The EU approach to regulating nanotechnology

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Abstract

Since nanotechnology can enable humans to control matter at the atomic level, nano-applications can be found across all sectors of industry. While some of these could be of relevance for medicine and climate-change mitigation, currently the main driving force of nanotechnology is its potential positive economic impact. Public funding has so far outweighed private investment and, since analysts are predicting a value of the world market for nanotechnologies of between 750-2000 billion euros by 2015, they are seen as the key technologies for the 21st century.

The working paper aims to examine the current European regulatory agenda for nanotechnologies and looks at questions on the ethical and health and safety issues raised by any new technology. It also draws attention to the views of consumers, environmental groups and trade unions as stakeholders involved in the discussions.

Introduction

The main driving force of nanotechnology is the positive economic impact it can have. Public funding has so far outweighed private investment, and analysts are predicting a value of the world market for nanotechnologies of between 750-2000 billion euros by 2015. Nanotechnologies and nanosciences are expected to bring multiple benefits and novel applications for society - from energy capture and storage, through water purification solutions to a new generation of lighter and stronger materials for aeronautics - and this is the main reason why they are seen as the key technologies for the 21st century.

The international policy debate on nanotechnologies kicked off in 2003 when the United States under the George W. Bush Administration adopted its first policy implementing the National Nanotechnology Program to provide long-term funding of nanotech research and development. This move positioned America as the leader in the emerging revolution.

In the early 2000s, nanotechnology became a top priority for the United States, eastern Asia, Australia and New Zealand, since when the US has experienced significant growth in this area. Its 2009 fiscal budget allocation is about $1.5 billion (National Science and Technology Council 2009: 39).

More than 60 countries have national nanotechnology programmes, and this is reflected in the increase in patents. According to the OECD (Igami and Okazaki 2007), the European Union, Japan and the USA have contributed the majority of all nanotechnology patents. The United States hold most patents, mainly in the fields of medicine, biotechnology, measurement, manufacturing and nanomaterials. Europe lags behind the US and Japan, with Germany taking the lead in Europe, followed by France, Switzerland, the United Kingdom, the Netherlands and Italy. The rapidly growing interest in this field reflects their economic growth potential.

The European Patents Office (EPO) database reveals the organisations with the most published patents to be the French cosmetics company L'Oreal, BASF AG, Bayer AG, *Centre National de la Recherche Scientifique* (CNRS), *Commissariat Énergie Atomique*, *Institut für Neue Materialien*, and Henkel Kgaa. (Li *et al.* 2007), but they are not top of the world list. The United States and Japan have published more patents, showing the lead they have taken in the nanotechnology race (Annexe 1).

This paper aims to examine the current European regulatory agenda for nanotechnologies. It first takes a broad look at what nanotechnology is and the issue of its definition. It then moves on to a general overview of the European Commission's vision for nanotechnologies and their potential benefits, with a particular focus on human health and the role of standardisation. Part three looks at the main pieces of legislation involved in nanotechnology issues, and the need for specific regulation. Then, the views of consumers, environmental groups and trade unions as stakeholders involved in the discussions are reviewed. The paper also illustrates some examples of national nanotechnology initiatives. It concludes with a few closing considerations.

Before proceeding further, however, it is important to clarify some terminology.

1. The basics of nanotechnologies

Nanotechnology is commonly viewed as the starting point of a new industrial revolution, and most probably a revolution for humanity. It could change the way society works in ways that would breach global justice and possibly produce social inequalities (Ballesteros 2000; Ballesteros and Fernández 2007). It is the understanding, control and manipulation of matter at dimensions of anything from 1 to 100 nanometres, where chemical and physical properties differ significantly from the large scale or bulk form of a material.[1]

Nanotechnology makes it possible to cause matter to behave in different ways or give it different properties. It can enable humans to control matter at the atom level and to converge with biotechnology, communications, computer sciences, synthetic biology, information technology or cognitive sciences, and achieve things that will bring science fiction within the realms of the possible.

Richard P. Feynman, Nobel Laureate in Physics, describes a field in which it would be possible to manipulate and control things at a minute scale, where a billion tiny factories could be built with countless tiny hands manufacturing simultaneously (Feynman 1959). His intention was to show that molecular manufacturing would be feasible according to the laws of physics operating in the very small world of atoms.

Despite there being no consensus on a single definition, and with the concept under policy discussion, the OECD currently defines it as "the set of technologies that enables the manipulation, study or exploitation of very small (typically less than 100 nanometres) structures and systems" (OECD 2009).

Materials in nano form and size – nanomaterials - can be natural or engineered. The former already exist in nature - e.g., volcanic ash, clouds and clay, forest-fire smoke and the sea salt resulting from the evaporation of water from ocean spray.

Engineered nanoparticles are designed and manufactured by man to achieve specific ends, and can take different forms. They have certain characteristics that set them apart from other materials - like high surface area, high activity, catalytic surface, proneness to agglomeration/aggregation or dispersion - and have a wide range of applications (Hester and Harrison 2007: 2-3).

1. A nanometre is one-billionth of a meter (1/1,000,000,000 of a metre).

Among the most common engineered nanomaterials on the market are carbon black, a very fine particulate form of elemental carbon, used in printing inks, toners, plastics and coating applications. Fullerenes are a third form of carbon (e.g. diamond and graphite) possessing a unique structure of 60 carbon atoms in a geodesic shape[2]. Their applications include drug delivery, medicines, and optical devices.

Nanosilver particles have antimicrobial properties, meaning the ability to kill or inhibit the growth of microbes including bacteria. The particles interfere with the outside membrane of the microbe, destabilizing it and releasing the content of the cell, which kills it. Nano-silver is currently being used in socks and sports clothes, children's toys, eating utensils, food packaging materials and refrigerators.

Carbon nanotubes (CNTs) are extended tubes of rolled graphene sheets. They can be of two types, single-walled - one tube - or multi-walled - several concentric tubes. Since they were first discovered (Iijima 1991) their uses have multiplied to an extraordinary extent, and they now have a significant role among nanomaterials for their novel electrical, chemical and physical properties. They are among the strongest materials, but also extremely flexible, resistant to deformation without undergoing structural alteration, and are extremely good electrical conductors. CNTs have a variety of applications in nanoelectronics (The Royal Society and Royal Academic of Engineering 2004), being used in coating processes, to create conductive structure, strengthen bicycle frames, or add power to a tennis racquet through rigidity, for example.

Other nano-applications can be found across all sectors of industry, materials and manufacturing, electronics and computing, health and medicine, biopharmaceuticals, energy, automotive, aeronautics¸ communications, national security and space exploration. While the forecasts are for exponential economic development, generally-speaking most research projects require at least 10 years to get the end product in market-ready shape. An overview of the current market is given below.

There are also applications that could be relevant for climate change mitigation. A United Nations University Report (Esteban *et al.* 2008) offers specific examples of how nanotechnologies could be implemented to that end.

Energy, for instance, will be a challenging issue for the decade ahead. Examples cited by the UNU Report that are using nanotechnologies include using semiconductors or photovoltaic solar cells as a potential unlimited source of emission-free renewable energy by converting sunlight into electricity. Anoth-

2. Fullerene is one of the four types of naturally-occurring forms of carbon. Its architectural structure resembles a football, or the geodesic domes designed by the architect and philosopher R. Buckminster Fuller; C60 is the most common, and consists of 60 carbon atoms. Fullerenes were discovered as recently as 1985, and their most striking properties - high symmetry, stability and versatility - give them a wide range of applications.

er is the possible move towards the hydrogen economy by developing hydrogen fuel cells, which are electromagnetic devices that convert a fuel (hydrogen) into electricity. However, as the Reports points out, the use of hydrogen fuel cells is not necessarily carbon neutral (Esteban *et al.* 2008).

Advances in nanotechnology harbour many potential uses in medicine that will help increase our understanding of the human body, its mechanisms and diseases, and how to restore it to health.

One possible application will be to customise medical treatment through personalised medicine delivery, where patients will be given the precise, controlled dose of their specific medication at the right time. Nanotechnologies will enable the development of nanostructures to deliver drug molecules directly into the cells. Nanoparticles can act as *drug-carriers* or Trojan horses by encapsulating the medication. They can travel around the body indiscriminately and deliver the medication to the patient at the molecule level at the required dose when it is needed (Bhattachary *et al.* 2008; National Nanotechnology Initiative 2005).

Other developments are the generation of nanomaterials that could be applied to improve tissue regeneration, like restoring cartilage function to overcome arthritis, *in vitro* engineered organ patches or biomaterials for *in situ* regeneration of bones. Nanotechnology could also help in the fight against cancer, by developing nanomaterial systems to attack and destroy tumours.

Their multiple properties give nanomaterials a wide spectrum of medical uses; some have a biocidal activity used in self-cleaning surfaces. Recent research has investigated the properties of fullerene compounds as antiviral agents to eliminate pathogens and bacteria in place of long-term antibiotic treatments, using nanostructures to deliver drugs molecules directly into the cells (Freitas 2005).

Behind this prospect, however, loom ethical and health and safety issues that any new technology raises, and which must be addressed to make a reasoned assessment of what is in view, in particular when it comes to applications in human bodies.

On ethical aspects, there is a wide-ranging discussion of the potential risks of nanomaterials and nanotechnologies for humans, as little is still known about how they interact with the human body in terms of toxicity and carcinogenicity. Yet it is not possible to know whether the effects will show in the short-, medium- or long-term, because the existing tests cannot probe that. This lack of knowledge is one reason why specific regulations are needed to control the use of nanotechnologies.

The implementation of nanotechnologies in healthcare systems will be fairly complex and costly, mainly because this technology requires expertise and precise biomedical equipment that may not be easily available. The question is, therefore, if nano-based treatments do become available for curing or treat-

ing diseases, how many people would be able to benefit from them? Will they be available to everyone? How many countries will be willing to implement this new technology in their health systems and medical centres? There may be some 'over-promising' on what nanotechnologies can deliver.

Nano-applications in humans should deliver a better quality of life and health, but there are inherent risks in the development of any new technology. Social and ethical issues must be considered to gain a more rounded view of what the consequences might be, and how society can respond to them. Ethical concerns have been raised in the sphere of health care in relation to implanting nano-devices and the possibility for human enhancement[3] offered by the use of nanotechnologies (STOA 2009).

The following section presents an analysis of the regulatory agenda for nanotechnologies in Europe. It finds that one of the complexities for the regulators to address is health and safety, and further scientific studies are needed to assess it correctly. The section also broadly reviews the legislative instruments related to nanotechnologies, the current standardisation process and work on adopting a definition which today presents an obstacle to the development of a proper regulatory regime.

3. Human enhancement is the idea that humans can achieve 'perfection' beyond their own nature or be endowed with better or even new qualities or performances.

2. Framing policy for nanotechnologies in Europe

Nanotechnologies are a building block of the converging technologies capable of transforming all areas, up to humankind itself. It must therefore be kept in mind that an innovative regulation of nanotechnologies must meet the challenges of ensuring that the benefits are reaped by everyone, the risks minimised as much as possible, and all harm avoided.

The early makings of an EU (European Union) nanotechnology policy came between 1998 and 2002 with Framework Programme 5 (FP5), and the creation of various European projects.[4] But nanopolicy in the EU really took off between 2002 and 2006 under Framework Programme 6 (FP6), when nanotechnology projects were made a priority.[5] Initially, the Commission framed its strategy and adopted the Communication *'Towards a European Strategy for Nanotechnology'* about mid-period (European Commission 2004).

The Commission Communication does not propose a legislative scheme for nanotechnologies, but contains recommendations on research and development, infrastructure, education and training, innovation, and advises developing dialogue with stakeholders and consumers. The Commission's inclusion of a stakeholder dialogue as a priority is creditable, as understanding their needs and interests helps to inform a more complete strategy. Nonetheless, the Commission could pay more heed to concerns about the possible health and environmental risks of nanotechnologies.

The strategies laid down in its Programmes notwithstanding, the European Union is not ahead of the game, and so far, the United States has held onto its leadership, followed by Asia. Arguably, this suggests that the Commission's aim is to strengthen the EU's market position by fostering industrial applications which would doubtless bolster industry's market share and patents. The

4. Such as the NANOFORUM internet platform to disseminate information to the community on nanotechnology developments. Other examples are NANOSAFE 1 and 2 (safe production and use of nanomaterials), IMPART (Improving the understanding of the impact of nanoparticles on human health and the environment), NANOCAP (capacity building on the understanding of environmental, occupational health and safety risks and ethical aspects of nanotechnology), etc.

5. As an example of the funding allocated for nanotechnologies development, the EC Cordis website dedicated to Nanotechnologies and Nanosciences, says "With a budget of EUR 1 429 million for 2002-2006, the NMP priority under FP6 is conceived to promote the transition towards knowledge-based products and services through breakthroughs in new applicable knowledge and long-term RTD. The NMP priority supports research projects in the area of Nanotechnology and nanosciences, knowledge-based multifunctional materials and new production processes and devices»." (Cordis 2010)

Commission is confronted by the commercial competitiveness strategy, and the health and safety of nano products for users.

One fundamental flaw in the Commissions' work is the poor dialogue and communication with stakeholders. For the current EU programme to have meaningful outcomes, there is a need to engage the public – citizens, consumers, workers, vulnerable groups – in a more direct and serious conversation on health issues. Study findings on the possible risks of nanoparticles for humans show that particle toxicity is a slow progression, meaning that long-term experiments are needed to identify the health effects in humans; it serves no interest to wait until a cancer develops before developing preventive measures. Existing studies on the numerous toxic effects on animals are sufficient evidence that health and safety is a fundamental issue that demands more funding for research. (Han *et al.* 2010; Simeonova 2009; Wick *et al.* 2010).

The Commission's second Communication announced the Action Plan for Nanotechnologies and Nanosciences (European Commission 2005), evidencing the Commission's interest in nanotechnology applications in a variety of sectors; funding for risk assessment and management rose from 25 million euros in the period 2003-2006 to more than 50 million euros in 2007-2008. By contrast, it argues that the protection of health, safety and the environment should be enhanced mainly through improved implementation of existing legislation, but offers no comparative figures. It also states that "The EU Scientific Committees have stressed the need for further research on safety for human health and the environment" (European Commission 2009:4).

Alongside this strategy, the EU adopted the Code of Conduct for Responsible Nanosciences and Nanotechnologies Research (European Commission 2008a), which calls for responsible development of research into this new technology. Voluntary codes of conduct are soft law instruments for self-regulation; they supplement regulations, and can be helpful when difficulties arise in laying down specific standards. But they are not legally binding, and so may be of limited effectiveness.

In this particular case, the EC Code of Conduct is a good tool for promoting cooperation between Member States; it is based on and promotes the principles of meaning, sustainability, precaution, inclusiveness, excellence, innovation, and accountability for achieving good governance of nanotech research. The weakness of this Code is that it is limited to research, lacks any implementation measures or indicators, and omits the safety aspect. On the other hand, as a non-binding instrument, it has the value of flexibility, enabling it to be modified as circumstances change. The EC will monitor and review the Code biannually, and hopefully by 2010 it may be improved such as to be effectively implemented, thus serving as a precursor towards a future agreement.

Responding to the Commission strategy for nanotechnologies, the European Parliament (European Parliament 2009) forcefully disagreed with the Commission's claim that current legislation in principle covers the relevant risks related to nanomaterials. The protection of health, safety and the environ-

ment should be strengthened by applying existing legislation, stressing that there is precisely a significant lack of data and information, as well as appropriate methods of risk assessment. Accordingly, Parliament called for a review of all relevant legislation, specifically to evaluate the need to review workers' protection legislation to ensure safety for all nanomaterial applications.

The Commission's strategy is to focus on increasing research funding to keep up with the development and marketing of the nanotechnologies it produces; to obtain relevant data for risk assessment, to improve test methods, to develop public databases; and to focus on the development of test guidelines and standards within the OECD, ISO and CEN (European Commission 2009: 9). As to the regulatory review, the Commission will present its revision to the European Parliament in 2011. The Commission is considering a Strategic Nanotechnology Action Plan (SNAP) for 2010-2015. At the beginning of 2010 it launched a public consultation, which attracted more than 700 contributions from citizens, organisations and public authorities. Most came from individuals, both researchers and non-researchers, followed by industries, NGOs, trade unions and public authorities. One big conclusion of the Commission's report is that an inventory is called for of the types and uses of nanomaterials that would include safety aspects (European Commission 2010).

2.1 Health and safety protection issues

As things stand, it is very difficult to frame a new regulation specific to nanotechnologies because the state of knowledge is so under-developed that emerging issues cannot be provided against by law. To devise a completely new law for such an emerging field where data is lacking is no easy task. Even so, it is possible to adapt the existing laws to lay down basic ground rules and provide legal security for society, and this is a matter of urgency given the hazards that are attendant on nanotechnologies, as it previously was with biotechnologies. (David and Thompson 2008).

At the present time, the big problem for lawmakers is defining nanotechnology and nanosciences. This has been a running battle between academia, institutions, governments and stakeholders. According to the Cambridge Dictionary, a definition is 'a description of the features and limits of something'. It is important because it helps to circumscribe the object of study. A definition is essential to frame social order; it provides legal security and can be recognized and enforced by the decision of a court. Only once a definition has been adopted can the legal and other sciences create the legal institutions needed for nanotechnologies.

So far, most of the definitions developed for nanomaterials have focused on scale – the nanometre - limiting the length from 0.10nm to 100nm. That range is a useful rule of thumb for deciding whether a certain technology fits the definition of nanotechnology or not. But the problem is that this pragmatic approach to defining nanomaterials by scale is arbitrary, because its essential criterion is exclusionary: some effects or even new functions of nanoparticles occur above 100nm (Schmid *et al.* 2003: 16-21).

Where working with nanomaterials is concerned, little attention has been paid to those who are in direct contact with them, it is not easy to discuss benefits without addressing the impacts that nanotechnologies could bring and who might suffer from them. The workplace is the first source of human exposure to nanomaterials, and worker protection should be a priority of the Commission's strategic programmes. The Commission's strategy is open to criticism as to whether the budget for health and safety is substantial enough. There is a need for serious research in this area and human resources to address these issues.

Nanotechnology cuts cross several sectors; the main laws covering those who are exposed to nanomaterials are found in cosmetics, chemical and labour legislation. Some key aspects of those regulations that are described in the following section, evidence the Commission's intentions toward the regulation of nanomaterials and the difficult role that players have to face in this debate.

An exploration of the different legislative rules entails considering a range of issues - whether products containing nanomaterials require a special regulatory framework, whether the precautionary principle is really included in the regulations in order to anticipate risks and harm, or whether further regulation is required to plug existing loopholes and to protect those closely exposed to nanomaterials. But also perhaps to consider a coordinated approach on nanotechnologies in the EU and the adoption of new institutional mechanisms that would deal with cross-cutting policy issues.

The Commission has argued that in principle, current legislation is enough to cover issues related to nanotechnologies, nanosciences and the potential risk for health and the environment (Brekelmans 2009; European Commission 2008b). The EU has no specific legislation on nanotechnologies; however the Commission has been working on several instruments for implementation - like guidance or standards - to reinforce current legislation.

From the outside, it is not clear whether the existing regulations within which nanotechnologies could fall are comprehensive enough to accommodate them, and a review might be required (European Commission 2004). The current regulations are based on a wide range of characteristics and requirements different to those of nanotechnologies at this time, and this makes the legal situation of nanotechnologies unclear.

Where protecting the health and safety of workers from the risks related to chemicals at work is concerned, Directive 98/24/EC - known as the Chemical Agents Directive - aims to reduce the risks of hazardous chemicals. It lays down minimum requirements for protecting the health and safety of workers from the risks related to chemical agents at the workplace. In principle, therefore, it should cover the health and safety risks of nanomaterials; but it can hardly be viewed as adequate for that. There has as yet been no discussion of whether to add specific provisions for nanotechnologies, like implementing risk reduction measures when the hazards of nanosubstances used are as yet unknown or the time-weighted concentration of nanoparticles in the air within a worker's breathing zone.

In terms of exposure scenarios, studies reporting close associations between nanoparticles and their adverse effects on human health are constantly being published. Emerging data suggests that exposure to nanomaterials may pose health risks to workers (Balas *et al.* 2010). However, current testing methods are limited, because there is no certainty of their working for all nanoparticles. Tests that measure transdermal absorption or respiratory nanoparticle absorption are limited and may require adaptation or new ones to be developed. There is therefore a need to recognize potential exposure and protect workers from possible risks before they suffer harm.

As the North Atlantic Treaty Organisation (NATO) reports, the problem with establishing occupational exposure limits is that, firstly they are normally based on a full risk assessment which at the moment cannot be done for nanoparticles. Secondly, the optimal parameters for determining nanoparticle toxicity are still not defined; and additionally, nanoparticles are not easily detected or monitored (Satterstrom *et al.* 2009: 334).

A health and safety regulatory gap emphasised by the European Trade Union Confederation (ETUC) in its 'Resolution on Nanotechnologies and Nanomaterials' is the lack of involvement by workers and their representatives in the organisation and carrying out of workplace risk assessments, and the selection of risk management measures. Accordingly, it is recommended that legislative provision be made for training and health surveillance for workers exposed to nanomaterials, and a description of specific protection measures and good working practices that should be widely implemented according to the properties of the different nanomaterials.

Convinced that nanotechnology is the next revolution, industry is enthusiastic about the potential benefits of nanotechnologies in many sectors. However, it has a duty of care to ensure that its products are safe before they are placed on the market. The chemical industry, for one, is confident that the current European regulation is enough to cover nanomaterials (CEFIC 2009a).

The global voluntary initiative "Responsible Care" is a programme set up by the chemical industries to share information, and seek dialogue and partnerships with stakeholders. In a similar vein, the "Long Range Research Initiative" promoted by the European Chemical Industry Council –CEFIC– has diverse projects for the safe implementation of technologies and the safe use of chemicals (CEFIC 2009b).

A study of industry practice shows that protective measures are already in place in some big firms that are equipped for it and have safety guidelines, e.g., working in closed systems. The problem is with small and medium-sized firms where such protective systems may be lacking. Efforts should focus more on identifying SMIs that are working with nanotechnologies. In these cases protective and precautionary measures need to be taken and hazardous nanomaterials should be replaced by safer ones.

Iavicoli *et al.* argue that occupational health and safety research can contribute to closing the gap on key issues such as toxicity, measurements, exposed workforce and work environment, medical surveillance and risk communication, based on the new technology's impact on the environment and human beings (Iavicoli *et al.* 2009).

2.2 Building up the standardisation strategy

Standardisation plays a key role in business. Until recently, there has been no international agreement on terminology and its core related concepts for nanotechnologies, and no protocols for toxicity testing of nanoparticles. Measurement techniques and instruments need to be developed and standardized. Once again, a wide range of disciplines are involved and stakeholders with different opinions; it is a rocky road to consensus.

Standards development is a private sector activity, and in principle an open process. Standards – and compliance with them - are voluntary measures that can support industry competitiveness, accelerate the introduction of new markets, and facilitate communication and common understanding, especially if the stakeholders in society are actively involved to identify the needs. Their representation is essential to ensure that standards benefit everyone. Moreover, the uniformity achieved through the introduction of standards and reference measurements is a significant support to product marketing, market development and technical understanding (Berger 2008). Standards are a tool that can provide support to the existing legislation and European policy.

The current nanotechnology activities of standards bodies like ISO, the European Committee for Standardization (CEN) and the Organization for Economic Cooperation and Development (OECD) are focused on nomenclature and definitions, test methods to characterise and identify nanoparticles, protocols for toxicity, test methods, health and safety issues as well as environmental aspects. They have set up working groups on nanotechnology and the use of nanomaterials, and work in close cooperation on certain matters so to avoid duplication and ensure that their output is complementary.

The short term priority (ISO *et al.* 2008) is to develop standards for protocols for pharmacokinetics, defining a minimum set of measurements, particle characterization protocols for nano-health, toxicology screening tests, methods to determine the stability of nanomaterials in biological matrices, and standards for drug delivery for the route of exposure to nanomaterials.

The three European standards bodies (CEN, CENELEC and ETSI) have been mandated by the Commission to devise a programme of standardisation. According to the European Committee of Standardisation's (CEN) report on Commission mandate M/409, the projects on standards in nanotechnologies will focus chiefly on 3 main category areas: "1) standards supporting health, worker and environment safety, 2) standards supporting the Lisbon agenda and 3) standards supporting the social agenda" (CEN 2008:4) CEN,

CENELEC and ETSI will carry out the Mandate in a joint body, producing roadmaps of the needs, drafting the process of documentary standards, and delivering technical specifications.

ISO standards are developed by consensus of national delegations of experts on the Technical Committee dealing with nanotechnology issues. It started work on nanotechnology in 2005 and is currently developing around 40 projects on it. In 2008, ISO published the first two standards that define the basic terms frequently used in nanotechnology literature. Technical specification 27687-2008 provides definitions and information for objects at the nanoscale and covers the terms nanoparticles, nanofibre and nanoplate; it has also been adopted by CEN. The second technical report is 12885: 2008 on health and safety practices in occupational settings relevant to nanotechnologies, which provides advice for companies, researchers, workers and others to prevent adverse health and safety consequences during the production, handling, use and disposal of manufactured nanomaterials.

The largest ISO working group is that dealing with terminology and nomenclature. Its remit is to 'define and develop unambiguous and uniform terminology and nomenclature in the field of nanotechnologies to facilitate communication and to promote common understanding' (ISO 2007). In order to reach out to society, the ISO also has 2 other working groups, on the consumer and societal dimensions of nanotechnologies, and on nanotechnologies and sustainability.

Collaboration between bodies serves the useful purpose of producing a harmonised standard and avoiding duplication. ISO and CEN can cooperate under the Vienna Agreement, enabling ISO standards become CEN standards and vice-versa. Concern about definitions is a topic on which ISO and CEN are agreed, although most of the work in this area is done by ISO which seems likely to favour size-related definitions. Size is a particularly thorny issue because of the uncertainties surrounding the risks to health and safety.

As a centre for political analysis and a forum for international policy dialogue, the OECD established a Working Party on Manufactured Nanomaterials in 2006 under the aegis of its Chemicals Committee to help countries address safety issues. The OECD initiative focuses primarily on the definition of nanomaterials as new or existing chemicals. It also addresses identification, characterization, terminology and nomenclature, testing methods, risk assessment and information sharing, as well as cooperation and dissemination. It will also focus on promoting cooperation on health and environmental safety and exposure implications of manufactured nanomaterials.

Discussions at the OECD centre on whether or not nanomaterials should come under existing regulations, focussing especially on the human health and environmental safety implications of manufactured nanomaterials, and aim to ensure internationally harmonised standard and test methods.

The recent 'Preliminary analysis of exposure measurement and exposure mitigation in occupational settings: Manufactured nanomaterials' (ENV/JM/

MONO(2009)6) makes recommendations on comparing guidance on personal protective equipment, on engineering and work practice controls and worker training and education, minimum exposure mitigation measures, exposure mitigation guidance for laboratories and analysing Exposure Mitigation frameworks.

European standards bodies are also acting. CEN Technical Committee 352 is working under Commission mandate M14 with its sister organisations, the European Committee for Electrotechnical Standardization (CENELEC) and the European Telecommunications Standards Institute (ETSI), to develop the "Strategy for European Standardisation for Nanotechnologies". Their priority is to achieve the classification, terminology and nomenclature of nanomaterials and metrology including sampling and measurements methods for European standards.

There is a need to define what role standards should play in this field. They should, for instance, be restricted to technical issues and not become a replacement for existing or future possible legislation. This is because there is no specific regulation that they could be directly linked to, and not all the stakeholders are represented in that dialogue. Regulation and the public interest should be safeguards for developing coherent standards.

3 Key regulatory instruments in the European agenda

This section reviews the main pieces of legislation currently under discussion within the European Commission and their relation to nanomaterials - namely the Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), the Cosmetics Directive and the Novel Food Regulation.

3.1 Nanoform substances in the REACH legislation

Europe's chemical industry is its third largest manufacturing industry. The Registration, Evaluation and Authorisation of Chemicals (REACH) regulation recently passed by the EU to control it is highly complex. Implementation of the new regulation is under discussion by the Commission as regards the treatment of nanomaterials and proper implementation of the rules.

Nanoform substances are small, reactive and unpredictable, and their legal status is unclear. There are something over 200 000 available at the time of writing. While acknowledging that REACH does not expressly cover nanomaterials, the Commission argues that it applies to all chemicals, and that since nanoparticles are composed of chemical elements and compounds, they are subject to the same regulations as chemicals.

However, a working group of experts from the EU Member States - 'REACH Competent Authorities sub-group on nanomaterials' (CASG) – has been set up to look into REACH's application to these nanoform substances and give clear guidance on identification of substances, like carbon nanotubes or fullerenes and also to come up with a clear definition of nanomaterials.

The question of whether substances at the nanoscale are new substances or different forms of substances - and hence to be treated as existing chemicals -, is a big focus of discussion within the CASG (European Commission 2008b). The recommendation of the UK's Royal Society and Royal Academy of Engineers on this, supported by other academics, is that chemicals in nanoparticle form should be treated as new substances because their size and surface area confer specific properties compared to larger particles that may or may not have adverse effects and they have different health and environmental impacts per unit mass (The Royal Society and Royal Academy of Engineering 2004; Oberdörster *et al.* 2005). Therefore the volume threshold and testing methodology should be revised, and nanomaterials should have a unique risk assessment in order to be safe in use.

Although a fairly new regulation, REACH is not well-suited to dealing with nanomaterials. Some authors have pointed to the regulation's weakness as regards registration of substances (Sass *et al.* 2008). According to REACH, substances produced or imported in quantities above 1 tonne per year must be registered in a database held by the European Chemicals Agency, and the timetable for registration is phased, with the most hazardous chemicals and those used in the largest volumes being registered first. Under this rule, some nanoform substances may not be registered because a few kilograms may be enough to manufacture the product concerned. Because they do not exceed the registration threshold, they would fall outside the safety requirements. Therefore, lower production volumes should be included in REACH for nanoform substances.

REACH is based on the precautionary principle, so a risk assessment should be performed for all hazardous substances. Chemical safety assessments should be done for all REACH-registered substances for which a nanometre scale use has been identified: this would go a long way to improving product safety and avoiding hazards.

Suppliers or importers of dangerous chemical substances have a mandatory obligation to provide Safety Data Sheets for information through the supply chain in order to prepare the specific risk management measures that users need to control the risks. Information on nanomaterials should be included on those safety data sheets with a specific mention that the reference is to nano-size particles. Nano-specific information requirements should be introduced into REACH.

It is crucial that information on intrinsic properties which may be relevant to exposure and the impact assessment of nanoform substances should be understandable. Safety Data Sheets could contain more and better quality information, especially on nanoscale substances, in order to control risks.

Current testing methods are not appropriate for nanoform substances; as the registration dossier data cannot be relied on, nanoproducts should not be allowed onto the market. Appropriate methods are needed to characterize nanoparticles, perform specific toxicological tests and obtain reliable results. It would be a useful exercise to review existing methods and determine their validity for certain nanomaterials. This might reveal that new instruments are required.

3.2 The Cosmetics Directive

Cosmetics are consumer products that come into direct contact with human skin, hair, nails, lips and genitalia. The cosmetics industry may claim that their products are safe and fully regulation-compliant, but nanoparticles used in cosmetics are known to have novel properties that enable them to penetrate the skin and enter the body.

Nanomaterials are used in cosmetics as nanoemulsions or nanopigments. To take practical examples: titanium dioxide and zinc oxide are used in UV fil-

ters to make clear sunscreens. Nanosilver is used in some toothpastes due to its anti-bacterial properties, and fullerenes are being used in anti-ageing products. These are well-known cases and still the focus of debate over their possible toxicity. Moreover, according to the nano-inventory compiled by the Project on Emerging Nanotechnologies, other nanoparticles may also be found in anti-ageing moisturizers, hair straighteners or cleansing face lotions, food, electronics and other consumer goods.

Because a position was needed on how to deal with these new products, the European institutions came to an agreement on adapting the main regulatory framework. This resulted in the approval of the Regulation amending Cosmetics Directive 76/768/EEC of 27 July 1976 (Council of the European Union 2009). The Regulation aims to ensure the safety of cosmetic products and place an added responsibility on manufacturers to ensure that products are safe before placing them on the market. It states that at present, there is inadequate information on the risks associated with nanomaterials, and that to better asses their safety, guidance should be provided by relevant bodies together with scientific committees.

The problem - acknowledged by a scientific committee set up by the Commission - is that the communication of information about the potential toxicity of nano-containing cosmetics is dependent on industry.

According to the Commission's independent Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), 'information on the presence of manufactured nanomaterials solely relies on information provided by manufacturers. In addition, exposure estimation is also hampered by lack of information on product use and use of multiple products containing manufactured nanomaterials' (SCENIHR 2009: 53).

The main innovation of Cosmetics Regulation EC 1223/2009 is that it is the first European legal instrument to contain specific rules on nanomaterials.[6] A definition is essential to a consensus of understanding, but that contained in the Regulation is limited and inaccurate since it will not apply to all nanomaterials but perhaps only to first-generation nanomaterials, and the technology is advancing apace.

For instance, it sets 100nm as the benchmark that defines a nanoparticle, but this is an arbitrary indicator. Better would have been to define the nanoparticle regime as the point at which a substance undergoes changes in chemical/physical properties at the nano-scale, when the properties of the particles differ from those of the bulk materials. However, the law provides that as new technical and scientific aspects of this young technology emerge, the Commission can, and will almost inevitably have to, adjust this definition.

6. Article 2,1 (k) Nanomaterial means an insoluble or biopersistant and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm.

The Regulation lays down other new rules on notification and labelling. They require a safety assessment procedure to be carried out for all products containing nanomaterials before they are allowed onto the market. All cosmetic products containing nanomaterials must be notified to the Commission. The Regulation also controls what may or may not be put into a cosmetic, and requires industry to provide information on the use of nanomaterials in cosmetic products as a means of strengthening market controls.

While the new rules are positive on the whole, not everything in the Cosmetics Regulation was passed on the nod. The labelling requirement was the focus of tough negotiations with the European Parliament and Commission, since it is the first source of information that reaches the user, either consumers or workers. Article 19 now provides that 'all ingredients present in the form of nanomaterials shall be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the word 'nano' in brackets'.

3.3 Nanomaterials and the Novel Foods Regulation

The food sector is also experiencing the impact of nanotechnologies, but developments are still as yet relatively slower than in other sectors. Industry observers forecast that food will be designed from the bottom up, and new products manufactured. The agrifood industry is focusing primarily on agricultural production, food processing, smart packaging, preservatives and interactive or personalised food that can interact with the consumerconsumer (Tiju and Morrison 2006: 7-8).

Innovative 'smart package' applications and food tracking with anti-microbial activators are being developed to keep products on supermarket shelves fresher for longer[7]. System nano-components are being explored to repair small holes, respond to environmental conditions like changes in moisture and alert the consumer if the product is contaminated or going off.

Other projects are looking into packaging films which are lighter, stronger and more resistant than current films, and have sensors capable of detecting food deterioration. A built-in tongue is being designed to taste the first signs of spoilage and activate a colour change as a warning for consumers (Kraft Foods 2009; Wolfe 2005).

Interactive food and drinks are being explored that can be personalised to fit consumers' needs and tastes. Interactive food would respond to the body's requirements and deliver nutrients more efficiently, or change colours and taste on demand. Researchers are trying to develop nanocapsules that can be incorporated into the food to deliver nutrients into the body.

7. Samsung's Nano Silver Refrigerator, for example, has an inner surface coated with nano-silver particles for an anti-bacterial and anti-fungal effect. The company has also developed products like washing machines and air conditioning units using their Silver Nano Health System. http://www.samsung.com/au/silvernano/site.html

Many companies are exploring the potentials of nanotechnologies. A survey (Wolfe 2005) reports the major firms with nano-food R&D activities as being Nestlé, Unilever, HJ Heinz, Hershey Foods and Kraft. As one example, Kraft Foods has established NanoteK, a consortium of researchers from 15 universities and government labs, to explore how nanotechnology can be used to make improvements for the food industry.

As yet, there is no regulation on labelling of nanoparticles in food or packaging materials, and hence no regulatory standard. The UK's Food Standards Agency says it is not possible to provide a definitive list of nanofoods and nanoscale food contact materials on the EU market, because of the absence of an EU register or inventory. Moreover, there are difficulties in characterising, detecting and measuring engineered nanomaterials in food, feed and biological matrices, which limits the assessment of exposure from possible applications and products in the food and feed area (Food Standards Agency 2009).

Whatever the nano-developments involved, safety of food is the main concern: nanomaterials could interact in the human body. In response to a request from the Commission, the *European Food Safety Authority* (EFSA) has therefore drafted a scientific opinion on the potential risks on food and feed safety (EFSA 2009).

The EFSA recommends that additional research and investigation is needed to address the many current uncertainties and data limitations, with a particular focus on the areas of physico-chemical characterization, exposure assessment and toxicokinetics and toxicity of nanomaterials, particularly in:

- The interaction and stability of engineered nanomaterials in food and feed in the gastro-intestinal tract and in biological tissues;
- The need for the development of routine methods to detect, characterise and quantify engineered nanomaterials in food contact materials, food and feed;
- Improvements of test methodologies to assess toxicity of engineered nanomaterials, including reliability and relevance of test methods; and
- Develop understanding of toxicity, including chronic exposure and carcinogenicity.

The key concerns are new toxicity risks for humans and the environment. As the UK House of Lords recommends in its Report on Nanotechnologies and Food, "Government should work within the European Union to promote the amendment of current legislation to ensure that all nanomaterials used in food products, additives or supplements fall within the scope of current legislation" (House of Lords 2010).

The Commission has put forward a proposal to update Regulation (EC) No 258/97 concerning novel foods and novel food ingredients to simplify the

product authorisation procedure and ensure food safety and human health. Responding to the proposal in its legislative resolution of 25 March 2009, the European Parliament calls for approved risk assessment methods for food that has been produced with nanotechnologies before they are included in the Community list.

Parliament also wants all the ingredients present in nanoform to be clearly indicated in the list of ingredients followed by the word 'nano' in brackets, and proposes that nanomaterials be defined in the regulation as "an intentionally manufactured material with one or more external dimensions or an internal structure, of order of 100 nanometres or less", meaning that materials above 100nm will be regarded as novel food, if they exhibit size-dependent properties.

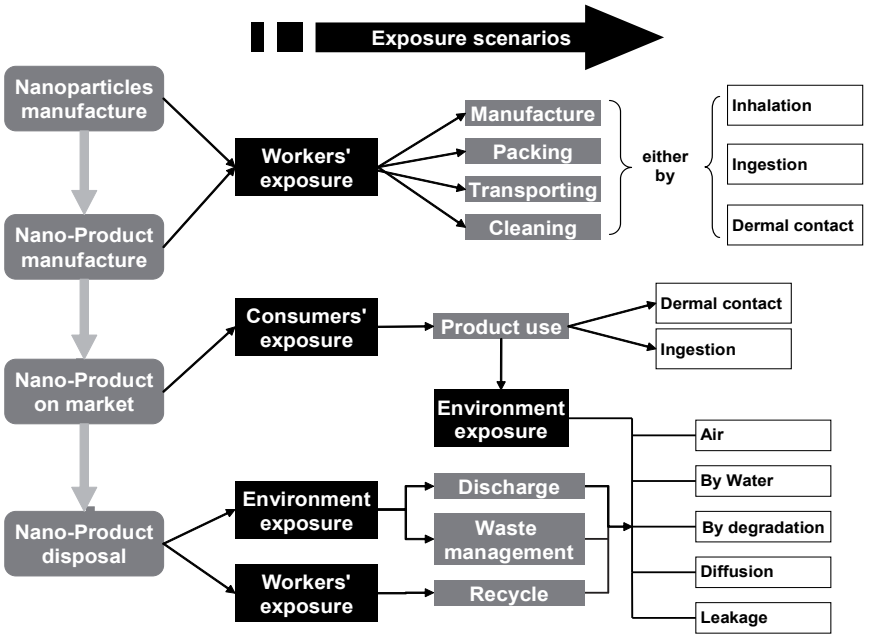
It is clear that the regulatory framework for nanotechnology has consequences for society and the workplace, and it is hard to tell what those impacts may be. Stakeholders - like the workers who make the product, and consumers who are in contact with the product over its life cycle - have voiced their own concerns on this issue. They have questions as to what nanotechnology is about and what its benefits may be. Their views are explored in the following section.

4 Stakeholders' reactions

This section considers the views of a wide range of societal groups that have their own agendas on the possibilities for safe nanotechnology use. Three stakeholders – consumer organisations, environmental lobbies and trade unions – are working from their different standpoints to raise community awareness of nanotechnologies. Consumer organisations are concerned about exposure of the general population and argue for the public interest. Environmental lobbies engage mainly with issues related to the environment and protection of nature, while trade unions are concerned with human exposure, mainly at the workplace.

The figure below illustrates the exposure scenarios of workers, the public and the environment though the whole life cycle of a nano-product from the manufacture of the nanoparticles through the manufacture of the product to being put into the shops, used and where it ultimately ends up.

Figure 1 **The life cycle of a nano-product and various exposure scenarios**



Source: author's composition

4.1 Consumer organisations

Invisible nanoparticles are being incorporated into a wide range of consumer products. A growing number of cosmetics, household cleaning products, toys, clothing and textiles are already on the market and may be being sold without a proper safety assessment. The first thing of importance is to know how many products there are on the market claiming to contain nanomaterials, plus their concentrations and types, in order to have a better understanding of the potential health risks which may depend on the possible hazards of, and the possible exposure to, the nanomaterials in these products (Wijnhoven *et al.* 2009a).

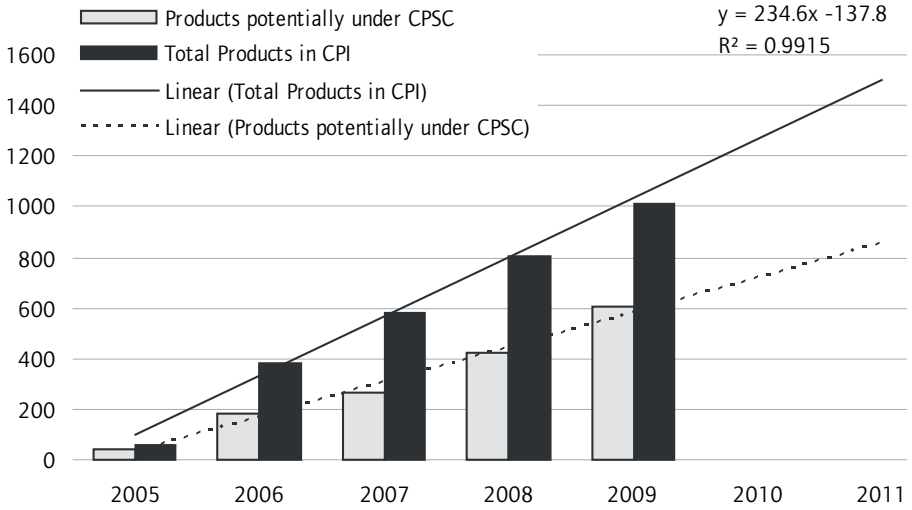
As the marketing situation stands, the general public cannot know what products contain nanomaterials, how they are to use them or what their implications may be. One constant question is: how can society be involved in the development of science and technologies? Consumer organisations have been highly engaged in the nanotech debate in the quest for answers to this. In the US for example, the Project on Emerging Nanotechnologies (PEN) was set up to actively inform the public and policy dialogue and to identify gaps in knowledge and regulatory processes. The result is an inventory that gives the public a useful view of the manufacturer-identified nanotechnology-based consumer products currently on the market.

This publicly-accessible Nanotechnology Consumer Products Inventory was put online in August 2008. The most recently updated version lists more than 1000 products from almost 500 companies in 20 countries, using information based on manufacturers' claims. The majority of these (540 products) are from the United States, followed by Asia with 240 and Europe with 154. According to the Inventory analysis, the most common materials explicitly referenced as contained in the products are silver, carbon including fullerenes, zinc, silica, titanium and gold.

To give an example of the market potential, the following figure shows the growth in number of manufacturer-identified, nanotechnology-enabled products listed on the PEN Consumer Product Inventory (CPI) from 2005 to 2009, which might fall under the jurisdiction of the Consumer Product Safety Commission in the United States.

European consumer bodies like the European Consumers' Organisation (BEUC); the European Consumers' Voice in Standardisation (ANEC) and the largest consumer body in the UK (Which?), have called to be informed about nanotechnology uses, fearing for the possible dangers from direct contact by inhalation or ingestion of nanoparticles in products, and uncontrollable risks. Consumer confidence in nanotechnologies appears to be less than absolute, mainly due to a lack of knowledge – the demand is for accessible information in order to plan and prevent (Scheleufele and Lewenstein 2005). Where the general public mainly hopes and expects to reap the benefits of nanotechnologies is in areas like medicine and health care, with the development of new drugs and nano-treatments (Chisholm *et al.* 2009).

Figure 2 **Growth in the number of manufacturer-identified, nanotechnology-enabled products listed on the PEN CPI from 2005 to 2009 (in black) showing products under possible CPSC jurisdiction (in grey). (Rejeski 2009).**



So far, awareness on the issue has created though surveys done by consumer associations in a handful of European countries – like *vzbv* in Germany; *Which?* in the United Kingdom; the Information Centre for Environment & Health in Denmark, and the Center for Technology Assessment in Switzerland. They concur that the public needs to be informed about nanotechnologies, and a civil society dialogue is needed on new technologies.

European consumer lobbies - the European Association for the Co-ordination of Consumer Representation in Standardisation (ANEC) and the European Consumers' Organisation (BEUC, Bureau Européen des Unions de Consommateurs) – issued a joint position paper in June 2009 (ANEC and BEUC 2009). As they explain, their major fear is the exposure of consumers and the environment to products containing free nanomaterials, or to nanomaterials which are not properly fixed in the material of the product and that may be released during the product life-cycle.

ANEC and BEUC call for wider public consultation on research needs that would allow scientific institutions help to deliver public policy objectives for the welfare of society. The consumer organisations disagree with the EU, arguing that current legislation does not cover the potential risks related to nanomaterials. They are disappointed to conclude that 'the Commission is not acknowledging and addressing the regulatory deficits which have been identified by various parties including scientific institutions, civil society organisations and governmental organisations'.

Their demands include labelling of nano-content in products, and mandatory notification of all nanomaterials used in products before the products are placed on the market and for those already on the shelves. The labels include

so much important information that is useful; they may increase consumer welfare through better protection and the provision of the possibility to make better informed choices, avoiding risks. These organisations want the Commission to work with the Member States on setting up a publicly-accessible inventory of all nanomaterials used in all products already on the market.

4.2 Environmental organisations

Clean air and water, and healthy soil are extremely important for the environment. The effect of interaction of nanomaterials on the environment and health is still unknown. The discharge of nanoparticles into the aquatic and terrestrial environments and the atmosphere poses a threat. Where human health is concerned, studies have shown that nanoparticles may undergo alteration in the organism (Oberdörster *et al.*, 2004, Radomski *et al.* 2005). However, there are variations in the degree of adverse effects and not all are likely to show the same toxic potency (Donaldson and Stone 2007). Likewise, it is not easy to predict what will happen from introducing materials into the ecosystem.

There is evidence that silver nanoparticles at low concentrations will harm aquatic invertebrates and fish (Wijnhoven *et al.* 2009b). Other studies suggest that microorganisms and plants may be able to modify and concentrate nanopar¬ticles that can then bioaccumulate along the food chain. The European Environmental Bureau (EEB) finds from a literature review that "release of nanosized titanium dioxide into wa¬ter could have detrimental effects on overall ecosystem health, especially given that the concentration is large enough to have some det¬rimental effect on organisms and that it readily accumulates in drinking water"(EEB 2009a).

The uncertainties surrounding the effects of nanomaterials on the environment and biodiversity are a major concern of environmental lobbies, prompting NGOs to call for sustainable governance and use of nanotechnologies and nanomaterials. At the European and international level, the European Environmental Bureau coordinates a network of environmental NGOs that review major concerns concerning nanotechnologies, such as water purification or removal of contaminants, renewable energy production, waste management and environmental remediation, as well as new materials.

Their key demands in positions taken on the actions needed at EU level are based on the sustainable development and precautionary principles. The regulatory regime needs to be amended to more explicitly and comprehensively address nanomaterials, and be strictly implemented if the level of safety for human health and the environment provisioned in existing laws is to be guaranteed.

The EEB's demands are as follows (EEB 2009b):

– Public participation initiatives that seek public opinion on the development and use of nanotechnologies should be a high priority for national governments.

- Develop a pre-market registration and approval framework, including a publicly available inventory for public and private research, and test-based assessment and approval of materials in the near-market-use stage.

- Undertake public consultation on technological innovation, including nanotechnologies and nanomaterials.

- Put in place an adequate policy and regulatory framework before further market penetration occurs.

- Prioritise research funding on the functioning of natural and human systems with respect to possible impacts of nanomaterials on these.

- Full lifecycle environmental, health and safety impacts must be assessed prior to commercialisation.

Another voice to be heard is that of those on the first line in the production chain, those who have to handle the nanomaterials that go into goods – the workers who are directly exposed to nanomaterials.

4.3 The labour movement

The number of workers exposed to nanomaterials grows every day around the world, yet it is not known how many industries use nanotechnologies. This makes it hard to say how many workers may be exposed to them, since most do not know what it is that they are handling.

From the workers' perspective, there are at present no labels, no specific training on nanotechnologies, no specific exposure levels, no specific risk assessment, and as reported by the ISO "quantitative health hazard and exposure data are not available for most nanomaterials. Therefore, health risk evaluation for the workplace currently relies to a great degree on professional judgments for hazard identification, potential exposures and the application of appropriate safety measures"(ISO 2008).

The ETUC adopted a first resolution on nanotechnologies and nanomaterials (ETUC 2008) prepared by its Nano Working Group (composed of national member organizations) supported by research under the EU's Nanotechnology Capacity Building (NANOCAP) project. The ETUC position is expected to be updated by the end of 2010.

The ETUC is convinced that nanotechnologies and manufactured nanomaterials might have positive potential for technological improvements and new job creation, but there are concerns about potential risks to human health and the environment. The ETUC Resolution points to the failings of health and safety at the workplace where nanotechnologies are concerned. It highlights the loopholes in the European legislation and calls for it to be amended.

Health and safety at work must have priority in any nanomaterials surveillance system. There is a great need for training, education and research in order to allow health and safety specialists preventing known and potential exposures to nanomaterials to be informed of the nature of the products present on their work places.

In order to have a safe workplace, employers must be required to implement appropriate risk reduction measures when the dangers of substances used are still unknown. This would enable all manufactured nanomaterials to be covered, along with many other substances that carry unknown health risks to which workers are exposed.

The research and development programme budget for health and environmental risk research should be increased. This means that at least 15% (from the current 5% according to personal communications from officials of the European Commission) of national and European public research budgets for nanotechnology must be earmarked for health and environmental risk research. At the same time, all nanotech research projects should include health and safety aspects as a compulsory part of their reporting.[8]

The Resolution also considers terminology as an important component. A standardised terminology for nanomaterials is urgently needed to prepare meaningful regulatory programmes. For that reason, the ETUC calls on the European Commission to adopt a definition of nanomaterials which is not restricted to objects below 100 nanometres in one or more dimensions.

The ETUC wants all consumer products to be labelled if they contain manufactured nanoparticles which could be released under reasonable and foreseeable conditions of use or disposal.

After examination of the current legislative framework the ETUC has identified several loopholes, and some regulatory changes are needed. They include:

- Amending the Chemical Agents Directive and REACH to achieve better coverage of all potentially manufactured nanomaterials. A Chemical Safety Report must be provided for materials on the market below 1 tpa production volume.

- Applying REACH's 'no data, no exposure' principle as a general rule for nanotechnology products that are intended to be introduced to the market, as well as a precautionary approach, so that worker exposure is avoided as much as possible. This will require the REACH registration procedure to be changed in order to cover all nanoform substances, including those produced or imported in quantities below 1 tonne per year.

8. For instance the Report on Nanotechnology and Food in the UK (House of Lords 2010) points out the lack of funding for health and safety aspects. Commenting on funding, the Report says "The public spending in the United Kingdom on human health and safety research in nanotechnologies is unclear" p. 37.

– Penalties should be available to ensure that preventive measures are properly implemented and to enforce compliance.

– Voluntary initiatives and codes of practices are useful if certain conditions are met, but nanotechnologies need proper legislation.

The precautionary principle features strongly in the Resolution, meaning that preventive actions must be taken where uncertainty and lack of knowledge prevail. Examples of the precautionary approach the ETUC is calling for include:

Workers must not be exposed in the absence of sufficient data to prove the safety of the substances. A precautionary approach helps to address the concerns about gaps in the knowledge of the potential risks of nanomaterials, until more detailed scientific data concerning intrinsic hazards and exposure become available.

Nanotechnologies are not specifically regulated at present. Legislation is the way to ensure safety. Learning the lesson of asbestos, the precautionary principle should be applied as early as possible, otherwise harm may not be avoidable and then control will not be feasible.

As part of the precautionary approach, the ETUC calls on Member State authorities to set up a national register on the production, import and use of nanomaterials and nano-based products. This could make it easier to monitor any human or environmental contamination and to identify where responsibility lay for any harmful effects.

These precautionary measures are essential prerequisites for the responsible development of nanotechnologies and for helping to ensure society's acceptance of nanomaterials. The REACH registration process for nanomaterials could be a clear example of the precautionary principle in action; risk assessment must be improved.

4.4 The innovative capacity of France and the Netherlands

The Member States that first started to regulate the manufacture, import or marketing of nanoparticle substances are France and the Netherlands. No attempt to follow their lead has yet been made by the others. France is the first country to mount a national public debate and the Netherlands has a proposal for a regulation on reference values for nanoparticles.

The Dutch government accepted 3 proposals from the Social and Economic Council – notification of nanoparticles in products, identification of reference values and an acceleration of risk research (Social and Economic Council of the Netherlands 2009). The government must now flesh these proposals out into practical measures.

The Dutch Social and Economic Council, which is an advisory body to the Dutch government and parliament on social and economic issues, emphasizes the importance of the obligation for companies that produce or import products containing nanoparticles to notify and inform all those in the production chain about the nanoparticles contained in them. The Council also calls on the government to require manufacturers of nano-containing products to produce a first (publicly available) risk assessment, so that research into possible risks can get under way at the start of 2010.

Where limit values are concerned, the Council wants the government to commission expertise to develop reference values for the most frequently-used nanoparticles, to be used by companies until the National Health Council is able to establish occupational exposure limits for the different nanoparticles.

It also recommends exposure registration by category of nanoparticles, and the implementation of safety warning systems. Good practice, guidance and knowledge dissemination are solid supports to the implementation of a Dutch policy on nanoparticles.

In France, the Grenelle 1 Act laying down environmental guidelines was passed unanimously by the National Assembly in August 2008 (Assemblée nationale and Sénat 2008). Given the need for surveillance of emerging risks, the government will promote a European plan for the evaluation of emerging technologies like biotechnology and nanotechnology. Specifically, within 2 years, manufacturers or importers of nanoparticles, organisms containing nanoparticles, or nanotechnology products will have to make a compulsory declaration of quantities and uses to an administrative authority and provide publicly available consumer information.

The French government tasked the ad hoc *Commission Nationale du Débat Public* under the Grenelle Act with conducting a national public debate on nanotechnologies, which it hoped would really engage the public. The debates ran over a period of 6 months in 17 different cities, aiming to provide the public with understandable information on the challenges, technical aspects and impact of nanotechnologies. The public were able to play into it with their views, informing the directions that France should take on research, toxicity, protection at the workplace, consumer protection and governance (Commission particulière du débat public 2009).

5 Concluding remarks

The fact that nanoparticles are ultra-fine – invisible to the naked eye - is a key aspect that makes nanotechnologies a special challenge. The complexity of the properties, the effects of nanomaterials, and even more so, the lack of knowledge, are reason enough to inform and make the public aware of the unresolved issues.

All the foregoing policy efforts notwithstanding, nanotechnologies are not specifically regulated. The existing laws were not designed for them, whence the clamour for an appropriate regulatory framework. The European Commission has come under heavy criticism for the approach it has adopted. The experience of other sectors like biotechnology – where it was also believed that regulation was unnecessary - or intellectual property, could provide useful object lessons of how to ensure safety and efficacy, and their experience may by extension be applicable to nanotechnologies. Perhaps a hybrid model of regulation (hard law/soft law) could be employed to adjust to new circumstances and challenges.

There is no doubt that existing EU legislation of relevance to nanotechnologies has to be adapted, because laws need new and additional tools to anticipate potential harm. Some areas - like human health and the environment - need to be tackled more directly. At present, it is mainly chemicals legislation that applies to nanotechnologies, but REACH and REACH-like laws deal only with the risks posed by the substance - they do not address other nano-related matters like ethical or social issues. Nanotechnologies must be governed by new, specific instruments directed mainly at preventing and resolving conflict in society.

Definitions are important, for we must know what we are talking about. There is an acute need for commonly-accepted definitions of nanomaterials and nanotechnologies and other relevant terms, for the lack of them produces legal uncertainties. Without a consensus on definitions, nomenclature and standards of classification and testing, it is extremely difficult to define or classify the object to be regulated (Bowman and Gilligan 2007). A short definition might only catch the first generation of nanomaterials, and this technology is developing apace. As the UK House of Lords recommends, a definition “should cover any material that reveals a change in any property that might affect how it behaves in the body as a result of being nanoscale” (House of Lords 2010).

In addition to the benefits mentioned, nanotechnology could also set the benchmark if the potential hazards could be avoided while the technologies and applications were under development. Learning from past experiences with asbestos and GMOs, it could be shown that it is possible to protect health and safety while preventing new or worse risks, by making it the first priority for European nanotechnology research.

Their published views suggest that some common ground exists between consumer, environmental and labour organisations on nanotechnology development. They agree on the need to tackle health and safety aspects though a precautionary approach, and for a safer incorporation of nanotechnologies.

That said, some differences can also be found in their positions. Environmental organizations would prefer a moratorium on products that are potentially controversial until safety can be proved (EEB 2009c), while trade unions want the legal principles contained in the main pieces of legislation (REACH, Workers Protection Legislation) that are based on the precautionary principle to be applied.

Transparency is key to the development of nanotechnologies. But there remains a lack of clarity about some matters: allowing certain products onto the market, nanotechnologies for food, exposure of workers and society at large, and the role of SMIs in the whole debate are issues that still need to be addressed.

This working paper identified three key issues that must be fully addressed. Firstly, there must be a move towards better collaboration and cohesion between all actors, including national governments. Secondly, there is a challenge for the European Commission to regulate an enabling technology, i.e., to design, provide and manage a better, specific legislative framework for nanotechnologies. Thirdly, a clear recognition is needed that health and safety must be ensured if European nanotechnologies are to succeed. An innovative regulatory regime is essential to drive nanotechnology forward, and could be achieved by meeting the challenges described to deliver sustainability and prosperity.

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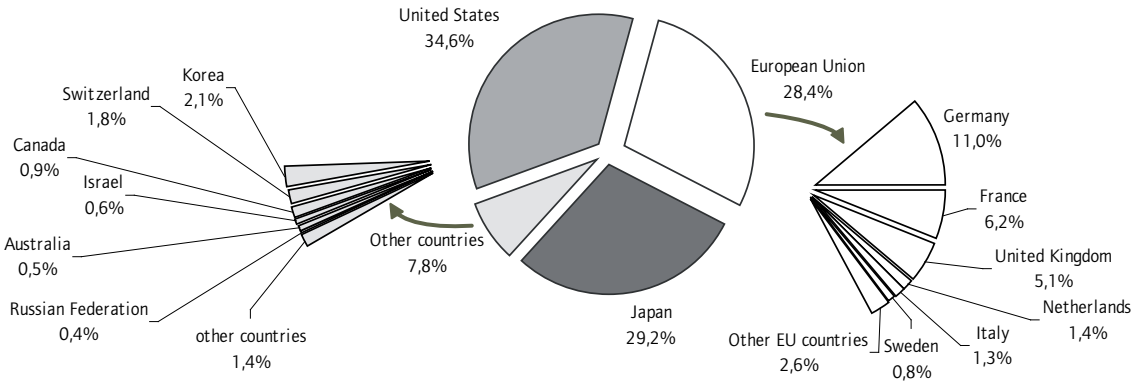
Annexe 1

Figure 3 **OECD countries' shares in nanotechnology patent applications to the EPO (1978-2005)**



Annexe 2

Different definitions of nanotechnology and nanomaterials

Source	Definition
EU: 7th Framework Programme (2007-2013)	Generating new knowledge on interface and size-dependent phenomena; nanoscale control of material properties for new applications; integration of technologies at the nanoscale; self-assembling properties; nano-motors; machines and systems; methods and tools for characterisation and manipulation at nano dimensions; nano precision technologies in chemistry for the manufacture of basic materials and components; impact on human safety, health and the environment; metrology, monitoring and sensing, nomenclature and standards; exploration of new concepts and approaches for sectoral applications, including the integration and convergence of emerging technologies.
European Patent Office (2008)	The term nanotechnology covers entities with a geometrical size of at least one functional component below 100 nanometres in one or more dimensions susceptible of making physical, chemical or biological effects available which are intrinsic to that size. It covers equipment and methods for controlled analysis, manipulation, processing, fabrication or measurement with a precision below 100 nanometres.
Japan: Second Science and Technology Basic Plan 2001-2005 Council for Science and Technology Policy (2001)	Nanotechnology is an interdisciplinary S&T that encompasses IT technology, the environmental sciences, life sciences, materials science, etc. It is for controlling and handling atoms and molecules in the order of nano (1/1 000 000 000) meter, enabling discovery of new functions by taking advantage of its material characteristics unique to nano size, so that it can bring technological innovation in various fields.
NASA (2009)	The creation of functional materials, devices and systems through control of matter on the nanometre length scale (1-100 nanometres), and exploitation of novel phenomena and properties (physical, chemical, biological, mechanical, electrical...) at that length scale.
US: National Nanotechnology Initiative (2001)	Nanotechnology is the understanding and control of matter at dimensions of roughly 1 to 100 nanometres, where unique phenomena enable novel applications. Encompassing nanoscale science, engineering and technology, nanotechnology involves imaging, measuring, modelling, and manipulating matter at this length scale.
ISO working definition TCC 229 (2007)	Understanding and control of matter and processes at the nanoscale, typically, but not exclusively, below 100 nanometres in one or more dimensions where the onset of size-dependent phenomena usually enables novel applications. Utilising the properties of nanoscale materials that differ from the properties of individual atoms, molecules, and bulk matter, to create improved materials, devices, and systems that exploit these new properties.

Source	Definition
German Chemical Industry Association (VCI, 2010)	Nanomaterials are defined as intentionally manufactured, solid, particulate substances, either in powder form or as dispersions or as aerosols, consisting of nano-objects and their aggregates and agglomerates, (i) which contain, when measured by standardized and recognized methods, at least 10 wt.-% of nano-objects, (ii) or which have, when measured by appropriate methods, a volume specific surface area larger than 6 x 1/100 nm. Nano-objects are discrete particles with one, two or three external dimensions between approximately 1 nm and 100 nm.
The Royal Society & The Royal Academy of Engineering. Nanoscience and nanotechnologies: opportunities and uncertainties UK (July2004)	Nanotechnologies are the design, characterisation, production and application of structures, devices and systems by controlling shape and size at nanometre scale. Although a broad definition, we categorise nanomaterials as those which have structured components with at least one dimension less than 100nm. Materials that have one dimension in the nanoscale (and are extended in the other two dimensions) are layers, such as a thin films or surface coatings. Some of the features on computer chips come in this category. Materials that are nanoscale in two dimensions (and extended in one dimension) include nanowires and nanotubes. Materials that are nanoscale in three dimensions are particles, for example precipitates, colloids and quantum dots (tiny particles of semiconductor materials). Nanocrystalline materials, made up of nanometre-sized grains, also fall into this category. Some of these materials have been available for some time; others are genuinely new.
New Substances Program Advisory Note 2007-06 Requirements for nanomaterials under the New Substances Notification Regulations (Chemicals and Polymers) Environment Canada (June 2007)	Although there is no internationally recognized definition of this type of substance, nanomaterials can be described generally as substances having one or more dimensions in a nanoscale range, typically[2] between 1-100 nanometres.
Gazette Chemical NICNAS Australian Government (February 2009)	There is currently no agreed national or international definition of nanomaterials. For the purposes of this interim position the following working definition will be used: industrial nanomaterials are those industrial materials intentionally produced, manufactured or engineered to have specific properties or specific composition, and one or more dimensions typically between 1 nm and 100 nm. This size range refers to individual particle size, and does not take into account agglomeration of particles.

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