

How to regulate the "nano-revolution"?

Nanotechnology policymaking is an extremely complex process. Safety is key to building confidence and trust, and gaining community acceptance, but the wide spectrum of products and applications means that different pieces of legislation are involved, and this further complicates matters.

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The international policy debate on nanotechnologies started in 2003 when the United States passed its first policy, implementing the National Nanotechnology Program to provide long-term funding of nanotech research and development.

In the early 2000s, nanotechnology became a top priority for the United States, eastern Asia, Australia and New Zealand. Since then, the US has experienced significant growth in this area; its 2009 fiscal budget allocation for the National Nanotechnology Initiative is about \$1.5 billion¹.

The early makings of an EU (European Union) nanotechnology policy came between 1998 and 2002 with FP5, and the creation of various European projects². But nanopoly in the EU really took off between 2002 and 2006 under FP6, when nanotechnology projects were made a priority. The Commission framed its strategy and adopted the *Communication Towards a European Strategy for Nanotechnology* (COM 2004-338) about mid-period.

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 should 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, but the Commission must draw a line between the commercial competitiveness strategy, and the health and safety of nano products for users.

One fundamental flaw in the Commission's work is the lack of communication with stakeholders. For the current EU programme to have meaningful outcomes, there is a need to engage the public – citizens, consumers, vulnerable groups – in a more direct and serious conversation on health and safety 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 acting. 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.

Commission and Parliament at odds

Alongside this strategy, the EU adopted the Code of Conduct for Responsible Nanosciences and Nanotechnologies Research (C(2008) 424 final), which calls for responsible development of research into this new technology. Voluntary codes of conducts are normally

¹ *National Nanotechnology Initiative, 2009, FY 2009 Budget and Highlights.*

² 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.

The EU Code of Conduct omits enforcement, indicators and safety.

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, Commission's 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 the 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 European Commission 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 Parliament³ forcefully disagreed with the Commission's claim that current legislation in principle covers the relevant risks related to nanomaterials, and that protection of health, safety and the environment 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, the EP called for a review of all relevant legislation, specifically to evaluate the need to review worker protection legislation to ensure safety for all nanomaterial applications

3. European Parliament (2009) non-legislative Resolution on Regulatory aspects of nanomaterials 24/04/2009.

4. EC 2008, 366 Regulatory Aspects of nanomaterials. Commission Staff working document. Accompanying document to the Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee.

Where working with nanomaterials is concerned, little attention has been paid to those who are in direct contact with 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 across multiple sectors; the main EU laws related to those who are exposed to nanomaterials are the cosmetics, chemical and worker protection legislation. Some key aspects of those regulations are described below; they illustrate the Commission's agenda for the regulation of nanomaterials and the difficult role that players have in this debate.

Exploring the different pieces of legislation raises a range of questions, like whether products containing nanomaterials require a special regulatory framework; whether the precautionary principle is really included in the regulations to anticipate risks and harms; or whether further regulation is required to plug existing loopholes and protect those working in close proximity to nanomaterials. And possibly even whether there is a need for coordination on nanotechnologies in the EC, and for new institutional mechanisms to deal with cross-cutting policy issues.

Can workers be protected by law?

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 environment⁴. The EU has no specific legislation on nanotechnologies; the only regulations to do with nanotechnologies are those related to medicinal products; medical devices, active implantable medical devices, cosmetic products, chemicals, clinical trials for medicinal products, data protection and patents.

Is the Commission's strategy underfunded on health and safety?

The Commission's claim notwithstanding, it is not clear whether those regulations are comprehensive enough to accommodate nanotechnologies, and a review might be required⁵. 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.

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. It is not easy to create a completely new law for such an emerging field where data is lacking; 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.

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 100nm⁶.

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 who are in contact with them. However, current testing methods are limited, because there is no certainty of their working for 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 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 monitored⁷.

A 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 measures⁸. 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.

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 SMEs that are working with nanotechnologies. The ETUC also calls for protective and precautionary measures to be taken, and for hazardous nanomaterials to be replaced by safer ones.

5. EC 2004, *Towards a European strategy for nanotechnologies*, Brussels, p. 17.

6. Schmid, G, Decker, M, Ernst, H, Fuchs, H, Grünwald, W, Grunwald, A, Hofmann, H, Mayor, M., Rathgeber, W, Simon, U, Wyrwa, D 2003, *Small dimensions and material properties. A definition of nanotechnology*, Europäische Akademie, No. 35, p. 16-21.

7. Satterstrom, FK et al 2008, "Considerations for implementation of manufactured nanomaterials policy and governance", *Nanomaterials Risks and Benefits*, NATO, Series C, Springer, p. 334.

8. ETUC 2008, Resolution on nanotechnologies and nanomaterials, <http://www.etuc.org/a/5163>.

9. The regulation will apply 42 months after its publication; as an exception, it will apply to products containing nanomaterials 36 months after publication.

Lawmakers' pressing problem is defining nanotechnology and nanosciences.

Carbon nanotubes can be used to produce "intelligent paint" that can make materials fire-resistant or prevent ship hulls from becoming barnacled.

Image: © Nanocyl, Th. Strickaert



The Cosmetics Directive: a first step

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 filters to make clear sunscreens; nano silver is used in some tooth-pastes 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 new "Cosmetics Directive 76/768 EEC" by the European Parliament and Council in June 2009, which will aim to simplify and im-

prove the existing Directive as a standard legal instrument applicable in all Member States⁹. The Directive 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.

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 Commissions' 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 nanomaterials¹⁰."

The main innovation of the revised Cosmetics Directive is that it is the first European legal instrument to contain specific rules on nanomaterials. A definition is essential to a consensus of understanding, but that contained in the Directive is limited and inaccurate since it will not apply to all nanomaterials but perhaps only to first-generation nanomaterials, and the technology is advancing apace¹¹.

For instance, it sets 100nm as the benchmark that defines a nanoparticle, but this

10. SCENIHR (January 2009) Risk assessment of products of nanotechnologies, Directorate General for Health and Consumers, European Commission, p. 53

11. "Nanomaterial means an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm", European Parliament legislative resolution of 24 March 2009 on the proposal for a regulation of the European Parliament and of the Council on cosmetic products (recast), Article 2,1 (k).

Standardisation and metrology are in their infancy

The road to consensus in standardisation is a rocky one. As yet, there is no internationally agreed terminology, no protocols for toxicity testing of nanoparticles and no standards to protect workers from the emerging risks of nanomaterials. This is compounded by the wide range of disciplines and stakeholders with different opinions involved.

Standards bodies like ISO, the European Committee for Standardization (CEN) and the Organization for Economic Cooperation and Development (OECD) have set up working groups on nanotechnology. They cover nomenclature and definitions, test methods to characterise and identify nanoparticles, protocols for toxicity, health and safety issues, as well as environmental aspects.

In 2008, ISO published the first two standards that define the basic terms in nanotechnology: technical specification 27687-2008 give definitions of and information on nano-objects, nanoparticles, nanofibres and nanoplates. This has also been adopted by CEN. Report 12885: 2008 advises on how to prevent adverse health and safety consequences during the production, handling, use and disposal of manufactured nanomaterials. Work on topics of mutual interest to ISO and CEN is being carried out under the "Vienna Agreement".

Other international bodies have launched ambitious initiatives on nanos. The OECD work programme for 2009-2010, for instance, focuses on specific nanotechnology sub-areas, covered by 6 working groups.

European bodies are also active. CEN Technical Committee 352 is working with its sister organisations, the European Committee for Electrotechnical Standardization (CENELEC) and the European Telecommunications Standards Institute (ETSI) to frame the "Strategy for European Standardisation for Nanotechnologies". Their priority is to produce a classification, terminology and nomenclature of nanomaterials and metrology, including sampling and measurement methods for European standards.

12. The Royal Society & The Royal Academy of Engineering 2004, *Nanosciences and nanotechnologies: opportunities and uncertainties*, London, p.71-72.
Oberdörster, G et al. 2005, *Nanotoxicology: An Emerging Discipline Evolving from Studies of Ultrafine Particles*, National Institute of Environmental Health Sciences.

13. Sass, J, Musu, T et al. 2008, "Nanomaterials: brief review of policy frameworks in the US and Europe and recommendations for occupational and environmental perspective", *European Journal of Oncology*, vol. 3, No. 4.

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 nanoscale, 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.

The Directive 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 Directive 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 Directive was passed on the nod. The labelling requirement was the focus of tough negotiations with the European Parliament and Commission. The provision now states 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".

Is REACH enough?

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 EC as regards the treatment of nanomaterials and proper implementation of the rule.

The status of substances that contain nanoparticles is unclear. 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 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 materials 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. 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 mass¹². 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 deal with nanomaterials; some authors have pointed to the regulation's weakness as regards registration of substances¹³. The regulation stipulates that a substance produced or imported in quantities of 1 tonne or more per year must be registered in a database held by the European

REACH is not appropriate for nanomaterials.

Chemicals Agency. Under this rule, some nanomaterials 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 nanomaterials.

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 a safety data sheets for information through the supply chain. Information on nanomaterials should be included on those safety data sheets with a specific mention that the reference is to nanosize particles.

It is crucial that information on intrinsic properties which may be relevant to exposure and the impact assessment of nanomaterials should be understandable.

Current testing methods are not appropriate for nanomaterials; the data in the registration dossier cannot be relied on and, as stated in the ETUC Resolution, 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.

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 are its benefits.

Consumers want information

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. Consumers 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, the Project on Emerging Nanotechnologies (PEN) was set up to actively inform the public and policy dialogue and to identify

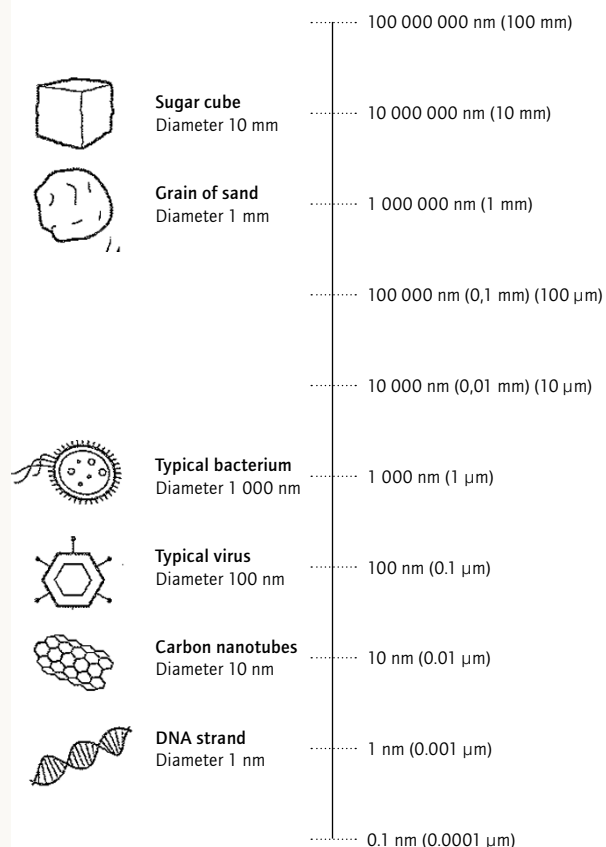
gaps in knowledge and regulatory processes.

A publicly-accessible Nanotechnology Consumer Products Inventory was put online in August 2008. The most recently updated version lists approximately 1000 products from 21 countries. By far most 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.

European consumer associations have expressed concern to be informed about nanotechnologies, 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. 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 treatments.

Length scale showing the nanometre in context

One nanometre (nm) is equal to one-billionth (1,000,000,000) of a metre, 10^{-9} m. Most structures of nanomaterials which are of interest are between 1 and 100 nm in one or more dimensions.



Source: *Novel Materials in the Environment: The case of Nanotechnology*, Royal Commission on Environmental Pollution, November 2008

There is public awareness on the issue. Surveys done by consumer groups in some European countries – like *vzbu* in Germany; *Which?* in the United Kingdom; the *Information Centre for Environment & Health* in Denmark, and the *Center for Technology Assessment* in Switzerland – concur that the public needs to be informed about nanotechnologies, and a dialogue with civil society 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 2009¹⁴. 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 science and 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. They 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.

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 nanos.

ETUC calls for more research funding

A Nano-Working Group of ETUC member organizations linked into the EU's Nanotechnology Capacity Building (NANOCAP) project prepared a European trade union position, which was adopted as the first ETUC resolution on nanotechnologies and nanomaterials in 2008. It is expected to be revised by 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 & 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.

REACH's "no data, no market" principle must be applied as a general rule for nanotechnology products that are intended to be introduced to the market. This will require the REACH registration procedure to be changed in order to cover all nanomaterials, including those produced or imported in quantities below 1 tonne/year. At the same time, better communication and risk assessment in the workplace is needed.

The research and development programme budget for health & environmental risk research should be increased. This means that at least 15% (from the current 5%¹⁵) 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.

14. Joint ANEC/BEUC position 2009, *Nanotechnology: Small is beautiful but is it safe?*

15. According to personal communications from Officials of the European Commission.

16. Commission particulière du débat public Nanotechnologies, <<http://www.debatpublic-nano.org>>.



Of the 1000-odd nanomaterial-containing consumer items logged to date, over a third are cosmetics, personal care or sunscreen products.
Image: © Belga, HMC

The case of nano-silver in the US

One example of current regulatory action taken in the US is the legal petition by the International Center for Technology Assessment on behalf of various organisations requiring the EPA to make rules that classify nano-silver products as a pesticide, require manufacturers to provide safety data, and to introduce mandatory and approved labelling requirements. EPA has opened a public comment period until a consultation meeting in November 2009 with the Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel.

Nano-silver has been used as a bactericide in a wide range of products like liquid condoms, soaps, textiles or dishwashing liquid.

Federal Register Vol 73, No 54, 2008

<http://edocket.access.gpo.gov/2008/pdf/E8-27204.pdf>

The ETUC Resolution also considers terminology: 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's examination of the current legislative framework has identified several loopholes, and some regulatory changes are needed.

They include:

- amend 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;
- apply the "no data, no exposure" precautionary approach so that worker exposure is *avoided as much as possible*;
- voluntary initiatives and codes of practices are useful if certain conditions are met, but nanotechnologies *need proper legislation*;
- penalties should be available to ensure that preventive measures are properly implemented and to enforce compliance.

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. 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.

The precautionary principle also features in the Resolution: preventive actions

must be taken where uncertainty and lack of knowledge prevail. This is an essential prerequisite for the responsible development of nanotechnologies and for helping to ensure society's acceptance of nanomaterials. The REACH registration process is a clear example of the precautionary principle in action.

France and the Netherlands show the way

The Member States that first started to regulate the manufacture, import or marketing of nanoparticle substances are France and the Netherlands. 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. The government must now flesh these proposals out into practical measures by the end of 2009.

The Dutch Social and Economic Council 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 products. 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.

In France, the Grenelle 1 Act laying down environmental guidelines was passed unanimously by the National Assembly in August. 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 has now tasked the ad hoc Commission Nationale du Débat Public under the Grenelle Act with conducting a national public debate on nanotechnologies, which it hopes will really engage the public. The debates will run 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 will be 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 governance¹⁶.

Need for transparency

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.



Small quantities of carbon nanotubes are already being used as reinforcement in carbon fibre tennis rackets and competition racing cycle frames. Even tennis rackets made entirely of carbon nanotubes are already being spoken of as a possibility.
Image: © Nanocyl

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 Commission has come under heavy criticism for its cautious approach to launching regulatory initiatives on nanotechnologies. 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 be applicable *mutatis mutandis* to nanotechnologies. Scholars have suggested that 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 ethical or social issues. Nanotechnologies must be governed by new, specific regulations.

Definitions are important, for we must know what we are talking about; clear definitions of nanomaterials and nanotechnologies

17. Bowman, D, Gillian, G 2007, "How will regulation of nanotechnology develop? Clues from other sectors", *New Global Frontiers in Regulation. The age of nanotechnology*, Edward Publishing Ltd., UK, p. 355.

are crucial, for the lack of them produces legal uncertainties. Without a consensus on definitions, nomenclature and standards of classification and testing, is extremely difficult to define or classify the object to be regulated¹⁷. Also, standards promote free trade, safety of workers and consumers, and environmental protection.

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 nanotechnology research. ●

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