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Public Authority Liability and the Regulation of Nanotechnology: A European Perspective

Nina Natalia Baranowska*

Abstract

This paper argues that in certain circumstances public authorities should be liable for regulating nanotechnology. Nanotechnology is an emerging field of technology that enables to control shape and size of various structures, devices and systems at nanometer scale on which one nanometer is equal to one-billionth of a meter. In spite of being a nascent field of science and technology, its scope of application – in the food, pharmaceuticals, cosmetics, construction, textile, electronics, and agricultural industries – is expanding rapidly. The risks associated to nanotechnology, however, and its long-term consequences are still largely unknown, particularly in regards to its health and safety impacts on individuals. In this context of uncertainty and ambiguity surrounding this emerging technology, it is highly problematic that the current legal liability framework in the European Union for defective products under Product Liability Directive (85/374/EEC), and the public authority liability for damage caused by EU institutions or by its servants in the performance of their duties under Article 340 (2) TFEU – fails to effectively protect users of nanotechnology.

Thus, it is imperative to ensure an adequate legal response in order to protect users of nanotechnology. This piece proposes a regulatory framework that will enable users to claim compensation from public authorities in cases of incomplete or insufficient regulations in regards to nanotechnology. The proposed liability scheme is based on (a) public authority liability as a secondary claim; (b) the infringement of objective precautionary principles; (c) whereby the burden of proof rests on the public authority; and (d) the limitation period for a claim for damages starts from the time of knowledge about the cause of damage.

Finally, this paper concludes by recommending the implementation of additional solutions to safeguard the protection of the users of nanoproducts. These include creating an innovation fund for companies to share their profits with

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public authorities; governmental research subsidies and programmes financed from public funds; and consumer awareness and education campaigns about risks related to nanotechnology.

I. INTRODUCTION

In what circumstances, if any, should public authorities be held liable for regulating the nanotechnology phenomenon? Such a question is not usually taken into consideration in discussions about regulations concerning nanotechnology¹, *i.e.* technology that includes structures measuring in the 100 millionths of a millimetre. The area of application of nanotechnology is extremely vast and includes such fields as the food industry, medicine, construction, and textiles. The potential of the use of nanotechnology is still growing and more and more products contain nanoparticles. Therefore, nanotechnology is being discussed from various perspectives including ethics and society, business, and global sustainability.² The legal aspects of nanotechnology are analyzed mainly from the point of view of regulations and recommendations of regulatory agencies in the areas of health and safety, the environment, international trade and intellectual property law (patent and copyright protection).³ Within the scope of tort liability, the issue of nanotechnology is raised mainly in the context of liability for defective products.⁴

The possibility of placing a duty on public authorities to regulate nanotechnology is a controversial issue. In general, the concept of public authority liability includes the non-contractual liability of a public authority to

¹ As explained below, discussion about regulating nanotechnology focuses mainly on the areas of health and safety (see e.g. Aida Ponce Del Castillo, *The EU approach to regulating nanotechnology* (Brussels: ETUI, 2010) at 33-34), environmental issues (see e.g. Nanowerk, “Nanowaste - Nanomaterial-containing products at the end of their life cycle,” online: < <http://www.nanowerk.com/spotlight/spotid=38848.php> > [“Nanowaste”]), and intellectual property law (see e.g. Hsinchun Chen et al. “Trends in nanotechnology patents” (2008) 3:3 *Nature Nanotechnology* 123; David S. Almeling, “Patenting Nanotechnology: Problems with the Utility Requirement” (2004) 1 *Stan Tech Law Rev* 1; Indrani Barpujari, “The Patent Regime and Nanotechnology: Issues and Challenges” (2010) 15 *Journal of Intellectual Property Rights* 206). The liability issue is analyzed (mainly) from the product liability perspective (see e.g. Geraint Howells, “Product Liability for Nanotechnology,” (2009) 32 *Journal of Consumer Policy* 381 [Howells, “Product Liability”]). The idea of regulating public authority liability for improper regulation of nanotechnology is missing in those discussions.

² See generally Donald Maclurcan & Natalia Radywyl, *Nanotechnology and Global Sustainability* (New York: CRC Press, 2011); Jo Anne Shatkin, *Nanotechnology: Health and Environmental Risks*, (New York: CRC Press, 2012); Michael T. Burke, *Nanotechnology: The Business*, (New York: CRC Press, 2008); Deb Bennett-Woods, *Nanotechnology: Ethics and Society* (New York: CRC Press, 2008).

³ See e.g. Prabuddha Ganguli & Siddharth Jabade, *Nanotechnology Intellectual Property Rights: Research, Design, and Commercialization* (New York: CRC Press, 2012).

⁴ See Howells, “Product Liability”, *supra* note 1 at 381; Patrick M. Boucher, *Nanotechnology: Legal Aspects* (New York: CRC Press, 2008).

make good any damage arising from its acts or omissions. The concept has evolved since the 19th century, when legal systems were initially based on the idea of full state immunity, expressed in a maxim “The King can do no wrong”.⁵ The “public authority” usually refers to central and local government (e.g. federal and provincial government), the legislative body (e.g. parliament), “the State” itself (if the State has a legal personality), as well as judges and judicial representatives. Therefore, the possibility of holding public authorities liable depends on the shape of a political and legal system in a given country, and attention must be paid to the specific bodies responsible for making policy and legally binding decisions. Further parts of this paper use the notion “public authorities”, with the reservation that it may concern the government or legislature in the context of a specific case or legal order.

This paper is concerned with European Union (EU) law, including the liability of the European Union as a policy-maker and maker of product liability law. However, the concepts presented here have a universal nature and concern general policy recommendations which can be applied in various legal systems. EU law is an interesting example of exercising public power. The EU is a political and economic union consisting of 28 Member States which has created an internal single market and, to certain extent, a standardized system of law.⁶ Looking back at the origin of the EU, and earlier at the creation of the European Communities, it should be noted that the deepened cooperation between states was, and still is, based on the growth of the internal market and economic trade, including the abolition of barriers to starting and conducting business activity.⁷ It would have been impossible, however, to put the idea of creating a common market into practice without conducting legislative activities at the level of the Union and the states, and creating a complete and coherent system of judicial protection.⁸ The Member States passed some of their law-making competencies to EU institutions, but at the same time they maintain their own internal legal systems.⁹ Therefore, in the EU, there are two levels at which public power is

⁵ See George W. Pugh, “Historical Approach to the Doctrine of Sovereign Immunity,” (1953) 13:3 *La L Rev* 476 at 479; Herbert Barry, “The King Can Do No Wrong,” (1925) 11 *Va L Rev* 349 at 352.

⁶ See also K.P.E. Lasok & D. Lasok, *Law and Institutions of the European Union* (London: Butterworths, 2001) at 3-21; Jean-Claude Piris, *The Constitution for Europe: A Legal Analysis* (Cambridge: Cambridge University Press, 2006) at 38-40; Nigel Foster, *Foster on EU Law* (Oxford: Oxford University Press, 2011) at 3-45.

⁷ See Art. 3 ust. 3 *Treaty on European Union* (Consolidated versions of the Treaty on European Union and the Treaty on the Functioning of the European Union, OJ 2012/C 326/01, 26/10/2012) [*TFEU*].

⁸ See Koen Lenaerts, Ignace Maselis & Kathleen Gutman, *EU Procedural Law* (Oxford: Oxford University Press, 2015) at 1-3.

⁹ See Francis G. Jacobs, “The Evolution of the European legal Order”, in Alison McDonnell, ed., *A Review of Forty Years of Community Law: Legal Developments in the European Communities and the European Union* (The Hague: Kluwer Law International, 2005) at 21-34.

exercised: national and EU.¹⁰ Both systems are combined within a web of legal enactments and legislative processes. The approximation of the systems of law in the EU Member States is done through the harmonization and unification processes. Harmonization includes all actions taken by the member states in order to adjust national systems of law. It involves primarily the introduction of similar legal solutions (especially in respect of minimum standards) or, in general, the introduction of “consistency”, in its broad meaning, into the systems of law. This consistency is derived from various traditions (Romano-Germanic, Scandinavian, and common law),¹¹ which demonstrate different legal mentalities and different approaches to law. The basic tool in the harmonization of laws in the EU is the Directive.¹² Unification, on the other hand, includes legislative activities undertaken by the Union legislator as well as the uniform application of legal norms by courts of law. Unification is mainly achieved by Regulations.¹³ Legislative actions of the EU, which acts as a public authority through Directives and Regulations, have a significant impact on determining common standards of protection for individuals. The problem of policy strategy in the case of nanotechnology is of key importance for EU legislators from the perspective of protecting individuals. Regardless of any specific public authority liability, the arguments used later in this paper show that, in certain circumstances, public authorities should be held responsible for acts or omissions in their regulation of nanotechnology. This paper will consider three aspects of liability. The first aspect is liability for the improper regulation of nanotechnology, for example, when nanoproducts harm a consumer. A “consumer” is a final user of a product containing nanoparticles, such as a user of clothes or paints produced with the use of nanomaterials.¹⁴ The gist of this liability would be, in one sense, a continuation of the liability for defective products (product liability). However, the difference is that the cause of the defectiveness of a product will be the lack of proper regulation, which would otherwise have ensured the user’s safety.

The second aspect is liability for the improper regulation of nanotechnology in situations when nanomaterials can cause damage to the “operators”, such as

¹⁰ See in-depth discussion on EU law and state sovereignty in Rene Barents, *The Autonomy of Community Law*, (The Hague: Kluwer Law International, 2004) at 23-106.

¹¹ See Jan Rajski, “On the Need for the Progressive Harmonisation of Private Law in the European Union: The Role of Legal Science and Education” (2006) XI *Juridica International* 20.

¹² Directives bind the member states in respect of the result, allowing them, as a rule, to freely choose the form and method to achieve that result (see *TFEU*, *supra* note 7, art. 288 para. 3). Due to the very extent of this freedom the directive is considered to be the most appropriate instrument for the approximation of laws.

¹³ Regulations have general application, they bind in their entirety and they are directly applicable in all Member States (see *TFEU*, *supra* note 7, art. 288(2)).

¹⁴ Compare Rafal Manko, “The Notion of ‘Consumer’ in EU Law,” (6 May 2013) *Library Briefing: Library of the European Parliament*.

the operators of nanomaterials during a production process or during their application (e.g. while using nano-devices). Some nanomaterials, like nanosilver, have toxic properties, so that operators are exposed to danger in relation to the application of nanomaterials.

The third aspect is slightly different and concerns liability for the improper regulation of nanotechnology where regulations cause harm to companies using nanomaterials. The introduction of unjustified restrictions on the application of nanotechnology may cause financial losses for the enterprises applying this technology. What is more, overregulating nanotechnology may curb technological development.

Improper regulation in given aspects could be both the lack of regulations (legislative omission), or imperfect regulation, *i.e.* regulation not resulting in proper protection or regulation that is too strict.

The main problem related to nanotechnology, and expressed in the paper, is to provide appropriate safety levels for nanotechnology's users (consumers and operators), while also providing a favourable environment for technological development, which to some extent is also desirable from a societal perspective.

The starting point of the paper is to present nanotechnology as an emerging technology, and show how its characteristic features such as size, unpredictability and the fact that it is still under development (Part II) lead to a key problem: increased risks (Part III). The current state of research on nanotechnology does not allow a determination of the long-term consequences of using nanoproducts (including the impact of nanoparticles on the human body and the environment, as well as the properties of materials reduced to nanoscale, etc.). Part IV explains the reasons why the market, social norms and "architecture" may not fully regulate for safety measures related to the use of nanotechnology, and why hard law regulations are necessary. As a result, legislation could play a central role in regulating nanotechnology. Part V concerns problems related to product liability regulation. According to an Organisation for Economic Cooperation and Development (OECD) report from 2013, the existing legal framework is able to cover nanoproducts.¹⁵ However, the report takes into account mostly regulatory aspects (mainly the food industry perspective), not liability issues. The product liability law that is now in force in the European Union (under Product Liability Directive 85/374/EEC¹⁶) does not effectively protect the users of nanotechnology, which means that in the case of damage caused by a nanoproduct, the users are deprived of adequate protective measures.

¹⁵ See Organisation for Economic Co-operation and Development (Working Party on Nanotechnology). "Regulatory Frameworks for Nanotechnology in Foods and Medical Products. Summary results of a survey activity" (OECD, 21 March 2013), online: <http://www.oecd-ilibrary.org/science-and-technology/regulatory-frameworks-for-nanotechnology-in-foods-and-medical-products_5k47w4vsb4s4-en> [*OECD 2013 Report*].

¹⁶ Council Directive, (85/374/EEC) (25 July 1985), *On the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products* [1985] OJ, L 210 at 29 [*Product Liability Directive*].

A proposed solution for these problems is to draft regulations which enable injured parties to claim compensation from public authorities in situations when policy-makers have not imposed the necessary regulations, or have enacted incomplete or insufficient regulations. This would establish regulation around public authority liability (Part VI). The scope of the EU's non-contractual liability, as a legal entity responsible for policy-making, for damage arising from the incomplete or lack of sufficient regulations does not currently cover nanotechnology.

This paper bases the proposed regulations on certain assumptions, including: a) the regulation will provide the aggrieved parties with compensatory damages when the injury was caused in connection with the use of nanotechnology; b) regulating public authority liability will create incentives for policy-makers so that they will take more effective and more precautionary actions; c) by regulating public authority liability tort law could regain its primary function which is the materialization of the idea of justice; d) although any additional regulations can result in stifling the pace of technological development, regulating public authority liability can slow down this pace potentially to a lesser degree than regulating the liability of companies because public authority liability does not affect the functioning of tech companies directly and thus it interferes less in the pace of technological development; and e) the public and businesses expect that the policy-makers will take regulatory steps.

Part VII will explain the elements of this type of liability. First, public authority liability should be a secondary claim. This regulation should be based on an objective infringement of law, informed by precautionary principles, and not a standard of subjective fault. The burden of proof should rest on the public authority, which means that the public authority will have to prove that it has not infringed precautionary principles. Because of the long-term consequences of nanotechnology, the limitation period should start from the time of knowledge about the cause of damage.

Apart from hard law regulation, there is a need to propose some mechanisms that will fulfill the presented concept. First, companies should share their profits with the government by contributing to a special "innovation fund". Public authorities could contribute to the research process not only by paying compensation but also by ordering additional research, subsidizing research centers, and providing various programmes financed from public funds. The last point is that the users of nanoproducts should be informed about nanomaterials used in products and about the risks related to nanotechnology.

II. NANOTECHNOLOGY — EMERGING TECHNOLOGY

Nanotechnology is the "design, characterization, production and application of structures, devices and systems by controlling shape and size at nanometre scale."¹⁷ One nanometre (nm) is equal to one-billionth of a metre (0.000000001

m). To put it vividly, a red blood cell is approximately 7000nm wide, while hemoglobin, the molecule in red blood cells, which carries oxygen, is approximately 5 nanometers.¹⁸ The concept of nanoscience and the possibility of manipulating materials at the size of atoms and molecules was described for the first time by Richard P. Feynman during the plenary session of American Physical Society in 1959. The term “nanotechnology” was used for the first time by Japanese professor Norio Taniguchi of the University of Science in Tokyo in 1974. In 1980 Eric Drexler, an American engineer, developed and popularized the potential of molecular nanotechnology in his book *Engines of Creation: The Coming Era of Nanotechnology*.¹⁹

Nanotechnology is a fast growing area with considerable potential. According to some authors, nanotechnology is “science’s next big thing”,²⁰ or even “the next industrial revolution”.²¹ The broad scope of the application of nanotechnology means that users are sometimes not aware of nanoparticles’ existence in various products or of the use of nanotechnology in everyday life. Nanotechnology is also an interdisciplinary field and involves expertise knowledge from different disciplines such as physics, chemistry, engineering, information technology, and biology.²²

The existence of nanoparticles in everyday products is not a new event. Nanomaterials have been used in the past, for example, in car tires.²³ However, the scope for the application of nanotechnology is broadening. Nanotechnology is now used in the food industry, the pharmaceutical industry, medicine (e.g. contrast agents used in diagnosis and biomedicine), cosmetics and sunscreens, construction (e.g. insulation materials, self-cleaning and automotive paints), the textile industry and sporting goods (e.g. smart clothes), the agricultural industry

¹⁷ See Royal Society & Royal Academy of Engineering, *Nanoscience and Nanotechnologies: Opportunities and Uncertainties* (London: The Royal Society, 2004) at 5, online:

< https://royalsociety.org/~media/Royal_Society_Content/policy/publications/2004/9693.pdf > .

¹⁸ “Cancer & Nanotech”, National Cancer Institute <https://nano.cancer.gov/learn/understanding/>, online: < <https://www.cancer.gov/sites/nano/cancer-nanotechnology/benefits> > [NCI, “Cancer & Nanotech”].

¹⁹ See Nikolay K. Tolochko, “History of Nanotechnology,” Encyclopedia of Life Support Systems (EOLSS), online: < <https://www.eolss.net/> > < <http://www.eolss.net/sample-chapters/c05/E6-152-01.pdf> > .

²⁰ See Jane Macoubrie, “Informed Public Perceptions of Nanotechnology and Trust in Government” (2005) Woodrow Wilson International Center for Scholars at 1, online: < <https://www.wilsoncenter.org/sites/default/files/macoubriereport1.pdf> > [Macoubrie, “Informed Public”].

²¹ See e.g. Christine Peterson, “Molecular Nanotechnology: the Next Industrial Revolution,” online: < <https://www.foresight.org/nano/IEEEComputer.html> > .

²² See Alan L. Porter & Jan Youtie, “How interdisciplinary is nanotechnology?”, online: < <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2988207/> > .

²³ See “Nanoparticles vs. Rubber - Could Nanomaterials Replace Rubber?” (15 August 2005) AZoNano, online: < <http://www.azonano.com/article.aspx?ArticleID=1351> > .

(e.g. pesticides), electronics, optics, aerospace, and the defense industry, etc.²⁴ It is difficult to estimate how many consumer products with nanoparticles are already on the market. Different authors indicate that the number of nanoproducts that have already been introduced to the market could vary from 500 to more than 1600.²⁵ The future and potential of nanotechnology are difficult to predict. Researchers are still working on nanodevices that could be used in cancer diagnosis.²⁶ In future, nanoparticles will probably be able to come together on their own and be self-replicating, so that they can function like living creatures.²⁷ It seems that all discussions about nanotechnology and its attendant problems are just beginning.

III. NANOTECHNOLOGY — MACRO-PROBLEMS

Although the use of nanotechnology is growing rapidly, with more and more products including nanoparticles, this technology poses certain threats and risks. One may claim that every new technology carries some risk, but as presented in this paper, the risks entailed by nanotechnology and its potential negative impacts are significant.

The first and most obvious observation is that nanomaterials have reached a size that requires highly-advanced research apparatuses such as nano-microscopes to apply nanomaterials in products and to control them. Therefore, not every laboratory or scientific centre will possess the essential equipment to carry on research on nanomaterials. It leads to dangerous consequences for the users of nanoproducts with regards to evidential proof problems. For example, in the case of injuries caused by a nanoproduct, the user will have a limited ability to prove that a particular nanomaterial used in the product caused their injury. This challenge is not restricted to nanotechnology. It is a previously known phenomena apparent from the use of other highly advanced technologies. However, in the case of nanotechnology it occurs with increased frequency, especially because the level of knowledge and the access to

²⁴ Compare Katharine Sanderson, “What You Need to Know About Nano-food,” *The Guardian* (26 April 2013), online: < <https://www.theguardian.com/what-is-nano/what-you-need-know-about-nano-food> > ; Sangeeta Bhatia, “This Tiny Particle Could Roam Your Body to Find Tumors,” Ted Talk, online: < http://www.ted.com/talks/sangeeta_bhatia_this_tiny_particle_could_roam_your_body_to_find_tumors > [Bhatia, “Roam Your Body”]; Anne Trafton, “Nanobionic Spinach Plants Can Detect Explosives,” *MIT News* (31 October 2016), online: < <http://news.mit.edu/2016/nanobionic-spinach-plants-detect-explosives-1031> > .

²⁵ See e.g. Nanotech Project, online: < <http://www.nanotechproject.org/cpi/> > .

²⁶ See Bhatia, “Roam Your Body”, *supra* note 24.

²⁷ See Art Molella, “In the World of Nanotechnology, Anything Is Possible,” *The Atlantic* (31 May 2011), online: < <https://www.theatlantic.com/technology/archive/2011/05/in-the-world-of-nanotechnology-anything-is-possible/239678/> > ; George Tulevski, “The Next Step in Nanotechnology,” Ted Talk, online: < http://www.ted.com/talks/george_tulevski_the_next_step_in_nanotechnology > .

highly advanced equipment which can examine nanoparticles are limited. The other difficulties refer to uncertainty concerning causality. Even if the injured party has access to the advanced equipment and thus the possibility of examining the effects of nanoparticles, in some cases it will still be impossible to prove what exactly caused the damage (the nanoparticle itself, the reaction with other particles, the technique by which it has been applied in the product, the way of using the product, etc.). This uncertainty is the result of basing production processes on technologies with effects that are not fully understood, and which may be uncontrolled.

The second argument, which is closely related to the previous one, is that this technology is still under development. Researchers and experts are working on new practical applications for some nanomaterials as well as new measurement methods. It is already scientifically proven that some materials change their features when they are minimized to nanoscale.²⁸ For example, some of them change their colors, while others can be extremely hazardous, even though the same material when “regular” size is not. For example, nanosilver is highly toxic.²⁹

Third, the long-term safety of nanomaterials is unverified and the risks related to their application are difficult to estimate. It also means that the consequences of nanomaterials for human health are mostly unknown. One of the potential uses of nanotechnology in medicine is that of enabling nanodevices such as nanotubes or nanoshells to circulate in the bloodstream. Because of their size, smaller than a human cell, nanodevices could get access to areas of the body which are now inaccessible. Owing to this ability, nanodevices could diagnose diseases and deliver treatments in a more precise and accurate way.³⁰ However, it is still unknown how the nanodevices would interact with human cells: how the organism would manage to eliminate them, and what the long-term consequences of circulating nanodevices in blood vessels could be. The second example regarding long-term safety refers to the level of protection after the period of the use of nanomaterials has ended. There is not enough research on how nanowaste will respond to thermal or biological treatment.³¹

IV. DECIDING WHEN AND HOW TO REGULATE NANOTECHNOLOGY

When facing challenges caused by technological innovations,³² policy-makers have in practice two possible scenarios to enact. In the first scenario, they

²⁸ See Steffen F. Hansen & Anders Baun, “When Enough is Enough,” (1 July 2012) 7 *Nature Nanotechnology* 409–411, online: < <http://www.nature.com/nnano/journal/v7/n7/full/nnano.2012.115.html> > [Hansen & Baun, “Enough is Enough”].

²⁹ Hansen & Baun, *ibid.*

³⁰ NCI, “Cancer & Nanotech”, *supra* note 18.

³¹ “Nanowaste”, *supra* note 1.

³² For example Brownsword describes new technologies as the challenge of regulatory

can introduce some regulations on the emerging technology. The regulations will usually impose limits on the application of the technology, set out requirements for introducing the technology to market, the conditions under which the technology can be used (e.g. safety standards) or, in the most extreme way, they can forbid the use of the technology. In the second scenario, policy-makers can simply wait and observe how the new technology is going to develop. Even though policy-makers do not take any steps to establish new regulations for the technology, the technology will usually be regulated, to some extent, by existing legal rules. In this case the concept of “translation”, developed by Lawrence Lessig, is of key importance.³³ According to Lessig’s concept, in the face of changing technological realities, “translation” protects the meaning and restores the original values of existing legal regulations. In some cases changing an interpretative practice and, for example, increasing the scope of the application of existing rules will be sufficient to deal with new technologies.³⁴

Moreover, the lack of legal actions from public authorities does not mean that the use of the technology is not regulated. According to Lessig, there are four modalities that could regulate it: legal norms, social norms, markets and “architecture”.³⁵ If legal regulations do not provide an adequate legal response for the new reality created by the emerging technology, other modalities will take the primary role. Lessig claims that social norms regulate the reality and are enforced by a community. Markets regulate people’s behavior by price. The last modifier that could operate in the absence of legal regulations is “architecture”. The “architecture” of the physical world has an impact on how technology is used. For example, it can make the application of the technology more common, encourage people to use it and build trust in it.³⁶

How can these modalities be relevant to the case of nanotechnology? First of all, the market could regulate the use of nanoproducts by their price. This would mean that if nanoproducts are cheaper than products which do not contain nanoparticles, people are encouraged to buy more nanoproducts. On the other hand, if the price of nanoproducts declines too far, consumers might start thinking of nanoproducts as being cheaper, less reliable and poorer quality replacements of regular products.

connection, see R. Brownsword *Rights, Regulation and the Technological Revolution* (Oxford: Oxford University Press 2008). Marchant, Allenby, and Herkert describe new technologies as the ‘pacing problem’, see G. Marchant, B. Allenby & J. Herkert, *The Growing Gap between Emerging Technologies and Legal-Ethical Oversight: The Pacing Problem* (Springer Netherlands, 2011).

³³ See Lawrence Lessig, *Code v.2.0* (New York: Basic Books, 2006) at 163-165 [Lessig, *Code*].

³⁴ Lessig, *ibid*.

³⁵ See Lawrence Lessig, “The Law of the Horse: What Cyberlaw might Teach” (1999-2000) 113 Harv L Rev 501 at 507 [Lessig, “Law of the Horse”].

³⁶ Lessig, *ibid* at 509.

The crucial element of regulating nanotechnology by social norms refers to the level of consumers' knowledge of this technology. A society which is well-informed about nanoproducts can make a conscious decision and generate norms about whether, and how, it wants to use nanoproducts.

The most challenging task is to apply "architecture" to nanotechnology. It should be noted that Lessig's concept of modalities refers primarily to new technologies with relation to cyberspace. Taking into account the nature of nanotechnology, which is a highly advanced and scientific field, and that nanoparticles are imperceptible by the regular user, the "architecture" modality will probably have a limited application to this technology. However, it can apply to the physical design of nanoproducts, especially their packaging. The package informing the user that nanomaterials are used in a production process can encourage or discourage people to buy the nanoproduct, depending on a current consumer fad. Furthermore, the amount of safety information a label contains can result in gaining or losing consumers' trust in a product.

All the modalities expressed by Lessig could have some impact on the manner that nanotechnology is regulated. However, their importance decreases when we take into account the need to establish a proper level of safety for nanoproducts, and the possibility for redress when damages are caused by nanoproducts. Neither social norms, the market, nor "architecture" can fully or effectively regulate for product safety and ensure sufficient protection from the risks nanotechnology involves and thus they will play minor roles. Precise safety requirements are an emerging issue related to nanotechnology.

The pace of technological development and its influence on legal regulations has induced wide-ranging and in-depth discussions among legal scholars.³⁷ Lyria Bennett Moses makes an interesting point that instead of trying to answer how new technologies should be regulated, one should answer how the adjustment of the legal response to socio-technical change might be institutionally managed.³⁸ Bennett Moses indicates that policy-makers have to find an adequate response, not because technology itself is a problem, but because innovations create a new socio-technical landscape with many new negative characteristics such as harm, risks, market failures, and inequality.³⁹ Tony Prosser identifies four rationales for regulating technologies. These are: 1) economic efficiency and market choice, (2) regulation to protect rights, (3) regulation for social solidarity, and (4) regulation as deliberation.⁴⁰ Bennett Moses explains that regulation processes

³⁷ See e.g. Roger Brownsword, Eloise Scotford, & Karen Yeung, eds., *The Oxford Handbook of Law, Regulation and Technology* (Oxford: Oxford University Press, 2017); Roger Brownsword & Karen Yeung, eds., *Regulating Technologies: Legal Futures, Regulatory Frames and Technological Fixes* (Hart Publishing, 2008).

³⁸ See Lyria Bennett Moses, "Regulating in the Face of Sociotechnical Change" in Roger Brownsword, Eloise Scotford, & Karen Yeung, eds., *The Oxford Handbook of Law, Regulation and Technology* (Oxford: Oxford University Press, 2017) at 1, 3, 8, 11, 19 [Moses, "Sociotechnical Change"].

³⁹ Moses, "Sociotechnical Change", *ibid.*, at 5.

have to take into account reframing regulatory design, regulatory institutions, regulatory timing, and regulatory responsiveness,⁴¹ while Julia Black has stressed the role of political considerations.⁴² Roger Brownsword, on the other hand, points out that technological development can have both positive and negative impacts on the liberty of individuals.⁴³ The use of some technologies might result in the loss of liberty⁴⁴ or contribute to the creation of a surveillance system.⁴⁵ Instead of paying attention to the normative backgrounds of technological use, Brownsword highlights the role of “technological management”, which might practically prevent users of a technology from taking certain actions.⁴⁶

Nanotechnology is a technology in which legal regulation could play a central role. The benefits of regulating nanotechnology could include, among other things, the protection of its users⁴⁷ and building public trust. Research done by the Woodrow Wilson International Center in 2005, titled “Informed Public Perceptions of Nanotechnology and Trust in Government”, shows that there is high demand for effective government regulation of nanotechnology.⁴⁸ The study was carried out with groups of citizens in Cleveland, Dallas, and Spokane, in the USA. A majority of the participants felt that government control beyond voluntary standards is necessary with respect to nanotechnology (55%). Among the preferred ways of government actions that will increase public trust, participants indicated: safety tests before market (34.5%), supplying more product information so people can choose (24.9%), showing how regulatory practices are sufficient (11.9%), and better tracking the product risks in market (9.6%).⁴⁹

⁴⁰ See Tony Prosser, *The Regulatory Enterprise: Government Regulation and Legitimacy* (Oxford: Oxford University Press, 2010) at 18.

⁴¹ See Moses, “Sociotechnical Change”, *supra* note 38 at 13.

⁴² See Julia Black, “Paradoxes and Failures: “New Governance” Techniques and the Financial Crisis” (2012) 75:6 Mod L Rev 1037.

⁴³ See Roger Brownsword, “Law, Liberty, and Technology” in Roger Brownsword, Eloise Scotford, & Karen Yeung, eds., *The Oxford Handbook of Law, Regulation and Technology*, (Oxford: University Press, 2017), at 1-2 [Brownsword, “Law, Liberty, and Technology”].

⁴⁴ See also Jonathan Zittrain, *The Future of the Internet* (Penguin, 2009); Siva Vaidyanathan, *The Googlization of Everything (And Why We Should Worry)* (University of California Press, 2011).

⁴⁵ See also David Lyon, *Surveillance Society* (Open University Press, 2001); Zygmunt Bauman & David Lyon, *Liquid Surveillance* (Polity Press, 2013).

⁴⁶ See Brownsword “Law, Liberty, and Technology”, *supra* note 43 at 3.

⁴⁷ See Marion Nestle, “Is Nanotechnology the New GMO?” *The Atlantic* (16 December 2011), online: <<https://www.theatlantic.com/health/archive/2011/12/is-nanotechnology-the-new-gmo/249982/>> .

⁴⁸ See Macoubrie, “Informed Public”, *supra* note 20.

⁴⁹ See Macoubrie, *ibid*, at 16-20.

On the other hand, policy-makers' actions to regulate a technology can stifle the pace of technological development and even result in blocking further development. For example, the way genetically modified organism (GMO) technology has been regulated in the EU (e.g. mandatory labelling) outpaced attention to the environmental, health, and safety implications,⁵⁰ while other products, such as hormones, remain less tested and monitored. The role of the policy-maker is thus to balance the necessity of ensuring an adequate level of protection while using nanotechnology (if the benefits outweigh the risks) to provide more advanced research and to foster innovation. The lack of knowledge about the long-term health effects of using nano-products causes difficulties in establishing one precise standard that can be applied to public authorities that are seeking to craft regulations that attempt to balance both health and safety considerations with the creation of conditions in which innovation in the nanotechnology area can thrive. Generally, it can be claimed that the standard should correspond to the safety level that the users are entitled to expect, based on the current state of knowledge, but also including justified predictions. Those expectations should be assessed from the normal and prudent user's perspective.⁵¹ Even though nanotechnology is usually operated by a specific group of users (e.g. scientists, researchers), the assessment of the safety of a nano-product should be made solely based on what a final, normal user could expect. The complexity of nanotechnology and the vast scope of its application justify taking into account the safety expectations of the final user. It means that the standard applied by public authorities should remain flexible and correspond to actual problems.

Too strict or too expanded a regulatory legal system can also lead to overregulation.⁵² Both the users of the technology and the companies working on the technology can be overwhelmed by the number of regulations. Moreover, when the regulations are very precise and detailed, they start losing their flexibility, and after some time, their importance. For example, if the policy-maker draws up a list of potential dangerous materials and provides the exact name or chemical composition, it can quickly turn out that a substance with a similar, but not exactly the same, chemical composition will be excluded from the application of this regulation, even though it has dangerous features. One solution to prevent such a situation is to create principle-based regulations, which would be more flexible and accurate.⁵³ Principal-based regulation is one of

⁵⁰ Compare Gary E. Marchant, Douglas J. Sylvester & Kenneth W. Abbott, "What Does the History of Technology Regulation Teach Us About Nano Oversight?" (2009) 37:4 *JL Med & Ethics* 724 at 727 [Marchant, Sylvester & Abbott, "Nano Oversight"].

⁵¹ Compare Y. Markovits, "La directive C.E.E. du 25 juillet 1985 sur la responsabilité du fait des produits Defectueux" (1990) *LGDJ* 307; A. Geddes, *Product and service liability in the EEC* (London: Sweet & Maxwell, 1992) at 22.

⁵² Compare *Commission Regulation (EC 2257/94) of 16 September 1994 laying down quality standards for bananas* (Text with EEA relevance), [1994] *OJ*, L 245 at 6.

the regulatory approaches which is based on the general and broad principles established by the public authority, instead of precise and detailed rules.⁵⁴ Owing to that, regulated entities (e.g. companies) have more freedom in choosing the methods of complying with these principles. At the same time, broad principles are less likely to be outpaced by the passage of time and fast-changing technological realities.⁵⁵

Regulation might also be a costly process. More regulations on technology, such as restrictions on a production process, higher safety standards and mandatory requirements like additional, more detailed safety tests, product labelling, risk tracking, mandatory maintenance and reviews of a product, can all impose extra costs on a company. These extra costs generated by additional regulations are usually passed on to the consumers of the final product.⁵⁶ When users receive a product which meets higher standards of protection, the price of a product will usually be higher. This means that the costs of raising a product's standards will be covered by the users of the technology, which at the end of the day can result in "throwing the baby out with the bathwater." Ensuring high quality and safety standards can lead to an increase in price to a level where buying a product is no longer cost-effective and lucrative. Users can thus make a decision not to purchase a product, but then they will be deprived of the real possibility of taking advantages of technological development. Therefore, setting disproportionate standards of protection can adversely affect users' decisions. Moreover, if users do not buy products, companies will not have enough revenue to invest in further innovations. Nonetheless, it can be observed that currently, more and more policy-makers and legal scholars recognize the problems associated with nanotechnology. Their works are devoted, for the most part, to public law regulations (administrative admission, registration of nanomaterials, etc.).⁵⁷ A report, "Regulatory Frameworks for Nanotechnology in Foods and Medical Products", by the OECD Working Party on Nanotechnology (WPN), published in 2013, suggests that the existing legal

⁵³ See Marchant, Sylvester & Abbott, "Nano Oversight", *supra* note 50 at 727.

⁵⁴ See Julia Black, "Forms and Paradoxes of Principles Based Regulation," (2008) 3:4 *Capital Markets Law Journal* 425 at 425-435 [Black, "Forms and Paradoxes"].

⁵⁵ See Marchant, Sylvester & Abbott, "Nano Oversight", *supra* note 50 at 727.

⁵⁶ See Roger Van den Bergh, "Subsidiarity as an Economic Demarcation Principle and the Emergence of

European Private Law" (1998) 5 *MJECL* 134 at 137-139.

⁵⁷ See e.g. Regulation EC, *Regulation* (EC 1223/2009) *of the European Parliament and of the Council of 30 November 2009 on cosmetic products*, [2009] OJ, L 342 at 59-209; Regulation EU, *Regulation* (EU 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*, [2012] OJ, L 167 at 1-123. See also U.S. Food & Drug Administration, "FDA's Approach to Regulation of Nanotechnology Products", online: <<https://www.fda.gov/ScienceResearch/SpecialTopics/Nanotechnology/ucm301114>> ;

European Commission, "Nanomaterials in REACH and CLP", online: <http://ec.europa.eu/environment/chemicals/nanotech/reach-clp/index_en.htm> .

framework is able to cover nanoproducts.⁵⁸ The European Commission also concluded that “foods and medical products that may contain nanomaterials, or otherwise involve the application of nanotechnology, are covered under existing national and/or regional legislative and regulatory frameworks that are relevant and applicable to food and medical products”.⁵⁹ The commentators are less optimistic. Clarence J. Davis argues that the existing regulatory and management scheme will probably not be able to deal with nanotechnology. Among the obstacles he points out are: lack of sufficient data, inability to monitor and control the development of nanotechnology by regulatory authorities, and insufficient funding of research and enforcement mechanisms.⁶⁰ There are also contradictory opinions about whether or not nanotechnology should be regulated. Sonia Arrison claims that nanotechnology could flourish only through “modest regulation, civilian research, and an emphasis on self-regulation and responsible professional culture”.⁶¹ The argument for self-regulation is that companies and private research centers can assess the actual risk in a better way than government.⁶² Certain groups such as the Natural Resources Defense Council and Greenpeace call for slowing down nanotechnology research and development.⁶³ A more balanced opinion has been expressed by Linda Breggin and Leslie Carothers. The authors propose a multi-pronged and integrated approach to the nanotechnology phenomenon. This approach could include “elements of regulatory and voluntary programs

⁵⁸ *OECD 2013 Report*, *supra* note 15. The report was based on a survey in which twelve voluntary delegations took part over 2011 and early 2012 — Australia, Canada, European Union, France, Germany, Japan, Korea, the Netherlands, Norway, Poland, the Russian Federation, and the United States.

⁵⁹ See Katharine Sanderson, “Putting Nanotechnology Regulation Under the Microscope,” *The Guardian* (24 June 2013), online: <<https://www.theguardian.com/what-is-nano/putting-nanotechnology-regulation-under-the-microscope>>; see also “OECD WPN Summarises Regulatory Frameworks for Nano in Foods and Medical Devices,” (24 May 2013) Nanotechnology Industries Association, online: <<http://www.nanotechia.org/news/news-articles/oecd-wpn-summarises-regulatory-frameworks-nano-foods-and-medical-devices>>.

⁶⁰ See Clarence J. Davis “Managing The Effects Of Nanotechnology,” (2006) Woodrow Wilson International Center for Scholars, Project on Emerging Nanotechnologies, at 3, 8-12, 27-30, online: <http://www.nanotechproject.org/file_download/files/PEN2_MngEffects.pdf> [Davis, “Managing Effects”]; see also Charles Q. Choi, “Nano World: New Nanotech Law Called for,” *UPI* (17 January 2006), online: <http://www.upi.com/Science_News/2006/01/17/Nano-World-New-nanotech-law-called-for/UPI-70721137543611/> [Choi, “Nano World”].

⁶¹ See Choi, “Nano World”, *ibid.*

⁶² See also Sonia Arrison, “Nanotechnology Needs Nano-Scale Regulation,” *TechNews-World* (13 January 2006), online: <<http://www.technewsworld.com/story/48272.html>>.

⁶³ See Satya Thallam, “Nanotech,” *Mercatus Reports* (Fall 2006) at 4-5, online: <<https://object.cato.org/sites/cato.org/files/serials/files/regulation/2006/10/v29n3-merc-report.pdf#page=2>>.

under existing environmental statutes; corporate stewardship; tort liability; federal, state, and local legislation; voluntary standards; disclosure; liability insurance; and international measures".⁶⁴

V. PROBLEMS WITH EUROPEAN PRODUCT LIABILITY LAW

So far, little attention has been devoted to the issue of liability with respect to nanotechnology.⁶⁵ Although nanotechnology generates new risks, there is no separate liability regime, which means that the traditional rules of existing tort law have to be applied in the case of injuries caused by nanomaterials. From the user's perspective, liability rules might be as important as health and safety regulations. This is because the safety rules are addressed mainly to the companies, and consumers are not directly identified by such regulations. The regulation of compensation for damages caused by products which do not meet certain safety requirements might be thus more interesting for the users of nanoproducts. This area is regulated by tort law, more precisely by product liability law, and its role in connection with the development of new technologies should primarily be users' protection.

Unfortunately, existing regulations in force in the EU Member States regarding liability for damage caused by defective products, implemented under the *Product Liability Directive*,⁶⁶ is not a fully adequate legal response to the risks connected with nanoproducts and fails to ensure appropriate levels of safety for users of this technology.⁶⁷

First of all, the *Directive* limits the scope of its application to "tangible" goods. According to Article 2 of the *Directive*, "product" means all movables, with the exception of primary agricultural products and game, even when incorporated into another movable or into an immovable.⁶⁸ The definition of a "product" causes some problems with respect to nanotechnology. Nanomaterials can be classified as tangible, but invisible, objects which are the components of the product. However, nanotechnology can also be used to produce products, for example by nanolaser,⁶⁹ as well as possibly being a part of a service, for example medical procedures or treatment,⁷⁰ which are not covered by the scope of the application of the *Directive*.

⁶⁴ Linda Breggin & Leslie Carothers, "Governing Uncertainty: The Nanotechnology Environmental Health & Safety Challenge," (2006) 3:2 Colum J Envtl L 285 at 310.

⁶⁵ See Howells, "Product Liability", *supra* note 1. In the article, the author focuses only on two themes: defect and development risk defense.

⁶⁶ *Product Liability Directive*, *supra* note 16 at 29.

⁶⁷ See also Piotr Machnikowski, ed., *European Product Liability: An Analysis of the State of the Art in the Era of New Technologies* (Cambridge: Intersentia, 2016) [Machnikowski].

⁶⁸ See Machnikowski, *ibid.*

⁶⁹ See Jae-Hyuck Choi et al., "A High-Resolution Strain-Gauge Nanolaser," (12 May 2016) 7 *Nature Communications*, online: <<http://www.nature.com/articles/ncomms11569>>.

Secondly, legal problems are related to a notion of “defectiveness”. Under Article 6 of the *Directive*, a product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account, including (a) the presentation of the product, (b) the use to which it could reasonably be expected that the product would be put, and (c) the time when the product was put into circulation. Also, a product shall not be considered defective for the sole reason that a better product is subsequently put into circulation. The phrase, “the safety which a person is entitled to expect”, shows that the *Directive* regime is based on a consumer expectation model.⁷¹ The crucial element of this model, however, is the necessity that consumers are well-informed so that they can make an informed decision as to whether or not they would like to use nanoproducts. Currently, there is no legal obligation to inform consumers about the risks associated with the use of nanoproducts, e.g. by labelling. Labelling issues remain controversial. Marchant, Douglas and Abbott introduced labelling as a discriminatory action, from the point of view of market mechanisms, because of its stigmatization effect.⁷² Similarly, Juni has pointed out the difficulties of companies in relation to the communication of the risks.⁷³ Introducing new technologies can cause fear and social concerns, and run into resistance against their use. In many cases this anxiety is unsupported and based solely on the fear of novelty. It often results from false, selective, or misinterpreted information about a new technology, as well as conflicting reports from the science world, “media storm”, and groups of opponents. An example of distrust in technological development might be the example of the “anti-vax” movement emerging in Europe and North America.⁷⁴ This movement originates from an article of Dr. Andrew Wakefield published in the *The Lancet* in 1998. According to Wakefield’s research, 8 of 12 children brought by their parents to a hospital in London exhibited symptoms of autism within 14 days after MMR vaccination (measles, mumps and rubella). The research was criticized by other experts and finally it turned out that in an examined group there was only one case of autism symptoms, which appeared a few months after the vaccination. Dr. Wakefield was removed from the register of professional medical practitioners and 12 years after it was published, his article was withdrawn from the journal.⁷⁵ Despite these facts, the “anti-vax” movement is growing and members of this group stigmatize vaccination technology.

⁷⁰ See Davis, “Managing Effects”, *supra* note 60 at 8.

⁷¹ See Howells, “Product Liability”, *supra* note 1 at 385.

⁷² See Marchant, Sylvester & Abbott, “Nano Oversight” *supra* note 50 at 725.

⁷³ See Robin L. Juni, “Product Liability Implications of Nanotechnology,” online: < www.jonesday.com/files/Publication/e411d864-2374.../Nanotechnology.pdf >, at 26-27.

⁷⁴ See “What’s behind the ‘anti-vax’ movement?”, *BBC News* (5 August 2015), online: < <http://www.bbc.com/news/health-33774181> > .

⁷⁵ See Nick Triggle, “Lancet accepts MMR study ‘false’”, *BBC News* (2 February 2010), online: < <http://news.bbc.co.uk/2/hi/health/8493753.stm> > .

The stigmatization effect can also be seen in case of GMOs. Although new technologies are usually introduced to the market under the assumption that they will be beneficial and bring improvement to existing technologies, they are sometimes rejected by the potential users for above mentioned reasons. In that case, labelling can magnify the effect of distrust and resistance, which can be seen in the social approach to GMO in the EU. The EU selectively targets products which are made through GM processes, although there is no evidence that proves that these processes are riskier than other methods of processing food.⁷⁶ Under EU Regulation No. 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms,⁷⁷ GMO products are subject to strict labelling and traceability, even though researchers are in agreement that GMO food products are not more hazardous than the non-GMO food, and are actually even safer.⁷⁸ Consumers are more aware of the existence of GMO food, but on the other hand they are not informed about hormones for example, which are less monitored, and at the end of the day consumers could make a biased decision.

Nonetheless, to some extent, labelling can be beneficial. First, since users do not know that the product contains nanomaterials, they have a limited ability to benefit, for example, from the protection provided by tort law. Accurate information enables users to make an informed decision about whether they want to use potentially dangerous technology and expose themselves to the possibility of harm.⁷⁹

Apart from labelling, users could also be informed about risks by the media or public campaigns. According to Howells, if risks are known and users are informed, the matter of defectiveness depends on whether the risks are socially acceptable.⁸⁰ Greater risk will probably be more acceptable in the area of medicine and pharmaceuticals, where the risk could bring considerable improvement, rather than in the cosmetics or entertainment industry.⁸¹ The moment of assessing the defectiveness of a product is when the product is put into circulation on the market, under Article 6(1)(c) of the *Product Liability*

⁷⁶ See Marchant, Sylvester & Abbott, “Nano Oversight”, *supra* note 50.

⁷⁷ See Regulation (EC No. 1830/2003) OJ L 268, 18.10.2003.

⁷⁸ See National Research Council, *Genetically Modified Pest-Protected Plants: Science and Regulation* (Washington: National Academies Press, 2000) at 43-44; National Research Council, *Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects* (Washington: National Academies Press, 2004).

⁷⁹ Compare Better Regulation Executive & National Consumer Council, “Warning: too much information can harm! A final report by the BRE and NCC on maximising the positive impact of regulated information for consumers and markets,” (London: BRE & NCC, 2007) [BRE & NCC, “Too Much Information”].

⁸⁰ See Howells, “Product Liability”, *supra* note 1 at 390.

⁸¹ See Machnikowski, *supra* note 67, at 699.

Directive. Under Article 6(2) a product shall not be considered defective for the sole reason that a better product is subsequently put into circulation.⁸²

The notion of defectiveness is tied to the admissibility of the development risk defence. According to Article 7(e) of the *Directive*, the producer shall not be liable if he proves that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered.⁸³ This defence is especially favourable to those producers who use new technological processes, the consequences of which are difficult to predict. The existing legal framework demands that companies make a reasonable decision based on data and research available only when the product is put into circulation. As indicated above, the most significant problem with nanoproducts is that currently, the risks and negative effects on the human body and the environment are mostly unknown. The growing pace of technological development in the area of nanotechnology could result in producers being able to easily free themselves from responsibility. The existing regulations also create an incentive to put products on the market carelessly and to do less research ahead of time.⁸⁴

The next problem relates to the limitation period. Under Article 10(2) of the *Directive*, the rights conferred upon the injured person to claim for compensation shall be extinguished upon the expiry of a period of 10 years from the date on which the producer put into circulation the product which caused the damage. Taking into account that the detrimental effects of nanotechnology applications might not present themselves for a long period of time, a 10-year limitation period from the date on which the producer put the product into circulation seems to be insufficient.

More general problems with the existing legal framework of product liability, related not only to nanotechnology, are concerned with how to assign responsibility for damage, establish causal links, and define the scope of the damage to be repaired.⁸⁵

VI. LEGAL RESPONSE: PUBLIC AUTHORITY LIABILITY

Given the aforementioned problems, the constantly expanding scope of the application of nanotechnology, and the increasing degree of risks, the discussion on regulating liability for damage caused by nanoproducts is urgent. The regulations presently in force for EU Members under the *Product Liability Directive* fail to ensure appropriate levels of safety for users of nanoproducts. As a result, users are deprived of full tort law protection, and in some cases of damage caused by nanoproducts, they will not be able to obtain compensation. It

⁸² See *Product Liability Directive*, *supra* note 16 arts. 6(1)(c), 6(2).

⁸³ See *Product Liability Directive*, *supra* note 16 art. 7(e).

⁸⁴ See *Product Liability Directive*, *ibid.*

⁸⁵ See also Machnikowski, *supra* note 67 at 699.

seems necessary to adjust tort law to these new challenges in order to ensure an appropriate level of protection.

This section focuses on legal remedies that will facilitate the efforts of nanotechnology's users in obtaining compensation. The proposal goes beyond the traditional concept of a product liability regime and concentrates not on product liability itself, but on a public authority liability focused on the case of the non-regulation, or improper regulation, of nanotechnology.

1. Justifying Regulation of Public Authority Liability

One may ask why policy-makers should be liable for taking any regulatory action. The decision on whether or not to regulate a new technology depends almost entirely on the vision of a particular policy-maker. Regulations are supposed to reflect the societal interactions and needs, as well as attitudes, existing in a society which usually expresses traditional, regional and cultural diversity. Policy-makers have the freedom to make decisions concerning the scope and form of regulations. This can help explain why GMO technology is regulated differently in the US and the EU.⁸⁶

One of the concerns around regulating for public authority liability with respect to new technologies is the excessive burden this would place on public authorities to foresee the effects of the legislative solutions that are adopted.⁸⁷ This leads to the more fundamental question of who should bear the risk of regulatory policy, and why. First, it seems justifiable to assume that public authorities should be aware of the consequences of their decisions. They have access to a wide range of the latest research results, and if in doubt, they can commission further analyses, evaluate regulatory proposals with experts and public opinion, and, based on that, weigh the pros and cons. The policy-makers' decision also has an impact on whether and how technology will be used by companies, and how products will be introduced to the market. Companies thus rely on legal regulation and adjust their production processes to the existing legal framework. On the other hand, there is a threat that the users will bear all the costs of introducing technology to the market.

It is clear that policy-makers are also the risk-taking actors when introducing new technologies into public use. In the discussion on the role of government in the innovation industry, one may find opinions such as the following, that:

Governments have always been lousy at picking winners, and they are likely to become more so, as legions of entrepreneurs and tinkers swap designs online, turn them into products at home and market them globally from a garage. As the revolution rages, governments should

⁸⁶ See Paul B. Thompson, "How We Got to Now: Why the US and Europe Went Different Ways on GMOs", *The Conversation* (5 November 2015), online: < <https://theconversation.com/how-we-got-to-now-why-the-us-and-europe-went-different-ways-on-gmos-48709> > .

⁸⁷ See Andrea Biondi & Martin Farley, *The Right to Damages in European Law* (The Netherlands: Wolters Kluwer, 2009) at 93-94 [Biondi & Farley].

stick to the basics: better schools for a skilled workforce, clear rules and a level playing field for enterprises of all kinds. Leave the rest to the revolutionaries.⁸⁸

To challenge this opinion Mariana Mazzucato puts a simple but relevant question: who actually funded these revolutionaries?⁸⁹ Taking as an example the smartphone's features such as internet connectivity, GPS, touchscreen, and microchip, one must notice that they were all funded by governments,⁹⁰ which often make decisions on commercialization policy. Although the opinion that all innovations flourish thanks to government action is exaggerated, one has to notice that policy-makers can have a real impact on the technological reality.

While Mazzucato stops her arguments at proving why the government is an active actor on the innovation field, thus explaining why companies should contribute to public funds, it is possible to go a step further. The contribution of public authorities to technological development can support the liability they should bear for their policy decisions.

The next argument for regulating public authority liability is that it can create incentives for policy-makers to take more effective and more precautionary actions in order to ensure adequate levels of user protection. Before making a legally binding decision on a regulatory policy, policy-makers can, for example, commission more research on the potentially detrimental effects of the technology to be regulated.

Liability for damages arising from the exercise of public authority can thus influence the effective exercise of power. Although the functioning of the public authority is not subject to basic economic assumptions, such as the assumption of maximizing profits, public authority liability can create incentives for policy-makers.⁹¹

2. Legal Basis for Regulation

Generally, to ensure an appropriate level of protection, there are other legal concepts to be applied. However, none of them separately represent a sufficient legal response to the challenges posed by nanotechnology.

One solution is to reconsider the existing legal framework of product liability rules based on the *Directive*, so that it can fully cover all injuries caused by nanotechnology. In other words, the regulation of product liability could be tightened for producers. Among the shortcomings in establishing stricter

⁸⁸ See "The Third Industrial Revolution," *The Economist* (21 April 2012), online: < <http://www.economist.com/node/21553017> > .

⁸⁹ See Mariana Mazzucato, "Government - Investor, Risk-taker, Innovator," Ted Talk, online: < http://www.ted.com/talks/mariana_mazzucato_government_investor_risk_taker_innovator#t-708914 > [Mazzucato, "Government"].

⁹⁰ See Mazzucato, "Government", *ibid.*

⁹¹ Compare Giuseppe Dari-Mattiaci, Nuno Garoupa & Fernando Gomez-Pomar, "State Liability" (2010) 18 *Eur R Priv L* 778.

regulation on product liability, the major one is the risk of hindering technological development and innovation.⁹² Over-regulating product liability rules can prevent companies from investing in further progress and research in nanotechnology.⁹³ It might be more profitable for the companies to use tested and better-known techniques rather than applying innovations which could expose them to the risk of paying high compensation. What is more, from an economic perspective, the higher costs of production resulting from overly strict legal requirements, or the more serious and real possibility of paying monetary compensation, are often passed on to consumers. At the end of the day, consumers would have to bear the costs of ensuring an adequate level of protection.⁹⁴

The other solution for balancing health and environmental risks against the commercialization of nanotechnology, which was proposed in the literature, concerns mandatory private-public insurance schemes.⁹⁵ So far, private-public insurance programs are typically applied to nuclear damage, where there is on the one hand low-probability, but on the other, high-loss.⁹⁶ According to Maksim Rakhlin, private-public insurance could cover nanotechnology if the elements were as follows: “(1) mandatory participation as a precondition to research and development, (2) creation of a cross-insurer pool of premiums and deductibles to use for claimant payouts, (3) federal government coverage of losses exceeding coverage provided by a cross-insurer pool, and (4) indemnification from tort liability of program participants.”⁹⁷ In spite of the fact that public-private insurance could possibly balance the risks posed by nanotechnology applications and the need for commercialization of nanomaterials and further technological development, this solution has certain shortcomings. First, it does not create incentives for government to introduce effective and well-balanced regulations. It also does not involve public authorities in the innovation process. Second, it affects companies directly by increasing the price of market participation.⁹⁸ It means that smaller companies

⁹² See James Pethokoukis, “Is Regulation Slowing Tech Progress and Innovation?” *AEIdeas* (3 June 2016), online: < <http://www.aei.org/publication/big-government-regulation-slowing-tech-progress-eli-dourado/> > ; Rich Karlgaard, “Is Technological Process Slowing Down?” *Forbes* (21 December 2011), online: < <https://www.forbes.com/sites/richkarlgaard/2011/12/21/is-technological-progress-slowing-down/> > .

⁹³ See Richard W. Rahn, “The Danger of Over-Regulation,” *Cayman Islands Journal* (11 October 2006), online: < <http://www.discovery.org/a/3762> > .

⁹⁴ Comapre Roger van den Bergh and Hans-Bernd Schäfer, “Liability of Member States for infringement of the EC Treaty: Economic Arguments in Favor of a Rule of Obvious Negligence,” (1998) 23 *Eur L Rev* at 552-567.

⁹⁵ See Maksim Rakhlin, “Regulating Nanotechnology: A Private-Public Insurance Solution” (2008) 7:1 *Duke L & Tech Rev* 1 at 1 [Rakhlin, “Regulating Nanotechnology”].

⁹⁶ See Robin M. Hogarth & Howard Kunreuther, “Ambiguity and Insurance Decisions,” (1985) 75:2 *The American Economic Review* 386 at 389.

⁹⁷ See Rakhlin, “Regulating Nanotechnology,” *supra* note 95 at 18.

could be excluded from the market and at the same time consumers may bear the additional costs.

Next, existing legal regulations around public authority liability are not an adequate solution to tackle the problems related to nanotechnology. The liability that the EU, as an entity with a legal personality, bears for damage caused by its institutions or by its servants in the performance of their duties, found in Article 340(2) *Treaty on the Functioning of the EU*⁹⁹ (*TFEU*), gives an illustrative example.¹⁰⁰ According to Article 4(2)(f) *TFEU*, consumer protection is one of the areas where the EU and the Member States share their competencies, which means that EU institutions can regulate nanotechnology from the perspective of consumer protection.

In the first place, it should be noted that Article 340(2) *TFEU* does not provide the specific prerequisites of liability, which are to be determined on the basis of the general principles common to the Member States. The formulation of the conditions of non-contractual liability lies with the Court of Justice of the European Union (CJEU), which is the only body that is competent to adjudicate complaints for damages.¹⁰¹ There is uncertainty around this provision. Both the general formulation of Article 340(2) *TFEU* and the diversification of liability rules in the Member States result in the CJEU having wide discretion in setting the rules for claiming damages. To some extent, this generality could be treated as an advantage, as it creates flexibility. However, CJEU judgments in many cases are inconsistent, often devoid of plausible justification, and the accepted jurisprudence is often not continued in subsequent cases. As a consequence, the liability of the EU is not predictable and cannot fully secure consumers' rights with respect to nanotechnology.

The CJEU formulates four conditions of liability for damages of the EU: infringement of the rule of law intended to confer rights on individuals, sufficiently serious breach, actual and certain damage, and direct causal link.¹⁰² The lack of presumptions for any of the conditions hinders fulfilling and proving all the requirements.

An interesting example with respect to the difficulties of proving causation is the case, *É.R.*¹⁰³ The applicants sought a remedy for damage allegedly suffered by them as a consequence of the infection and subsequent death of members of their families who developed a new variant of Creutzfeldt-Jakob disease ("mad

⁹⁸ *Ibid.*

⁹⁹ *TFEU*, *supra* note 7 at 47—390.

¹⁰⁰ See Koen Lenaerts, Ignace Maselis & Kathleen Gutman, *EU Procedural Law* (Oxford: Oxford University Press, 2015) at 480 [Lenaerts, Maselis & Gutman].

¹⁰¹ Lenaerts, Maselis & Gutman, *supra* note 100 at 508.

¹⁰² See Takis Tridimas, *General Principles of EU Law* (Oxford: Oxford University Press 2006), at 486; Pekka Alto, *Public Liability in EU Law: Brasserie, Bergaderm and Beyond* (Oxford and Portland, Oregon: Hart Publishing, 2011) at 86.

¹⁰³ CFI, *É. R., O. O., J. R., A. R., B. P. R. and others v Council of the European Union and Commission of the European Communities*, T-138/03, [2006] ECR II-04923 [*É.R.*].

cow disease”). The applicants brought actions for damages against the EU for allegedly unlawful conduct in failing to adopt appropriate measures to prevent the risks presented by “mad cow disease”. The probable origin of the disease was a change in the preparation of cattle feed, which contained proteins derived from sheep infected with scrapie. Transmission of the disease came about mainly through the ingestion of feed, in particular, meat-and-bone meal containing the infectious agent that had not been eliminated.¹⁰⁴ The applicants contended that the European Council and European Commission persistently and deliberately favoured the interests of traders on the market in beef and veal to the detriment of the health of consumers when they assessed and managed the risks linked to the disease. The applicants claimed that there were wrongful omissions on the part of those institutions in carrying out their duties and obligations in the area of animal and human health and that they adopted insufficient, incorrect, inadequate or belated standards and measures to deal with the risks resulting from “mad cow disease”.¹⁰⁵ The Court concluded that the allegedly unlawful actions and omissions of the Council and the Commission cannot be considered to be a definite and direct cause of the infection. In the light of the circumstances of the case, the Court stated that it had not been shown that if those institutions had adopted, or had adopted earlier, the measures which the applicants criticized them for not adopting, the damage in question would not have occurred. As a result, the Court concluded that there was no causal link between the damage pleaded and the allegedly unlawful conduct by the EU institutions.¹⁰⁶

The next problem is related to the limitation period. According to Article 46 of the Statute of the Court of Justice of the European Union,¹⁰⁷ proceedings against the EU in matters arising from non-contractual liability shall be barred after a period of five years from the occurrence of the event giving rise thereto. The formula of limitation can drastically limit the possibility of claiming redress. First, the beginning of the limitation period is counted from the materialization of the damage, not from the moment of awareness of the damage.¹⁰⁸ Second, there is no detailed regulation addressing postponement, which would facilitate a significant extension of the running of the limitation period.¹⁰⁹ Third, five years seems to be relatively short when we take into account the long-lasting effects of

¹⁰⁴ *É.R.*, *ibid* at para. 1.

¹⁰⁵ *Ibid*, at para. 58.

¹⁰⁶ *Ibid*, at paras. 146-147.

¹⁰⁷ Article 281 *TFEU*, *supra* note 7, states that the Statute of the Court of Justice of the European Union shall be laid down in a separate Protocol.

¹⁰⁸ See Case 145/83, *Stanley George Adams v Commission of the European Communities*, [1985] ECR 03539. The Adams case has been widely discussed in the literature, see e.g. A.I.L. Campbell, *Confidentiality and EEC Law*, (1986) *The Journal of the Law Society of Scotland* at 125-126; N. March Hunnings, *The Stanley Adams Affair or the Biter Bit* (1987) 1 *Common Market Law Review* at 65-88.

¹⁰⁹ See P. Oliver, “Limitation of actions before the European Court” (1978) 3 *Eur L Rev* 12.

nanotechnology. Therefore, the existing regulation on EU liability might not be a sufficient legal response.

3. Regulation as the Best Form of Action?

As mentioned in Part IV, the non-legal regulatory mechanisms on their own, which are the market, social norms and “architecture”, cannot guarantee a sufficient level of protection with respect to the nanotechnology phenomenon. The arguments discussed in Part IV remain relevant while analyzing the public authority problem.

It should be noted that the liability for damage caused by acts or omissions committed by a public authority is a common principle in European legal systems.¹¹⁰ The lack of regulation or regulations providing an inaccurate response to the risks created by nanotechnology results in law losing its function as a regulatory mechanism for social relations. However, there are some problems related to public authority liability. The uncertainty in determining the proper standard of care is a challenge, and could cause liability to be blurred, or create ineffective stimuli. Where liability is imposed excessively, a decreased level of activity on the part of authorities could result. Conversely, if liability is excessively tempered, an increase in the abuse of authority could result. Secondly, liability will have an impact in terms of the costs of indemnification. Public authorities paying compensation may also lead to a deterioration in state budgets and increase the fiscal burden imposed on citizens. In order to avoid these problems, non-legal mechanisms, such as an “innovation fund” will be presented in Part VII.

4. The Appropriate Level(s) of Action

In the discussion on the appropriate level of regulating new technologies, the main argument supporting the idea of unified, international regulations on standards of protection is the transnational scope of the application of most new technologies, the existence of international companies, and the world-wide transfer of innovations.¹¹¹ However, in the case of public authority liability, the scope of regulation will be restricted to a defined political area. First, the development of non-contractual liability is to a great degree different in individual countries. Second, public authority liability will refer by nature to a particular policy-maker. It means that the central point is to define the policy-maker that has made a legally binding decision on nanotechnology. It could make a significant difference when the same area of law can be regulated by different bodies. For example, consumer protection is one of the areas where the European Union and the Member States share their competencies.¹¹²

¹¹⁰ See Biondi & Farley, *supra* note 87 at 1.

¹¹¹ See Marchant, Sylvester & Abbott, “Nano Oversight” *supra* note 50 at 729.

¹¹² *TFEU*, *supra* note 7, art. 4(2)(f).

5. Do the Benefits of Regulation Justify the Costs?

Undoubtedly, any regulation will create some costs. As noted above, in the case of public authority liability these are mainly the costs of the compensatory process. However, the proposed solution does not affect companies directly, so it will probably not hinder technological development, which is always a serious concern when regulating technologies. The government, on the other hand, will not be left alone with the burden of the compensatory process if a general “innovation fund” is created. Companies will thus contribute to the compensatory process and public authorities will not have look for additional funding, for example, in the form of a tax increase. Owing to this regulation, users will receive a mechanism to recover their losses, which means that they will not bear all the costs of introducing technology to the market alone, and therefore the benefits of regulation will justify the costs.

6. Transparency of the Distribution of Effects Across Society

One factor that policy-makers should take into account while drafting any new regulation, is to assess the impact of the regulation on society, including different social groups. This is a general and universal goal of regulatory transparency. The riskier a technology is, the greater the effort policy-makers should undertake to create transparent regulations related to public health and the environment. On the one hand, transparency ensures that no groups will be excluded from protection or be unjustifiably affected. On the other, it should enable technology users a choice between the various possible technological options.¹¹³ The necessity of transparency was also pointed out by the European Commission in 2000,¹¹⁴ when the Commission stressed that the decision of whether or not wait for more scientific data before taking steps towards regulating emerging technology should be based on transparency. In December 2000, the European Parliament endorsed a resolution of the Commission on the precautionary principle,¹¹⁵ where in point 14 the European Parliament agreed with the Commission that, before any decision is taken on measures to be adopted, the decision-maker should have an overview of the available knowledge on the risks of the activity or substance, carried out by experts who are independent of the interested parties, recognized by the international scientific

¹¹³ See Roberto Andorno, “The Precautionary Principle: A New Legal Standard for a Technological Age” (2001) 1:1 *Journal of International Biotechnology Law* 11 [Andorno, “Precautionary Principle”].

¹¹⁴ See European Commission, *Communication from the Commission on the Precautionary Principle* (COM/2000/0001), online: <<http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52000DC0001&from=EN>> [EC *Precautionary Principle*].

¹¹⁵ See European Parliament, *Resolution on the Commission communication on the precautionary principle* (COM(2000) 1 - C5-0143/2000 - 2000/2086(COS)) [European Parliament *Resolution*].

community for their expertise in the field concerned, and appointed by means of a transparent procedure.¹¹⁶

This proposal on public authority liability promotes the position of consumers, taking into account that consumers are directly vulnerable to the detrimental effect of using nanotechnology. Liability rules can thus ensure that the users are not the only entities forced to bear the costs of technological development.

However, it should be noted that regulatory decisions also affect companies, businesses, and private research centers. The tougher regulations are, the more precautionary measures and cost-benefit calculations companies have to undertake to resolve convenient risk-optimizing behaviour, which in turn can reduce incentives for investing in innovations.¹¹⁷ Stricter regulations could also increase the costs of running a business. Policy-makers will usually justify the decision of imposing more regulations on the ground that there is a fundamental necessity to protect the environment and users of technology. The regulations, however, need to be balanced and take into account the risks of using the technology as well as its benefits. Decisions on how to balance regulatory steps somewhere between an irrational fear of novelty and the potential harmful effects of using nanotechnology should be based on the precautionary principle.¹¹⁸ Literature and international acts use various definitions of the precautionary principle.¹¹⁹ The UNESCO's World Commission on the Ethics of Scientific Knowledge and Technology (COMEST) tried to find a common core from different wordings and definitions and proposed a general working definition for the precautionary principle:

“When human activities may lead to morally unacceptable harm that is scientifically plausible but uncertain, actions shall be taken to avoid or diminish that harm¹²⁰ (. . .) [and] the judgement of plausibility should be grounded in scientific analysis. Actions are interventions that are undertaken before harm occurs that seek to avoid or diminish the harm. Actions should be chosen that are proportional to the seriousness of the potential harm, with consideration of their positive and negative consequences, and with an assessment of the moral implica-

¹¹⁶ *European Parliament Resolution*, *supra* note 115.

¹¹⁷ See Kenneth S. Abraham, “Environmental Liability and the Limits of Insurance,” (1988) 88:5 *Colum L Rev* 942 at 944.

¹¹⁸ See Andorno, “Precautionary Principle”, *supra* note 113.

¹¹⁹ See e.g. *London Declaration* (Second International Conference on the Protection of the North Sea 1987); *Rio Declaration* (United Nations 1992); *EC Precautionary Principle*, *supra* note 114. See also Cass Sunstein, *Laws of Fear: Beyond the Precautionary Principle* (Cambridge: Cambridge University Press, 2005).

¹²⁰ See UNESCO, “The Precautionary Principle” *World Commission on the Ethics of Scientific Knowledge and Technology* (COMEST, 2005) at 11-13, online: <<http://unesdoc.unesco.org/images/0013/001395/139578e.pdf>> [UNESCO, “Precautionary Principle”].

tions of both action and inaction. The choice of action should be the result of a participatory process.”¹²¹

As Roberto Andoro points out, adequate regulatory steps are based on common sense and practical observations of technological implications and should be taken when there is enough empirical evidence and reliable hypotheses that a new product or technology might be potentially dangerous for its users.¹²² According to the European Commission, the lack of scientific proof of the detrimental effects of using new technologies cannot be used to justify inaction. All scientific advice and views should be taken into account, even if they represent a minor fraction of the scientific community.¹²³

Without a balanced decision-making process, the most convenient and easiest solution would be either a complete ban on nanoproducts production, until all the risks are precisely determined, or the opposite scenario, not regulating nanotechnology at all, because of a lack of sufficient knowledge. Those solutions seem unrealistic, impractical, and would be contrary not only to market rules but also to societal needs.

To protect companies and businesses from the threat of the overregulation of new technology, it is important to consider the right of companies to claim for compensation if the regulations are too tight. Although this solution is an after-the-fact protection, it could probably create incentives for policy-makers to introduce more balanced regulatory schemes and therefore companies will not be excluded from protection.

Taking into account the existing legal framework in EU law, the major problem with liability for legal actions concerns the prerequisite of unlawfulness. In the context of liability for damage caused by overregulation, it might be difficult to prove the unlawfulness of the legal acts. There was a lively and long-lasting debate over the liability for lawful conduct. Initially, in the case *Biovilac*, the Court of Justice stated that if the concept of liability without fault were accepted in Community law (now European Union law), the action for damages for lawful legislative action can succeed only if the damage alleged by the injured party exceeds the limits of the economic risks inherent in operating in the sector concerned.¹²⁴ The liability for lawful acts referred to the German law concept of “Sonderopfer” [special sacrifice] and the French law concept of “rupture de l'égalité devant les charges publiques” [unequal discharge of public burdens].¹²⁵

¹²¹ UNESCO, “Precautionary Principle”, *ibid.*

¹²² See Andoro, “Precautionary Principle”, *supra* note 113 at 12. See also Peter T. Saunders, “Use and Abuse of the Precautionary Principle”, *Institute of Science in Society* (ISIS) submission to the US Advisory Committee on International Economic Policy (ACIEP) Biotech Working Group (July, 2000), at 13, online: < <http://www.i-sis.org.uk/prec.php> > .

¹²³ *EC Precautionary Principle*, *supra* note 114.

¹²⁴ See ETS, *SA Biovilac NV v. European Economic Community*, 59/83, [1984] ECR 4057 at 4058 [*Biovilac*].

¹²⁵ *Biovilac*, *ibid.*, at 4063.

However, in the *FIAMM* case,¹²⁶ the Court of Justice rejected the concept of liability for lawful acts. It based its decision on the argument that:

. . . comparative examination of the Member States' legal systems enabled the Court to make at a very early stage the finding concerning convergence of those legal systems in the establishment of a principle of liability in the case of unlawful action or an unlawful omission of the authority, including of a legislative nature, that is in no way the position as regards the possible existence of a principle of liability in the case of a lawful act or omission of the public authorities, in particular where it is of a legislative nature".¹²⁷

The Court of Justice also stressed that the legislative context is characterized by the exercise of wide discretion, which is essential for implementing Community policy. Therefore, the Community cannot incur liability unless the institution concerned has manifestly and gravely disregarded the limits on the exercise of its powers.¹²⁸ It means that the wide scope of legislative freedom is crucial for the making of EU policy decisions and thus the existing legal rules would probably not cover the case of the overregulation of nanotechnology if injured companies are limited to compensation only in the case of unlawfulness.

Although the Court of Justice rejects liability for lawful acts, there are certain arguments in favour of this solution. Such regulation will provide the aggrieved parties with compensatory damages suffered in connection with the use of nanotechnology, when it is not possible to obtain compensation directly from a producer (e.g. due to the limitation period or to legal requirements by a producer, etc.) and thus strengthen protections for users. On the other hand, companies will have the opportunity to obtain compensatory damages in the case of overregulation. In this way, a balance between all stakeholders will be maintained, and users and companies will have an indirect impact on actions taken by policy-makers.

7. Keeping the Regulations Clear, Consistent, Comprehensible, and Accessible to Users

It seems that the more complex and complicated technology becomes, the more the rules of liability should be simple and straightforward.¹²⁹ In the case of nanotechnology, highly specialized and detailed knowledge is necessary to understand all the complex processes that are involved. What makes

¹²⁶ ETS, *Fabbrica italiana accumulatori motocarri Montecchio SpA (FIAMM) and Others v. Council of the European Union and Commission of the European Communities*, C-120/06 P and C-121/06 P, [2008] ECR I-06513 [*FIAMM*].

¹²⁷ *FIAMM*, *ibid*, at para. 175.

¹²⁸ *Ibid*, at para. 174.

¹²⁹ See Ulrich Magnus, "Germany" in Piotr Machnikowski, ed., *European Product Liability: An Analysis of the State of the Art in the Era of New Technologies* (Cambridge: Intersentia, 2016) at 237.

nanotechnology even more complicated is its interdisciplinary approach, which necessitates cooperation between experts in biology, physics and chemistry. The complexity of this issue also has an impact on regulations. It seems that certain regulations remain specific and scientific (e.g. rules directed to researchers or producers on the minimum/maximum quantities of nanomaterials in a product). However, the regulations which are addressed to an “ordinary” user as well as the general liability principles should be kept simple. One of the ideas for making this a reality is to establish principle-based regulation, which can be adjusted to changing and more complex technological problems.¹³⁰ Undoubtedly, such a regulation would ensure flexibility, which means that the legal act does not have to be changed that often. On the other hand, it could not guarantee the stability of the law. Moreover, simple and straightforward regulation requires more initiative from the authorities which apply the law, including courts and regulatory bodies.

8. Presenting Views by Stakeholders

Recent research shows that the public expects the government to take regulatory steps in the area of nanotechnology,¹³¹ which means that the voice of the users of nanotechnology is important in the debate on nanotechnology. At the same time, the companies using nanomaterials might be interested in imposing public authority liability, as legal regulatory acts influence business decisions including the necessity of adjusting production processes in line with established requirements.¹³² Before introducing new regulation, policy-makers should take into account the views of all stakeholders, for example, through public debates, or by hearing from groups of experts working on nanotechnology. Any legislative initiative, which is not preceded by reliable public and expert debate, might be socially destructive. The role of policy makers is to initiate discussions, which should be held at the national as well as the essential local level. At the national level, policy-makers could lead an information campaign through traditional and social media, or hold public consultations through government online platforms. Examples of such actions might include public consultations organized by the European Commission and certain agencies of the European Union such as the European Food Safety Authority. These consultations concern policy approaches that can ease the development of emerging technologies such as the Internet of Things,¹³³ as well as nanotechnology.¹³⁴ The results of consultations can be analyzed and discussed

¹³⁰ See Marchant, Sylvester & Abbott, “Nano Oversight” *supra* note 50 at 727; Julia Black, “Forms and Paradoxes”, *supra* note 54, at 425.

¹³¹ See Jane Macoubrie, “Informed Public”, *supra* note 20.

¹³² See Kip W. Viscusi, “Frameworks for Analyzing the Effects of Risk and Environmental Regulations on Productivity” (1983) 73:4 *The American Economic Review* 793 at 793.

¹³³ European Commission, “Conclusion of the Internet of Things public consultation”, online: < <https://ec.europa.eu/digital-single-market/en/news/conclusions-internet-things-public-consultation> > [*EC Consultation*].

by a group of independent experts from different research centers. Policy-makers can also commission additional reports on the effects of imposing public authority liability on state budgets.

However, in practice public consultations have their limits. The most significant problem is that information about public consultations reaches only a limited number of people. For example, in public consultations on the Internet of Things, organized by the European Commission in 2012, only 600 people responded.¹³⁵ It seems that the circulation of information is insufficient. Perhaps more effective actions can be performed at the local level by local authorities. For example, they could manage information campaigns in schools or public debates at universities. They could prepare and spread brochures, and invite citizens to take part in various surveys. Information could also be included in local newspapers or posters. At the local level, important tasks are undertaken by non-governmental organizations, which are independent of government but can cooperate with local authorities.

VII. ACHIEVING COMPLIANCE — DRAFTING REGULATIONS

According to Van Dam, “in establishing liability of public authorities, courts have to steer between not hampering a good government on the one hand, and correcting bad government on the other”.¹³⁶ In EU law, public authority liability is regulated in the *Treaty of the Functioning of the European Union* and by the decisions of the CJEU.

Public authority liability in the case of nanotechnology would remain a part of the tort law system. One may, however, pose the question as to whether public authority liability should cover only nanotechnology and exclude other emerging technologies. While it is true that nanotechnology is used widely in everyday products and its long-term consequences are still unknown, it has to be noted that many other products pose considerable challenges for regulatory decisions due to their high risk for users’ safety (e.g. asbestos, mercury). Just as the sphere of unknown technological processes is growing, there will probably be more and more examples of technologies, such as genetic engineering, causing similar problems. Excluding other technologies from the scope of legal regulations on public authority liability thus seems unjustified and impractical.

The potential elements and features of the proposed regulation shall be as follows. Public authority liability should be a subsidiary claim to the one against the producer of nanoproducts. If the infringed party does not receive compensation from the company (e.g. when the company followed legal requirements while monitoring production processes), then s/he could make a claim for compensation from the public authority. If the infringed party received

¹³⁴ European Food Safety Authority, “Public consultation: guidance on nanomaterials”, online: < <https://www.efsa.europa.eu/en/press/news/180112> > .

¹³⁵ *EC Consultation*, *supra* note 133.

¹³⁶ Cees Van Dam, *European Tort Law* (Oxford: Oxford University Press, 2006) at 472.

compensation from the company, s/he will not have a right to sue the public authority. The claim against the public authorities, however, could be a recourse claim, meaning if the company provided the compensation and the injury is the result of inadequate regulatory measures, the company could make a claim in restitution for the public authority to return the previously paid compensation.

Furthermore, with regard to nanotechnology, subjectively understood fault should be replaced with objective criteria such as the infringement of the legal rules and/or precautionary principles, and move from fault-based liability to strict liability. In extreme cases, when the damage is unpredictable and has enormous scope, compensation should be granted even if the actions of public authorities were lawful.

The next element is that of causal link. As shown in the *É.T.* case, proof of a direct causal link can be a serious obstacle when seeking compensation. Furthermore, European law contains a general principle that the party which makes a claim bears the burden of proof regarding that claim. This is also applicable to a defence.¹³⁷ In the case of nanotechnology, the injured party usually does not have a real possibility of gathering all the detailed information on the causal link or exact source of damage. Creating presumptions or changing the burden of proof will mitigate the barriers posed by the current process of proving causality. This would mean that the policy-maker will have to prove that it has *not* infringed precautionary principles. With this change in the burden of proof, the injured party will receive a real chance of obtaining compensation.

Taking into account the fact that the long-term consequences of nanotechnology are mostly unknown, the limitation period plays an important role in regulating public authority liability. The length of the limitation period in the case of the EU liability is now five years from the moment of the event giving rise to liability. The Court of Justice's case-law indicates that the length of that period has been determined from the perspective of the necessary amount of time that the aggrieved party needs in order to collect the relevant information in order to submit a claim, and to review the facts that are to be invoked in support of that claim.¹³⁸

This argument does not correspond with the nature and problems related to nanotechnology. Unknown long-term consequences justify the proposal of starting the limitation period from the time of an injured party's knowledge about the cause of the damage. The five-year limitation period itself seems adequate as the scope of protection of the aggrieved party's interests depends not only on the length of the limitation period, but also on the manner in which its

¹³⁷ See Lenaerts, Maselis & Gutman, *supra* note 100 at 765. See Koen Lenaerts, "Some Thoughts on Evidence and Procedure in European Community Competition Law" (2007) 30:5 Fordham Intl LJ 1463.

¹³⁸ See ETS, *Autosalone Ispra dei Fratelli Rossi Snc v. European Atomic Energy Community*, C-136/01 P, [2002] ECR I-06565 at para. 28; CFI, *C-Content BV v. European Commission*, T-247/08, [2010] ECR II-00205 at para. 54; CFI, *Ehcon BV v. Commission of the European Communities*, T-140/04, [2005] ECR II-3287 at paras. 53, 57.

inception is determined (e.g. the moment of occurrence of damage, the moment of knowledge about the damage, the moment of knowledge about the source of damage) and the possibilities for its interruption and/or suspension (e.g. the impact of force majeure, the mediation, etc.).

It should be noted that the objective of the limitation period is, on the one hand, to ensure protection for the rights of the aggrieved party and to give that party sufficient time to file a claim, while on the other hand, to prevent a situation in which the aggrieved party could endlessly delay pursuing their right to compensation. The limitation period is intended to encourage the aggrieved party to take action, and after its expiry, to stabilize the legal situation.¹³⁹ The primary objective of the limitation period concept is the more general protection of the interests of the tortfeasor.

In conjunction with the fact that claims for damages against a public authority can involve a financial burden on the public authority and thus the state, the limitation period in the case of public authority liability is directly associated with the necessity of solicitude about public finances.¹⁴⁰ The limitation period thus allows the state to protect its finances from the demands of individuals who have not displayed the necessary diligence and failed to take advantage of their rights in the time provided.¹⁴¹ The five-year limitation period, counting from the time of knowledge about the source of damage seems an appropriate balance.

To achieve an effective protection system, there are certain mechanisms that should accompany hard law regulations. To avoid the situation in which the cost of indemnification procedures will be incurred by citizens, it is necessary to create a mechanism, which will separate payment of compensation by public authorities from the state budget. A solution to this problem is the creation of a special “innovation fund”. The essence of such a fund would be to create a general return mechanism and promote cooperation between public authorities and private companies. The primary assumption of the innovation fund is that companies using nanotechnology will share their profits with the government. It could be, for instance, 0.05% of annual income or one pre-determined contribution per five-year period. The innovation fund could serve a dual function. First, public authorities can use it as a special fund to pay potential compensation. If the public authority is found liable for taking inadequate regulatory steps, injured parties will have a guarantee that there is a source to pay compensation. At the same time, the payment of the compensation will be not

¹³⁹ See e.g. CJEU, *Evropaiki Dynamiki — Proigmena Systimata Tilepikoinonion Pliroforikis kai Tilematikis AE v. European Commission*, C-469/11 P, ECLI:EU:C:2012:705 at para. 53.

¹⁴⁰ See CFI, *Sanders et al. v. Commission of the European Communities*, T-45/01, [2004] ECR II-3315 at para. 59 [*Sanders et al.*]. The case concerned a labour dispute, but remarks concerning prescriptions from the Workplace Regulations were useful in explaining the function of prescription in general

¹⁴¹ *Sanders et al.*, *ibid* at para. 69.

imposed on all citizens, which would be the case if the public authority had to pay it from public funds (and public funds are based on taxation). Moreover, the private sector's contribution to the innovation fund will burden private companies to a lesser degree than if the compensation was paid directly by companies, mainly because it will only consist of a small part of the company's profits. Nevertheless, such a contribution does, to a certain extent, transfer the financial burden to the private sector. This scheme should be considered appropriate, as the companies are those parties which make the most profits.

The aim of the innovation fund is not only compensatory. The second function performed by this fund would be the contribution to further technological development, first by subsidizing further research and also by ordering additional research. This role of the innovation fund distinguishes it from an insurance scheme.

The financing of research and development (R&D) is of particular interest to many modern policy-makers. A general objective of the EU, adopted in the 2010 under the Europe 2020 Strategy,¹⁴² is to increase total expenses on R&D to the level of 3% of GDP.¹⁴³ Statistics presented by the World Bank in 2015 show that the percentage of GDP devoted to R&D looks as follows: World 2.23%, OECD 2.55%, USA 2.79%, and European Union 2.05%. The data also presents important differences between EU Member States, e.g. Sweden 3.26%, Denmark 3.01%, and Finland 2.90%, as compared to Greece 0.96%, Latvia 0.63%, and Romania 0.49%.¹⁴⁴ In 2017, the OECD published a new edition of Research and Development Statistics (RDS), which covers recent data on R&D in all OECD countries and selected non-member states.¹⁴⁵

It suggests that two-thirds of the expenditures on R&D should come from the private sector.¹⁴⁶ To encourage companies to spend more on stimulating innovations, public authorities offer R&D subsidies to companies.¹⁴⁷ However, the impact of R&D subsidies on increasing expenditures in the private sector and thus on fostering the innovation process is under discussion.¹⁴⁸ There is also

¹⁴² See European Commission, *Europe 2020 Strategy*, online: < https://ec.europa.eu/info/business-economy-euro/economic-and-fiscal-policy-coordination/eu-economic-governance-monitoring-prevention-correction/european-semester/framework/europe-2020-strategy_en > .

¹⁴³ See European Commission, "R&D expenditure", online: < http://ec.europa.eu/eurostat/statistics-explained/index.php/R_%26_D_expenditure > .

¹⁴⁴ See World Bank, "Research and development (% of GDP)", online: < <https://data.worldbank.org/indicator/GB.XPD.RSDV.GD.ZS> > .

¹⁴⁵ See OECD, "Research and Development Statistics (RDS)", online: < <http://www.oecd.org/sti/inno/researchanddevelopmentstatisticsrds.htm> > .

¹⁴⁶ See Tommy Hyvarde Clausen, "Do subsidies have positive impacts on R&D and innovation activities at the firm level?" (2009) 20:4 *Structural Change and Economic Dynamics* 239 [Clausen, "Subsidies"].

¹⁴⁷ Clausen, "Subsidies", *ibid.*

¹⁴⁸ See P. David, B. Hall & A. Toole, "Is public R&D a Complement or Substitute for

uncertainty as to whether such subsidies help to improve an internal technology strategy in a company and what their impact is in the long-term on a company's development.¹⁴⁹ Some research shows that while subsidies on research (activities "far from the market") result in a larger budget on research activities, subsidies on development (activities "close to the market") decrease the expenditures for development activities.¹⁵⁰ Therefore, direct subsidies are not a fully adequate mechanism for supporting R&D.

The other possibility for supporting further innovation lies in various programmes financed from public funds, which are managed by research funding agencies, either national or international. At the EU level, a grant system is administered by the European Research Council (ERC). Funding awarded by the ERC is based on open competition and is not limited to certain disciplines.¹⁵¹ The funding scheme is now, however, mainly dependent on Horizon 2020, the European Union's Research Framework Programme for 2014 to 2020.¹⁵² It means that the grant system is limited to the framework adopted under this programme. Furthermore, a seven-year period might be in some cases too long for the same grant scheme. The scope and intensity of technological development are evolving and growing faster than policy-makers can react.

Therefore, an innovation fund could provide a more efficient, flexible and adequate response to the needs and requests of the private sector. Companies and research centers should have the possibility of receiving funds on a regular basis, not only within special programs or frameworks. The application for funding should be based on a peer-review grant system, and the application, including detailed objectives and research steps, should be assessed by an independent and diversified commission composed of experts in a specific field. Perhaps double-blind reviews would be sufficient to reach an objective decision.

Due to the two functions of the innovation fund, it should be organized by a government agency and supervised by a relevant ministry (at the EU level, by an EU agency and the European Commission respectively). The scope of application should not be limited and should include both basic and applied research, as well as development activities.

Private R&D: A Review of the Econometric Evidence" (2000) 29 *Research Policy* 497-529; B. Hall, *Government Policy for Innovation in Latin America* (June, 2005), online: < https://eml.berkeley.edu/~bhall/papers/BHH05_LAC_innov.pdf > .

¹⁴⁹ See L. Georgiou, "Evaluation of Behavioural Additionality Concept Paper" (2003) presented

at the Meeting of the TIP Working Group of the OECD, online: < <https://pdfs.semanticscholar.org/75a3/374eb2210ba66b6827a9076cd724c9a83f79.pdf> > .

¹⁵⁰ See Clausen, "Subsidies", *supra* note 146, at 43.

¹⁵¹ See European Research Council, "Mission", online: < <https://erc.europa.eu/about-erc/mission> > .

¹⁵² See European Commission, "Horizon 2020", online: < <https://ec.europa.eu/programmes/horizon2020/what-horizon-2020> > .

Funds collected by the public authority should remain non-refundable, which means that after the limitation period they would not be returned to the companies.

At the same time, the users of nanoproducts should be informed of the nanomaterials used in products as well as of the risks related to nanotechnology. Labelling, educational programs at schools, financed for example by the innovation fund, and the contribution of the media, would be beneficial for users, companies and public authorities. Users could then make a more informed decision about whether they want to expose themselves to the possible risks.¹⁵³ Along with educational programs, public authorities should perform a duty of monitoring regulation on nanotechnology by creating constant commissions and mandatory periodic reviews of existing legal rules (e.g. every three-five years).¹⁵⁴

VIII. CONCLUSION

Nanotechnology undoubtedly poses new regulatory challenges. Although it has certain known benefits, it poses considerable risks to its users, with unknown and unpredictable long-term consequences. While looking for solutions to ensure the adequate level of protection and to enable users the possibility of seeking redress for damages caused by nanotechnology, I have examined the existing legal framework for product liability in the EU. The notion of product defectiveness, the shape of the development risk defence, and the limitation period indicate that the application of the *Product Liability Directive* to nanotechnology might be limited. In order to provide users with an adequate tort law mechanism, I propose regulating a public authority liability for legislative omissions. Policy-makers should take an active part in the compensatory process since if and how technology will be used by companies usually depends on governmental decisions. Users, on the other hand, should not bear all the costs of introducing technology to the market. This proposal argues that public authority liability should be a subsidiary claim to a claim against the producers of nanoproducts, and be based on objective criteria. The burden of proof should be changed in such a way that policy-makers will have to prove that they have not infringed precautionary principles as they apply in regulating nanotechnology. Further, the limitation period should run from the time of knowledge about the cause of damage. There is also a need to introduce certain mechanisms accompanying hard law regulation such as a special “innovation fund”, labelling, educational programs on nanotechnology, as well as mandatory periodic reviews of existing legal rules by government commissions.

¹⁵³ Compare BRE & NCC, “Too Much Information”, *supra* note 79.

¹⁵⁴ See also Marchant, Sylvester & Abbott, “Nano Oversight” *supra* note 50 at 727.