International Hazardous Substances Newsletter

December 2013

Dear Clients and Colleagues,

Please find below the third Hogan Lovells update on legal developments relating to regulated and potentially hazardous substances prepared by our Product Liability Network.

We hope that it will be of interest to you.

Rod Freeman & Sylvie Gallage-Alwis

EU

NEW CHEMICAL REQUIREMENTS FOR TOYS ENTER INTO FORCE

The EU's new chemical requirements for toys started applying from 20 July 2013, with the intention of increasing the level of protection of child safety in the EU. By way of background, on 30 June 2009, a new Toy Safety Directive was published (Directive 2009/48/EC), expanding the existing rules for the marketing of toys that are produced and imported into the EU with a view to reducing toy related accidents and achieving the highest level of health and safety standards. This new Directive came into force on 20 July 2009 and companies had until 20 July 2011 to comply. However, the European Commission recognising that this is a complicated area, decided that the parts of the Directive relating to chemical content would only come into force on 20 July 2013.

The general ban on substances which are carcinogenic, mutagenic or toxic to reproduction, as well as on 55 allergenic fragrances, is now expressly incorporated in the new Toy Safety Directive regime. In addition, labelling is now required for 11 potential allergens. Finally, strict limits apply for 19 so-called "heavy elements" such as lead or cadmium.

For more information, contact Rod Freeman *or* Cécile Duchesne

NEW BIOCIDES REGULATION IMPROVES HUMAN HEALTH AND ENVIRONMENTAL PROTECTION

A new Regulation on biocidal products (Regulation EU 528/2012), concerning the placing on the market and use of biocidal products, applies from 1 September 2013. It repeals and replaces the former Directive 98/8/EC.

The new Biocides Regulation is intended to significantly increase the safety and simplify the authorisation procedure of biocides used and placed on the market in the EU. Biocides are chemicals used to suppress harmful organisms such as pests and bacteria, including insect repellents, disinfectants and industrial chemicals like material preservatives. The new Regulation offers the possibility to request an EU-wide authorisation for biocidal products, which will allow the industry to directly place their products on the entire EU market. This new Regulation is also the first piece of legislation to integrate the new Commission definition on nanomaterials.

For more information, contact Rod Freeman *or* Cécile Duchesne

EUROPEAN COMMISSION TAKES ACTION AGAINST CYPRUS AND ESTONIA FOR FAILURE TO ADEQUATELY ENACT ROHS LEGISLATION

In October 2013, the European Commission urged Cyprus and Estonia to send details about how EU legislation on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS) is being enacted in their domestic laws.

Both Cyprus and Estonia have failed to enact technical measures on exemptions for certain equipment containing lead or cadmium. Cyprus has also failed to enact rules on the limitation of hazardous substances in electronic equipment into national law. If Cyprus and Estonia fail to act within two months, the cases may be referred to the European Court of Justice, where financial penalties may be imposed.

For more information, contact Rod Freeman *or* Cécile Duchesne

THE DIRECTIVE ON RADIOACTIVE SUBSTANCES IN WATER INTENDED FOR HUMAN CONSUMPTION HAS JUST BEEN PUBLISHED

The Council Directive 2013/51/Euratom of 22 October 2013 lays down quality standards and establishes monitoring process with regard to radioactive substances in water intended for human consumption. It applies to water intended for drinking, cooking, food preparation or other domestic purposes, regardless of its origin. It also applies to water used in food-production unless the national authorities believe the quality of the water could not affect the wholesomeness of the foodstuff in its finished form. Natural mineral waters and waters which are medicinal products are excluded from the scope of the Directive. Member States may exempt from the Directive water intended exclusively for purposes for which the authorities have acknowledged that the quality of the water has no influence on the health of the general public and water from an individual supply providing on average less than 10 m^3 per day, or serving fewer than 50 persons, unless the water is supplied as part of a commercial or public activity.

Member States will have to set parametric values of radioactive substances in water above which they will assess whether the presence of radioactive substances presents a risk to human health. A monitoring of these values and of the indicative dose[1] will have to be undertaken by Member States. In case of a failure to comply with a parametric value, an investigation will be carried out. If a risk to human health is identified, actions will be taken and the public informed and advised on precautionary measured.

The Member States have until 28 November 2015 to bring into force all the laws and regulations necessary to comply with the Directive.

For more information, contact Sylvie Gallage-Alwis *or* Claire Massiera

[1] The indicative dose is the committed effective dose for one year of ingestion from all the radionuclides whose presence has been detected in a supply of water intended for human consumption, excluding tritium, potassium-40, radon and short-lived radon decay.

Australia

PESTICIDES: FORMER STEWARD CLAIMS THAT HIS PARKINSON'S DISEASE HAS BEEN TRIGGERED BY THE SPRAYING OF PESTICIDES IN PLANES

A former steward of Qantas airlines claims that he has developed Parkinson's because of the use of pesticide sprays in planes (before take-off and landing). He states that he has no family history of Parkinson's and alleges that studies show that this disease would be linked to pesticides.

According to his statements to the media, he intends to file his claim in 2014. His Counsel stated that a significant number of other former cabin crew workers would be ready to launch similar proceedings.

For more information, contact Sylvie Gallage-Alwis

France

NEW REGULATION ON THE PROTECTION OF WATERS AGAINST POLLUTION CAUSED BY NITRATES FROM AGRICULTURAL SOURCES

Two orders have recently been published in order to finalise the creation of action and monitoring programmes aiming at reducing pollution by agricultural nitrates.

Both orders have been published on 23 October 2013 and implemented in accordance with the EU Directive of 12 December 1991 (91/676/EEC) concerning the protection of waters against pollution caused by nitrates from agricultural sources.

The first order contains provisions regarding the use of nitrogen fertilisers on slopes or water-saturated soil. It also provides for a minimum area of vegetation near waterways. The function of this vegetation is to prevent the risks of percolation of nitrates, in particular during periods of rain, which could otherwise contaminate the waters.

According to the second order, a working group should shortly be created in order to establish regional monitoring programmes. This group will be comprised of representatives of the authorities, of manufacturers and of consumers. Members of non-governmental agencies focusing on the protection of the environment should also participate.

These orders have been published after a decision handed down by the Court of Justice of the European Union on 13 July 2013 according to which France did not correctly implement the Directive of 12 December 1991.

For more information, contact Sylvie Gallage-Alwis *or* Constance Tilliard

RECOMMENDATION OF THE COUNCIL ON THE SAFETY TESTING AND ASSESSMENT OF MANUFACTURED NANOMATERIALS

On 19 September 2013, the Organisation for Economic Co-operation and Development (OECD) published a new recommendation, numbered C(2013)107 on "*the safety testing and assessment of manufactured nanomaterials*". Under this Recommendation, the members of the OECD are advised to apply the existing international and national chemical regulatory frameworks or other management systems when they face issues relating to the management of the risks of manufactured nanomaterials. In the absence of any specific regulations regarding manufactured nanomaterials, the members are advised to try to find a solution to adapt the existing regulations to take into account the specific properties of manufactured nanomaterials.

For this purpose, the members of the OECD are invited to use tools listed in the Annex to this Recommendation.

In France, the issue relating to the lack of specific regulations concerning nanomaterials has been addressed in a report of the French Inspectorate General for Social Affairs published in June 2013. In this report, the incompatibility of the provisions of the French Labour Code with the issues regarding nanomaterials was underlined and the report asked for a new regulatory framework.

For more information, contact Sylvie Gallage-Alwis *or* Constance Tilliard

HEALTH HAZARDS LINKED TO BITUMEN ACKNOWLEDGED BUT NOT QUANTIFIED BY THE FRENCH AGENCY FOR FOOD, ENVIRONMENTAL AND OCCUPATIONAL HEALTH & SAFETY

On 11 September 2013, the French Agency for Food, Environmental and Occupational Health & Safety published a report on bitumen. Initially, the Agency had been requested, by the French Federation of Employees in the Construction Sector ("Fédération Nationale des Salariés de la Construction" (FNSC-CGT)), to summarise the studies on materials used to build roads. The Agency has widened the scope of its analysis, in order to assess the health risks arising from the use of bitumen products and its additives in all business areas. This report was published approximately a year after a company was found guilty of gross negligence after the death from skin cancer of an employee exposed to both bitumen and UV Rays.

According to the Agency, there is a health hazard linked to the exposure to bitumen binders and their emissions. However, in light of current knowledge, it is impossible to quantify this risk. The effects of such exposure on the respiratory system are highlighted (increased risk of asthma and chronic obstructive pulmonary diseases). Cardiovascular and immunotoxic effects are also suspected. Concerning the risk of cancer, the Agency explains that the literature does not establish a statistically significant link between skin cancers and the exposure to bitumen emissions.

The experts who carried out the study recommend preventing the risks of exposure by using ventilation and smoke aspiration systems. They also recommend using products and procedures that would reduce the exposure. They suggest adapting the work hours to prevent the impact of heat and the exposure to both UV Rays and bitumen. Finally, the experts suggest using personal protective equipment to protect the skin and the respiratory system and to monitor the dermatological and respiratory conditions of the exposed workers.

The Agency draws the attention of the reader to the fact that, considering the current economic context, the majority of roadworks today will be renovation and maintenance works of the existing network. As a consequence, the Agency advises to closely monitor the potentially dangerous emissions caused by recycling and planing works.

For more information, contact Sylvie Gallage-Alwis *or* Claire Massiera

Germany

STATEMENT BY THE GERMAN FEDERAL GOVERNMENT ON HEAVY METALS AND OTHER POTENTIALLY TOXIC METALS IN GERMANY

Due to a formal request by several Members of Parliament, on 13 June 2013, the Federal German Government published a 7-page statement on the health risks due to multiple exposures to heavy metals and other potentially toxic metals in Germany (the statement is available in German only under http://dip21.bundestag.de/dip21/btd/17/136/1713688.pdf).

The key points in the statement are as follows:

- The German Federal Government stresses the importance of the protection of the environment from heavy metal pollution. It further states that it will have a particular focus on food and commodities as well as on pharmaceutical and medicine products.
- The German Federal Government stated that – for now – the existing exposure limit values for metals (especially for lead and mercury) are sufficient and effective.
- The German Federal Government stated that – currently – it does not see the need to restrict heavy metals or other potential toxic metals with respect to toners used in laser printers. Moreover, the German Federal Government also stated that it does not intend to introduce any new labelling requirements in this regard.
- The German Federal Government stated that it sees no need to change the practice of using aluminium as an adjuvant in vaccine.

For more information, contact Sebastian Lach, Sebastian Polly *or* Nicole Boeck

JUDGMENT BY THE HIGH ADMINISTRATIVE COURT OF BADEN-WÜRTTEMBERG: PESTICIDE RESIDUES IN NATURAL MINERAL WATER ARE ACCEPTABLE

In its judgment dated 20 June 2013, the High Administrative Court of Baden-Württemberg (*Verwaltungsgerichtshof Baden-Württemberg*) held that there is no general requirement that natural mineral water be free of pesticide residues and other loading substances (case numbers 9 S 2883/11, 9 S 2884/11, 9 S 2885/11, 9 S 2886/11 and 9 S 2887/11).

A federal state authority had detected pesticide residues in five sources of water. As a consequence, the authority revoked the permissions of seven mineral water companies using water from the respective sources and also banned the sale of the mineral water potentially affected.

The court held that – for this particular case – there are no applicable limit values in the German law and therefore the authority's actions were unlawful.

For more information, contact Sebastian Lach, Sebastian Polly *or* Nicole Boeck

Italy

GUIDELINES ON MICROBIOLOGICAL ANALYSIS OF COSMETIC PRODUCTS

The National Health Institute (Istituto Superiore di Sanità, which is the technical and scientific agency of the Italian Ministry of Health "ISS") has recently issued guidelines on the microbiological analysis of cosmetic products.

Current legislation on cosmetic products does not state that cosmetics should be sterile per se, although it provides that the presence of microorganisms in cosmetic products has to be limited.

Neither Regulation no. 1223/2009 nor the previous legislation specify which testing procedures should be followed to conduct microbiological analysis for cosmetic products. ISS has issued specific guidelines in order to help all those involved in this testing procedure, providing analytical methods for the detection of microbiological parameters, helpful for evaluating safety characteristics of cosmetics. The guidelines have been published on the ISS website (http://www.iss.it/binary/publ/cont/13_15_web.pdf).

For more information, contact Christian Di Mauro *or* Jacopo Bartolomeo

RESEARCH OF THE UNIVERSITY OF TURIN ON TITANIUM DIOXIDE

Titanium dioxide is a compound often used in cosmetic products (for example, in sunscreens), in products for personal hygiene (such as toothpaste) and also in the food industry (as an additive, colorant, under the abbreviation E171), and it is generally considered a safe product. A team of Italian researchers at the University of Turin, however, has suggested that- following in vitro tests - in the presence of ultraviolet radiations, the compound can cause toxic effects and that it may alter the structure of outer skin. In this respect, they suggest a system to improve the safety profile of these products. The results of the study were presented on the review Chemical Research in Toxicology.

For more information, contact Christian Di Mauro *or* Jacopo Bartolomeo

The Netherlands

DUTCH SENATE ACCEPTS THE LEGISLATIVE PROPOSAL FOR A BASE NETWORK FOR THE TRANSPORTATION OF HAZARDOUS GOODS

The legislative proposal for the introduction of the Base Network (*Basisnet*) for the transportation of hazardous goods has now been approved by the Dutch Senate (*Eerste Kamer*).[2] By setting 'risk maxima' for the transportation of hazardous goods over roads, railways and navigational routes, the Base Network is intended to provide more clarity about the maximum and acceptable risks in relation to the transport of hazardous goods. The Base Network is furthermore intended to increase the safety of people who live in residential homes that are built close to the infrastructure. Moreover, the Base Network is intended to make sure that the transportation of hazardous goods between important industrial locations in the Netherlands and abroad can be guaranteed, now and in the future.

For the introduction of the Base Network, amongst other acts, the Carriage of Dangerous Goods Act and the Carriage of Dangerous Goods (Act) Decree have been amended. It is expected that the Act on the Base Network will enter into force on 1 January 2014.[3]

For more information, contact Karen Jelsma

[2] Reference is made to the 2nd Edition of the International Hazardous Substances Newsletter.

[3] http://www.eerstekamer.nl/wetsvoorstel/32862_wijziging_wet_vervoer and http://www.gevaarlijkestoffen.net/index.php/502-eerste-kamer-stemt-in-met-wet-basisnet

ANNOUNCEMENT OF SAFETY MEASURES FOR LARGE CHEMICAL COMPANIES

On 3 September 2013 the Dutch government has provided the House of Representatives with a package of measures that should improve safety at large chemical companies falling within the scope of the Major Accidents Risks Decree 1999 (*Besluit risico's zware ongevallen*), the so-called "Brzo-companies".[4]

The measures are a response of the government to a recent investigation carried out by the Dutch Safety Board (*de Onderzoeksraad voor de Veiligheid,* the "OvV")[5] and a related advice of the Council for the Environment and Infrastructure (*Raad voor de leefomgeving en infrastructuur,* the "Rli").

Firstly, like the OvV and the Rli, the government has considered that it is primarily the business industry itself that is responsible for the safety and protection of employees and of the environment. On this basis, the government urges industry to develop initiatives to improve the level of safety.

In addition, the government has indicated that the current structure of supervision will remain as it is. Upon the instruction of the provinces and municipalities, the Regional Implementation Services (*Regionale Uitvoeringsdiensten,* the "RUD") is entrusted with the supervision of companies that work with large quantities of hazardous substances. The government is convinced that the RUD is able to fulfill this role.

Having said that, the government wants to create the opportunity to take action in exceptional cases. In this respect, the State Secretary of Infrastructure and Environment (S*taatssecretaris van Infrastructuur en Milieu*) will be given the authority to take direct and immediate action if the safety of humans or the environment is at risk. This could happen, for example, in case of imminent disasters or when a company does not comply with its licensing requirements.

Furthermore, together with the Association of Provincial Authorities (*Interprovinciaal Overleg*), the Association of the Netherlands municipalities (*Vereniging van Nederlandse Gemeenten*), the Inspection Service of the Ministry of Social Affairs and Employment (*Inspectie Sociale Zaken en Werkgelegenheid*) and the Public Prosecution Service (*Openbaar Ministerie*), the government will prepare a long-term plan for points of further improvement. The government has already emphasized that, amongst other things, this long-term plan should cover the overlaps in the different licensing requirements and the creation of a uniform supervision of the companies.

For more information, contact Karen Jelsma

INSPECTIONS OF THE COMPLIANCE WITH REACH AND CLP LEGISLATION

The REACH and CLP inspections performed in the Netherlands in 2012 showed that companies are complying well with their obligation to (pre)register their substances and preparations. However, in respect of the required Safety Data Sheets and the presence of certain substances in products (such as Substances of Very High Concern (*ernstige zorgstoffen*), the "SVHC's"), the inspections showed that further improvement is necessary.[6]

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4 http://www.rijksoverheid.nl/onderwerpen/gevaarlijke-stoffen/nieuws/2013/09/03/veiligheid-bij-grote-chemische-bedrijven-wordt-versterkt.html and http://www.rijksoverheid.nl/documenten-en-publicaties/kamerstukken/2013/09/03/kabinetsreactie-op-ovv-rapport-en-rli-advies-over-odfjell.html

5 In relation to the safety at the Odfjell Terminals Rotterdam during the 2000-2012 period. For an English summary of the report of the OvV reference is made to: http://www.onderzoeksraad.nl/uploads/phase-docs/339/d477bf4d8c42rapport-odfjell-web-en-beveiligd.pdf

6 http://www.vwa.nl/actueel/nieuws/nieuwsbericht/2035882/europese-regels-voor-chemische-stoffen-niet-allemaal-even-goed-nageleefd and for the English version of the Annual Report reference is made to: http://www.inspectieszw.nl/Images/Annual-Report-of-Enforcement-of-REACH-and-CLP-2012_tcm335-343664.pdf

This appears from the 'Annual Report of Enforcement of REACH and CLP 2012 dated 25 June 2013' prepared by the Human Environment and Transport Inspectorate (*Inspectie Leefomgeving en Transport*), the Netherlands Food and Consumer Product Safety Authority (*Nederlandse Voedsel- en Warenautoriteit*), and the Inspectorate SZW (*Inspectie Sociale Zaken en Werkgelegenheid*). Every year, these inspectorates carry out inspections at companies handling chemical substances and mixtures (*i.e.* producers, importers, traders and end-users) to determine to what extent these companies comply with the REACH and CLP legislation. The results of these inspections and the enforcement by the inspectorates are included in the Annual Report.

According to the Report, all the inspected companies in 2012 had carried out the mandatory (pre)registration of their substances by registering their substances with the European Chemicals Agency (the ECHA). The inspections, however, also identified violations in relation to the required Safety Data Sheets: more than half of the companies failed to meet their labeling obligations and their obligations to provide sufficient information about the hazards of the substance or mixture involved. This was particularly the case at end-users and smaller companies that produce mixtures (such as paint, and washing and cleaning products). The inspectorates have indicated that smaller companies generally still do not have sufficient knowledge and experience to classify and label hazardous substances accurately.

The inspectorates also inspected the compliance of companies with the prohibitive provisions of REACH and compliance with the obligation to notify the presence of SVHC's in products. During this inspection it was found that, amongst other things, of the samples of toy products analysed, 27% contained excessive concentrations of banned plasticizers. In addition, it was identified that certain of the products sampled contained more SVHC's than the legal limit at which a notification of the presence SVHC's is compulsory.[7]

Next year the inspectorates will continue their inspections. The inspectorates have emphasized that they will enter into discussions with the industry associations, trade unions, professional associations and the health and safety authorities to establish what they can do to improve the compliance with the REACH and CLP legislation.

For more information, contact Karen Jelsma

Spain

NEW REGULATION FOR COSMETICS AND HEALTH PRODUCTS IN SPAIN

Until recently, cosmetic and health products are regulated in Spain in Royal Decree 1599/1997, of 17 October 1997. This Royal Decree implemented Directive 76/768/EC which was intended to unify the provisions and characteristics to which cosmetic products must conform and prescribe rules for their labeling and for their packaging.

However, the implementation of the EU Directive in different Member States had resulted in a diverging application of EU law. To ensure that legal requirements were implemented more uniformly throughout the Community, the European Parliament and the Council of the European Union published the Regulation nº 1223/2009 of 30 November 2009. The aim of this Regulation is to strengthen certain elements of the regulatory framework for cosmetics in order to ensure a high level of protection of human health.

In order to complement the provisions established in the new Regulation, the Spanish Parliament will soon publish a Royal Decree which regulates the cosmetic and personal care products, and complements the provisions of Regulation nº 1223/2009. According to the provisions contained in the Draft of the Royal Decree, which has already been published in the Spanish Ministry of Health website, cosmetics will be included in the same regulation that controls the production and distribution of medicines.

[7] http://www.inspectieszw.nl/Images/Annual-Report-of-Enforcement-of-REACH-and-CLP-2012_tcm335-343664.pdf

The entry into force of this Royal Decree is going to deeply affect the actual regulation in Spain of cosmetic and personal care products. This means cosmetic manufactures will have to design a new monitoring and evaluation processes in order to comply with this new regulation.

The new Royal Decree establishes new obligations for distributors, strengthens market surveillance mechanisms and establishes a new license that must be obtained by manufactures and distributors of cosmetic products from the Spanish Agency of Medicines and Medical Devices ("AEMPS").

In line with the provisions of Regulation nº 1223/2009, when a cosmetic product presents a risk to human health, public authorities shall apply corrective measures to bring that product into conformity. These measures may provoke the removal of the product from the market or the withdrawal of the license granted by the AEMPS.

Finally, with the aim to ensure the implementation of these guarantees, the Royal Decree establishes a new regime of penalties for infringements. The penalties vary from minor infringements –i.e. obstructing an inspection-, serious infringements –i.e. distribution of cosmetic products which does not comply with the existing regulation- and very serious infringements –i.e. distribution of cosmetic products which present a risk to human health-.

Summing up, the entry into force of this Royal Decree involves a new legal framework for cosmetic products, strengthening the practical effects of the regulation and establishing new control mechanisms, which aim to ensure a higher protection of human health. Manufacturers and distributors of cosmetics products will need to be quickly adjusted to this new regulation in order to assure the correct compliance in Spain.

For more information, contact Joaquín Ruiz Echauri *or* Marta Jaureguizar

Switzerland

ENVIRONMENTAL TOXIN REPORT 2013

On 5 November 2013, the Environmental Toxin Report 2013 was released in Zurich by the independent environmental organisation Green Cross Switzerland and the US-based Blacksmith Institute.

The report provides information on the progress and challenges in remediating polluted places. (The report is available online under http://www.greencross.ch/uploads/media/pollution_report_2013_top_ten_wwpp.pdf).

Additionally, the report features an updated list of the world's ten most polluted places (This list is available online under http://www.greencross.ch/en/news-info-en/case-studies/environmental-reports/ten-most-polluted-places-2013/2013.html).

For more information, contact Sebastian Lach, Sebastian Polly *or* Nicole Boeck

United Kingdom

GOVERNMENT GUIDANCE ON THE RESTRICTION OF THE USE OF CERTAIN HAZARDOUS SUBSTANCES IN ELECTRICAL AND ELECTRONIC EQUIPMENT (ROHS) REGULATIONS 2012

In September 2013, the Department for Business Innovation and Skills published Government guidance notes for RoHS Regulations 2012. By way of background, the RoHS Regulations 2012 implement the provisions of the Recast RoHS Directive (2011/65/EU), and replace the original Regulations that came into force on 1 February 2008.

This guidance applies from 2 January 2013 (which is the date the RoHS Regulations 2012 came into force in the UK), and is addressed to all businesses and individuals placing electrical and electronic equipment on the UK market. It explains the law in brief, how to assess products to see if they are included in the scope of the UK RoHS Regulations 2012, and lists the products which are specifically excluded or exempted from the application of the RoHS Regulations 2012. It also explains the requirements and the compliance obligations imposed on economic operators at different stages in the supply chain (manufacturers, importers, distributors) in relation to the placing and making available on the market of electrical and electronic equipment. This guidance will be updated on a regular basis as necessary.

For more information, contact Rod Freeman *or* Cécile Duchesne

United States of America

WEST VIRGINIA HIGH COURT APPROVES SETTLEMENT REQUIRING 30 YEARS OF MEDICAL MONITORING FOR TOXIC TORT CLASS

On 22 November 2013, in Allen v. Monsanto Company, et al., No. 13-0418 (W.Va. Nov. 22, 2013), The West Virginia Supreme Court of Appeals upheld the settlement of a mass tort class action that could require the defendants to fund over US$100 million in property remediation and medical monitoring for certain class members over a 30-year period.

The Allen plaintiffs claimed personal injuries and property damage from the release of toxic dioxin gas from a Monsanto chemical plant between 1948 and 1968 (related to Monsanto's "2,4,5-T" herbicide operation, i.e., "Agent Orange"). After over three years of hotly contested litigation, the Circuit Court certified two distinct classes: (1) The Medical Monitoring Class, comprised of all residents, full-time workers, and full-time students within a five-mile radius of the plant during the relevant period; and (2) The Property Class, comprised of all current owners of real estate within the same area.

After an additional four years of contentious litigation including discovery and motion practice, trial preparation, and even jury voir dire, the parties reached a global settlement agreement that required Monsanto to (i) fund between US$21 million and US$84 million in medical monitoring over a 30-year period for certain members of the Medical Monitoring Class; and (ii) fund US$9 million in property cleanup for certain members of the Property Class. The parties agreed that the settlement would apply to a smaller geographic area than the 5-mile radius contemplated by the court's certification order. The agreement also would require Monsanto to pay up to US$29.5 million in attorney fees and costs.

Upon counsel and individual class members' objections to the settlement agreement, the trial court allowed extensive discovery and briefing and held a "fairness hearing" to determine whether the settlement was "fair, adequate, and reasonable."

The trial court noted that the fairness hearing is critical, because the settlement agreement is "put to a public test" and "the judiciary lends its moral force to the deal." In its opinion, the court carefully analysed 14 distinct factors, recognizing, among other things, the competency of class counsel, the apparent fairness of the negotiations, the fact that prior medical monitoring cases had not been very successful in West Virginia, and that prior claims against Monsanto for its 2,4,5-T production had been "uniformly unsuccessful."

Ultimately, the court concluded that the settlement was appropriate, overruled the objections, and dismissed the plaintiffs' claims.

On appeal, the petitioners raised ten assignments of error, most of which were subject to review for abuse of discretion; two of their objections implicated due process concerns, and thus were subject to de novo review. Nevertheless, the Supreme Court of Appeals found that the trial court had exercised proper discretion, and had not committed any legal errors.

The court's opinion, which drew on federal precedent under Rule 23 of the Federal Rules of Civil Procedure, discussed several points which may be applicable to mass tort settlements generally:

1. Upon approving the settlement, the trial court vacated its prior order decertifying the Property Class, and due process did not require the court to hold a hearing or provide a mechanism for Property Class members to opt out.

2. Although the settlement provided medical monitoring and property remediation for only a subset of the certified classes, the settlement was based on the objective evidence after extensive discovery, and in any event, settlements are not required to benefit all class members. "Class membership entitles just that - membership - but, not necessarily benefits."

3. There was no conflict of interest or collusion between the Medical Monitoring Class and the Property Class. The court distinguished the case from Amchem Products, Inc. v. Windsor, 521 U.S. 591 (1997), which involved an intra-class conflict between members presently suffering the effects of asbestos exposure and those who may suffer such effects in the future. In Allen, there was no evidence of divergent interests, especially since each class had separate funds earmarked and claims processes established.

4. The appellants were not permitted to obtain discovery concerning the parties' settlement negotiations. The court credited "the evolution of the evidence" for the disparity between class counsel's original settlement demand and the final agreement.

5. Defendants who shared expert witnesses were permitted to agree that if one defendant settled, the remaining defendants could no longer use the settling defendant's expert witnesses.

Clearly, the 30 years of medical monitoring is the most alarming aspect of the settlement. Thus, defendants should be aware of the factors that could lead to a costly medical monitoring claim, such as the following: (i) plaintiff has been significantly exposed to a proven hazardous substance, (ii) as a result, plaintiff now has an increased risk of contracting a serious latent disease, (iii) as a result, plaintiff requires periodic medical examinations, and (iv) examination procedures exist that make the early detection of disease possible.

For more information, contact Barry Thompson *or* David Skaar

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CALIFORNIA PLACES THE COMMONLY USED PLASTICIZER DIISONONYL PHTHALATE ON ITS OFFICIAL LIST OF CARCINOGENS

Effective December 20, California environmental and health regulators are placing the commonly used plasticizer diisononyl phthalate, or DINP, on its official list of carcinogens under the state's Safe Drinking Water and Toxic Enforcement Act (Proposition 65).

This decision was made on the recommendation of California's Carcinogenic Identification Committee that DINP should make the cancer-causing chemical list. The committee examined data from 12 dietary carcinogenicity studies in rats and mice, which revealed significant increases in mononuclear cell leukemia, renal tubule cell carcinomas and hepatocellular tumors. The CIC was further convinced by structure activity comparisons with other phthalates, including the compound DEHP that has been classified as a carcinogen by the U.S. Environmental Protection Agency. These findings and the resulting recommendation were directly contrary to the American Chemistry Council's claims that DINP poses no danger to human health at typical exposure levels.

Diisononyl Phthalate (DINP) is a complex of branched C-9 isomers that is used as a general purpose plasticizer to render polyvinyl chloride (PVC) flexible. It has a broad range of applications in toy manufacturing, construction, and general consumer products. Examples include beverage and food containers, vinyl flooring, roofing materials, gloves, toys and garden hoses, among others. The CIC claims that exposure is most like to occur through those consumer products.

According to reports, annual production volume of DINP, including imports to the U.S., is in the range of 100 million to 500 million pounds.

The ACC disputes the scientific basis of the state's decision, arguing that the chemical has been reviewed by several other regulatory bodies around the world that have found no evidence that the common low levels of exposure cause cancer in humans and claims that the data summaries used by the CIC are misleading. According to the ACC, high phthalates like DINP are among the most studied compounds in the world and have been reviewed by regulators in the U.S., Europe and Australia. DINP has not been labeled a carcinogen by either the EPA or the U.S. FDA. According to a 2001 report to the U.S. Consumer Product Safety Commission,"*the available data indicate that humans do not receive DINP doses from current uses of DINP-containing consumer products that are associated with a significant increase in cancer risk*.".

Of course, for our clients, the fact that this substance has been added to the list of carcinogens recognized in California is cause for some concern. There should be little doubt that plaintiffs' lawyers specializing in Proposition 65 cases are already targeting manufacturers, distributors and retailers of products containing DINP. These lawyers typically sue companies looking for a quick settlement and information allowing them to pursue other parties.

Under Proposition 65, businesses are required to provide a "*clear and reasonable warning*" before exposing anyone to a listed chemical, including placing a label on items for sale that contain the substances.

Notifications must be given unless exposure is low enough to pose no significant risk of cancer, defined by the state as causing no more than one cancer case per 100,000 people exposed over 70 years. Companies have 12 months after a chemical is listed to comply with the warning requirements. Violations of Proposition 65 subject a company to daily fines, penalties and allows for the recovery by plaintiffs of all of their attorneys' fees.

Thus, we would recommend to our clients that they carefully examine the DINP content of products sold or offered for sale in California and either conduct tests to determine the potential exposure from those products or provide the warning required by Proposition 65. In any event, we expect to see an increase in litigation relating to products allegedly containing DINP.

For more information, contact Mark Goodman