The ELD: Applicability to Nanotechnology Risk and the Liability Implications of Environmental Damage

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Abstract

This paper examines the potential impact of the European Union's Environmental Liability Directive (ELD)[1] *on the nanotechnology (NT) sector. In terms of risk governance the ELD represents a new paradigm, affording the environment an enhanced status both in legal and indeed ontological terms. However, the nature of the NT industry itself is such as to create complexity in the implementation of the ELD. Whilst the field of nano-toxicology is making advances, debate still prevails around issues pertaining to exposure, (eco)-toxicity, metrics, potential impact and legal causation. Levels of uncertainty remain high and hence measuring environmental impact is problematic. The paper addresses the potential environmental liability exposures of NT manufacturers and producers pursuant to the provisions of the ELD and by extension highlights the importance of the insurability of the liability risk all of which bears significance for the sustainability of the industry. It also examines the legal and regulatory challenges of the application of the ELD in the context of the NT industry, highlighting the challenges which this pervasive technology presents for regulatory policy. A cursory discussion of the legal theoretical underpinning of the directive helps to explain the rationale of the directive.*

I. Introduction

The nanotechnology (NT) industry poses a number of challenges for the regulatory community. Risk assessment and management in the sector remains problematic and this is reflected in the nascent risk transfer to the insurance industry which is critical for the sustainability of the industry. These risk assessment and management difficulties are, in the main, due to significant gaps in scientific knowledge in the NT field. A lack of consensus among the scientific community in the area of nano-toxicology has created uncertainty across stakeholder groups as to the threat posed by NT to both human health and the environment. Knowledge gaps persist among regulators on the nature and scale of NT operations and traditional command and control regulation has largely been unable to fully capture the activities of the NT industry across the value chain. For those

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1 Council Directive 2004/35/EC of 21 April 2004 on environmental liability with regard to the prevention and remedying of environmental damage [2004] OJ L143/56.

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charged with application and enforcement of the Environmental Liability Directive (ELD), NT represents a particular challenge. The unique nature and idiosyncratic physico-chemical properties of the materials which in themselves give the materials their value of application, could make establishing legal causation in the case of environmental damage extremely challenging. In addition, the *state of the art* defence magnifies the urgent need to narrow the gaps in the scientific knowledge. Potential liability exposures of NT under tort law in occupational settings have been previously discussed.[2] However, little discussion has taken place in relation to the potential environmental liability exposures of NT manufacturers and producers pursuant to the provisions of the ELD, which bears significance for the sustainability of the industry. The paper also examines the legal and regulatory challenges of the application of the ELD in the context of the NT industry, highlighting the challenges which this pervasive technology presents for regulatory policy.

The pervasiveness of the NT industry and early warnings of the potential for costly NT-related claims[3] is significant in the context of the insurability and sustainability of the NT industry. While no NT liability claims have been adjudicated upon to date, the scientific evidence has raised the spectre of potential latent liability exposures. Legal risk is relevant for nanomaterials (NM) manufacturers and producers who want to commercialise their products and make a profit without having to deal with claims. Legal claims are problematic from the perspective of the potential impact on profit and market share, and there is also the uncertainty in relation to when they might arise and decision-making surrounding financial reserve provision for potential latent claims. These matters pertain to the ability to transfer risk to insurance companies as risk carriers. Without insurance cover, NM manufacturers/producers carry the financial burden of remediation of damage and any ancillary legal costs themselves or, in the absence of the enactment of the financial security provision,[4] in the directive by individual Member States, the environment is left without a remedy for damage and the loss may be left to lie where it falls. For insurers, the ability to evaluate legal risk is paramount. In the absence of NT claims data, insurance companies cannot use existing actuarial methods to underwrite risk[5] and the scale of potential claims may lead insurance companies to decide either to offer cover at a rate which is not commercially viable or not to offer cover at all. Acknowledgement of the gravity of concerns surrounding NT risk led major insurers and reinsurers including Lloyds[6], Allianz[7] and Swiss Re[8] to publish reports about the potential risks and difficulties which they envisage in relation to NT insurance premium pricing, underwriting strategies and long tail risk and legal liability. We focus

[2] EM McAlea et al., "Engineered nanomaterials: risk perception, regulation and insurance" (2016) 19(4) *Journal of Risk Research* 444; Karena Hester "Nanotort Liability at Common Law", in F Murphy et al. (eds), *Managing Risk in Nanotechnology: Topics in Governance, Assurance and Transfer* (Springer 2016) 117.

[3] M Mohan et al., "Integrating Legal Liabilities in Nanomanufacturing Risk Management" (2012) 46 *Environmental Science & Technology* 7955.

[4] ELD, Art. 14.

[5] M Mullins et al., "The insurability of nanomaterial production risk" (2013) 8 *Nature Nanotechnology* 222.

[6] Lloyd's Emerging Risks Team Report, "Nanotechnology, Recent Developments, Risks and Opportunities" (2007).

[7] Allianz report in co-operation with the OECD International Futures Programme, "Small sizes that matter: Opportunities and risks of nanotechnologies" (2005).

[8] Swiss Reinsurance Company, "Nanotechnology: Small matter, many unknowns" (2004).

on the consideration of these issues and the legal and regulatory challenges of the application of the ELD in the context of the NT industry.

II. The Environmental Liability Directive

The ELD is the first environmental framework[9] directive to recognise the need for the environment[10] itself to have recourse in the event that it suffers by the actions of an economic operator.[11] The environment, in the context of the ELD, deals specifically with damage to water, land and biodiversity (flora and fauna) and does not afford a cause of action to private parties pursuing compensation for economic or any other loss suffered as a result of an environmental incident. While the prevention and remediation of environmental damage are the primary objectives, the protection of human health against damage as a result of damage to the environment is a more discreet but equally important objective of the directive. There are a significant number of references to the threat of damage to human health arising from environmental damage in the directive.[12] In fact, the directive is specifically intended to apply strict liability provisions "as far as environmental damage is concerned, to occupational activities which present a risk for human health or the environment".[13]

The rationale for the ELD is based on the preventative principle[14] and the polluter pays principle (PPP)[15] but its conceptual significance is more far reaching. One of the most interesting facets of this directive is its civil liability regime. As such it transcends the normative formula of alternative deterrence strategies inherent in traditional regulatory instruments. As a civil liability regime, it speaks directly to the competing theories of tort law. Aside from a cursory discussion, this scholarship is outside the remit of this paper, but presents an opportunity for further debate. We submit here that a mixed theory of tort law and distributive justice underpins the rationale of the directive. The first theory understands tort liability as an instrument aimed at the goal of prevention explained

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9 The ELD is described as a framework directive due to its intention to accompany and support existing Member State legislation and also due to the existence of numerous amendments which are implemented in each individual Member State at their own discretion.

10 Previous "environmental" legislation dealt with compensating third party property and person arising from an environmental incident caused by an operator.

11 An operator is considered to be those who have a financial interest in, **and** control over the operation of an occupational activity. An occupational activity is that which is carried out in the course of an economic activity, irrespective of whether it is a public or private enterprise or whether it is of a profit or non-profit nature

12 ELD, Preamble paras. 1, 7, 8, Art. 2; Annex 1 criteria for determination of "significant damage"; Annex II para. 1; Annex II paras. 1.3.1, 1.3.3; Annex II, para. 2.

13 ELD, Preamble, para. 8.

14 The preventative principle is a public international law principle. It is also an EU environmental policy that is related to the precautionary principle and is intended to prevent harmful effects of known risks. The precautionary principle, by comparison, is designed to prevent unknown and probable risks (Gert Van Calster, "European Union" in R Seerden et al., *Public International Law in the European Union and the United States – A Comparative Analysis* (Vol 5 Comparative Environmental Law & Public Policy Series (2002)) 480, cited in Lucas Bergkamp and Barbara J Goldsmith (eds) *The EU Environmental Liability Directive A Commentary* (Oxford University Press 2013) 28.

15 The PPP is an EU environmental policy principle that is intended to internalise the cost of preventative measures to prevent environmental damage and, if it does occur, to restore the environment by remediation. The PPP and preventative principles are related: the PPP becomes relevant once the application of the preventative principle has been exhausted, damage having occurred. The operator is then liable to pay for the environmental damage it causes: Bergkamp and Goldsmith, supra note 14, 26.

within the framework of the economic theory of law and deterrence, the other regards tort law as a method of achieving corrective justice.[16] A justice conception is an articulation of ordinary moral conceptions of agency and responsibility, wrongdoing and harm and reparation. As such, corrective justice links responsibility for harm with the duty to repair by the requirement of proof of causation. The causation requirement required by the fault-based provisions of the directive fits entirely within the theory of corrective justice. An economic theory articulates public morality based on the prevention of harm causing activity by deterrence.[17] It regards prevention and compensation as distinct dimensions of welfare, where the optimal sanction is financial liability. Strict liability provided for in the directive makes NT insurability all the more critical. Subjecting non-reciprocal risks to strict liability offsets the unfairness of a situation where the injured party is not in an equal position to the injuring party. When risks are not reciprocal, losses of security (harm and the risk of harm) and increases in liberty (benefits accrued from risky commercial activity) are not equally distributed from the perspective that the freedom of the injuring party to inflict harm exceeds the security of the injured party from having harm inflicted on them and their own right to impose equal risk of harm. Subjecting non-reciprocal risks to strict liability offsets this unfairness, on the basis that ex post compensation is intended to redress the harm suffered by an injured party who does not benefit from the right to impose equivalent risks on injurers who do benefit from the ability to impose such risks. It effects a more robust mutuality of benefit and distributes risk more fairly ex post. The rationale for remediation under the directive can be seen to be intended not as redress for wrongful damage but as a way of making the distribution of the burdens and benefits of non-reciprocal risks more fair than it would otherwise be and as a method of rectifying injustice. Or in other words, a regime of strict liability for non- reciprocal risks is the regime which is most advantageous to the freedom and security of those who are most disadvantaged. Accordingly, the directive speaks to aspirations of social contract theory and to the broader concept of fairness and distributive justice.[18] The precept of this view being that the burdens and benefits of beneficial yet potentially risky and harmful activity should be structured, in order that those who impose non-reciprocal risks and reap the benefits bear the burdens.[19] Considerations of distributive justice thus help us to make sense of the rationale for the structuring of the strict liability regime.

Therefore, we can say that the civil liability regime encompasses a mixed theory of tort law,[20] which could be thought of in terms of "protective justice".[21] It serves as an instrument both to deter harm by the imposition of ex-ante preventative obligations and ex-post compensation for damage caused, while appealing to distributive justice in relation to the strict liability provisions.

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[16] Christopher H Schroeder "Corrective Justice and Liability for Increasing Risks" (1989) 37 *UCLA Law Review* 439; Gary T Schwartz, "Mixed Theories of Tort Law: Affirming Both Deterrence and Corrective Justice" (1996–1997) 75 *Texas Law Review* 1801.

[17] Richard L Abel, "A Critique of Torts" (1990) 37 *UCLA Law Review* 785.

[18] GP Fletcher, "Fairness and utility in tort theory" (1972) *Harvard Law Review* 537.

[19] Gregory C Keating, "Distributive and Corrective Justice in the Tort Law of Accidents" (2000) 74 *Southern California Law Review* 193.

[20] Schwartz, supra note 16.

[21] KW Simons, "Jules Coleman and Corrective Justice in Tort Law: A Critique and Reformulation" (1992) 15 *Harvard Journal of Law and Public Policy* 849.

Recourse, in terms of the ELD, is in the form of primary, complementary and compensatory remediation for which the operator (polluter) is liable both in terms of carrying it out and bearing the costs. Therefore the ELD can be said to adopt an ecocentric rather than an anthropocentric approach whereby the preservation of the environment is not just necessary to preserve economic growth, it has an intrinsic value worthy of preservation.[22]

The polluter is liable to remediate the damage caused to the environment to the point of baseline condition – an approach aligned to the tort law concept of *restitutio in integrum* – that is, to place the environment back to the sustainable condition it was in before the event occurred.[23] If such a baseline condition is unattainable at the site of pollution the operator must therefore achieve baseline condition at an alternative site in as close proximity as possible to the original site.[24] There is recognition that the environment, in the context of ecological progression, can be impeded during these remediation measures and therefore the offending operator can also be liable to compensate the environment for any interim loss.[25] This can manifest itself in two forms: improve the ecological function of biodiversity that was affected; or improve the natural services the environment provides to the public.

Compensation is, however, the ELD's secondary focus; its primary intention is to advance prevention of environmental damage in the first instance, based on the preventative principle. Restoration in the form of heavy sanctions imposed by the ELD for damage caused are to be enforced by member state competent authorities and, coupled with the preventative principle, the ELD is designed to deter potential offenders by the internalisation of the costs of preventative measures in the first instance and restorative measures when the option of preventative measures has been exhausted. In public policy terms the ELD has shifted environmental policy from using liability regimes of compensation only to a regime of primarily prevention and restoration with compensatory measures playing a secondary role.

III. Nanomaterials

There are currently 1,800 nano-enabled consumer products registered on the consumer products inventory[26] including cosmetics and sunscreens, food additives, supplements and packaging, clothing, sports equipment, electronics and household appliances. The most common application is in the category of health and fitness products[27] and within that category personal care products comprise the largest proportion of products.

NT is also used in many non-consumer product based applications which will have a very positive impact on human life, such as in the fields of medical diagnostics

22 Tom Regan, "The Nature and Possibility of an Environmental Ethic" (1981) 3(1) *Environmental Ethics* 19.

23 Primary remediation: ELD, Annex II para. 1(a).

24 Complementary remediation: ELD, Annex II para. 1(b).

25 Compensatory remediation: ELD, Annex II para. 1(c).

26 Project on Emerging Nanotechnologies (2013). The Consumer Products Inventory is available at: <http://www.nanotechproject.org/cpi> (accessed 6 January 2017).

27 Health and fitness category comprises 742 products or 42% of all consumer products. Of that personal care products comprise 39%.

(rapid testing systems, in body diagnostic systems) and monitoring in medical treatment (targeted drug delivery devices, prostheses and implants). In environmental applications there are existing and potential applications including but not limited to soil and groundwater remediation, toxic exposure sensors and in water purification. Energy applications include clean energy production, lighting, batteries, solar energy, and fuel changing catalysts. So the benefits of this rapidly emerging and pervasive technology to individuals and society are expected to be enormous, but at the same time there are concerns that the unique properties that make NT so beneficial may give rise to hazards to the environment that will cause direct environmental damage, and in turn will cause damage to human and animal health in relation to which there are still significant gaps in the scientific knowledge of the acute and latent effects of NT.

Nanomaterials are not a uniform group of substances and are produced in many forms, sizes and matrices each with varying physico-chemical properties and behavioural differences. It is generally accepted that when NM are bound or embedded into solid matrices or materials, the probability of their effluence is generally low unless they are released in the process of degradation at the end of the life cycle. Consequently the expectation is that these particles are unlikely to be physically "free" to be airborne or water-borne to present a toxicological hazard to the environment because in a physically-bound state they are effectively "quarantined" and unable to interact with biological systems and processes and impact on human and animal health and environmental safety.[28]

Free NM on the other hand have unique physico-chemical properties such as greater mobility and ability to permeate, and due to their size, large surface area and different surface chemistry and physics can interact with biological systems and processes and thereby impact on environmental safety and human and animal health. They have the potential to cross barriers such as the blood-brain barrier and the placental barrier. Among the other physico – chemical properties of NM which are a cause of concern are their reactivity due to large surface area to mass ratio, toxicity, surface charge, capacity to accumulate or agglomerate, persistence and insolubility. Materials reduced to the nano scale show different properties to their bulk form which enable their unique applications. For example, opaque substances become transparent, stable materials become combustible, inert materials become catalysts, insulators become conductors and solids liquefy at room temperature.[29]

IV. NM – TOXICITY, ECO-TOXICITY AND RISK

Of the animal studies which have been carried out, NM have been shown to induce cytotoxic and genotoxic effects and studies have shown that some nanoparticles (NP) are potentially acutely toxic[30] However the effects and risks, especially latent risk of acute

[28] *Nanoscience and Nanotechnologies: Opportunities and Uncertainties* (The Royal Society and Royal Academy of Engineering 2004), available at: <https://royalsociety.org/~/media/Royal_Society_Content/policy/publications/2004/9693.pdf> (accessed 6 January 2017).

[29] Danial Hristozov and Ineke Malsch, "Hazards and Risks of Engineered Nanoparticles for the Environment and Human Health" (2009) 1 *Sustainability* 1161.

[30] Supra note 6.

and chronic exposure to NPs still remain uncertain.[31] Limitations in the research to date means limited availability of exposure and genotoxicity data, which means that the research is lagging the alacrity and pervasive development and commercialisation of NM products. However, research has established that exposure to NM has been associated with a number of health effects.[32] Carbon nanotubes and nano titanium dioxide at low doses[33] are known to induce pulmonary inflammation and fibrosis in animals.[34] Exposure to single and multi-walled carbon nanotubes have been shown to induce inflammatory cells and mediators in the broncho-alveolar fluid and increase pulmonary granulomas and fibrosis in rats;[35] nano titanium dioxide has been shown to cause pulmonary inflammation.

In the marine environment, NM are emerging as a new class of pollutants with eco-toxicological impacts because the NM particles can be contained in sewage waste, industrial waste and consumer product waste and can end up in waterways and reach the sea. Recent laboratory studies in invertebrates and fish suggest that exposure to NM could have harmful effects.[36]

V. ELD and NM Risk

In its incubation phase, the ELD had the potential to address the unknown risks of NT and other emerging technologies. The White Paper[37] that preceded the ELD was based on concerns expressed by members of the European Parliament and comprised sector-specific applications that would incorporate areas such as biotechnology[38] and, by extension, NT. However, the EC decided against this approach and the rationale for the horizontal approach which was ultimately adopted was that it "*would be difficult to explain*",[39] thus the directive remained in the remit of the occupational activities as it now stands.

The directive[40] was designed to provide a common framework for preventing and remediating certain forms of environmental damage by placing responsibility on

[31] Jun-Gang Li et al., "Comparative study of pathological lesions induced by multiwalled carbon nanotubes in lungs of mice by intratracheal instillation and inhalation" (2007) 22(4) *Environmental Toxicology* 415; Julie Muller et al., "Clastogenic and aneugenic effects of multi-wall carbon nanotubes in epithelial cells" (2008) 29(2) *Carcinogenesis* 427.

[32] Kai Savolainen et al., "Nanotechnologies, engineered nanomaterials and occupational safety – A Review" (2010) 48(8) *Safety Science* 957.

[33] For a review of exposure research see Kai Savolainen et al., "Risk assessment of engineered nanomaterials and nanotechnologies – A Review" (2010) 269(2-3) *Toxicology* 92.

[34] Edilberto Bermudez et al., "Pulmonary response to subchronic inhalation of ultrafine titanium dioxide particles" (2004) 77(2) *Toxicological Science* 347.

[35] Anna A Shvedova et al., "Unusual inflammatory and fibrogenic pulmonary responses to single-walled carbon nanotubes in mice" (2005) 289(5) *American Journal of Physiology – Lung Cellular and Molecular Physiology* L698; Anna A Shvedova et al., "Critical issues in the evaluation of possible adverse pulmonary effects resulting from airborne nanoparticles" in Nancy A Monteiro-Riviere and C Lang Tran (eds) *Nanotoxicology – Characterisation, Dosing and Health Effects* (New York: Informa Healthcare, CRC Press, Taylor & Francis Group 2007).

[36] Valeria Matranga and Ilaria Corsi, "Toxic Effects of Engineered Nanoparticles in the Marine Environment: Model Organisms and Molecular Approaches" (2012) 76 *Journal of Marine Environmental Research* 32.

[37] *White Paper on Environmental Liability*, Com (2000) 66 Final, 9 February 2000.

[38] To which a natural bridge exists between it and nanotechnology (Yang Dayong et al., "DNA materials: bridging nanotechnology and biotechnology" (2014) 47(6) *Accounts of Chemical Research* 1902).

[39] Supra note 37.

[40] On the distinction between directives and regulations, see <http://europa.eu/eu-law/decision-making/legal-acts/index_en.htm>.

operators to take preventative measures in the case of a threat of environmental damage, to prevent or limit further environmental damage and the adverse effects thereof on human health and to take remedial measures for damage caused. Pursuant to the polluter pays principle, which is a keystone of the directive, it provides for the cost of remediation to be borne by operators. By venturing into the highly-sophisticated national legal and doctrinal traditions of the Member States, the directive is an ambitious attempt to create a harmonised legal regime by imposing an obligation on public authorities to put mechanisms in place whereby the polluter pays principle can operate. It thereby creates a link between a civil law determination of liability and a public law compensation scheme.[41]

The definition of "environmental damage" is contained in Article 2(1). For our purposes the most relevant components of what constitutes such damage are: (a) damage to protected species and natural habitats; (b) water damage; and (c) land damage, which creates a significant risk of human health being adversely affected as a result of the direct or indirect introduction in, on or under land, of substances, preparations, organisms or micro-organisms. Under the ELD, "damage"[42] means a measurable adverse change in a natural resource or measurable impairment of a natural resource service which may occur directly or indirectly.

A strict liability regime applies to significant environmental damage caused by any of the occupational activities listed in Annex III of the directive and to any imminent threat of such damage occurring by reason of any of those activities. The idea being that strict liability should apply to those activities that are considered to be risky, which pose a potential or actual risk to human health and the environment. In the context of NM, paragraph 7(a) and (b) of Annex III specifically provide that the manufacture, use, storage, processing, filing, release into the environment and onsite transport of dangerous substances[43] and dangerous preparations[44] respectively can constitute environmental damage. Paragraph 7(d) of Annex III specifically provides that the manufacture, use, storage, processing, filling, release into the environment and onsite transport of biocidal products[45] can constitute environmental damage. The provisions of Regulation EC No 1272/2008 on classification, labelling and packaging of substances and mixtures and Regulation EU528/2012 on Biocidal Products are outside the scope of this paper, except to highlight the fact that NM fall within the ambit of both regulations, hence the substances regulated thereunder are relevant "activities" pursuant to Annex III of the ELD. Unlike the provisions of the REACH regulation,[46] there is no volume

41 Gerd Winter et al., "Weighing up the EC Environmental Liability Directive" (2008) 20(2) *Journal of Environmental Law* 163.

42 ELD, Art. 2(2).

43 Formerly regulated under Directive 67/548/EEC and now regulated under Regulation EC No 1272/2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

44 Formerly regulated under Directive 199/45/EC and now regulated under Regulation EC No 1272/2008.

45 Biocidal products are regulated under Regulation EU528/2012 and the regulation explicitly defines NM and makes regulatory provisions in relation to them.

46 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), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission

threshold to trigger application under the directive, hence "significant" damage caused by substances even in negligible quantities such as NM will bring the activities within the scope of the directive.

Under a strict liability regime there is no need to prove the subjective element, meaning that liability is established without proof of intention, recklessness or negligence. The rationale for a strict liability regime is that the operator is carrying out a high-risk activity and accordingly should be held responsible for the damage which that activity causes.

A negligence or fault-based liability regime applies to damage and to imminent threat of damage to protected species and natural habitats – not to water and land – caused by any occupational activities other than those listed in Annex III. Fault or negligence-based liability has a subjective element and reasonable foreseeability is normally an ingredient of it.

For an operator to be held liable for damage to species and habitats, significant[47] damage must be caused to species or habitats designated under previous EU legislation such as the Wild Birds Directive[48] and Habitats Directive[49] the natural resources of which jointly comprise the Natura 2000 programme.[50] If an industry is not exposed to such areas, whether at source, pathway or receptor, and the transposing legislation of the Member State in which it operates does not expand the scope of designated species or areas, then no exposure can arise under the ELD.

Causation in both strict liability and fault-based cases must be established under the ELD. Causation is more difficult to prove than negligence in environmental liability cases and proof of causation under the ELD is fraught with difficulties pertaining to cases of multiple causation and uncertain causation. The directive has extended civil liability, which normally applies to personal injuries and damage to private property, to damage to the wider environment. However, it is silent in terms of the scope of liability and the standard of proof to be applied, leaving both matters to the discretion of the transposing legislation of individual Member States.

VI. NM exposure scenarios leading to environmental damage

There are several ways in which NM may be released into the environment and the concern in this regard is in relation to the potential for them to cause "environmental damage" pursuant to Article 2(1)(a), (b) and (c) and to have a negative impact on human health via contamination of the food chain. The primary conduit that could give rise to

(F'note continued)
Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC [2006] OJ L 396.

47 "Significant" is not expressly defined in the directive. The criteria to assess the significance of the effects of environmental damage referred to in Art. 2(1)(a) are set out in Annex I. Broadly speaking, it refers to damage which has adverse effects on reaching or maintaining the favourable conservation status of habitats or species. "Damage with a proven effect on human health must be classified as significant damage".

48 Council Directive 2009/147 EC of 30 November 2009 on the conservation of wild birds [2010] OJ L20/7.

49 Council Directive 92/43 EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora [1992] OJ L206/7.

50 <http://ec.europa.eu/environment/nature/natura2000/index_en.htm>.

strict liability under the ELD is via water contamination. Air is specifically excluded, possibly by reason of its diffuse nature and the fact that it would be difficult to establish a direct causal link between the damage and the activity responsible for it. The data for soil contamination is insufficient to draw conclusions.

At all stages of the NM lifecycle, from production of raw materials to manufacture of products to end of life, there is potential for NM to be released in sewage waste, industrial waste and waste water and consumer waste into ground water, waste streams, waterways, lakes and coastal waters. They could impact upon the water itself, the land via absorption or diffusion and the biological processes of plant, animal and aquatic life and ultimately under certain circumstances enter the food chain. Dose response assessment studies suggest that toxicity of NM is not necessarily mass dependent. Therefore it would not be necessary for a paradigmatic catastrophic event such as an oil spillage, chemical spill or nuclear explosion to occur in order for NM to cause environmental damage. For example, nanosilver is the most frequently used NM in consumer products due to its well-documented microbial properties (nanosilver is contained in 435/1815 products or 24% of total consumer products listed by the Project of Emerging Technologies[51]). Simply using the products as intended causes silver nanoparticles to end up in rivers and other bodies of water, where they can be ingested by fish and interact with other marine life. For scientists, a key question has been to what extent organisms retain those particles and what effects they might have. A new study by the University of California Centre for Environmental Implications of Nanotechnology has found that smaller silver nanoparticles were more likely to enter fishes' bodies, and that they persisted longer than larger silver nanoparticles or fluid silver nitrate.[52] The results seem to indicate that smaller particles penetrated deeper into the fishes' organs and stayed there longer because they dissolve faster than the larger particles and are more readily absorbed by the fish.

When textiles containing nanosilver are washed, or industrial wastewater containing nanosilver is disposed of, the waste water or waste products will contain the nanoparticles, which will be released into the environment. Studies have shown that silver nanoparticles can be toxic to many aquatic organisms and bioaccumulate in the food chain. In addition, the process of treating waste water includes microbes which break down waste products. Nanosilver itself is a micro biocide. This leads to the question whether or not the nanosilver could reduce the ability of the microbes intended to deal with the degradation of waste to do so.

It is not yet known whether iron nanoparticles used for environmental remediation pose a threat to human health. The iron nanoparticles can be absorbed by the soil and plants and eaten by animals, potentially ending up in the food chain. It has been found that while iron nanoparticles do not cause mutagenicity as evaluated against various S. typhimurium and E. coli strains, they have moderate cytoxic effects and cause interstitial inflammation in the lungs of rats,[53] giving rise for concern in relation to their potentially adverse impact on human health.

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51 Supra note 26.

52 "Smaller silver nanoparticles more likely to be absorbed by aquatic life", *Nanowerk News*, 8 October 2015.

53 Brigitta Szala et al., "Potential Toxic effects of Iron Oxide NP in in vivo and in vitro experiments" (2012) 32(6) *Journal of Applied Toxicology* 446.

When electronic and electrical equipment containing embedded NM are disposed of, over time the products may begin to break down, releasing previously fixed NM into the ecosystem and ultimately into the food chain. The concerns about the potentially toxic effects of NM substances on biological processes are exacerbated due to their potential persistence and insolubility and their capacity to accumulate and agglomerate in environmental compartments such as water and soil. There is more concern about the risk of latent rather than acute nanotechnology-related environmental damage, which potentially could give rise to liability.

Article 4(5) of ELD provides that the directive shall only apply to environmental damage or to an imminent threat of such damage caused by pollution of a diffuse character, where it is possible to establish a causal link between the damage and the activities of individual operators. Pollution is not defined but is interpreted to mean "significant damage", more particularly described in Annex I in relation to human health. It is argued here that chemical substances and biocidal products containing NM could be responsible for environmental damage, which will give rise to liability. It is notable that sanction for non-compliance with the provisions of the BPR, REACH and Cosmetics Regulation does not exclude potential liability under the ELD. In the case of diffuse pollution, the requisite causal link between the environmental damage and the operator could be established because under Article 2(6) an operator includes the holder of a permit or authorisation (REACH, BPR) for an activity or the person registering (REACH) or notifying (Cosmetics Regulation) such an activity. The standard of proof of a direct causal link is not provided for under the directive but it is reasonable to infer that by virtue of the fact that the liability regime under the directive is a civil one, the standard of proof which will apply will depend on the standard of proof pertaining to civil matters in each Member State. For example in the UK, which is a common law jurisdiction, the appropriate standard of proof will be on the balance of probabilities, that is, based on the evidence it is more likely than not that a particular operator caused the environmental damage. The standard of proof has been reduced significantly under common law, leading some commentators to suggest that it is arguable that not only has a new test/s for causation been established but that a new tort of "material increase in risk of harm" has in fact been created. Per Laleng opined[54] that the reduced evidentiary burden which dispenses with the concept of causation altogether as a mechanism for allocating responsibility for harm effectively collapses firstly the orthodox conceptual division between factual and legal causation, and secondly causation into fault. If disputes in relation to liability come before the courts, the question will be whether this lower standard of proof of causation – which, as stated, presents the biggest legal hurdle to be overcome in probabilistic causation/evidentiary gap cases – could apply in an environmental pollution case.

Strict liability[55] applies to environmental damage caused by occupational activities listed in Annex III and to any imminent threat of such damage occurring by reason of any of those activities. The activities most relevant in the context of NM are found in Annex III 7(a), (b) and (d) and they are dangerous substances, dangerous preparations

[54] Per Laleng, "Causal Responsibility for uncertainty and risk in toxic torts" (2010) 18 *Tort Law Review* 102.

[55] ELD, Art. 3(a).

and biocidal products. Nanomaterials contained in biocidal products are specifically defined and regulated under the provisions of the Biocidal Products Regulation.[56] Nanomaterials contained in cosmetics products are specifically defined and regulated under the provisions of the Cosmetics Regulation.[57] Nanomaterials contained in chemical substances are not specifically defined or provided for in REACH, but it has been confirmed by the EC that NM do fall within the regulatory ambit of REACH and accordingly are subject to the same risk assessment and management provisions as bulk substances.[58]

Several studies have shown that NM accumulate to a significant extent in the sludge of Sewage Treatment Plants (STP).[59] Sewage sludge is used as fertiliser in many countries.[60] Therefore it is a relevant source of NM entering soil affecting terrestrial organisms and, indirectly, humans. A long-term study has been performed that investigates the effect of sewage sludge contaminated with NM as applied to soil (simulation of agricultural practice).[61] It is hypothesised that many nanomaterials are (designed to be) persistent, which might lead to long-term exposure. Annex III(3) of the ELD specifically authorises Member States to exempt the spreading of sewage sludge from STP, treated to an approved standard for agricultural purposes, from the strict liability provisions of Annex III: 12 Member States, including the UK, France, Austria and Luxembourg, took the option to exempt this activity from the remit of the strict liability provisions.

VII. Causation

Under the ELD, "damage" means a measurable adverse change in a natural resource or measurable impairment of a natural resource service which may occur directly or indirectly, and environmental damage must be "significant". In the context of damage to human health, "damage with a *proven* effect on human health must be classified as significant damage". Fortunately, there are no documented incidences of major releases

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[56] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (Text with EEA relevance) (OJ L 167, 27.6.2012).

[57] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342).

[58] Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee – Regulatory Aspects of Nanomaterials, COM (2008) 366 final; Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee – Second Regulatory Review on Nanomaterials, COM (2012) 572 (final).

[59] K Tiede et al., "Application of hydrodynamic chromatography-ICP-MS to investigate the fate of silver nanoparticles in activated sludge" (2010) 25(7) *Journal of Analytical Atomic Spectrometry* 1149; R Kaegi et al., "Behaviour of Metallic Silver Nanoparticles in a Pilot Wastewater Treatment Plant" (2011) 45 *Environmental Science & Technology* 3902; MM Shafer et al., "Removal, partitioning, and fate of silver and other metals in wastewater treatment plants and effluent-receiving streams" (1998) 17 *Environmental Toxicology and Chemistry* 630; L Hou et al., "Removal of silver nanoparticles in simulated wastewater treatment processes and its impact on COD and NH4 reduction" (2012) 87 *Chemosphere* 248; Y Yang et al., "Potential nanosilver impact on anaerobic digestion at moderate silver concentrations" (2012) 46 *Water Research* 1176; Y Wang et al., "Fate and biological effects of silver, titanium dioxide, and C60 (fullerene) nanomaterials during simulated wastewater treatment processes" (2012) 201 *Journal of Hazardous Matter* 16.

[60] B Wiechmann et al., *Klärschlammentsorgung in der Bundesrepublik Deutschland* (Bonn: Umweltbundesamt 2012).

[61] K Schlich et al., "Hazard assessment of a silver nanoparticle in soil applied via sewage sludge" (2013) 25 *Environmental Sciences Europe* 17.

of NM into the environment but this means that there has not been an opportunity to observe how such an incident might be dealt with.

As outlined earlier there is a legislative lacuna in the directive, which is silent on the standard of proof to be applied to prove causation of environmental damage. It is left to the discretion of the Member States to define causation and it will be the competent authority and, ultimately, the courts which will determine the standard of proof to be applied. Traditionally burdens of proof in civil matters range from the highest standard of proof: proof *beyond reasonable doubt to* a mid-range burden: *the preponderance of the evidence rule* to the lowest standard: *a reversal of burden of proof.* Under proof beyond a reasonable doubt an operator will be held liable if it is very likely that it has caused the damage. Under the preponderance of the evidence rule, causation will be established if it is more likely than not that the operator caused the damage. Under the reversal of the burden of proof, there is an ex ante rebuttable presumption of liability and it is a matter for the operator to prove that it did not cause the damage.

There have been instances in the past where the courts have been forced to resolve claims based on uncertain causation in situations of limited and/or uncertain scientific knowledge,[62] where the application of the traditional rules of causation would have led to injustice. In these cases, the courts have exercised judicial discretion to create exceptions by adopting expansive causation principles to compensate deserving plaintiffs for damage or injuries caused by culpable defendants. In so doing, causation can be regarded as an elastic concept, which can be stretched and shrunk according to the circumstances of the particular case. In environmental liability cases it has been argued that a very high standard of proof will lead to a low standard of care by operators and vice versa[63] and accordingly that legislators are correct to leave discretionary power to courts which allows them to choose the standard of proof conditional on the particular circumstances of each case, such as the degree of uncertainty over causation and the information available about the care levels taken by operators. In these situations, the courts have the freedom to strike a balance between the interests of the parties and a third interest – morality and social justice.

As previously outlined, cause in law and biological cause in both strict liability and fault-based cases must be established under the ELD. In other words, causation analysis must determine that the operator's activities caused the damage and that the observed significant environmental damage is due to the damage caused. Significantly, in the case *Rada di Augusta*[64] the ECJ held that the ELD does not preclude national legislation which allows a competent authority to operate on a presumption of a causal link between an operator/s and environmental damage, however, in accordance with the polluter pays principle there must be plausible evidence of the causal link. The standard of proof required depends on the standard of proof inherent in national law. For example in the UK the standard is on the balance of probabilities. In Germany, France, Belgium,

[62] Mark Geistfeld, "Scientific Uncertainty and Causation in Tort Law" (2011) 54 *Vanderbilt Law Review* 1011.

[63] Eberhard Feess et al., "Environmental Liability under Uncertain Causation" (2009) 28 *European Journal of Law and Economics* 133.

[64] Case C-378/08 *Raffinerie Mediterranee (ERG) SpA v Polimeri Europa SpA and Syndial SpA v Ministero dello Sviluppo economico* [2010] ECR I-01919.

Portugal, Iceland, Norway, Sweden, Denmark and the Netherlands, the standard is much higher.[65]

The scope of liability to prevent or remedy environmental damage under the directive in cases of multiple causation is also left to the discretion of Member States' transposing legislation. In multiple causation cases damage has been caused by one or a number of multiple entities but it is not clear which one/s are responsible. There are two options: joint and several liability; and proportionate liability. Joint and several liability[66] is the most common form of liability. If a competent authority does not take action against an operator, and that operator is considered by the operators that *have* been held to have caused or contributed to the environmental damage to have also caused or so contributed, then it would be open to the liable operators to join that operator to the preventative or remedial action and/or the associated costs by way of a third party action seeking indemnity and/or contribution, or such similar proceedings depending on the regime for such actions under the national law of the particular Member State.

If an operator is held liable for damage to water the operator will be responsible for restoration of the water to its baseline condition and removal of any significant risk to human health. Restoration is achieved by way of primary remediation. Reflective of this dual use enabling technology and in contrast to the potential risks of NM to the environment, NT is being used in environmental applications such as in water treatment and remediation, air pollution and remediation.[67] In Bangladesh a water filtration system using a composite iron matrix was used to remove arsenic from drinking water in poisoned wells.[68] In water purification applications,[69] nanomembranes, nanoporous zeolites and polymers are used for desalination and detoxification and degradation of pesticides and pollutants;[70] nanosensors can be used for the detection of contaminants and pathogens; nanofilters can separate petroleum hydrocarbons from crude oil and remove bacteria from water.[71] If primary mediation is not possible, complementary or complementary and compensatory remediation are the next best options. Complementary remediation is action taken to compensate for the fact that primary remediation does not result in fully restoring the damage. What is required is the provision of resources at a similar level as the baseline condition, including if necessary at an alternative site. In addition compensatory

65 Stevens & Bolton LLP (2013), The Study on Analysis of integrating the ELD into 11 national legal frameworks, Final Report prepared for the European Commission – DG Environment; Feess, supra note 63.

66 Joint and several liability is a designation of liability by which members of a group are either individually or mutually responsible to a party in whose favour a judgment has been awarded. Joint and several liability is a form of liability that is used in civil cases where two or more people are found liable for damages. The winning plaintiff in such a case may collect the entire judgment from any one of the parties, or from any and all of the parties in various amounts until the judgment is paid in full. In other words, if any of the defendants do not have enough money or assets to pay an equal share of the award, the other defendants must make up the difference. Defendants in a civil suit can be held jointly and severally liable only if their concurrent acts brought about the harm to the plaintiff. The acts of the defendants do not have to be simultaneous: they must simply contribute to the same event. For example, if a number of operators contribute to the cause of environmental damage to water or land then all of them can be held jointly and severally responsible.

67 Nina Liao, "Combining Instrumental and Contextual Approaches: Nanotechnology and Sustainable Development" (2009) *Journal of Law, Medicine and Ethics* 780.

68 Ibid.

69 BR Bürgi and T Pradeep "Societal implications of nanoscience and nanotechnology in developing countries" (2006) 90(5) *Current Science* 645.

70 Ibid.

71 Ibid.

remediation may be required which is an interim measure taken to compensate for interim losses. Interim losses are losses arising from the fact that the damaged natural resources are not able to perform their ecological function or provide services to other natural resources or to the public until the primary or primary and complementary measures have taken effect. Payment of monetary compensation to members of the public is specifically excluded. Although the directive is based on a civil liability regime, it is one founded on administrative law to remedy pure ecological damage where restoration is the core objective. Finally, if an operator is held liable for damage to land, the objective of the measures to be taken are to remove, control, contain or diminish the contaminants so that the land no longer poses a significant risk to human health.

VIII. Defences – to liability or to costs?

If an operator is held liable for preventative and/or remedial, action the issue for them will be whether there are defences or mitigating factors which can be relied upon to mitigate or negate the liability. Where an operator can show that the damage or threat of such damage was caused by a third party or caused as a result of compliance with an order or instruction from a public authority, it must carry out the preventative or remedial measures and then bring a cost recovery action against the third party it holds responsible for the damage or the public authority. It would appear that if the third party cannot be located or is not a target for the costs of the measures taken, the operator that carried out the work will not have any recourse.

Article 8(4)(a) makes provision for the permit defence and Article 8(4)(b) makes provision for the state of the art defence. Member States have largely interpreted the defences as a defence to liability for costs[72] or preventative or remedial measures. Denmark and the UK are the only Member States that have interpreted the defences as defence to liability. The permit defence[73] provides that an operator will not be liable for the costs of remedial action where it can prove that it was not at fault i.e. not negligent *and* that the damage was caused by an event or emission[74] expressly authorised and fully in accordance with the conditions of an authorisation for Annex III activities granted under community legislation. This defence could dilute the strict liability which could otherwise apply to biocidal products, cosmetic products and chemical substances containing NM which are held to have caused environmental damage. *However*, the operator must be able to prove that it was not at fault. Transposition of the permit defence was left to the discretion of the Member States. It has been adopted in 16 Member States, including Belgium, the UK and Italy.

The "state of the art defence"[75] applies where the operator can prove that the damage was not its fault, i.e. it was not negligent, *and* that the emission or activity or manner of using a product was not considered likely to cause environmental damage according to the everal liability is a designation of liability by which members ostate of scientific and technical

[72] "Costs" means cost of assessing environmental damage or a threat of environmental damage, assessment of alternative actions, administrative legal and enforcement costs, data collection costs, monitoring and supervision costs.

[73] ELD, Art. 8(4)(a).

[74] "Emission" is defined as "the release in the environment, as a result of human activities, of substances, preparations , organisms or micro-organisms".

[75] ELD, Art. 8(4)(b), also known as the development risk defence.

knowledge at the time the emission was released or the activity took place. If an operator can successfully prove that its risk identification, analysis and management practices are based on the most advanced technical and scientific levels of knowledge (state of the art) and therefore the event was unforeseeable, it may be able to avoid liability. Therefore proof of objectively unforeseeable or unpreventable harm will exonerate the operator. Leaving aside the proof that the operator was not at fault for the emission, it is questionable whether an NM manufacturer or producer could rely on this defence in consideration of the awareness of the potential hazards of NM to the environment. Although there may not be conclusive evidence or a definite causative link between an NM substance and environmental damage, it is arguable that there is sufficient evidence to raise concern about the potential risks of NM for the environment and human health which cannot be controlled to the extent that the defence will not be applicable or capable of being relied upon. Therefore, whether an operator would successfully be able to rely on this defence is an open question, particularly in the case of a strict liability occupational activity (i.e. Annex III activity). Transposition of the state of the art defence was left to the discretion of the Member States. The state of the art defence has been adopted in 16 member states including Belgium, France, Italy and the UK.

For those countries that impose joint and several liability and have adopted the permit and state of the art defences, difficulties can be envisaged if a number of Annex III operators (for example authorised producers or users of biocidal products or substances which are classified as "dangerous" but authorised under REACH) are held jointly and severally liable for damage for instance, to land. If one or more of these operators can absolve themselves of liability and successfully rely on one of the defences, the remaining one or more operators will be responsible for the totality of the costs of the remedial action. For those countries which impose a proportionate liability, liable operators who cannot adduce exculpatory evidence of no-fault will only be responsible for the proportion of the damage which can be attributed to them. This raises the question which is as yet unanswerable: what would happen to the remainder? Would competent authorities, and ultimately public funds, be used to remedy the damage?

IX. Limitations in scientific knowledge which could give rise to difficulties proving causation

It is submitted here that notwithstanding the fact that NM are neither explicitly referred to nor defined within the provisions of the ELD, NM comprised in chemical substances and biocidal products could cause damage to water and/or land that would fall within the scope of the definition of "environmental damage" in the ELD and accordingly could theoretically be subject to the liability provisions pursuant to the directive. Theoretically the two defences in the directive discussed above could be invoked by operators to mitigate or negate their liability. However, owing firstly to the uncertainty surrounding the scientific data which would be necessary to render operators liable, and secondly uncertain causation, NM manufacturers/producers would – on the balance of probabilities – be able to avoid liability. The directive is limited in scope and in the context of NM may realistically have very little real significance.

There are two major impediments to the establishment of liability under the ELD. The first is the lack of scientific knowledge tailored specifically to NM and the second is in relation to uncertain causation. In the case of scientific knowledge, validated analytical methods for characterisation, detection and measurement of NP are needed to produce toxicological data and to that end nano-specific instrumentation and metrics are needed. The experience of the ECHA in the evaluation (risk assessment) of applications for registration of chemical substances under REACH has been that there have been difficulties in substance identification and hazard identification of substances in their bulk form. Of the three NM which have been evaluated by the ECHA, the additional information requested from registrants was in relation to the identification of the substances as NM.[76] In addition, research needs to be done in relation to "nano-hybrids" and multiple exposures from single and multiple NM compounds[77] to examine toxicity effects which could be additive, synergistic and antagonistic.

Exposure data and toxicological study results are needed and the availability of both may well be further hampered by regulatory restrictions on animal testing.[78] Specifically, in relation to environmental hazard assessment, toxicity has been reported but further investigation is needed before hazard can be identified; environmental fate and biological pathway studies results are largely inconclusive and environmentally-relevant concentration levels (Predicted No Effect Concentration Levels – PNEC) are required. In addition, difficulties in monitoring exposure (exposure assessment) and realistic exposure scenarios are needed. Long-term studies would also be necessary to determine the long-term risk of environmental impact.

NM themselves need to be characterised and dose descriptors determined and agreed to enable identification of clear causality between inherent properties and adverse effects/damage. This would assist with determination of which properties of NM account for inherent hazards. Standardised sampling and testing methods, standards and protocols are needed to detect, identify and quantify NM and to determine the degree of mobility, concentration levels and propensity to persist and bioaccumulate in different environmental compartments. Information in relation to the potential environmental processes that can influence the behaviour and the properties of NM are also needed.

In relation to causation, only when a causal link is proven between the activity and the effect and the criteria for both environmental damage and significance are met can it be established that there has been significant environmental damage.[79]

X. Conclusion

The paper set out to address both the potential environmental liability exposures of NT manufacturers and producers pursuant to the provisions of the ELD and to examine the legal and regulatory challenges that the NT industry presents in the context of the application of the ELD.

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76 <http://echa.europa.eu/documents/10162/13628/evaluation_report_2014_en.pdf> (accessed 6 January 2017).

77 Nanosilver and titanium dioxide are used together in cosmetics and electronics; titanium dioxide and zinc oxide are used in cosmetics, sunscreens and paint; calcium and magnesium in supplements; nanoceramics and nanosilver used in water filtration and cosmetics.

78 REACH: <http://echa.europa.eu/chemicals-in-our-life/animal-testing-under-reach>.

79 Supra note 15, 294.

The ELD endeavours to harmonise environmental liability by attempting to create a level playing field across Member States. The definitions of "operator" and "occupational activity" mean that NM users along all stages of the life cycle of the materials have a potential liability exposure under the ELD, and whether the optional defences under the directive would be available to NM operators remains to be seen. Two major impediments have been identified in this paper: first, the gaps in the scientific knowledge in relation to NM hazard and damage effects; and second, difficulties in causation arising from the legislative lacuna in the directive. On that basis the application of the ELD to NM may be limited.

In addition there is divergence in the implementing provisions of the directive between Member States, which creates the overall impression of a fragmented framework. The threshold for environmental damage is set at "significant", which sets the bar at a level which may not catch damage that is not of the magnitude envisioned by the ELD, but which has a serious impact on environmental compartments.

In the same way that NT is expected to revolutionise so many aspects of society, scientific advances might hold the key to determining causation in future cases of liability under the ELD by producing new forms of evidence to which courts will adapt legal treatment of proof of causation, thereby reducing or eliminating the need for reliance on traditional risk assessment studies. For example chemical biomarking enables scientists to observe biomarkers even at the molecular level, allowing the detection of previously undetectable, intermediate molecular changes between exposure and the manifestation of damage, which will allow scientists to draw definitive conclusions about the consequences of exposure[80] and will narrow the gulf between scientific evidence and legal causation.

Toxicogenomics[81] and toxicogenetics[82] may also provide dramatic advances in the identification and characterisation of toxins which may be used as biomarkers of exposure to demonstrate a causal link between exposure to a substance and biomarkers of effect to diagnose early progression of a damage process. This would make causation analysis and proof of a causative link between toxic substance exposure and the consequences of that exposure much more straightforward. In the event of a dispute, determination in relation to liability will ultimately be an issue for determination by the courts. In that regard, as we have already seen, the courts have in the past relaxed the evidentiary burden of proof of causation in previous toxic claims and mass claims scenarios to afford a remedy to plaintiffs and in accordance with general social justice where medical or scientific expertise cannot arrive at a definitive conclusion. There is no reason to believe that similar approaches would not be applied in the case of damage within the scope of the ELD. For NM operators, prevention – which is the primary objective of the ELD – will always be better than cure, and to that end sound environmental risk assessment and risk management procedures will be critical.

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80 Jamie Grodsky, "Geonomics and Toxic Torts: Dismantling the Risk-Injury Divide" (2007) 59 *Stanford Law Review* 1671.

81 Toxicogenomics is the study of the relationship between the structure and activity of the genome and the adverse effects of chemical substances. It combines the emerging technology of geonomics and bioinformatics to identify and characterize the mechanisms of action of known and suspected toxins.

82 Toxicogenetics is a high-speed, high-volume technology which can scan a human genome for chemically-induced changes.