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THE PROTECTION OF WORKERS EXPOSED TO NANOPARTICLES: REFLECTIONS ON EUROPEAN AND ITALIAN SOFT AND BINDING REGULATIONS

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Abstract

The rapid development of nanotechnologies has brought a large nanotechnology entrepreneurial sector that imposes risks, uncertainties assessment, and management procedures. This study focuses on the needs for nanotechnology specific regulation in the workplace particularly in the European Union (EU) with special reference to the Italian perspective. This paper analyses the legal protection duties for employers and investigates whether existing regulations in workers' health safety cover nanotechnologies efficiently.

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1. Nanotechnologies and Safety in the Workplace in the EU: Uncertainties and the Need for Protection

The European Union has recently shown an interest in the Research and Development (R&D) sector of nanotechnologies. In 2004 the EU Commission launched a *European Strategy in Favour of Nanotechnologies*.¹ In this communication the Commission fixed as primary objectives the reinforcement and development of European knowledge, not only scientific but also, and above all, industrial and economic in a competitive vein. The document also stressed that nanotechnology must be developed in a safe and responsible manner. Parallel to this the Commission underlined that concerns about safety must be taken into account.² Nanotechnologies also present new challenges for assessing and managing risks so new approaches are necessary. The strategy document specified that there are real risks, potential risks and perceived risks. This means that it is necessary to ensure confidence from consumers, workers and investors and to combine the added value of scientific and industrial competitiveness with protection of the environment and health in an “integrated, safe and responsible approach”.³

The particular nature of nanotechnologies requires their re-examination and a possible revision of existing regulations. The harmful potential of nanotechnologies may require reliable and quantitative means of characterisation as well as measurement techniques that can underpin the competitiveness and reliability of future products and services, but also could ensure the necessary safety in their processes. In these terms, particular importance is given to workers’ health protection: workers may be exposed to dangerous fine dust or nanoparticles while doing research, while handling products, in post-production while washing workplaces and machinery, or when disposing of wastes. Nanoparticles are produced in many industrial and research endeavours that can unintentionally release them into the workplaces’ atmospheres.

Addressing the potential risks of nanotechnologies to health requires evaluating the possible re-use of existing data, if any, and generating new, nanotechnology-specific databases on toxicology, including dose response and exposure data, in the research and production sectors.

Health and safety at work is now one of the most important and most highly developed aspects of EU policies on employment and social affairs. Regulations impose specific obligations on Member States where legislation is binding. In the Lisbon strategy, the EU and Member States acknowledged the major contribution that

¹ Commission (EC) COM (338) final, 12 May 2004.

² Conclusions of the European Council, Doc 12487/04 (24 September 2004); Commission (EC) “Nanoscience and Nanotechnologies: An Action Plan for Europe 2005-2009” (Communication) COM 243 final, 7 June 2005; European Parliament Resolution (2006/2004(INI)); *VII Run Down of the Scheme of Research, Technological Development and Demonstration (2007-2013)*, Dec. n 1982/2006/EC from the European Parliament and Council (18 December 2006); Commission (EC), “Nanoscience and Nanotechnologies: An Action Plan for Europe 2005-2009” (Communication) COM 505 final, 6 September 2007; Dec. Commission 2008/721/CE (5 August 2008), setting up a consultancy made up of scientific committees of experts in the area of consumer safety, public health and the environment.

³ European Council Conclusions, Doc 12487/04, see note 2 above.

guaranteeing quality and productivity at work can play in promoting economic growth and employment.

Scientific knowledge on the consequences of exposure and on the definition of tolerability doses still appears to be limited; serious difficulties continue regarding the precise measurement of the parameters of the nanoscale.

In certain areas the necessary metrology tools are simply not currently available: the range of properties in potential relevance to risk assessment highlights the principal needs for extremely sensitive methods of detection. The commitment of various agencies and organisations at international and EU level towards the clear assessment of the different levels of toxicity has been demonstrated by studies undertaken by the EU and the Organisation for Economic Co-operation and Development (OECD).⁴ However, there remain many unknown details about the interaction of nanoparticles and biological systems.

The same difficulties are reported in procedures of risk assessment and risk management, in medical screening, and in the monitoring of the workplace: the necessary adjustment of those procedures has to consider the particular issues associated with nanotechnology applications.⁵

The lack of homogeneity in methods and analysis of measurements, standards and technical parameters of toxicity puts in evidence the potential risks associated with the manufacture and use of products incorporating engineered nanomaterials.⁶

The OECD, in particular, has set up a database of the research results on the health and environmental safety (*Database on Human Health and Environmental Safety Research*) and another into the safety of manufactured nanomaterials (*Database of Research into the Safety of Manufactured Nanomaterials*). There are also on-going projects for assessing the safety of a representative sample of manufactured

⁴ European Commission, Joint Research Centre, *Testing Methods* (22 September 2008), available at <http://ecb.jrc.ec.europa.eu/testing-methods> (accessed 19 Nov 10); OECD, *Guidelines for the testing of chemicals* (22 September 2008).

⁵ E Bergamaschi, "Occupational Exposure to Nanomaterials: Present Knowledge and Future Development" (2009) 3(3) *Nanotoxicology* 194–201, at 197; P Schulte et al, "Options for Occupational Health Surveillance of Workers Potentially Exposed to Engineered Nanoparticles: State of the Science" (2008) 3(3) *Journal of Occupational & Environmental Medicine* 517-526, at 518; W Luther, "Industrial Application of Nanomaterials - Chances and Risks: Technology Analysis" (2004), 93 available at <http://www.zukunftigetechnologien.de/11.pdf> (accessed 19 Nov 10); O Witschger and J Fabriés, "Particules Ultra-Fines et Santé au Travail. 2- Sources et Caractérisation de l'Exposition" (2005) *Hygiène et Sécurité du Travail – Cahiers de Notes Documentaires* 37-54. See also A Marconi, "Particelle Fini, Ultrafini e Nanoparticelle in Ambiente di Vita e di Lavoro: Possibili Effetti Sanitari e Misura dell'Esposizione Inalatoria"(2006) 28:3, *Giornale Italiano di Medicina del Lavoro ed Ergonomia* 258-265.

⁶ E Bergamaschi et al, "A Toxicological Approach to Hazard Assessment of Carbon Nanotubes: Implications for Workers' Health Protection" (2009) 50:10 *International Journal of Environment and Health* 249-263, at 253; V Murashov et al, "Occupational Safety and Health in Nanotechnology and Organisation for Economic Cooperation and Development" (2009) 11 *Journal of Nanoparticle Research* 1587-1591, at 1589; AC Lin, "Size Matters: Regulating Nanotechnology" (2007) 31 *Harvard Environmental Law Review* 349-408, at 371; SCENIHR opinion 10 March 2006, *The Appropriateness of Existing Methodologies to Assess Potential Risks Associated with Engineered and Adventitious Products of Nanotechnologies*; SCENIHR opinion 21-22 June 2007, *The Appropriateness of Risk Assessment Methodology in Accordance with Technical Guidance Documents for New and Existing Substances for Assessing the Risks of Nanomaterials*. Also RIVM Report 601785003/2009, *Nanotechnology in Perspective: Risks to Man and the Environment* (2009) 57.

nanomaterials (*Safety Testing of a Representative Set of Manufactured Nanomaterials*) and on the subject of manufactured nanomaterials to set out guidelines for assessment tests (*Manufactured Nanomaterials and Test Guidelines*). Several documents are in progress on measurement and mitigation of exposure (*Exposure Measurement and Exposure Mitigation*), on alternative methods in nanotoxicology (*The Role of Alternative Methods in Nanotoxicology*), on the impacts and business environment (*Impacts and the Business Environment*); lastly we can refer to the co-operation on assessing the risks (*Co-operation on Risk Assessment*).⁷

The Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) expressed an opinion on risk assessment in connection with nanotechnologies in 2006.⁸ However much progress the current toxicological and ecotoxicological methods have made, the Committee has nonetheless highlighted the inadequacy of parameters, portable instrumentations and knowledge for developing appropriate protection standards and tools, based on metrical doses.⁹ The Committee suggested the importance of adopting new sampling techniques and strategies for exposure assessment at the workplace and especially the desirability of establishing Occupational Exposure Limits for chemicals in the form of nanoparticles. The SCENIHR report mentioned that, in principle, the traditional risk assessment procedure could be an appropriate tool for assessing the risks from exposure to nanoparticles. But, if we consider the EU health protection policy in workplace, we can recognise that higher requirements for safety are needed. In the most recent Occupational Health Strategy, EU Commission focused its attention on finalising the methods for identifying and evaluating new potential risks associated with nanotechnologies.¹⁰ The Risk Observatory of the European Agency underlined the need for a framework plan to enhance risk anticipation: the aim is to include risks associated with new technologies in the assessment of occupational health and safety, the industrial risk management, the improvement of protective equipment and structural safety.

At the international level, there are documents, adopted within the International Organization for Standardization (ISO) which provide guidelines for risk management in the workplace (ISO TS 12901-2-2008) and relate general rules (ISO/TR 12885-2008). These do not appear to have been acknowledged within the EU. The EU has, however, commissioned the European Committee for Standardization (CEN) to propose a programme for revising existing standards or drawing up new ones on the subject of health and safety.¹¹ It needs to be stressed that the EU and Member States are participating in the activities of the ISO/TC 229 for the development of methods and standard nomenclature of nanoparticles.

Despite this progress, the problems associated with nanotechnologies are far from being resolved.

The traditional risk assessment methodology required by Directive no 89/391/CEE cannot be adequately applied to the risks of nanoparticles. The regulatory

⁷See <http://www.nanotechproject.org/> (accessed 19 Nov 10).

⁸ SCENIHR opinion 10 March 2006, see note 6 above.

⁹ RIVM Report, 57, see note 6 above.

¹⁰ See Commission (EC), "Improving Quality and Productivity at Work: Community Strategy 2007-2012 on Health and safety at Work" (Communication) COM (62) final, 21 February 2007.

¹¹ See UNI CEN ISO/TS 27687:2010, *Nanotechnologies: Terminology and Definitions for Nano-Objects - Nanoparticle, Nanofibre and Nanoplate* (14 January 2010).

requirements for risk assessment and risks management are settled on risks (real or potential) related to recognised or knowable materials. Nanoparticles/nanomaterials research and manufacture sectors are relatively new: epidemiology or environmental monitoring data are available but they have very limited relevance. No official guidelines on what constitutes an appropriate testing regimen yet exist: ISO and the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulation, this one for the production and commercialisation, are expressed as mass rather than particle size, as the SCENHIR report highlights.

As we shall illustrate below, the existing occupational health protection requires the identification of the risks, both real and potential, that may differ depending upon the nature of the materials to which organisms are exposed or on different particle size distribution, environmental conditions, or production methods. If the data on the harmful exposure consequences is not yet available or these are not surely demonstrated, then only limited hazard identification and assessment may be made: this does not meet safety requirements. In addition, the lack of detailed guidelines on the risk assessment of nanoparticles, especially for the potential wide range of production processes, can frustrate the need to ensure adequate work equipment and collective measures in workplace. In particular, specific work conditions must be considered when selecting work protection measures, the characterisation of hazards and of the workplace and the workers involved. Without clear and sufficient knowledge concerning nanoparticles characterisation, their detection, measurement and workers' protection are inefficient; without adequate toxicology data, it is impossible to create satisfactory risk assessments.

2. The Precautionary Principle and the Code of Conduct

The EU Commission considers that a more specific regulation of the risks, including occupational risks would be opportune, but that assumption has been proposed abstractly.

In the first stage the EU Commission preferred not to adopt directly binding regulations on specific measures of prevention and protection.

The Communication on the regulatory aspects of nanomaterials¹² seems to accept the alarms highlighted in medical literature: the EU Commission wants to strengthen investments in R&D sectors, balancing the interests involved and referring to the general principles on safety at work, already found in various legislative dispositions on the subject.¹³

Framework Directive 89/391/EEC and its large number of obligations on employers fully apply to nanomaterials in EU Commission's opinion. Other directives, adapted to risks related to carcinogens or mutagens exposure at work,¹⁴ chemical agent risks at work,¹⁵ the use of work equipment¹⁶ and the use of personal protective equipment at

¹² Commission (EC), "Regulatory Aspects of Nanomaterials" (Communication) COM (366) final, 17 June 2008. Also AC Lin, see note 6 above, at 383-384.

¹³ Council Directive (EEC) 89/391. See also E Cosimo, "Il Principio di Precauzione fra Stati Membri e Unione Europea" (2006) *Diritto Pubblico Comparato e Europeo* 1121-1140, at 1126.

¹⁴ Council Directive (EC) 2004/37 (29 April 2004).

¹⁵ Council Directive (EC) 98/24 (7 April 1998).

¹⁶ Council Directive (EEC) 89/655 (30 November 1989).

the workplace,¹⁷ could be applied totally. These provisions, as minimum requirements, could be enhanced at the national authority level with more stringent rules.

However, considering the uncertainty about on the nanomaterials hazards, the existing regulatory and the implementation work presents many difficulties and needs the support of the (future) scientific knowledge. Effective workers' protection at present may meet difficulties as well considering legal general duties.

The 2008 code of conduct for nanotechnologies,¹⁸ elaborated by the EU Commission, is marked by general principles of safety, especially the precautionary principle.¹⁹

The end users of EU documents are the Member States, as they were for the Communication on the precautionary principle;²⁰ both these documents are not binding by nature: national legislators and decisions makers are invited to encourage voluntary adoption, perhaps while providing incentives,²¹ of the code of conduct and to develop responsible research on nanotechnologies, inspired by the precautionary principle. However, the document only considers the R&D sector and leaves out the industrial sector: at present the code does not actually refer to workers but it invites

¹⁷Council Directive (EEC) 89/656 (30 November 1989). See also Commission (EC), "Amended Proposal for a Directive Covering the Minimum Safety and Health Requirements for the Use of Work Equipment by Workers at Work" (Communication) COM (111) final, 29 February 2008.

¹⁸ Commission (EC), "On the Code of Conduct for Responsible Research in the Sector of Nanoscience and Nanotechnologies" (Recommendation) C 0424, 7 February 2008.

¹⁹ Commission (EC), "On Appealing to the Precautionary Principle" (Communication), COM (1), 12 February 2000, 19-20. See also E Comiso, "Il Principio di Precauzione fra Stati Membri e Unione Europea" (2006) *Diritto Pubblico Comparato e Europeo* 1121-1140, at 1127; L Butti, "Nanotecnologie, Ambiente e Salute: Un'Applicazione Equilibrata del Principio di Precauzione per lo Sviluppo Sostenibile" in L Butti and L De Biase (eds), *Nanotecnologie, Ambiente e Percezione del Rischio* (Milano: Giuffrè, 2005) 3-43, at 25; T Marocco, "Il Principio di Precauzione e la sua Applicazione in Italia e negli altri Stati Membri della Comunità Europea" (2003) *Rivista Italiana Diritto Pubblico Comunitario* 1233-1245, at 1238; M Peterson, "The Precautionary Principle is Incoherent" (2006) 26 *Risk Analysis*, 595-601, at 600; A Philippopoulos-Mihalopoulos, "The Silence of the Sirens: Environmental Risk and the Precautionary Principle" (1999) 2 *Law and Critique*, 175-197, at 180.

²⁰ See Comest (World Commission on the Ethics of Scientific Knowledge and Technology), *The Precautionary Principle* (Paris: UNESCO, 2005), at 12; G Reynolds, "Nanotechnology and Regulatory Policy: Three Futures" (2003) 17 *Harvard Journal of Law & Technology* 180-209; M Rogers, "Risk Analysis under Uncertainty, the Precautionary Principle, and the New EU Chemical Strategy" (2003) 37 *Regulatory Toxicology and Pharmacology* 370-381, at 371-374; L Boisson de Chazournes, "Le Principe de Précaution: Nature, Contenu et Limites" in C Leben and J Verhoeven (eds), *Le Principe del Précaution: Aspects de Droit International et Communautaire* (Paris: LGDJ Diffuseur, 2002) 65-92, at 69; T O'Riordan and A Jordan, "The Precautionary Principle, Science, Politics and Ethics" (1995) 02 *CSERGE Working Paper*, available at http://www.uea.ac.uk/env/cserge/pub/wp/pa/pa_1995_02.htm (accessed 19 Nov 10) 1-26, at 8-9. Doubts are expressed by A Rip, "The Tension between Fiction and Precautionary in Nanotechnology" in E Fischer, J Jones and R von Schomberg, *Implementing the Precautionary Principle: Perspective and Prospects* (Cheltenham: Edward Elgar, 2008) 270-283, at 270-271; G Marchant and K Mossman, *Arbitrary & Capricious: The Precautionary Principle in the European Union Courts* (Washington, DC: AEI Press, 2004), at 14-15; A Gragnani, "Il Principio di Precauzione come Modello di Tutela dell'Ambiente, dell'Uomo, delle Generazioni Future" (2003) II *Rivista Diritto Civile*" 9-45, at 29.

²¹ See models of business management, defined conforming to the UNI-INAIL *Guidelines for a System of Health and Safety Management at the Workplace (SGSL)* (28 September 2001) or at British Standard OHSAS 18001:2007, compared to which in Italy presumption of conformity to legal requirements operates and adoption of these by employers is encouraged (art 30 D.lgs. n 81/2008).

the responsible and safe development of nanotechnology that we can probably extend its application.

On the other hand, the precautionary principle is expressly codified in art 191.2 of the Treaty on the Functioning of the European Union (TFEU) which refers explicitly only to the EU's environmental policy; according to majority opinion, this principle is in any case generally applicable²² and so it could also be invoked in workplace safety. Moreover, the precautionary principle is not defined in the TFEU, neither is it easy to define; for this reason the Council, in its resolution dated 13 April 1999, asked the Commission to draw up clear and efficacious directions to facilitate its application. According to the Commission, the precautionary principle can be invoked when:

the potentially dangerous effects of a phenomenon, a product or a process have been identified through objective, scientific evaluation, but when this evaluation does not permit the risk to be determined with sufficient certainty.

The Commission has underlined that the principle can only be invoked for potential risks and cannot justify taking an arbitrary decision.²³ Accordingly, the distance from an extremist (and unrealistic) vision of the precautionary principle is clear: considering everything that is not demonstrably innocuous as presumed harmful would be paralysing as well as being wrong. When uncertain, it is impossible to have negative proof of the lack of risk and the contrary, i.e. that the risk under consideration is not harmful.

The precautionary principle,²⁴ adopted by the Commission in its weak form, is considered a shared general rule; nevertheless it also presents limits because of its lack of binding force.²⁵ At the same time, it does not specify which level of scientific uncertainty is being applied.²⁶

The EU Communication on the precautionary principle underlines that it

forms part of a structured approach to the analysis of risk, as well as being relevant to risk management. It covers cases where scientific evidence is insufficient, inconclusive or uncertain and preliminary scientific evaluation indicates that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the high level of protection chosen by the EU.

In the EU Commission's opinion, the precautionary principle intervenes

²²In this sense also the Commission (EC), COM (2000) 1 final, see note 14 above, for which the field of application of the principle is much vaster.

²³R Von Schomberg R., *The Precautionary Principle and its Normative Challenges* (2008); E Fisher, J Jones and R Von Schomberg (eds), *Implementing the Precautionary Principle: Perspectives and Prospects* (Cheltenham, UK, Northampton, USA: Edward Elgar, 2008) 21-41.

²⁴See European Parliament, "On Regulatory Aspects of Nanomaterials" (Resolution) P6_TA 0328, 24 April 2009, 2008/2208(INI).

²⁵Contra: O Renn and M Roco, "Nanotechnology and the Need for Risk Governance" (2006) 8 *Journal of Nanoparticle Research* 153-191, at 184.

²⁶On the technical difficulties of really effective risk assessments see P Schulte et al, "Occupational Risk Management of Engineered Nanoparticles" (2008) 5(4) *Journal of Occupational and Environmental Hygiene* 239-249, at 243.

when concerns are such that risk management measures are considered necessary, as is currently the case for nanomaterials...for production and marketing, the effects of poorly soluble and difficultly degradable nanoparticles must be examined.²⁷

The disputes, the broadness of the problems, and the related duty of precaution cause peculiar problems when defining the employers' duty of workers health and safety protection. In fact, the precautionary principle is always adapted and widely accepted in both EU and national legislation.²⁸

EU safety and health protection in the workplace regulation (Framework Directive no 89/391/CEE and Directive 98/24/EC, especially, but also other directives) requires ensuring that the workplace as safe as possible and replacing situations, in so far as is technically possible, by substances, preparations, or processes which, under its conditions of use, are not dangerous or are less dangerous to workers' health or safety, as the case may be. Art 1(2) of Directive no 89/391/CEE contains general principles concerning the prevention of occupational risks, the protection of safety and health, the elimination of risk and accident factors and general guidelines for the implementation of those principles. Art 6(3)(a) imposes an obligation on the employer to evaluate the risks to the safety and health of workers, taking into account the nature of the activities of the enterprise and/or establishment. Subsequent to that evaluation, and as necessary, the preventive measures and the working and production methods implemented by the employer must ensure an improvement in the level of protection afforded to workers with regard to safety and health and be integrated into all the activities.

Moreover, European Court of Justice (ECJ) case law steadfastly affirms that professional risks are to be assessed by employers not just once, but that assessments must be renewed regularly and when any change occurs in the conditions which may affect workers' exposure: they must adapt protective measures to new and safer standards and when new data becomes available.²⁹ Risk assessment and management procedures, based on substances exposure, nature, degree and duration of workers' exposure must also be determined to decide the best measures to be taken. Those commitments could be compromised by the lack of relevant legislation to ensure safety, the absence of legislative provisions, instruments of implementation, and the absence of comprehensive science-based definitions and standards for nanomaterials in EU legislation.

The main question posed by nanotechnologies is if the risk assessment and the safety and health measures as decided by the employers are really efficient. Can we generally assume that legal provisions are respected when facing new materials when clear toxicology data or binding legislative solutions are lacking?

Nanomaterials, throughout their life cycles, raise major challenges for occupational health and safety. Many workers along the production chain are exposed to these

²⁷ Recommendation by the Commission, 7 February 2008, see note 13 above.

²⁸ See part 5 below.

²⁹ Case C-127/05 (ECJ 14 June 2007) in *Foro Italiano* 2007, 10, 500; Case C-5/00 (ECJ 5 February 2002); Case C-49/00 (ECJ 15 November 2001), in *Massimario di Giurisprudenza del Lavoro* 2002, 256 comment by Maretti; in *Lavoro nella Giurisprudenza* 2002, 1041 comment by Pasquarella; in *Diritto del Lavoro* 2002, II, 208 comment by Pietropaoli in *Foro Italiano* 2002, IV, 432 comment by Ricci; Case C-2/97 (ECJ 17 December 1998).

materials without knowing whether the safety procedures implemented and the protection measures taken are adequate and efficient. The “safe, responsible and integrated approach to nanotechnologies”, advocated by the EU Commission, conducts the protection of health and safety as enhanced by improved implementation of current legislation and adapting this it to new risk elements. As the EU Commission underlined in the regulatory policy (but limited to substances authorisation), it is necessary to qualify waste as hazardous, to reinforce conformity assessment by reclassification, and to introduce restrictions on the marketing and use of chemical substances and preparations.

The effectiveness of the way suggested by EU Commission for implementing legislation, particularly of risk assessment procedures, “through ‘Comitology’ procedures” and with non-binding documents for voluntary use, such as regulatory guidance inspires doubts. Focusing on occupational health protection, nanotechnology risks regulation, and all protective measures have to be fixed in legislative cogent tools, as the right to working conditions which respect workers’ health, safety and dignity requires (art 31 EU Charter of Fundamental Rights; in generally art 168 TFEU).

3. The Limits of Soft Law in the European approach

Specifically referring to exposure to nanomaterials both the EU Parliament and the European Economic and Social Committee criticise the adoption of only non-binding documents³⁰ and point out how the application of the precautionary principle could leave some unanswered questions or give rise to draconian measures.³¹

Soft law tools are certainly flexible and they can more easily guarantee the spread of standards and practices.³² Binding regulations in contrast foresee rigidity and may not be able to keep up with scientific and technological progress. However, waiting for shared standards and protective measures to become legally binding as the safety workplace regulation requires, such as the extent voluntary adoption of conduct codes, may lead to unacceptable delays in real and effective human health protection.

In a Communication of October 2009, the Commission seemed to have taken these positions into account and started to work towards the revision and adaptation of the existing regulation framework, although it still stated that “on the whole” current regulations can cover the potential risks of nanomaterials.³³

Even so, this approximate opinion gives rise to some perplexity.

³⁰ CESE Opinion, “On the Communication about the Regulatory Aspects on the Subject of Nanomaterials” (11 September 2009); European Parliament Resolution P6_TA (2009) 0328 (24 April 2009); See also note 18 above.

³¹ See CR Hahn, “The Precautionary Principle as a Basis for Decision Making” (2005) 2(2) *The Economist’s Voice*, article 8, available at SSRN: <http://ssrn.com/abstract=721122> 1-9, at 5; Marchant and Mossman, see note 20 above, at 15 and 71.

³² E Pariotti, “Regulating Nanotechnology: Towards the Interplay of Hard and Soft Law” (2009) 25:94 *Notizie di Politeia* 29-40, at 34-35. See also G Marchant, D Sylvester and K Abbott, “Risk Management Principles for Nanotechnology” (2008) *Nanoethics* 43-60.

³³ Commission (EC), “Nanoscience and Nanotechnologies: An Action plan for Europe 2005-2009. Second Report on its Putting into Effect 2007-2009” (Communication) COM (607), 29 October 2009; previously Commission (EC), “Regulatory Aspects on the Subject of Nanomaterials” see note 12 above.

The general principles of Directive 89/391/CE on the protection of the health and safety of workers from the risks related to harmful agents at work remain applicable at all times. That protective system includes the determination of the risk assessment; the risk prevention by specific measures, which concern currently known risks, but also have to follow scientific development, and the information and training plans for workers.

Considering employers' duties, a really effective risk assessment and management survey might encounter difficulties in guaranteeing a workplace safe at the maximum level, due to an incomplete knowledge of outcomes and related probabilities. For example, if we consider the new risks posed by nanomaterials, replacing the old equipment with new safer equipment, if any, and implementing training on the new ones put in doubt the employers' real capacity to keep up with science, where there still is no shared data on nanoparticles; on the other hand, an uncertain risk assessment could yield a greater net cost, when there is no confidence about the protective results and the conformity to legal commitments.

Perhaps the work on technical and regulatory standardisation, as stressed by the European Economic and Social Committee (EESC), could support an evaluation of nanotechnologies' risks more safety oriented, but that work that would then become the core of the EU nanotechnology's governance, in the "integrated, safe and responsible approach". The EESC recommends that:

an optimal governance system needs to be able to maintain equilibrium between the various aspects of responsible development of nanomaterials.

At the same time, the EESC underlines the need of strengthening:

interdisciplinary education and training measures, including risk assessment and prevention, and European centres of excellence in this area.³⁴

As the EU Parliament underlines:

the importance for the Commission and/or Member States to ensure full compliance with, and enforcement of, the principles of Community legislation on the health and safety of workers when dealing with nanomaterials, including adequate training for health and safety specialists, to prevent potentially harmful exposure to nanomaterials.

EU Commission and Member States should provide an additional regulatory framework, in the direction proposed by the Parliament: drawing attention to the need for prevention and risk reduction measures particularly when dangers related to substances used are unknown.

EU Parliament invites employers

in the context of the implementation of Directive 89/391/EEC, to consider the need for an adequate instrument to deal with the exposure of nanoparticles in the workplace as soon as further research on the "knowledge gaps", in particular with regard to hazards and exposure risks, are resolved, allowing a comprehensive understanding of the properties and risks of those materials.

³⁴ COM 366, see note 12 above.

This reference to REACH represents a useful starting point because it takes a precautionary approach and offers balanced assessments: in this context further guidance and advice on nanomaterials, in particular a specific adaptation of risk assessment methods, are needed.³⁵ Nonetheless, this needs revision to open the questions up to include nanomaterials.³⁶

On the other side, the precautionary principle could be the guiding principle, along with the principle of the elimination of risk at source, in order to maintain a high level of health protection.

To ensure greater protection from exposure to nanoparticles, some governmental or international reports suggest resorting to parameters and measures which are already widespread in the chemical industry (e.g. systems of anti-particle filtering EN 149:2001 and EN 143:2000, individual anti-particle facemasks, HEPA filters), as effective and adequate protective standards.³⁷

Uncertainty about health hazards produces a desire to fix broad uniform and binding rules at the European level: the tools required belong principally to hard law systems which are well-supported by a shared risks assessment procedure and governance rules. Supplementary soft law solutions can integrate hard law regulatory frameworks.

That double attitude also appears among EU institutions.³⁸ On one hand, there is the “softer” position of the EU Commission that deems the existing regulations are sufficient for ensuring workers’ health protection – especially Directive no 89/391/CEE, Directive 98/24 /EC and REACH – saving minor adjustments made necessary by specific shared standards.³⁹ On the other hand, the European Parliament⁴⁰ is more careful and advises the Commission in implementing Directive 89/391/EEC with adequate instruments to deal with the exposure of nanoparticles in the workplace. The Commission rightly classifies nanoparticles as possible cancerogenous “materials” or as dangerous chemical substances and considers the relevant existing regulation to be applicable. However, doubt remains about the real danger of the substances at the nanoscale and as it is not yet possible to determine adequate occupational exposure limit values.

³⁵ Council Regulation (EC) 1907/2006, “Concerning the Recording, Assessment, Authorization and Restriction of Chemical Substances (REACH)” (18 December 2006), esp point 69.

³⁶ See also Council Regulation (EC) 987/2008 (8 October 2008), where carbon and graphite are mentioned at the nanoscale level.

³⁷ UK Institute of Occupational Medicine (2004) 42-43; Commission Decision (EC) 2006/216 (16 March 2006), regarding the publication of references for norm EN 143:2000 “Equipment to Protect the Air-Ways-Anti-Dust filters: Requirements, Tests, Marking”. See A Seaton et al, “Nanoparticles, Human Health Hazard and Regulation” (2009) *Journal of Royal Society Interface* 1-11, available at <http://rsif.royalsocietypublishing.org> (accessed 19 Nov 2010), at 6; P Schulte et al, “Occupational Risk Management of Engineered Nanoparticles” (2008) 5:4 *Journal of Occupational and Environmental Hygiene* 239 -249, at 242; K Ludlow, D Bowman and D Kirk, “Hitting the Mark or Falling Short with Nanotechnology Regulation?” (2009) 27(11) *Trends in Biotechnology* 615-620; W Luther, “Industrial Application of Nanomaterials - Chances and Risks: Technology Analysis” (2004), available at <http://www.zukuenftigetechnologien.de/11.pdf> (accessed 19 Nov 10), at 86. See also MD Rogers, “Risk Analysis under Uncertainty, the Precautionary Principle, and the New EU chemical Strategy” (2003) 37 *Regulatory Toxicology and Pharmacology*, 370-381.

³⁸ G Van Calster, “Risk Regulation, EU Law and Emerging Technologies: Smother or Smooth?” (2008) 8 *Nanoethics* 61-71.

³⁹ See also CESE Opinion, “On Regulatory Aspects of Nanomaterials” (2008/2208 INI) (3 December 2008).

⁴⁰ European Parliament Resolution P6_TA (2009)0328 (24 April 2009), see note 18 above.

Regarding nanotechnologies, the question turns around how and whether risks assessment and risks management procedures are effective. A clear assignment of liability to employers arising from the harmful use of nanomaterials: considering the employers' obligations posed by the Framework Directive 89/391/CEE and the legal consequences, a specific binding regulation is necessary and in keeping with European and national legal commitments. This needs to go beyond the "responsible innovation", recommended in a Corporate Social Responsibility framework because the entire occupational safety system requires legal and binding commitments.⁴¹

4. Obligations of Employers in Italy: a) Risk Assessment

The European Union has not yet issued specific binding regulations for the health protection of workers exposed to nanomaterials. Nonetheless specific employers' obligations can be identified in application of the Member States' regulations.

The Italian system of health and safety protection in the workplace is based on (as well as arts 32 and 41, para 2, of the Constitution) art 2087 cc and in D.Lgs. n 81/2008, a codification of rules on safety in the workplace which, without substantial modifications to the general framework, substituted D.Lgs. no. 626/1994.

The civil code perspective turns around the contractual relationship between the employer and the workers⁴² regarding safety obligations. The 306 clauses of D.Lgs. no 81/2008 carry into effect the Community directives, integrate them, and establish procedures for fulfilling the employers' duty of occupational safety which is supported by administrative and criminal sanctions to guarantee its efficacy. The different provisions of the civil code one and the legal regulations do not restrain a broad interaction between them. Common opinion is that the safety obligations defined in the D.Lgs. no 81/2008 also specify the content of the obligation foreseen by art 2087 cc.⁴³ Their interaction is evident from the interpretation point of view and *ratio legis*: while it was formerly essentially taken as a claim and compensation tool, art 2087 cc's prevention function is increasingly emphasised⁴⁴ in relation to national and EU safety frameworks.

In my opinion, for reasons which I will set out, these Italian regulations could be deemed sufficient in the existing legal occupational health protection system, even for safeguarding the health of workers exposed to nanomaterials. Italian legislation states that all employers must guarantee the health and safety of their workers in all aspects connected to the job; the regulations apply to:

all the substances and all working activities, including the manufacture and use of chemical substances at all levels of the production process,

⁴¹ F Santanastaso, "Principio di 'Precauzione' e Responsabilità d'Impresa: Rischio Tecnologico e Attività Pericolosa 'Per sua Natura': Prime Riflessioni su un Tema di Ricerca" (2005) *Contratto e Impresa/Europa*, 21-105.

⁴² The violation of art 2087 cc produces a contractual liability. A job contract is integrated by law (in accordance with art 1374 cc) with the safety obligation fixed in civil code and this duty becomes one of the synallagmatic relations in contract (recently, Cass. 25 May 2006, n 1245; Cass. 13 August 2008, n 21590).

⁴³ P Albi, "Adempimento dell'Obbligo di Sicurezza e Tutela della Persona: Art 2087" in P Schlesinger and F Busnelli (eds), *Il Codice Civile: Commentario* (Giuffrè: Milano, 2008) 3-361, at 216 and notes.

⁴⁴ P Albi, see note 43 above, at 246; E Gragnoli "L'Obbligo di Sicurezza e la Responsabilità del Datore di Lavoro" in M Bessone (ed), *Trattato di Diritto Privato*; F Carinci and A Perulli (eds), *Il Lavoro Subordinato* (Giappichelli, Torino 2007), 443-479, at 452 and authors mentioned therein.

independently from the number of workers concerned, the amount of material produced and the technologies employed.

Prevention is particularly important and is based primarily on risk assessment as a means to subsequently adopt effective measures of prevention and protection for workers.

The employer is obliged to assess all risks⁴⁵ – including those regarding groups of workers exposed to particular risks – and to draw up a risk evaluation document; Italian legislation specifies that the risk assessment and the relative document

must be drawn up updating risks evaluation...when modifications of the production process or the organization of work affect the health and safety of the workers, or in relation to technological evolution, new prevention and protection measures or following important injuries or when the health inspections results highlight some changes or the update.

Extending the assessment procedure to all types of risk means that the employer has precise obligations towards the workers even when uncertainty exists or scientific certainty is lacking, in order to determine the danger or harmfulness of substances or manufacturing process: employers are obliged in any case to adopt safety measures to reach the highest safety level technologically available.

Italian literature extends the employers' obligation of updating by stating that:

[the] person liable for safety cannot shirk tackling potential risks, even if the negative consequences, from the workers' health damages point of view, have not yet been ascertained unequivocally or shared by the scientific community of occupational medicine.⁴⁶

Also,

it is not possible to distinguish between certain risks and merely probable risks; in fact implicit in the very notion of risk is the probability that the event may or may not take place.⁴⁷

Moreover, the problems of undertaking more reliable risk assessments cannot be underestimated. It is in fact very difficult to ensure workplace safety.⁴⁸ Difficulties depend on many factors. One of these is the heterogeneity of risks depending on the different types of nanoparticles or nanomaterials: the standard settings and definitions of risks are very complex. Despite this, it is important to emphasise that the employer must in any case carry out a risk assessment and adopt appropriate protective measures to eliminate or reduce exposure to risks.

Risk assessment is to be made *ex ante*, the adequacy of safety measures must be evaluated *ex ante*; it means that, even though the employer's duties are particularly

⁴⁵ Case C-49/00 (ECJ 15 November 2001) condemned Italy which in its previous legislation had not prescribed that the employer had to assess all health risks. The decision was published in *Foro Italiano*, 2002, IV, 18 and 432 with note by Ricci.

⁴⁶ See L. Montuschi, "Il Rischio Amianto: Quale Tutela? Introduzione al Dialogo" in L. Montuschi and G. Insolera (eds), *Il Rischio da Amianto: Questioni sulla Responsabilità Civile e Penale* (Bologna: Bononia University Press, 2006) 9-21, at 803.

⁴⁷ O. Bonardi, "La Corte di Giustizia e l'Obbligo di Sicurezza del Datore di Lavoro: Il Criterio del Reasonably Practicable è Assolto per Insufficienza di Prove" (2008) *Rivista Italiana di Diritto del Lavoro* 12-21.

⁴⁸ *Ibid.*, §1-3.

wide-ranging and though particularly incisive action is required, it cannot be transformed into “a game played in the dark...because it is easy to say *ex post* that something could have been done”.⁴⁹

5. Employers’ Obligations: b) Measures of Prevention and Protection

Once a risk assessment has been carried out, employers must adopt adequate measures of prevention and protection for their workers. Art 2087 cc states that the employer is obliged to adopt

the measures which, according to the characteristics of the job, experience and technology are necessary to protect the physical integrity and personal moral status of the employees.

That principle has been detailed and expanded by D.Lgs. no 81/2008. According to national and EU regulations, some authors have interpreted this duty as

any action or practical omission to the carrying out of the aim of protecting the safety and dignity of the worker falls within the subject matter of the obligation.⁵⁰

The civil code commitment to protecting people’s health at work must be applied in any case, independently from more specific existing regulations. For that, Italian doctrine sees the precautionary principle as a binding principle already present in the working relationship⁵¹ as a strong definition: the employer must adopt any initiatives to protect workers’ health even a complete risk assessment is not yet possible or there is no sufficient certainty on dangerous effects of substances, products or process present in workplace. Broadly speaking, the employer is obliged, whether facing real or only potential hazards, to adopt adequate measures:⁵² the health protection system states that employers must consider work process characteristics when fulfilling their legal obligations including a major assessment which includes all of the elements which feature in production and generally within the workplace from the point of view of risk.⁵³

However, so as not to over increase the employers’ duties, Italian case law stresses the words “according to experience and technology”, as contained in art 2087 cc. The questions are: how far is the employer obliged to reduce potential risks? And, how far is the criminal or administrative liability extended?

Since occupational health protection from nanoparticles exposure is still at an early stage, the employer may adopt the protective measures already tested for risks that can be, in a precautionary way, considered similar, i.e. chemical, carcinogen or

⁴⁹ A Vallebona, *Breviario di Diritto del Lavoro* (Torino: Giappichelli, 2009), at 269.

⁵⁰ E Gragnoli, see note 44 above, at 455.

⁵¹ P Albi, see note 43 above, at 215; L Butti see note 19 above, at 26.

⁵² A Viscomi, “Amianto: Precauzione, Prevenzione e Responsabilità” (2006) in L Montuschi and G Insolera G (eds), *Il Rischio da Amianto: Questioni sulla Responsabilità Civile e Penale* (Bologna: Bononia University Press, 2006) 45-56, at 50. The workers’ health protection regulation contains a “weak” precautionary principle because it does not impose an absolute obligation to respect every possible and unnamed caution. The aims are to avoid any damage and to exclude an employer’s liability for professional negligence.

⁵³ S Bertocco, “La Tutela della Salute e Sicurezza nei Luoghi di Lavoro” in F Carinci (ed), *Diritto del Lavoro: Commentario*, vol. 2 of C Cester (ed), *Il rapporto di Lavoro Subordinato: Costituzione e Svolgimento* (Torino: Utet, 2007) 963-1014, at 969 and further references therein.

mutagen agents exposure during work, until shared results are available. As jurisprudence has stated, the risk evaluation procedure consequently has to be professionally assessed and objectively followed even in its updating part: in other words, employers cannot declare a personal ignorance of any new risks.

This technological reference has ignited a debate about the duties of employers (and their relative liabilities): it is not completely clear if the employer must guarantee higher safety degree as “technologically possible” or only as “reasonably feasible”.

In principle, the Italian civil code, as well as the EU occupational health protection framework, refers to a general principle of prevention, with the greatest safety degree technologically possible. This means that employers must keep abreast of professional risks and update the measures they adopt regarding scientific and technological progress. The lack of further technical protective standards or detailed protective procedure rules imposes proactive behaviour to pass out-dated measures: employers must adapt safety measures without passively awaiting a legally imposed update without any evaluation of economic costs – except for unreasonably large costs for shared or experimental tools. The safety obligation in art 2087 cc therefore has an elastic content which imposes continuous revisions regarding new risks linked to new technologies.

The principle of the maximum degree of safety at the workplace should be defined considering that we cannot expect

that the employer researches new preventive measures or carries out experiments at his own expense;

Therefore he or she must apply

measures that are known and necessary according to experience and prudence and taking account of the technical knowledge acquired by science.⁵⁴

Moreover the employer cannot be charged with workers’ health injuries where negligence cannot be proven. However, professional negligence should be noted when, for example, all the occupational exposure limits have been respected but further investigation on toxic consequences even in presence of doubts or uncertainties has not occurred.⁵⁵

Considering the use of nanoparticles or nanomaterials, all the processes are developed by technological advanced companies or research centres: in my opinion, their activities should justify an enhancement of the protective obligation for them to adopt advanced safety measures because their legally required professional diligence. In other words, they must be able to update or follow scientific conclusions and results to ensure the highest safety degree in adopting sufficiently shared standards, even if their activities are at an experimental stage. The innovative character of nanotechnology also involves protective measures.⁵⁶

⁵⁴ Cass. (9 May 1998) n. 4721 in *Giustizia Civile*, 1999, I, 539 Cass. (12 July 2004) n 12863.

⁵⁵ Cass. (1 June 2004) n 10510 and Cass. (10 May 2000) n 6018. But see also Cass. (2 July 1999) in *Foro Italiano*, 2000, II, 260, with note by Guariniello. See also G Tranfo, “Su Nanotecnologie e Sicurezza Occupazionale Raccomandazioni per il Controllo dell’Esposizione” (2006) 12 *Igiene e Sicurezza* 25-26.

⁵⁶As an example, it is useful to consider the Supreme Court’s position on advanced or experimental technologies sectors in decision dated 25 July 1996, *Alfieri*, n 312. Considering the duty of ensuring a

6. The Most Specific Applicable Regulations

The general principles of D.Lgs. no 81/2008 and art 2087 cc impose workers' health protection duties even when employers face uncertain or insufficiently specified risks.

Moreover, more specific measures are required to ensure the effective safety at the workplace in the European and Italian occupational health protection frameworks when considering exposure to harmful substances at work. None of the protective measures, such as individual and collective all protective equipment, decontamination instruments, in-air concentration measurements, refers explicitly to nanomaterials or nanoparticles. Nonetheless, some of these regulations seem to be applicable to nanotechnology when thinking about ways to define the employer's general safety obligation. The EU Commission's Communication⁵⁷ on regulatory aspects refers to some EU Directives, in particular on the exposure to carcinogens or mutagenic agents at work, chemical agents exposure risks, on the use of work equipment and individual protective devices by workers during work, and on the protection of workers exposed to explosive environments risks.⁵⁸ The Commission holds

that the key elements of these directives, in so far as they concern nanomaterials, are the risk assessment, the measures of prevention and protection, the rights to information and consultation and the right to training.

The Italian discipline, for example, does not permit risk assessment using standardised procedures. For that, companies where these activities are performed and which expose workers to chemical, biological, explosive environments, carcinogens and mutagenic agents (art 27 D.Lgs n 81/2008) must provide bespoke risk assessments.

The EU Commission's Communication issued in 2008 considers it a priority to ensure adequate protection for workers exposed to nanoparticles, but, whilst the Directives directly consider specific harmful agents and impose precise protection duties on employers, the EU Commission documents are merely indications and recommendations. As underlined above, all EU documents on nanoparticles and nanotechnologies risks do not have directly binding effects for the Member States and even less direct efficacy in contractual obligations.

As already emphasised, in the Italian framework hazards evaluation must consider all risks, real or potential, and any related documents must be updated to include all

protective measures in relation to changes in organization and production that are relevant to the health and safety of the job, in accordance to the protection standards' evolution and of technological progress.

The content and application of that commitment necessarily depends on scientific knowledge and advisable protection standards on all levels. So the soft law tools, i.e.

safety level as reasonably practicable, this means that employers have to adopt measures that, in different sectors and different manufacturing processes, correspond to "generally practised technological applications and as many generally acquired organizational and procedural precautions".

⁵⁷ COM (366), see note 12 above.

⁵⁸ Council Directive (EC) 2004/37 (29 April 2004); Council Directive (EC) 98/24 (7 April 1998); Council Regulations (EEC) 89/655 and 89/656 (30 November 1989); Council Directive (EC) (1999/92). See part 3 above.

codes of conduct or good practices, could be binding integrating the employers' duties when generally shared as precautionary measures and standards, generally considered useful to prevent risks. Broadly speaking, all these non-binding tools could integrate shared prevention standards and apply them to the risk faced by exposure to nanoparticles. This is probably the intention behind consulting experts and international committees and in drawing up reports.

Due to the general principle mentioned in art 2087 cc, Italian courts would probably consider those practises gaining in importance and integrating protective legal issues. Facing negative consequences of exposure the employers who omit updating their risk assessments with those mixed standards would be condemned. With this mechanism and due to their nature of the possible specification of the general principles, even soft law tools can determine an augmentation of employers' protection duties and increase criminal or civil liability.