

Product Stewardship: Regulatory Update

March 2013

This is the first of a series of updates focused on product-related regulatory and liability issues which may impact manufacturers, importers, distributors and retailers of a broad range of consumer goods. Please do get in touch if you would like to discuss these developments or any other product-related concerns.

Doug Bryden, Head of Environment & Safety Law

GENERAL DEVELOPMENTS

The rise of Environmental, Social and Governance (ESG)

Consumers, the media and NGOs are increasingly scrutinising business activities and ethics. The recent furore over tax avoidance in the UK by large multi-nationals, bribery and corruption scandals, the horsemeat concerns and activism by the likes of Greenpeace on manufacturing practices in China and emerging economies, provide stark evidence of how reputational and non-financial risk factors can impact on business value, performance and investment risk.

Unsurprisingly, therefore, environmental, social and governance performance issues (whether under the banner of ESG, sustainability, corporate social responsibility, etc.) are appearing higher on the agenda of businesses. Although prompted in part by developments in UK, EU and international legislation (including the UK's Bribery Act 2010), these changes are largely being driven by institutional investors, shareholders and customers.

In addition to the above, recent case law also points to a harsher, less forgiving approach to enforcement as well as increasingly substantial fines and damages for regulatory non-compliance in relation to ESG type issues and product liability more generally. Notably, the English courts have recently shown a willingness to circumvent the corporate veil and find parent companies liable for the safety failings of their subsidiaries.

Meanwhile, greater NGO and media scrutiny, both at home and abroad, is adding to the pressure and prompting difficult choices about whether to engage in dialogue with these antagonists or to keep them at arm's length.

Our work last year providing legal support to members of the UK delegation at the UN's Rio+20 conference demonstrated, if nothing else, that companies will need to be more transparent on how they perform in relation to a range of environmental, climate change, social and governance indicators. Failure to do so may not only damage reputations and give rise to legal liabilities, but also limit funding and investment opportunities.

Businesses, particularly those with a consumer interface, need to consider how to integrate ESG and sustainability systems and processes and crucially decide how best to report on performance.

It is becoming increasingly clear that simply making general and often aspirational policy statements will no longer suffice.

Additionally, whilst high profile marketing-led ESG initiatives may initially seem attractive, to maintain credibility and brand value in the long-term, the main focus must be the robust management of strategic legal, governance and reputational risks.

UK consumer law reform

The Department for Business Innovation and Skills (BIS) conducted a number of consultations on proposed changes to UK consumer law in 2012.

Of particular note, a consultation on 'enhancing consumer confidence by clarifying consumer law' sought views on proposals to simplify and clarify the law in relation to the supply of goods, services and digital content.

Key proposals with respect to the sale of goods include the introduction of:

- ▶ consistent definitions for 'consumer', 'trader' and 'goods' across UK consumer laws;

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- ▶ a new system of statutory guarantees (to replace the current system of implied terms in consumer contracts) which clearly state the quality standards that goods must meet and the remedies available to the consumer if these guarantees are breached; and
- ▶ the introduction of a defined period for the short term right to reject within which consumers can get a full refund for faulty goods.

Other proposals seek to clarify the operation of remedies regarding repair and replacement, how deductions for use are calculated and introduce consistency of remedies across different transaction types.

The Government is expected to publish its consultation response shortly. It will be interesting to see how these proposals develop - whatever the final outcome, detailed guidance is likely to be required to explain the new rules to consumers and businesses.

Changes to EU's product safety regime

In February 2013, the European Commission proposed new rules to improve the safety of non-food products and to increase 'market surveillance' (i.e. policing). In particular, the 'Product Safety and Market Surveillance Package 2013' includes proposals for new regulations on Consumer Product Safety and Market Surveillance of Products.

The proposed new Consumer Product Safety Regulation (Regulation) is intended to clarify the existing EU framework for consumer products to meet the challenges of a globalised market. Unlike Directive 2001/95/EC on General Product Safety (GPSD), which it would replace, the proposed regulation would not require implementation via national legislation, thereby increasing harmonisation across the Member States (although enforcement penalties would still be set at Member State level).

The proposed regulation retains the basic principle in the GPSD that all consumer products placed on the market must be safe, but places increased emphasis on enhanced product identification and traceability to enable a swift and effective response to safety problems (e.g. recalls). It also seeks to clarify how the Regulation will interact with sector-specific legislation applicable to consumer products and introduces simplified procedures for the development of new or updated product safety standards.

The proposed new Market Surveillance Regulation aims at simplifying the "fragmented and confusing" EU framework for market surveillance of non-food products to make it more effective in protecting human health and safety. Under the proposal, existing market surveillance procedures will

be consolidated and streamlined (for example, the provisions regarding market surveillance and RAPEX that are currently contained in the GPSD have been transferred to the proposal for a new single Market Surveillance Regulation). Additionally, market surveillance authorities will be required to be adequately resourced for the proper performance of their tasks and to better cooperate and coordinate their efforts.

The above legislative proposals are accompanied by a rolling plan for market surveillance, which sets out 20 actions to be undertaken to improve market enforcement and policing under the current regulatory framework until the new rules are formally agreed and come into effect (anticipated to be in 2015).

Limitation periods in personal injury and toxic tort-related claims

In the recent case of *Ministry of Defence v AB [2012]*, the UK's Supreme Court considered the application of the statute of limitations in the context of personal injury claims.

Although the case relates to liabilities following the testing of thermonuclear devices in the South Pacific in the 1950s, it nonetheless provides an insight into the potential treatment by the courts of personal injury claims which relate to toxic exposures with injuries that manifest at a later date.

The court agreed that the claimants were time barred. It was noted that the claimants believed as early as the 1990s that their injuries were linked to the nuclear testing (even without evidence to justify this belief).

The court held that the three-year limitation period started to run at this point even though specific evidence required to prove it to a legal standard was not available until later.

The court also refused to extend the relaxation of the ordinary 'but for' causation test in line with the earlier asbestos case of *Fairchild*. In *Fairchild*, the claimants had contracted mesothelioma from exposure to asbestos dust whilst working from more than one employer. However, it was impossible to prove, on the balance of probabilities, when the relevant exposure had occurred. The House of Lords held that in cases involving mesothelioma, for public policy reasons, claimants should be able to recover compensation from the defendants, jointly and severally, without having to satisfy the usual 'but for' test of causation.

Therefore, in most circumstances, it will remain the case that where a claimant is unable to show that 'but for' the defendant's misconduct the injury would not have been caused or suffered, the claim will fail.

In summary, there are a number of important points which can be drawn from this case:

- ▶ the application of the rules outlined in *Fairchild* are becoming increasingly limited to the facts of that case (i.e. the courts appear reticent to extend the relaxation of the 'but for' causation rules beyond asbestos-related toxic tort type cases);
- ▶ in relation to personal injury claims, the time limitation period may begin to run from when the claimant first reasonably believed that the injury suffered was due to wrongful conduct or exposure; and
- ▶ when assessing the operation of time periods, even in group litigation, this will be a question of individual proof.

U.S. introduces disclosure rules on use of conflict minerals

The U.S. has introduced legislation on conflict materials (i.e. those mined in conditions of armed conflict). The new regulations, introduced in August 2012 under the Dodd-Frank Act, will require certain companies that report to the U.S. Security and Exchange Commission (SEC) to disclose the use of conflict minerals that originated in the Democratic Republic of the Congo (DRC) or an adjoining country annually from May 2014.

The new regulations only apply where the use of such minerals is "necessary to the functionality or production" of a product manufactured or contracted to be manufactured by the company.

Whether or not similar legislation is adopted in other countries, the UK Foreign and Commonwealth Office recommend UK companies adopt the Dodd-Frank standard modes of due diligence and certification (see www.fco.gov.uk/en/global-issues/conflict-minerals).

Companies who use minerals including tantalum, tin, gold or tungsten and seek to do business with SEC-listed companies may well be affected as due diligence practices by SEC reporting companies will result in these requirements being passed down the supply chain.

Global product recall portal launched

A new product recall database jointly developed by the U.S., the OECD, the EU, Canada and Australia has recently been launched.

The Global Recalls Portal is intended to combine in one place details about dangerous non-food product recalls around the world.

The online searchable database, which is publicly available, will be updated on a regular basis with alerts on dangerous products from the EU, U.S., Canadian and Australian authorities.

CHEMICALS

Additional substance restrictions under REACH

Additional substance restrictions under Annex XVII of the EU's REACH regime were published in the Official Journal back in September 2012 and more recently in February 2013. These include further restrictions on:

- ▶ the use of **mercury** in consumer measuring devices such as medical thermometers and other medical devices;
- ▶ the use of **lead** in jewellery articles where the lead concentration is equal to or greater than 0.05 % by weight of the individual part, unless it can be demonstrated that the rate of lead released does not exceed the limit of 0.05 µg/cm²/h. Naturally occurring lead in crystal glass and vitreous enamels, non-synthetic or reconstructed precious and semiprecious stones is exempted. Of note, Sweden has submitted a proposal to the EU for a wider restriction on the use of lead in consumer products earlier this year – this proposal is currently the subject of technical scrutiny; and
- ▶ the use of **cadmium** in jewellery, brazing alloys and PVC.

Further 'black list' substances

In December 2012 an additional 54 Substances of Very High Concern (SVHCs) were added to the REACH Candidate List.

In the four years since the first SVHC consultation, 138 substances have been added to this so called substance 'black list'.

The European Commission has, therefore, achieved its political goal of having 136 SVHCs by the end of 2012.

Inclusion on the 'black list' may impose communication and notification requirements on manufacturers and importers using such substances and on suppliers of preparations and articles containing them.

In March 2013, a public consultation on a further 10 potential SVHCs was commenced.

Regulation of nanomaterials

In October 2012, the European Commission published its second regulatory review on nanomaterials (a follow-up to its 2008 review).

The review was intended to assess the adequacy and implementation of EU legislation for nanomaterials. Of note, the review concludes that:

- ▶ there is no need to amend the Commission's 2011 definition of nanomaterials at this stage, although a review is planned for 2014;

- ▶ overall, the existing EU chemicals regime, REACH, remains the best possible framework for the risk management of nanomaterials when they occur as substances or mixtures; and
- ▶ more specific requirements for nanomaterials under REACH are necessary (the Commission envisages modifications to some of the annexes to the REACH Regulation and encourages the European Chemicals Agency (ECHA) to develop further guidance for registrations after 2013).

The Commission's Communication was accompanied by a Staff Working Paper on Nanomaterial Types and Uses. The Working Paper provides information on the definition of nanomaterials, their uses, benefits, health and safety aspects and risk assessment, and information and databases on nanomaterials.

In a related development, Denmark has announced that it intends to create a national database of mixtures and articles containing or releasing nanomaterials, as well as imposing a reporting duty on producers and importers of these products. France has already adopted legislation to create its own mandatory database of nanomaterials. Other EU states are also considering similar national databases.

EU's Biocidal Products Regulation

The EU's new Biocidal Products Regulation, which will apply from 1 September 2013, seeks to simplify the existing EU requirements without reducing the level of protection.

Although much will stay the same, there are some changes under the new regime. In particular, if you import an article into the EU that is treated with a biocide, you will have to ensure that the active substance that was used is approved under the regulation.

Further guidance on key elements of the new regime is expected throughout 2013.

ELECTRONIC EQUIPMENT

Recast Waste Electrical and Electronic Equipment Directive (WEEE) enters into force

The recast WEEE Directive came into force on 13 August 2012 and Member States have until 14 February 2014 to transpose it into national law. In particular, the WEEE Directive 2012:

- ▶ extends the scope of electrical and electronic equipment (EEE) covered from the ten categories of EEE specified in the original Directive to include all EEE from August 2018;
- ▶ requires all Member States, with the exception of those Member States that currently lack the required infrastructure and have low EEE consumption, to

recover at least 45 per cent of the WEEE produced in that Member State (as opposed to a collection target of 4kg per person per year under the old Directive) from 2016, rising to 65 per cent from 2019;

- ▶ introduces tougher controls to help ensure that WEEE is only exported for legitimate purposes, such as repair or reuse, rather than disposal; and
- ▶ introduces a new collection obligation on retailers occupying premises with EEE sales areas greater than 400m² to collect very small household WEEE free of charge (even where consumers are not buying replacement goods).

RoHS to control additional substances

The European Commission is consulting on new substances to be controlled under the Restriction of Certain Hazardous Substances (RoHS) in Electrical and Electronic Equipment Directive. The three-stage consultation is being managed by the Austrian Environment Agency, working in close cooperation with the Commission.

An initial consultation, which ran until 10 February 2013, asks stakeholders to nominate hazardous substances in electrical and electronic equipment as potential candidates for further control. A consolidated list of proposed substances will then be produced with further consultations and stakeholder meetings planned throughout 2013. A final report is scheduled to be published in November 2013.

We understand that four substances, the flame retardant hexabromocyclododecane (HBCDD), and the phthalates bis (2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP) and dibutyl phthalate (DBP), are being considered, along with tetrabromobisphenol A (TBBP-A). These substances were previously identified as high priority substances.

FOOD

New EU rules on health claims

On 14 December 2012, Regulation (EU) 432/2012, which establishes a list of permitted health claims that can be made on foods, came into force.

Health claims are defined as claims that state, suggest or imply that a relationship exists between a food category, a food or one of its constituents and health. An example of an approved health claim in relation to foods low in saturated fats is "*Reducing consumption of saturated fat contributes to the maintenance of normal blood cholesterol levels*".

Only health claims featured on the approved list of 222 general function health claims will be permitted on foods marketed in the EU.

Food manufacturers must, therefore, ensure that any health claims that they use on their products appear on the approved list and that any associated conditions of use are met.

UK consults on the EU Food Information to Consumers (FIC) Regulation

In November 2012, the UK Department of Environment, Food and Rural Affairs (Defra) launched a 12-week consultation on draft legislation to enable enforcement of the EU Food Information to Consumers (FIC) Regulation (No. 1169/2011) and replace 14 existing pieces of food legislation.

The aims of FIC are to improve the information provided to consumers to enable them to make informed choices about the food they buy and to update legislation to reflect current industry practice and consumers' changing information needs.

FIC requires that food information (including labelling, advertising and packaging) must be accurate, clear, easy to understand and not misleading.

In addition to these and other general obligations, FIC contains specific provisions with respect to a number of high profile issues, including:

- ▶ mandatory nutrition declarations;
- ▶ voluntary nutrition labelling;
- ▶ quantity and country of origin labelling; and
- ▶ allergenic ingredient information and labelling.

Responsibility for food information primarily falls on the operator under whose name the food is marketed or, if that operator is not established in the EU, the party importing into the EU.

Additionally, all food business operators have obligations not to supply food which they know or presume, on the basis of the information in their possession as professionals, to be non-compliant with FIC.

The majority of FIC provisions will apply from 13 December 2014, with the obligation to provide mandatory nutrition information taking effect two years later. Once in force, any food intended for supply to the consumer or to mass caterers must be accompanied by food information in accordance with FIC.

Food safety and horsemeat contamination

In February 2013, the UK's Food Standards Agency (FSA) received the second set of food industry test results relating to the presence of horse DNA in products that are labelled as beef.

The FSA's current focus is on gross contamination, where there is more than 1% horse DNA detected in a beef product.

The FSA believes that such levels indicate either gross negligence or deliberate substitution (i.e. fraudulent) of one meat for another and has stated that it is *"committed to pursuing enforcement action where we can, to ensure that those who were at fault take full responsibility for their actions. We are determined to get to the bottom of this to find out exactly what happened - and to make sure it doesn't happen again"*.

There have been and continues to be instances where food businesses have withdrawn products due to trace contamination levels, or on a precautionary basis (the FSA recommends that any retailers or producers that have sourced beef products from certain suppliers should conduct a precautionary withdrawal of product).

On the basis of the evidence to date, the FSA does not believe these products represent a food safety risk and no tests on samples containing horse DNA have yet found the veterinary medicine phenylbutazone (bute). That said, testing is ongoing for some products and we will not know the full extent of these issues until testing is complete.

As the international fallout from the scandal continues, impacted food businesses are working hard to determine their potential exposure to product liability and reputational issues.

From a wider industry perspective, the scandal has revealed significant weaknesses in some supply chain diligence processes and companies should take the opportunity now to confirm that they have adequate controls in place to ensure the safety, traceability and authenticity of products supplied to and by them (including procedures to ensure a measured but swift and effective response in the event that an issue is identified).

Consideration should also be given to the adequacy of existing product liability insurance and contractual protection.

The scandal has raised consumer awareness and expectations in respect of food traceability, labelling and safety. Whether consumer buying habits will be affected in the long-term is yet to be seen, but it seems clear that there will be increased political, media and regulatory scrutiny of the UK food industry as a consequence of this scandal for some time to come.

We will shortly be releasing a more detailed briefing on food safety and liability issues, which will examine some of the steps food businesses should take to manage their wider risks and liabilities.

TEXTILES

Major clothing manufacturers under NGO pressure on chemical use

Major clothing manufacturers are under continuing pressure from NGOs (particularly Greenpeace, via its international Detox Campaign) to reduce the level of allegedly harmful chemicals in their products.

An October 2012 report by Greenpeace Germany, 'Chemistry for any weather', found what it described as *"environmentally damaging toxins in outdoor clothing"* and called for brands including Jack Wolfskin, North Face and Patagonia to stop the use of production chemicals such as perfluorinated compounds (PFCs) in their products.

The Greenpeace report further demanded that all PFCs be put under scrutiny for a possible regulatory ban and also raised concerns about the use of nonylphenol ethoxylates (NPEs).

Greenpeace's continued scrutiny of the clothing and textiles sector is, for some, giving rise to significant challenges. Although engagement might give rise to short-term (such as positive PR) as well as long-term gains (a more sustainable business), care should be taken to fully consider where such a collaboration may lead and if indeed your key businesses and product lines can adapt and survive. That said, when something like Greenpeace's Detox Campaign gains momentum, it may be reputationally neigh on impossible not to sign up.

Sweden calls for EU to legislate on hazardous substances in textiles

The Swedish delegation to the EU Council of Ministers recently called for more coherent legislation at EU level regulating the impact of textile chemicals on health and the environment.

The Swedish government is concerned that large amounts of chemicals are used in the manufacture of textiles and many of them may remain in finished textile products.

Although not all such chemicals are hazardous for the environment and health, the Swedish government believes that there are many examples of substances with hazardous properties in finished products (e.g. they are carcinogenic, mutagenic, endocrine disruptors etc.). Whilst acknowledging that current voluntary environmental labelling schemes and restrictions imposed by some companies on the chemicals used in textile production were commendable, the delegation believes this cannot replace the need for common legal rules across the EU.

The Swedish government is also expected to send a letter to the European Commission urging the Commission to take action in this respect.

FIRM NEWS

Recent instructions

We have recently advised:

- ▶ a multi-national sports apparel and equipment company on the application of the WEEE directives and wider EU chemicals and nanotechnology law;
- ▶ a multi-national bicycle and equipment company on EU and Danish restrictions on lead and other chemicals;
- ▶ a food container manufacturer on product safety issues and potential U.S. and UK safety notifications and recall requirements;
- ▶ on significant product safety and liability issues (including group action litigation) associated with a medical devices company; and
- ▶ on UK food safety and labelling obligations.

Awards

We are delighted to have won the Law Firm of the Year 2012 award at the Legal Week awards ceremony.



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