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Product Liability Risks for the Chemicals Industry – Recent Developments in Europe

The present publication is a multi-jurisdictional overview on recent legal developments with regard to product liability risks for companies from the Chemicals industry. This combined effort was undertaken by various members of the Hogan Lovells Global Chemicals Product Liability Industry group. This two-part publication will in its first part focus on recent developments in Germany, the UK, Italy and France. The respective authors are Dr. Sebastian Lach (Germany), Dr. Hannah von Falkenhausen (Germany), Alex Woods (UK), Christian Di Mauro (Italy), Thomas Rouhette and Christelle Coslin (both France). The second part will focus on China and the US. The respective authors of these country parts are Trevor Jefferies, Courtney Colligan (both US) and Eugene Chen (China).

I. General Developments

2011 is a special year for the Chemicals industry. Following an initiative of the IUPAC (the International Union of Pure and Applied Chemistry) and of UNESCO (the United Nations Educational, Scientific, and Cultural Organization), 2011 has been declared to be the International Year of Chemistry, during which actors of the Chemicals industries and institutions organise worldwide activities aiming at acknowledging the contribution of chemistry in today's world.

At the same time, 2011 may also be a year of rising concerns. During the first quarter of 2011, chemical risks represented approximately 20% of the notifications made to the European RAPEX system according to the monthly statistics of the European Commission. In addition, the Chemicals industry has recently been confronted with a large number of new legal requirements in the various jurisdictions all over the world. For globally acting companies it is therefore of increased interest to monitor these developments to ensure utmost compliance of the business and to minimise liability risks. Moreover, case law has continued to develop and has interpreted these new legal developments. This article provides an overview of the most relevant legal developments in practice in some of the most important jurisdictions for such companies in the Chemicals industry. Due to the amount of topics for the Chemicals industry and the complexity of the legal issues, this publication is of course only a starting point, but shall at the same time raise awareness for topics that should be on the agenda of international companies doing business in this industry.

II. Germany[1]

In Germany various legal issues have arisen for the Chemicals industry in recent years. For example, there are ongoing discussions about compliance with the Chemicals regulation REACH (Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and restriction of Chemicals – "REACH Regulation") and its consequences for legal practice. The same applies to the Chemicals regulation CLP (Regulation (EC) No. 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures – "CLP regulation"). In addition, there are ongoing discussions about environmental topics like a recently published report about the transposition of the Environmental Law Directive 2004/35/EC by the European Commission (Directive 2004/35/EC on environmental liability with regard to the prevention and remedying of environmental damage of 21 April 2004 – the "Environmental liability directive"). Furthermore, the Federal Government of Germany rendered a new draft law for the transposition of the Directive 2009/31/EC on Carbon Capture and Storage ("CCS directive"). Simultaneously, discussions about the legal treatment of nanomaterials and according legal requirements continue.

As regards case law, the main focus in product liability lay on the proof of causation. The main question to be answered was whether plaintiffs could prove causation by demonstrating a mere increased risk (based on studies of varying value) for suffering a health complaint. Various courts, including the Federal Court of Justice ("BGH"), have recently rendered judgments that have come to varying conclusions. Such rulings may have consequences for all liability claims brought against Chemicals companies.

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1 Authored by Dr. Sebastian Lach and Dr. Hannah von Falkenhausen.

1. Developments in Statutory Law

In general, product liability in Germany is governed by the Produkthaftungsgesetz and general tort law. These laws mainly require a defective product, damages suffered by a claimant and a causal connection between the damages suffered and the alleged product defect. The Produkthaftungsgesetz is a system of strict liability that does not require fault. However, various exceptions apply. The amount of damages that can be recovered is limited to 85 million Euro overall for a defective product[2]. In addition, property that is used for professional purposes is not protected[3]. This might have significant relevance especially in business to business situations. In contrast, tort law does not provide for such exceptions. At the same time, general tort law requires claimants to prove the companies' fault as regards the alleged defect. However, it is established case law[4] that in product liability situations, the burden of proof under tort law also shifts from claimants to manufacturers who then have to prove that they did not act negligently in this regard.

For certain products, the legislator has also created special laws with stricter requirements. One example with relevance for the Chemicals industry is the German Arzneimittelhaftungsgesetz. This body of law has implemented a presumption of causation if a product is merely capable of having caused certain health damage in the individual case[5]. It is, however, doubtful whether this system of increased liability is in line with the Product Liability Directive[6].

In addition, liability risks can of course also arise from contractual provisions in the supply chain if contractual obligations regarding products are not met. If not stipulated otherwise, fault is also presumed by statutory law on contracts which again puts the burden of proof on manufacturers.

Taking these legal schemes, the questions whether a product is defective will often be decisive. In this regard, various new regulatory provisions for Chemical products will have an impact on the notion of defect. These regulatory requirements will set a minimum standard. If this minimum standard is not met, courts may very likely find a product defective.

The most important new regulatory requirement for Chemicals companies in recent years in Europe has been the REACH regulation. The new framework introduced by this regulation has been discussed at length throughout the industry and has been the subject of various publications[7]. This article shall therefore focus on possible questions of liability. The question of a product defect will therefore be subject to additional interpretation under this new regulation. The most obvious consequence will be that any breach of this regulation as a regulatory standard may automatically indicate a defect of the according product. This will especially be true if a product has not taken the hurdle of authorisation or is not in line with restrictions for substances under REACH. Furthermore, REACH has introduced various obligations to publish information on Chemical products. As information can also be accessed via the internet, claimants and plaintiffs will have the possibility to access the information and use it to substantiate their claims. They will also use this information to substantiate so called "failure to warn" claims, if any information available on the internet is not correctly reflected in the product information. In addition, it has to be noted that these requirements under REACH will not be applicable in various countries outside of Europe, most importantly the US. If the standard of environmental and consumer protection is higher in European countries, than for example in the US, plaintiffs will bring this as an argument that individuals in these countries do not benefit from the same protection. This could be an argument for a defect of the products on the market in these countries, as courts react quite sensitively if local individuals receive less protection than in Europe. It is therefore necessary that – also from a liability point of view – companies ensure that the level of information and protection provided in non-European countries corresponds to the level provided for in Europe. In addition, companies have to pay attention whether information made public through REACH has to be included in the product information and whether this information is clear and understandable enough to satisfy product information requirements.

As regards specifics for Germany, one has to note that criminal and administrative penalties under REACH are governed by the specific national laws. According to Sec. 27b of the German Chemicals Act, the potential sanction for infringing the obligations under REACH is up to two years of imprisonment or a monetary fine. In the event that the life, health or property of significant value of another person is endangered, a criminal offence shall be up to five years of imprisonment or a monetary fine. If the liable person acted negligently, the act shall generally be considered as an administrative offence which may be fined with a maximum amount of EUR 100,000.00. If the liable person did not comply with Article 4 and Article 39 Para. 1 REACH by negligence, the act shall be considered

2 Sec. 10 of the German Produkthaftungsgesetz.

3 Sec. 1 of the German Produkthaftungsgesetz.

4 BGHZ 51, 91; BGHZ 104, 323.

5 Sec. 84 Para. 2 of the German Arzneimittelhaftungsgesetz.

6 Art. 4 of the Product Liability Directive (Directive 85/374/EEC) states that "the injured person shall be required to prove the damage, the defect and the causal relationship between defect and damage". It can be argued that Sec. 84 Para. 2 of the German Arzneimittelhaftungsgesetz is not consistent with this clear provision governing the burden of proof as the effect of Sec. 84 Para. 2 of the German Arzneimittelhaftungsgesetz is that the causal link between the alleged use of the drug and the alleged damage is "presumed" and need not be proven by the claimant.

7 Bauer, Lach, PharmR 2007, 408; Bauer, Lach, RAJ 9/2008, 589–592; Bauer, Lach, RAJ 7-8/2008, 239 – 242.

as criminal offence which may be fined with up to one year of imprisonment or a monetary fine.

The CLP regulation focuses on the classification, labelling and packaging of Chemical products. It introduces new safety related requirements. Non-compliance may therefore lead to a lack of information for the relevant individuals and courts could find a failure to warn. It is therefore necessary that companies ensure product compliance also with respect to CLP. As with REACH, enforcement will be governed by national laws. Criminal and administrative penalties are governed by Sec. 27 of the German Chemicals Act and generally correspond to the penalties for non-compliance with REACH obligations.

2. Other Recent Developments

Another recent development with relevance for the Chemicals industry is the Environmental liability directive. The focus shifted onto this directive again as the European Commission prepared a report on questions regarding the effectiveness of the transpositions within the member states[8]. The Commission rendered the report on 12 October 2010[9]. One significant aspect of the Environmental liability directive was its framework character and the broad scope of discretion for the member states[10]. This inter alia led to variations regarding the liability scenarios. For example, the Directive left the option for member states to decide whether or not to provide their national laws with a "permit defence" and/or a "state of the art defence" that both lead to an exemption from liability[11]. It is remarkable that fewer than half of the member states allowed both defences and fewer than the other half decided to allow none of these defences[12]. There were only very few member states that chose a "compromise". Germany decided not to allow any of these defences[13]. That is understandable concerning the "permit defence". Under German law it is a known principle (e.g. in building law[14]) that a regulatory permit does not automatically release companies from liability.

A very recent legal development in Germany is the CCS law. The CCS Directive was the starting point of this legal issue. It has to be transposed by member states by 25 June 2011[15]. The Directive aims at stabilising greenhouse gas concentrations in the atmosphere at a level that would prevent possibly dangerous anthropogenic interference with the climate system[16]. A new procedure to achieve this goal is capturing carbon dioxide from industrial installations, transport it to and inject it into a suitable underground geological formation for the purposes of permanent storage[17]. The German "Bundesregierung" rendered a draft transposition on the Directive on 12 April 2011. A well recognised part of the draft is the liability for any damages that might occur in relation with CCS. The German transposition of the Directive is mostly based on existing liability laws in Germany[18]. This means that a system of strict liability and an assumption of a causal link between possible incidents and damages will be implemented.

Another topic that has been under discussion in the German legal community is liability for nanomaterials[19]. This is a very innovative technology that carries significant benefits for every day life[20]. Nonetheless, the German environmental agency has published a paper in 2010 warning of the use of nanomaterials and calling for meticulous warnings for consumers. The concern is that nanomaterials might cause health complaints similar to those caused by asbestos. General provisions governing this technology do not exist as of yet[21]. However, civil liability may arise under the general provisions of German tort law and the German Produkthaftungsgesetz.

This would require a product defect. Such a defect can, first of all, arise from a defective design. The product has to be "state of the art". A decisive point here is whether at the time of the release of the product is a risk for the user had to be avoided through a different design. This could, for example, be the case if nanomaterials carry a risk that could be avoided and/or not justified in relation to the benefits they bring. From a scientific point of view, a conclusive assessment of the effects of nanomaterials on the

8 Cf. Article 14 (2) of the Directive 2004/35/EC.

9 Report from the Commission to the Council, the European Parliament and Social Committee and the Committee of the regions of 12 October 2010 ("Report from the Commission").

10 Cf. page 2 of the Report from the Commission.

11 Cf. l.c.

12 Cf. l.c.

13 Cf. l.c.

14 A permission to build a real estate does not include a guarantee that the real estate is compliant to any administrative laws, see e.g. sec. 29 (2) Building law ("Baugesetzbuch") or Art. 68 (1) of the Bavarian building code ("Bayerische Bauordnung"). Contrary, the laws explicitly state that the permission does not include other public laws.

15 Cf. Article 39 of the Directive 2009/31/EC.

16 Cf. the first recital of the Directive 2009/31/EC.

17 Cf. the fourth recital of the Directive 2009/31/EC.

18 Cf. the reasoning on sec. 29 of the draft law. It is stated that the liability should be consistent to comparable laws as Environmental Damages Act ("Umweltschadensgesetz"), Federal Mining Act ("Bundesberggesetz"), Environmental Liability Law ("Umwelthaftungsgesetz") and Act on Genetic Engineering ("Gentechnikgesetz").

19 Lach, Koester, PHI 5/2010, P. 181; Lach, Koester, PHI 5/2009, P. 170–171; Lach, Koester, Bauer, StoffR 1/2010, 2–11

20 Federal Ministry of Education and Research, Nanotechnology – A Future Technology with Visions, http://www.bmbf.de/en/nanotechnologie.php.

21 The regulation (EC) No 1223/2009 of 30 November 2009 on cosmetic products provides specific provisions as regards cosmetics. The regulation replaces the cosmetics directive of 1976. Most of the provisions of this new regulation will be applicable as from 11 July 2013.

environment and human health is not yet possible. It can thus not be assumed that an increased risk exists. There are therefore good reasons for denying a design defect of nanomaterials as such.

Furthermore, a failure to warn due to a lack of information provided could be discussed in regard to nanomaterials. A failure to warn exists if the producer omits required warning information and this failure is considered a breach of duty to implement safety precautions. It is important at which point in time the producer has reasonable grounds to assume a duty to inform. In this context it has even been discussed that a producer has to issue a warning even at a strong but not urgent suspicion if there is a serious health risk[22]. Again, despite the information issued by the German environmental agency, there are good arguments that a risk has not yet been determined. Nonetheless, companies should verify whether they should already at this point issue additional information as a precaution to minimise liability risks.

The producer also has the duty to observe the products after a product has been placed on the market (*"Produktbeobachtungspflicht"*)[23]. The duty to observe the products and the corresponding duty to collect information is particularly important with regard to complex new product developments with a possible high potential for damages. Producers of possibly dangerous products are advised not only to acknowledge domestic publications with respective content but also international professional journals. Should possible risks increase through further scientific knowledge, the duty to observe can reach from a public warning to expensive recalls. However, the above said again applies with respect to the duty to observe a product after it has been placed on the market: It can be argued that the latest state of knowledge regarding nanomaterials currently does not require specific and immediate action[24].

3. Relevant Case Law

In 2010, the BGH rendered a decision on causation in drug liability cases. The BGH ruled[25] on the proof of a causal link between the use of a drug and health damages suffered by a claimant. In the case at hand the claimant suffered a heart attack and alleged a causal link between taking of a drug and his personal injury. The claimant deemed prima facie evidence applicable in this scenario as studies allegedly show that the drug could cause such health damage (the presumption of causation was not applicable in this case for various reasons).

The court stated that prima facie evidence applies in cases where the general experience of life shows that a damage event constitutes a typical consequence of the breach of duty. This means such cases where, inter alia, no other possible causes for the personal injury are evident. The court denied the applicability of a prima facie evidence already on the basis of this fact as other causes for the health damage were evident.

In addition, as the claimant considered the product to be defective, he asked for a reversal of the burden of proof on causation. The claimant referred to case law relating to gross medical malpractice by a doctor where such shifting of the burden of proof had been granted[26]. However, the BGH decided that the case at hand was not comparable to a gross medical malpractice case: Possible infringements of warning or information duties in product safety matters – that did not even exist in this case – do not have the same significance as a case of a gross medical malpractice.

Recently, it has also been discussed whether a damage claim could be based on a mere increased risk of suffering health damage. If this were the case, plaintiffs could refer to studies that would show such increased risk due to exposure to a substance, for example, and then claim damages even if the relevant illness has not broken out as yet. In 2008, the District Court Berlin had to deal with such a case in which the plaintiff claimed compensation as his hip prosthesis was allegedly defective and might burst at any time. The plaintiff argued that the increase in the risk of suffering damage severely confines his quality of life. The District Court Berlin found that the mental stress alone caused by the increased risk of bursting of the hip prosthesis justifies a claim for pain and suffering[27]. However, this decision is not in line with a recent decision of the BGH. In this decision the BGH again had to deal with prima facie evidence with respect to causation in drug liability cases. In this case, the claimant again alleged to have suffered a heart attack after the taking of a drug. The BGH ruled that the increase in the risk of heart attacks asserted is not sufficient for the principles of prima facie evidence to apply[28]. It might thus be concluded that according to the BGH a claim for damages may not be based on a mere increase in the risk of damage.

III. United Kingdom[29]

As in Germany, the REACH and the CLP regulations as well as the Environmental liability and the CCS Directives also bring forward new developments in statutory law for the UK.

22 Lach/Koester, PHi 6/2009, p. 239 with reference to Wagner, Münchner Kommentar zum BGB, 5th ed. 2009, Sec. 823, recital 639.

23 BGHZ 80, 186, 191; 80, 199, 202 f; 99, 167, 171; BGH NJW 1981, 2250, 2251; 1990, 906, 907; 1994, 3349, 3350; 2009, 1080, 1081; VersR 1971, 80.

24 Lach/Koester, PHi 6/2009, p. 239.

25 BGH VI ZR 64/09, Decision of 16 March 2010.

26 Cf. BGHZ 82, p. 212 ff.

27 District Court Berlin 5 O 467/07, Judgment of 9 December 2008.

28 BGH VI ZR 72/09, Decision of 26 January 2010.

29 Authored by Alex Woods.

1. Developments in Statutory Law

The starting point for product liability in the UK is the Consumer Protection Act 1987 ("CPA 1987"), which enacted the European Community Directive on Liability for Defective Products 1985 (85/374/EEC) ("Product Liability Directive").

In addition to claims brought under the CPA 1987, there is the possibility of contractual claims, based normally on the breach of an express or implied term relating to quality or safety. Advantages of such contractual claims are that there is no need to prove negligence on the part of the defendant, and that damages for pure economic loss (usually loss of profits) are recoverable in addition to those for personal injury and property damage. However, contractual claims generally require a direct contractual link between the manufacturer and the consumer.

For claimants who may have suffered personal injury or property damage from a product, there may also exist a cause of action under the tort of negligence. However, this requires the claimant to establish fault on the part of the manufacturer/supplier of the product, and is therefore unlikely to be as appealing to a consumer as the strict liability regime imposed by the CPA 1987. It is important to note that, different to Germany, there is no presumption of fault under in tort law in product liability cases.

The UK did not, unlike Germany, choose to enact the optional provision of the Product Liability Directive which caps damages recoverable for a defective product, so there is no limit on the amount that can potentially be recovered in an action under the CPA 1987. However, the same restriction exists in relation to the nature of the product at fault, which must be non-commercial property. The claimant has the burden of proving that the product was defective and that the damage suffered was caused 'wholly or partly' by the defect.

In addition to the general product liability regime in the UK, there is a regulatory framework which relates specifically to chemical product liability and safety. Recent relevant regulation includes: (1) Registration, Evaluation, Authorisation and restriction of Chemicals Regulations 2007 ("REACH"); (2) The REACH Enforcement Regulations 2008; (3) CLP Regulation (came into force in the UK in January 2009); (4) Chemicals (Hazard Information and Packaging for Supply) Regulations 2009; (5) Environmental Damage (Prevention and Remediation) Regulations 2009[30]; and (6) Control of Major Accident Hazards (COMAH).

In the UK as in the other EU member states, REACH imposes a variety of duties in relation to the manufacture, importation, supply and use of substances. The enforcement regime for REACH in the UK has been implemented by the REACH Enforcement Regulations 2008 (the "REACH Regulations"). The REACH Regulations allocate responsibility for REACH enforcement to a number of enforcing authorities, and provide these enforcing authorities with the powers necessary for enforcement. They also set the offences and corresponding penalties for contraventions of the requirements of REACH.[31]

The Competent Authority for the enforcement of REACH in the UK is the Health and Safety Executive ("HSE"), although it shares enforcement responsibility with a number of other agencies.[32] It has powers for the purposes of inspection and investigation such as powers of entry and powers to seize evidence. There are also powers for formal enforcement of the legislation, for example powers to serve various kinds of enforcement notice, or to prosecute offences under REACH.

Contravention of a REACH provision can result in prosecution in a Magistrates' Court, with maximum penalties of £ 5,000.00 and/or up to three months imprisonment, or in a Crown Court, where the maximum penalties are an unlimited fine and/or up to two years imprisonment. The REACH Regulations also create a number of other ancillary offences, for example obstruction of inspectors, provision of false statements, or failure to comply with enforcement notices. The penalties for these ancillary offences are the same as above for contravention of substantive REACH provisions.

As regards the practical aspects of enforcement, in June 2010, the HSE announced the first two substances that it will trace through the supply chain in order to identify companies that have failed to register substances in accordance with their obligations under REACH. The substances are ammonium dichromate and methylene diphenyl diisocyanate (MDI).

The UK implementation of REACH in stages is intended to progress over the coming years. The next key approaching deadline is 31 May 2013 for manufacturers/importers producing/importing substances of 100 tonnes or more per year; and then 31 May 2018 for manufacturers/importers producing/importing substances of 1 tonne or more per year. However, the supplier or marketer must

30 And for the constituent parts of the United Kingdom: the Environmental Damage (Prevention and Remediation) (Wales) Regulations 2009; the Environmental Liability (Prevention and Remediation) Regulations (Northern Ireland) 2009; and the Environmental Liability (Scotland) Regulations 2009.

31 They also require the enforcing authorities to cooperate and share information with other bodies connected to REACH enforcement both within and outside of the UK.

32 These are the Health and Safety Executive for Northern Ireland; the Environment Agency; the Scottish Environment Protection Agency; the Northern Ireland Environment Agency; the Department of Energy and Climate Change; and local authorities, which cover occupational health and safety as well as consumer protection (trading standards) issues. Other agencies, though not specifically given enforcement powers, may play an important role in any enforcement action, for example the UK Border Agency (detaining good suspected of being in breach), HM Revenue and Customs (disclosure of relevant information to enforcing authorities), and the Home Office (animal testing issues in England) and the Department of Health, Social Services and Public Safety (animal testing issues in Northern Ireland).

be pre-registered for this, and there are further requirements for substances of very high concern ("SVHC").

In the UK, enforcement of the CLP Regulation is governed by the Chemicals (Hazard Information and Packaging for Supply) Regulations 2009 ("CHIP"), which empowers the HSE to enforce the CLP Regulation under its remit from the Health and Safety at Work etc Act 1974. The HSE's powers include the serving of improvement or prohibition notices, which require suppliers either to make improvements to labelling and packaging or to cease providing products which do not comply with the CLP Regulation. It may also bring a prosecution where there has been a serious breach of the CLP Regulation. The fine for such a prosecution could be up to £ 20,000.00 if the matter is dealt with in the Magistrates' Court, or unlimited if dealt with in the Crown Court.

2. Other Recent Developments

The Environmental Liability Directive was implemented in the UK by the Environmental Damage (Prevention and Remediation) Regulations 2009. The Environment Agency is the enforcing authority for most significant activities requiring environmental permits, and local authorities for other activities. Although there are no criminal penalties available for environmental damage alone, failure to comply with notices (for example one served under regulation 13(2) to take measures to prevent imminent environmental damage) is subject to the same maximum criminal penalties as for a contravention of REACH and as set out above. Interestingly, while the English Regulations referred to above do permit the "permit defence" and "state of the art defence"[33], this is not consistent across the UK's constituent parts. The Welsh Regulations remove both defences for users of genetically modified organisms.

Carbon capture has also been the subject of government debate in the UK. Although the CCS Directive was largely implemented into UK law through various amendments to the Energy Act 2008, there have been other publicly discussed aspects of this issue, and some political controversy around the independent Committee on Client Change. In May 2011, the Climate Change Secretary announced the 2011 Carbon Budget, stating that the government plans to set legally binding targets for reducing greenhouse gas levels by 2025 to 50 % of the level of 1990. The focus of the Carbon Budget is the introduction of a cap on total carbon emissions and other measures to limit emissions such as a minimum carbon price. The Chemicals industry has voiced its concern to the government, asking for the introduction of transitional provisions in order to cushion the Budget's impact, particularly on companies in carbon-intensive industries.

As regards nanotechnologies, the UK Government introduced a revised strategy in March 2010. The strategy set out key actions in order to achieve its vision, including: (1) improving co-ordination of government environmental, health and safety research on nanotechnologies; (2) setting up an ongoing portfolio of Government and publicly-funded research into environmental, health and safety issues for nanotechnologies; (3) building on the Government's work on a pilot voluntary reporting scheme (that ran from 2006 to 2008) to include products as well as nanomaterials; (4) monitoring the success of upcoming amendments to EU directives on novel foods and cosmetics with respect to nanomaterials, and seeking to ensure that nanomaterials are "robustly covered" in amendments to the EU chemicals regime under REACH; and (5) reviewing whether other legislation will have to be amended in the future.

3. Relevant Case Law

In March 2010, the Court of Appeal gave judgment on *Hertfordshire Oil Storage Ltd v R*[34] regarding the fallout from the Buncefield Oil Storage facility and the compliance of the manager of the facility, Hertfordshire Oil Storage Limited, with the Control of Major Accident Hazards Regulations ("COMAH Regulations"). This has impacted the way Chemicals producers need to guard their sites against hazards, and comply with the COMAH Regulations in deciding who is to be considered the operator by the relevant COMAH authority.[35]

In the court's view, for the purposes of regulation 4 of the COMAH Regulations, the "operator" is the person that has identified itself to the COMAH competent authority as the operator of the installation and is treated as such by the competent authority. If a person has identified itself as the operator, then that person cannot say that it was not "in control of the operation" for the purposes of the COMAH Regulations. The court said it would make a mockery of the COMAH Regulations if an operator was allowed to "wriggle out" of its responsibilities on such a technicality. The court therefore takes a very formal approach and it will be difficult for Chemicals companies to bring legal defence arguments based on the factual situation if they have identified themselves as operator to the competent authority.

IV. Italy[36]

Chemicals companies operating in Italy also have to deal with new legal developments arising from the CLP and REACH Regulations as well as from the Environmental Liability and the CCS Directives.

33 Regulation 19(3)

34 [2010] EWCA Crim 493

35 Likely to be either the HSE or the local authority.

36 Authored by Christian di Mauro.

1. Developments in Statutory Law

In Italy product liability is based either on the general principle of tort law under Articles 2043[37] and 2050[38] of the Italian Civil Code or on the strict liability regime set forth by the Consumer Code, implementing the Product Liability Directive.

Under the fault-based tort liability approach (Article 2043 Civil Code), consumers may sue in tort manufacturers for damage caused by defective products. Under Article 2043 Civil Code, the plaintiff must prove: (1) the defect; (2) the damage suffered; (3) the existence of a causal relationship between defect and damage; and (4) negligence or fault on the part of the defendant. It can be particularly difficult for a consumer to provide evidence of fault in connection with products whose manufacturing processes are particularly complex. Although negligence is to be considered a necessary element in order to establish liability, some case law found that the defective nature of a product per se would prove negligence in the manufacturing process. Thus the manufacturer's fault can be proved by the very existence of the defect generating the injury. This might make a company's legal defence under tort law more difficult in Italy than in the UK for example.

Some court decisions have applied the strict liability regime set forth by Article 2050 Civil Code to the marketing and distribution of toxic Chemicals substances[39]. Although Article 2050 Civil Code only applies to activities that are either "hazardous" by express provisions of law, or considered inherently dangerous and likely to cause damage to the user even if appropriately handled, some decisions have ruled that it can also apply to products (e.g. gas tanks) whenever the dangerousness of the activity is "transposed" into the final product and the latter preserves a harmful potential vis-à-vis consumers. In issues connected to damages arising from performing a dangerous activity (Article 2050 Civil Code), the injured party must prove: (1) that the injurer performed a dangerous activity (according to the definition provided by case law); (2) the damage suffered; and (3) the existence of a causal relationship between the dangerous activity and damage; but (4) no evidence of fault is required (fault is presumed from the very fact of carrying out a hazardous activity).

The Consumer Code introduces a strict product liability regime. It provides detailed definitions of "product", "defective product", "manufacturer" and "supplier", and defines the scope of manufacturers' and suppliers' liability. It explicitly states that the injured party must prove the damage, the defect and causation. Proving the manufacturer's fault is not required.

Lately, recourse by plaintiffs to this cause of action has become increasingly frequent and, as the Consumer Code allows consumers to seek (alternatively or cumulatively) other forms of protection provided by law, a product liability case is mostly brought based on claims under both the Consumer Code and Articles 2043 and 2050 Civil Code (whenever applicable).

Under the Consumer Code the damages for injury to life or limb, and destruction or deterioration of property other than the defective product itself are recoverable. Redress may only be sought if recoverable property damages exceed EUR 387.00. There is no maximum limit on the amount of damages awarded.

If the victim is suing under tort law, recoverable damages include both patrimonial and non-patrimonial damage. As in Germany a basic principle of Italian tort law is that a victim may recover nothing more than the damage actually suffered. Hence, punitive damages are not contemplated in the Italian legal system. In addition, foreign judgments allowing for punitive damages have been considered as being contrary to public order and, as such, are not recognisable and enforceable in Italy.

As regards criminal and administrative penalties under REACH Regulations specific national laws apply. Legislative Decree 133/2009 provides for criminal and administrative sanctions which apply in case of violation of the obligations set forth by the REACH Regulations. Sanctions are severe and may include administrative penalties up to EUR 90,000.00 which may even apply to downstream users. Failure to make the registration is sanctioned with a penalty of at least EUR 15,000.00, as well as failure to provide the safety report can trigger a penalty of EUR 10,000.00. Legislative Decree 133/2009 sets forth criminal offenses in case of violation of the provisions regarding restriction of fuse and authorisation under the REACH Regulations. Penalties include up to three months of imprisonment and sanctions up EUR 150,000.00.

As regards specifics for Italy the CLP enforcement scheme has not been yet enacted. With reference to specific substances reference has been made to the sanctions set forth either by the Consumer Code in relation to the commercialisation of dangerous products (penalties from a minimum of EUR 10,000.00 to a maximum of EUR 50,000.00), or by Legislative Decree 133/2008 concerning the violation of REACH Regulations.

2. Other Recent Developments

The Environmental Liability Directive has been enacted in Italy by Legislative Decree n. 152/2006. As to the implementation of the directive it is worth noting that, although

37 Article 2050 Civil Code provides that whoever injures another in carrying out an activity which is dangerous per se or due to the means used is (strictly) liable for damages unless he proves that he adopted all possible measures to avoid occurrence of the damage.

38 Article 2043 Civil Code provides that any person who by wilful or negligent conduct causes unfair detriment to another must compensate the victim for any resulting damages suffered (the neminem laedere principle). Such negligence liability encompasses both the general lack of prudence or diligence and the violation of "Statutes, Regulations, Orders or Rules".

39 See Court of Venezia, 19 June 2008; Supreme Court, III Division, 10-10-1997, n. 9866.

the Decree is in force for already five years the relatively limited number of cases which have been brought before the Italian courts or treated by the competent authorities, does not allow to thoroughly appreciate the level of effectiveness of the Italian Regulation implementing the Directive.

In line with the choice made by many other member states, the Legislative Decree contains a broad definition of "operator" which include any individual or legal entity, private or public, exercising or controlling a professional activity having environmental relevance or whoever has the power to decide over technical and financial aspects of such activity including the holder of the authorisation of carrying out such activity. This could therefore also include the mother company of an affiliate doing business in Italy. Through this law, plaintiffs could therefore also direct their claims to an entity that is domiciled outside of Italy.

As regards the case of exclusion of liability the Legislative Decree has provided for both the "permit defence" and the "state of the art defence" that may be invoked by operators. According to the Italian Regulation liability is excluded – *inter alia* – when the damage is caused by an event or accident occurred before the date on which the decree has entered into force, or if whenever the damage occurred after 30 years as from the date of the event or accident.

Like in Germany, the implementation of CCS Directive is a hot topic in Italy. A draft transposition of the directive is under discussion. On 23 March 2011 the Italian government approved a draft decree which, in accordance with the EU Directives, sets forth measures to capture and storage of underground geological formation of carbon dioxide. This technique is already under experimentation in the ENEL plants of Brindisi in the context of the EU program European Energy Programme for Recovery (EEPR) and of the program NER 300. The decree shall be in conformity – *inter alia* – with the following principles.

The activity of capture and storage of carbon dioxide shall be subject to a specific authorisation to be granted by the Ministry of the Economic Development, in accordance with the Ministry of Environment, upon specific investigations aimed at assessing the suitability of the underground formation involved. Specific safety measures shall be identified through monitoring analysis and studies carried out by independent bodies and relevant costs shall born by the applicants. Adequate warranties, both technical and economic shall be granted by those who apply for the relevant authorisations for the activity of capture, transportation and storage of carbon dioxide. Finally, effective and clear information shall be provided to the public concerning the environmental data of the plants and transportation infrastructures.

3. Relevant Case Law

New legislation to govern consumer class actions in Italy (the "Law") was enacted in December 2007. The Law was originally intended to come into force in June 2008, but in January 2009 was pushed back still further to address some of the concerns expressed. The Law finally entered into force on 1 January 2010.

Approximately 15 class actions have been filed since January 2010. The first class action filed – relating to alleged overdraft fees charged by a major Italian bank – was declared non admissible by the Court of Turin last April.

By an order published on 27 December 2010 the 8th Division of the Civil Court of Milan declared the admissibility of a class action sponsored by Codacons (one of the most active Italian consumers associations) against a medical devices company in connection with a do-it-yourself detection test of the A and B flu viruses, including the virus for swine and avian flu. The order by the Court of Milan is the first decision in Italy to declare a class action admissible and the first decision issued in connection with a class claim relating to a product. The Court of Milan, besides ruling on certain procedural issues declared non admissible the class claim for product-related damage, on grounds that the defendant was not the manufacturer of the product; and declared admissible the class claim for unfair commercial practices, on grounds that the information and advertising material of the product were, prima facie, misleading, in particular because they did not warn of the risk that the test could produce false-negative results.

The order of the Court of Milan is of great significance not only because it is the first decision by which a class action has been declared admissible in Italy, but also because the court acknowledged that class actions for damage related to unfair commercial practices can in principle be brought (and could be declared admissible) in respect of incorrect or incomplete product information if it can lead consumers into purchasing a product which they would not have purchased otherwise. In addition, by ruling that the product-related claim was non admissible only on grounds that the defendant was not the manufacturer, the decision implicitly admits the possibility of class actions for product-related damage.

In light of the above, developments on class actions might become relevant for the Chemicals industry. Companies might therefore want to monitor these developments.

V. France[40]

In France, the Chemicals industry remains a major sector and is picking up again after a few difficult years with the industry production increased by more than 10% and the industry turnover up by 14% (to reach 77.1 billion Euro) in 2010[41]. The importance of the French Chemicals

40 Authored by Thomas Rouhette and Christelle Coslin.

41 Source: French trade union for the Chemicals industries (*"Union des industries chimiques"*) http://www.uic.fr/actualite-26862-2010-annee-reprise-significative-industrie

industry within Europe is furthermore reflected by the fact that almost 10% of the dossiers submitted pursuant to the REACH declaration process originated from France[42].

As elsewhere, actors of Chemicals industry have nowadays to comply with an increasing number of regulatory requirements in France. Indeed, the current French regulatory framework in compliance with European law could be enriched by the prohibition of specific chemical substances in a foreseeable future.

1. Developments in statutory law

French rules on chemicals are codified in the French Environmental Code. Two ordinances were recently adopted to implement in France the European Regulations related to chemicals: the Ordinance no. 2009-229 of 26 February 2009 and the Ordinance no. 2010-1232 of 21 October 2010. These texts have completed the obligations with which producers, importers or downstream users have to comply, as well as the sanctions attached to such obligations.

Chemical products (as any products) shall, under normal conditions of use or under other reasonably foreseeable circumstances, provide the safety that can legitimately be expected from them and shall not create any danger to public health (Article L. 221-1 of the French Consumer Code). This text sets out a general safety standard that any producer or importer of chemical substances has to meet.

In addition to this general safety requirement, the obligations imposed by European Regulations on producers, importers and downstream users also apply under French law. Indeed, the French provisions which were enacted directly refer to such European Regulations on Chemicals safety. Regarding the REACH Regulations, for example, the French Environmental Code explicitly states that *"the manufacturing, the placing on the market, the use of these substances contained in mixtures or articles are regulated by Regulation (EC) n° 1907/2006 [...]"* (Article L. 521-1). Similarly, concerning the CLP Regulation, the same Code provides that *"the rules of classification, packaging and labelling of substances and preparations are defined by European regulations or, in case, by a Decree in order to implement European Directives"* (Article L. 521-9).

Some of these rules are furthermore reiterated in the French Labour Code, such as those stating that the supplier of Chemicals substances or dangerous preparation has to provide to the recipient a safety data sheet in compliance with Annex 2 of the REACH Regulation (Article R. 4411-73 of the French Labour Code).

All manufacturers and importers have to stay informed of the evolution of knowledge and have to notify the administrative authority any new information they have regarding the dangerous properties of the substances they use (Article L. 521-5 of the French Environmental Code). However, this information is not required if the producer or importer has already informed the European Chemicals Agency ("ECHA").

Having complied with this notification process may be of critical importance when it comes to assessing the liability arising from a Chemical product. Indeed, according to the strict product liability regime provided in the French Civil Code (as a result of the implementation of the European Directive no. 85/374 concerning liability for defective products), the producer may be exonerated from its liability if he may prove that the state of scientific and technical knowledge, at the time of the entry of the product into circulation, was not such as to enable the discovery of the defect.

The French Ministry for Ecology, Energy, Sustainable Development and the Sea is as a matter of principle the authority responsible for the enforcement of European Regulations on chemicals. This being said, however, the French Environmental Code delegates this responsibility to other authorities empowered to the effect of performing such function. This Code also provides for offences and penalties associated to infringements of European law.

Administrative authorities, such as custom officials, agents of the General Directorate for Consumers Affairs and against Fraud (the "DGCCRF"), or investigators of the French Health Products Safety Agency (the "AFSSAPS") are allowed to control the accurate implementation of the following European Regulations by any businesses located in France (Article L. 521-17 of the French Environmental Code):

- Regulation no. 1005/2009 on substances that deplete the ozone layer,
- Regulation no. 689/2008 concerning the export and import of dangerous chemicals,
- Regulation no. 850/2004 on persistent organic pollutants,
- Regulation no. 842-2006 on certain fluorinated greenhouse gases,
- Regulation no. 1907/2006 concerning the Registration, Evaluation, Authorisation and restriction of Chemicals (REACH)
- Regulation no. 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP).

Producers, importers and downstream users have to make available to such authorities a technical file on the substances they use. Non-compliance with such standards might lead a company to be ordered to pay a fine of a maximum amount of EUR 15,000.00 under a daily penalty of EUR 1,500.00 per day of delay (Article L. 521-18 of the Environmental Code). Permanent measures may

42 Statistics available on ECHA website http://echa.europa.eu/doc/press/registration_stats_20101201_en.pdf

also be pronounced and they consist of prohibiting the importation, production or distribution of such substances.

Under some circumstances, the harmful effects of a product or substance may constitute grounds for criminal liability and sanctions. For instance, producers might incur liability for the following offences: deceit, endangering the life of others, or manslaughter. The importation of unregistered substances under REACH may lead to criminal sanction being ordered against the producer or the manufacturer. This might result in the order to pay a fine of a maximum amount of EUR 75,000.00 and two years of imprisonment.

2. Other Recent Developments

The impact of Chemical products is nowadays debated often in France. Such discussions have a large scope since they may lead to the adoption of new specific labelling requirements, the prohibition of some large categories of Chemicals substances such as phtalates and parabens or the prohibition of exploitation of shale gas because of the extensive use of chemicals in the extraction process.

As a recent example of additional labelling requirements, one should note that pursuant to a Decree of 23 March 2011, producers of construction products such as walls and ceilings coverings, paints and varnishes are now obliged to mention any polluting substances on the packaging of their products. As a result, all chemical substances which may cause adverse effects on human health shall be mentioned. These new provisions apply to all products put on the market after 1st January 2012. For products put previously on the market, such labelling will have to be implemented by 1st September 2013.

On 3 May 2011, the Assemblée Nationale voted, in first reading, in favour of a ban on two categories of Chemicals substances largely used, namely phthalates and parabens. Phthalates are chemical compounds used in a large variety of consumer products, such as plastic wrapping, shoes, bags, toys, among others. Parabens are preservatives used in a large variety of formulas, mainly in the cosmetics industry. These substances are blamed for alleged hormone disrupting effects which may affect the human reproductive process.

The draft bill thus prohibits "*the manufacturing, the importing and the sale of products containing phthalates, parabens and alkylphenols*", even though the hazards of all phthalates substances would not be demonstrated to date. Other countries outside Europe (Canadia, California, Japan) also consider taking measures to limit the use of phthalates in consumer products. In Europe, phthalates have already been the subject of restriction of use in some kinds of products (for example, toys under the Directive no. 2005/84/EC of 14 December 2005 implemented into French law by the Decree no. 2006-1361 of 9 November 2006, medical devices under the Directive no. 2007/47/EC of 5 September 2007 implemented into French law by the Ordinance no. 2010-250 of 11 March 2010 and in cosmetic products under the Directive no. 76/768/EEC modified by Directive no. 2004/93/EC of 21 September 2004 implemented into French law by five amended Ordinances of 6 February 2001).

A divisive debate on shale gas is currently ongoing not only among French politicians but also French citizens. Several proposed bills were introduced before the French National Assembly to prohibit permanently the exploitation of shale gas and cancel the licences already granted to operators to explore some parts of the south of the French territory in their search for shale gas. Critics highlight the environmental damage that could result from the drilling methods: the exploitation of shale gas indeed requires large volumes of water and detergents which would likely cause severe pollution.

On 11 May 2011, the National Assembly approved one bill pursuant to which shale gas exploration and exploitation would be banned and the companies holding exploration licences will submit a report within two months after the enactment of this bill describing the methods used foe exploration purposes. Depending on this report, licences could be cancelled and it is also proposed to implement a EUR 75,000.00 penalty and one year of imprisonment against those who would perform unauthorised drilling and hydraulic fracturing (or fracking) activities. This bill will be considered by the French Senate in June.

3. Relevant Case Law

The French Supreme Court has recently developed a specific line of case law about causation in pharmaceutical cases. Indeed, the burden of proof has been alleviated in favour of alleged victims of defective products. With six judgments handed down on 22 May 2008, the French Supreme Court modified its position to require from the judges that they support their decisions with sufficient factual arguments notwithstanding epidemiology showing a causal link or not. In this respect, the judges can rule on the basis of serious, precise and concordant presumptions. On the contrary, they can no longer rely only on the lack of scientific certainty to dismiss the claims. As per the current position of the French Supreme Court, trial judges must primarily refer to individual circumstances and have, on this, the discretionary power to find causation or not.

Furthermore, still in the pharmaceutical field, the burden of proof of causation is nowadays partially amended compared to the general rule of tort liability according to which the burden of proof falls on the claimant (Article 9 of the French Civil Code of procedure). The French Supreme Court held on 24 September 2009 that, once it is established that the damage suffered by a victim results from a certain hormone, it is the manufacturer's duty to prove that it is not the drug which it

marketed which is at the origin of the damage. If it cannot be established which one of several possible producers manufactured the product, the victim may obtain full compensation for his or her injury from any of the companies which allegedly and possibly contributed to the damage. Indeed, there is no market-share liability under French law.

Consequently, the case law is currently unsettled on causation and may lead to inconsistent decisions of judges ruling on the merits of claims related to damages allegedly caused by vaccines or medications. In the future, it cannot be excluded that similar positions could be adopted in relation to other kinds of Chemicals substances.

VI. Interim Conclusion

This concludes the first part of this overview on recent developments on liability topics for the Chemicals industry. It can be summarised that various topics are simultaneously debated in the various European countries. However, their treatment and legal requirements may differ. It will therefore be important for companies to monitor these variations to maintain control over liability risks. A consistent approach that nonetheless respects national peculiarities will be key in this regard. This article will be continued in the next issue with overviews on recent developments in China and the US.

*Bettina Enderle und Markus Masseli**

Die Verbotsodyssee eines Stoffes – Zum Dilemma stoffrechtlicher Verbote am Beispiel von Dimethylfumarat

I. Einleitung

Im Mai hat die Kommission nunmehr ihre Konsultation zu Dimethylfumarat (DMF) abgeschlossen. Damit tritt voraussichtlich bis Ende 2011 die Beschränkung von DMF in Erzeugnissen in Kraft. Dies wird der letzte „Hafen" nach einer regelrechten Verbotsodyssee des Stoffes sein, der wegen vermuteter akuter Gesundheitsgefahren schon Ende 2008/Anfang 2009 durch nationale Maßnahmen in Belgien, Frankreich und Spanien in Produkten verboten worden war.

Der Biozid-Wirkstoff DMF ist ein illustratives Beispiel für eine immer deutlicher werdende Schwäche der REACH-Verordnung:[1] Die vorgesehenen Verfahren sind wegen der umfassenden Beteiligung von betroffenen Kreisen und Behörden und der Abwägung betroffener Interessen schwerfällig und langwierig. Eilinstrumente stehen für den Fall akuter Gefahren nicht zur Verfügung. Bei den "schneller" wirksamen Verboten der Biozid-Richtlinie und des Produktrechts verbleiben jedoch wesentliche Schutzlücken. Das REACH-System stößt in seiner jetzigen Form somit selbst in vergleichsweise alltäglichen Fällen an seine Grenzen. Auch löst die REACH-Verordnung nicht ihr Versprechen ein, die Vereinheitlichung und Konsolidierung des Stoffrechts voranzutreiben und dafür einen einheitlichen und möglichst umfassenden Regelungskodex zu schaffen.[2]

Der folgende Beitrag versucht aufzuzeigen, welche Konsequenzen aus dem Beispiel Dimethylfumarat gezogen werden können, um das Stoffrecht weiter zu vereinheitlichen, zu vereinfachen und damit schlagkräftiger zu machen.

II. Dimethylfumarat (DMF)

DMF[3] wird vor allem als Wirkstoff in Bioziden verwendet, um Produkte vor Schimmelpilzbefall während der Lagerung und des Transports bei feuchtem Klima zu schützen. Es ist oft in kleinen Trockenmittel-Beuteln enthalten, die entweder an den Produkten befestigt (z. B. bei Ledermöbeln) oder den Verpackungen beigefügt sind (z. B. in Schuhkartons). DMF kommt jedoch nicht nur in der Lederindustrie, sondern auch bei anderen Produkten zum Einsatz, z. B. in Verpackungen von Elektro(nik)geräten oder in mit Stoff verkleideten Schmuckschatullen. Zuweilen werden Produkte auch direkt mit DMF-haltigen Gemischen imprägniert (Bekleidung, Vorhänge, Ledermöbel, Spielzeug und viele andere Produkte).[4]

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1 Verordnung (EG) Nr. 1907/2006 vom 18. Dezember 2006 zur Registrierung, Bewertung, Zulassung und Beschränkung chemischer Stoffe (REACH-Verordnung) (ABl. EU L 396/1 vom 30.12.2006), in Kraft getreten am 1. Juni 2007, zuletzt geändert durch Berichtigung der Verordnung (EU) Nr. 143/2011 vom 17. Februar 2011 zur Änderung von Anhang XIV der REACH-Verordnung (ABl. EU L 44 vom 18.2.2011).

2 Siehe etwa Erwägungsgrund 9 der REACH-Verordnung.

3 EC Nr. 210-849-0, CAS Nr. 624-49-7.

4 Vgl. Beschränkungsvorschlag Frankreichs vom 15.4.2010, S. 11 f., abrufbar (in Englisch) unter http://echa.europa.eu/doc/restrictions/annex_xv_restriction_report_DMFu_en.pdf.