014); and

Allen & Others v Depuy International Limited [2014] EWHC 753 (QB)

Facts

In *Kainz v Pantherwerke*, a question arose as to which country's courts should have jurisdiction. The Claimant had purchased a bicycle from a retailer in Austria where he was resident. The bike had been manufactured in Germany, which was also where the Claimant had sustained injuries during a bike ride. The Claimant commenced proceedings in Austria against the German manufacturer. Relying on Article 5(3) of the Brussels Regulation ((EC) 44/2001), which provides that a person domiciled in a Member State may be sued "*in the courts of the place where the harmful event occurred or may occur*", the Claimant argued that the Austrian Court had jurisdiction. Case law has established that this means either the place where the damage occurred, or "*the place of the event giving rise to [it]*". The Claimant argued that the "*place of the event giving rise to the damage*" was Austria, this being where the bicycle had been sold. The Defendant maintained that the relevant place was Germany since this was where the bicycle had been manufactured and originally brought into circulation. The Austrian Court referred the matter to the European Court of Justice (the "ECJ").

In *Allen v Depuy*, a slightly different question arose, this time under the Private International Law (Miscellaneous Provisions) Act 1995 ("the 1995 Act") - which country's law should apply to the claim? In this case, the Claimants alleged that they had suffered injury arising from the insertion of prosthetic hip implants manufactured by the Defendant in England. Although the Claimants were not domiciled in England, had been operated on outside of England, and had not suffered their alleged symptoms or injuries in England, they chose to issue proceedings here as this was where the Defendant was domiciled. Seeking to rely on the Consumer Protection Act 1987 (the "CPA"), the Claimants argued that English law was applicable as this was where the prostheses had been designed and manufactured, and where the Defendant was registered. The Defendant argued that the relevant "*events giving rise to damage*" were not simply the manufacture or supply of the goods, but rather whether any biological reaction to the implants led to the damage.

Decisions

In *Kainz v Pantherwerke* the ECJ held that the "*place of the event giving rise to the damage*" was where the product was manufactured, which in this case was Germany, and the German Courts should therefore have jurisdiction to hear the claim.

In *Allen v Depuy*, the English Court considered the general rule under the 1995 Act that the applicable law to a claim is the law of the country where the injury was sustained. This rule can be displaced where it is substantially more appropriate for the law of another country to apply, but in this case the judge found no good reason to do so, save in one case, where the marketing, implementation, and revision surgery all took place in New Zealand, in which case the applicable law was the law of New Zealand. In relation to the CPA, the Court said that even if the applicable law was English law, the Claimants would not have the benefit of the CPA, because "*consumers who suffer damage outside the EEA and who have no connection with the EEA, and where marketing and supply of the defective product was outside the EEA are not within the scope of the CPA*".

Comment

Kainz v Pantherwerke is unusual, in that the injuries were not sustained in the Claimant's own jurisdiction. It is clear from this case that the *"place of the event giving rise to the damage"* will often be the place of a product's manufacture and therefore the courts of that country that will often have jurisdiction to hear the claim. However, whilst a court may have jurisdiction in a particular case, it does not necessarily follow that the laws of that country will apply. *Allen v Depuy* is a good reminder that applicable law will often depend on which country's laws the court considers most appropriate to the case. Overseas claimants may also find, after *Allen v Depuy*, that the CPA does not apply to them even if the applicable law is held to be English law.

For more details, please contact Sarah King or Devina Shah

Leave it to the experts: issues of causation in defective product cases

Hufford v Samsung Electronics (UK) Ltd [2014] EWHC 2956 (TCC); and

Joseph Simon Love v Halfords Ltd [2014] EWHC 1057 (QB)

Facts

In *Hufford v Samsung Electronics*, the Claimant issued proceedings against the Defendant under the Consumer Protection Act 1987 (the "CPA") following a fire at his home. The Claimant said that his Samsung fridge-freezer, which caught fire, was defective within the meaning of s. 3 of the CPA. Specifically, the Claimant alleged that the fire originated inside the fridge-freezer, in the machinery compartment at the rear. The Defendant, however, contended that the fire had originated in some combustible material external to the appliance.

In *Love v Halfords*, the Claimant purchased a mountain bike from the Defendant. Nine months later, whilst cycling on a tarmac cycle path, the Claimant lost control of the bike and sustained a serious head injury. The Claimant similarly brought an action under s. 3 of the CPA, as well as under the Sale of Goods Act 1979 and the Supply of Goods and Services Act 1982, arguing that the accident had been caused by fracture of the bike's steerer tube, a defect that had been present since the bike's supply. The Defendant denied the existence of a defect on purchase, contending that the Claimant had either been involved in a previous accident which had damaged the steerer tube, following which damage had been exacerbated due to inadequate repair, or that the tube had fractured as a result of the accident in question.

Decisions

Considering the evidence in the whole, the Technology and Construction Court found, in *Hufford v Samsung Electronics*, that the Claimant had not discharged his burden of proof in showing either that there had been a defect in the product or that the origin of the fire had been in the machinery compartment. The Court held that the burden of proof was on the Claimant throughout, whose duty it was to prove the existence of a product's defect and that the defect had caused the accident. The Court found the Claimant was not required to specify the defect with accuracy or precision, but had to prove its existence in broad or general terms, which he had failed to do. The claim was dismissed.

The High Court also dismissed the claim in *Love v Halfords*. Attaching significant weight to the expert evidence adduced, the Court held that it was appropriate to infer from the Court-appointed fractographer that there had been nothing defective about the design of the product, its assembly, or the steel from which it had been made. The expert found that the fracture was the result of a different accident, involving considerable speed and force. The damage caused by this earlier accident had been exacerbated by amateur repair and incompetent straightening. Whilst the Defendant could not be specific as to how and when that had happened, reasonable inference from the evidence led the Court to conclude that a botched attempt to the repair the tube had made it worse. The Claimant's significant evidential shortcomings, including his lack of memory of the incident and the absence of any eye-witnesses, hindered his case. As he was unable to establish that the cause of the accident was due to a defect at the point of sale, the claim failed.

Comment

The above cases serve as a reminder that the burden of showing a product defect exists and causation of damage under the CPA sits squarely with the claimant. They also show how crucial factual and expert evidence can be in CPA litigation.

For more details, please contact Sarah King or Devina Shah