NanoCap is a European project that sets up a consortium of 5 environmental civil society groups, 5 trade unions and 5 universities. It focuses on capacity building enabling the project partners to work in the field of safe and sustainably developed nanotechnologies and their applications. It aims to deepen the understanding of environmental and occupational health impacts, safety risks and ethical and regulatory aspects of these technologies.

The project is funded by the European Commission FP6 Science and Society programme. It runs from September 2006 until September 2009.

The European Environmental Bureau (EEB) is a federation of over 150 environmental civil society groups based in most EU Member States, most candidate and potential candidate countries as well as in a few neighbouring countries. These organisations range from local and national, to European and international. Our office in Brussels was established in 1974 to provide a focal point for our members to monitor and respond to the EU's emerging environmental policy.

EEB's aim is to protect and improve the environment by influencing EU policy, promoting sustainable development objectives and ensuring that Europe's citizens can play a part in achieving these goals. EEB stands for environmental justice and participatory democracy.

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NANOTECHNOLOGIES IN THE 21ST CENTURY

A CRITICAL REVIEW OF GOVERNANCE ISSUES IN EUROPE AND ELSEWHERE

Issue 3. August 2009

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Index

The context of this series of papers

Nanotechnologies are the science and business of manipulating matter at the atomic scale. Materials produced with the aid of nanotechnologies are starting to be used in many areas of everyday life (cosmetics, clothing fabrics, sports equipment, paints, packaging, food, etc). As the applications expand, many proponents are positioning nanotechnologies as part of a greener, more sustainable future. Is there a basis to these claims, or will nanotechnologies only lead to more toxic materials, more production and consumption, and a decrease of control over how to create and live our lives?

In this context, it is essential for environmental NGOs to gain knowledge on different aspects of the emerging nanotechnology development and governance debates, especially in relation to critically discussing the promotion of nanotechnologies for use in green technologies (i.e. for renewable energy production and water filtration). Environmental NGOs also need to clarify and become aware of the importance of their involvement in the governance of nanotechnologies and their products and become actively involved in public dialogue about the future development and direction of their use. It is crucial that as nanotechnologies expand into the "green" sector, environmental NGOs formulate political demands and become involved in public debates concerning the sustainable and responsible development of nanotechnologies.

This series of papers is meant to serve as a capacity building tool empowering environmental NGOs to work actively in the field of sustainable governance and use of nanotechnologies and nanomaterials. This objective will be met through the production of four separate publications between April and July 2009. The outline of the issues addressed in each publication is as follows:

1. Challenges and opportunities to green nanotechnologies
2. Environment, health and safety research and emerging concerns about the sustainability of nanotechnologies and nanomaterials
3. Regulatory status and initiatives in Europe and rest of the world on nano materials
4. NGO guidelines on sustainability assessment of nanotechnology and nanomaterials

The third paper of four in this series reviews the current uncertainties associated with the governance of nanotechnologies. Nanotechnology development and commercialisation is currently outpacing government oversight, risk management and public debate. This report will examine the state of play of broad governance issues including regulatory initiatives and responses, voluntary codes and practices, as well as the progress of international cooperation efforts in coordinating nanotechnology governance. Finally, it will review NGO responses and initiatives regarding nanotechnology regulation with particular reference to the application of the precautionary principle and pre-market registration demands in Europe.

Nanotechnology regulation will remain complex for some time

There are a number of factors that make timely and effective nanotechnology regulation difficult, including:

- The range, diversity and number of nanomaterials and applications being developed and the lack of a common internationally agreed definition
- The current limited knowledge about the toxic and ecotoxic effects of nanomaterials'
- The proprietary nature of information and hence prevalent lack of data sharing on safety and risk assessment of nanomaterials between industry, regulators and the public
- The continuing lack of standardisation in nomenclature, metrics, and materials, which may take a further 5-10 years to overcome
- The potential inadequacy of statutory authorities' ability to respond and legislate[1]

Current regulatory regimes need to be adjusted to address nanomaterial specific issues, including regulations pertaining to chemicals and materials, cosmetics, foods, occupational health and worker safety, environmental safety, and medical devices and pharmaceuticals. Key issues in current regulatory discussions are the nature of regulatory triggers (e.g. production volumes), classification and identification of nanomaterials, the provision of safety data and information sharing with the end user (i.e. labelling, creation of inventories of nanomaterials and nanomaterials-containing products). For example, regulatory triggers in the EU are set at a one tonne production threshold as part of general chemicals legislation designed before nanotechnologies were on the agenda, whereas Canada has proposed a much lower threshold (1 kg). On identification and classification, there is as yet no agreed international standard for these, and there are also discrepancies between different pieces of legislation (in the EU context for example).

To date there have been a number of responses by government, industry and NGOs to the above regulatory challenges, including:

- Knowledge-gathering activities, both in terms of scientific research directions and the evaluation of existing regulatory frameworks
- Voluntary codes and voluntary registration of nanomaterials
- Transnational efforts to develop standards and develop intergovernmental cooperation (e.g. OECD, ISO)

Not all of the above efforts have yielded the hoped for results. For instance, voluntary schemes have clearly failed to deliver results and mandatory notification schemes are starting to emerge as a possible solution. Again, the standards and definitions for nanomaterials, their measurement and their characteristics are still largely being defined.

To regulate or not?

An ever increasing number of nanotechnology-based products are available on the market, and the complexity of nanomaterials means that the same nanomaterial behaves differently according to its specific application. Despite this situation, governments have generally been astonishingly reluctant to create new regulations to deal with these new materials. Almost unanimously, regulators in Europe, the US and elsewhere have claimed that while existing regulations have some shortcomings, they are perfectly adequate in dealing with these new materials.

Governments appear trapped between the need to ensure public safety by regulating for unknown potential risks, while at the same time feeling obliged to promote a technological innovation that promises to revolutionise products and services and to boost economic activity. The pressure to remain 'competitive' globally appears more important than the need to protect the public from potentially dangerous materials.

Industry proponents and many government regulators favour a so called "evidence-based" approach to regulation, which argues that nanomaterials should be presumed safe until proven otherwise. They argue that if and when there is more and conclusive scientific evidence that demonstrates that nanomaterials may be harmful, 'evidence-based' regulations will be necessary[2]. This approach has advantages for the nanotechnology industry and government because it removes the burden of proof from industry and it is cheap in the short term. Unfortunately, it also requires a level of knowledge regarding nanomaterial risks that experts believe may be many years away, depending on whether or not adequate investment is made in risk research. We have discussed in the previous report in this series the evidence of potential harm from certain nanomaterials that is starting to emerge (for more information see Issue 2: Nanomaterials health and environmental concerns). For example, carbon nanotubes are suspected of causing asbestos-like lung damage, and nanosilver has the potential to be very toxic to soil bacteria and may harm aquatic organisms including fish.

Voluntary Codes of conduct - do they work?

Voluntary codes of conduct are private governance mechanisms that could theoretically play a role in regulating commercial behaviour. They are often framed as enhancing rather than replacing regulatory tools. Yet many codes have suffered sustained accusations of only serving industry interest, lacking accountability, enforceability and the legitimacy of government regulation.

Regulators are struggling to define nanotechnologies, how to test them and how to mitigate their risk, providing further evidence of the inability of public policy to 'keep up' with faster evolving technologies. Voluntary codes of conduct for nanotechnology have been promoted by industry and some governments as a means of overcoming existing slow, inflexible and overly formal regulatory regimes and as stop gap measures that would allow regulatory schemes to 'catch up'. Getting industry to sign up to voluntary codes could in theory be used to efficiently gather data and develop risk management frameworks.

Additionally, voluntary codes are said to provide more scope for "innovation, creativity, and flexibility, while … being pragmatic and consensual rather than politically driven"[3] . However, many environmental NGOs perceive them as window dressing exercises that ultimately lack legitimacy, support and 'bite', and appear to only serve to delay regulation and hinder public decision-making.

To be at all useful and effective a code will need to be transparent, contain effective monitoring of implementation, an enforcement mechanism and/or sanctions, and a third party oversight mechanism[3]. In the area of nanotechnology a number of voluntary 'nano codes' from a range of stakeholders have been put forward. Table 1 outlines the voluntary codes of conduct put forward by the European Commission, the Swiss Retailers Association and the UK's Responsible Nanocode. While the first two at least claim to be based on the precautionary principle, all three lack enforcement or third-party oversight mechanisms. Unfortunately, without the latter nano codes might provide vague guidance to industry and government, but will probably achieve little in safeguarding against unwanted nanotechnology developments.

Table 1: Comparison of three "nano" codes of conduct

	European Commission code for nano research [4]	Swiss Retailers Association [5]	UK Responsible Nanocode [6]
Aim	Encourage and promote safe, responsible, and sustainable research		"Establish a consensus of good practice… and provide guidance on … good governance"
Major Principles	Seven principles: • Comprehensibility • Sustainability • Application of the precautionary principle • Inclusiveness of stakeholders • Excellence • Innovation • Accountability	• Personal responsibility for product safety • Requesting information from across the value chain on benefit, nano-specific actions and risk potential • Informing consumers openly	Seven principles: • Board accountability • Stakeholder involvement • Worker health and safety • Public health and safety, including considering risk and lifecycle assessment • Engage with business partners • Transparent and regular reporting
Overall approach	Demonstrate good governance by ensuring environmental and human safety	A risk management approach throughout the entire value chain	"To help achieve the technologies' potential for good"
Based on / applying the precautionary principle	yes	yes	Not mentioned as such
Enforcement mechanism	No	No	No
Limitations and prohibitions	No research funding for areas that involve violations of fundamental rights/ ethical principles and non- therapeutic enhancements of the human body	None as such	• Not intended to delay legislation • An auditible set of standards or performance guidelines

Partly as a response to the lack of regulation and governance of nanotechnology a group of NGOs in 2007 published a set of "principles of oversight". These principles have now been signed by over 80 NGOs worldwide, and are discussed in more detail near the end of this document. It is important to note that this set of principles is not a code of conduct, but a minimal set of principles that governments and industry should be required to adhere to.

Voluntary reporting schemes: not very successful

Some governments have responded to the regulatory vacuum and lack of information on nanotechnology risks by initiating "voluntary reporting initiatives" or so called "stewardship programmes". The intended purpose of these schemes is to gather data on material characteristics and toxicity from industry and research and to use this information to further the development of regulatory responses[3]. Schemes have been initiated in several countries, including at the EU level, UK, US and Australia.

For example, the United States Environmental Protection Agency (EPA) launched the Nanoscale Materials Stewardship Program (NMSP) in January 2008. It was envisaged that the voluntary programme would add to information on current risk management practices used by manufacturers and processors of nanomaterials, encourage the sharing of test data, and further the responsible development of nanomaterials. However, a year after its introduction the programme can be declared a failure. The EPA only received information on about 10% of around one thousand nanomaterials available on the market, with little detail on health and safety data being shared by the participating companies. A quarter of the companies claimed their information to be confidential and hence not publicly accessible. Out of all the participating companies (29 in total), only four companies were prepared to conduct any voluntary tests of their nanoscale material [7].

Schemes initiated in other countries have produced equally poor results. In the UK, DEFRA's (Environment Ministry) voluntary reporting programme was established in September 2006 and concluded in 2008. It received a total of 13 submissions[8]. DEFRA conceded that with the large amount of information requested, confidentiality and resource issues were amongst the primary reasons for low participation in the scheme

Voluntary regulatory measures mission impossible

Purpose:
To promote responsible development of nanotechnology without appearing to impede business and market development

Success rate:
Mostly unsuccessful due to low participation rates and unwillingness by industry to share data.

Key missing ingredients:
Willingness by industry to share safety data freely and without restrictions. Additionally, a lack of enforcement or third-party oversight mechanisms to make the codes effective.

Mandatory reporting schemes are in the pipeline

Unsurprisingly, some governments have concluded that perhaps mandatory reporting schemes will yield the required information about nanomaterials. In principle there are two types of mandatory schemes: reporting measures (such as gather information on health and safety data applicable to nanomaterials) and responding to surveys (tracking of manufactured nanomaterials, for instance).

Since 2007, France is in the process of improving its environmental legislation following an unprecedented multi-stakeholder dialogue process called “The Grenelle Project”. In this context the Ministry for Ecology, Energy, Sustainable Development and Territorial Development proposed in early 2009 that all manufactured or imported nanoparticle substances be declared before being placed on the market. Furthermore, should the authorities require it, hazard and exposure information regarding these substances must be made available and all information relating to the identity and uses of these substances be made public[1].

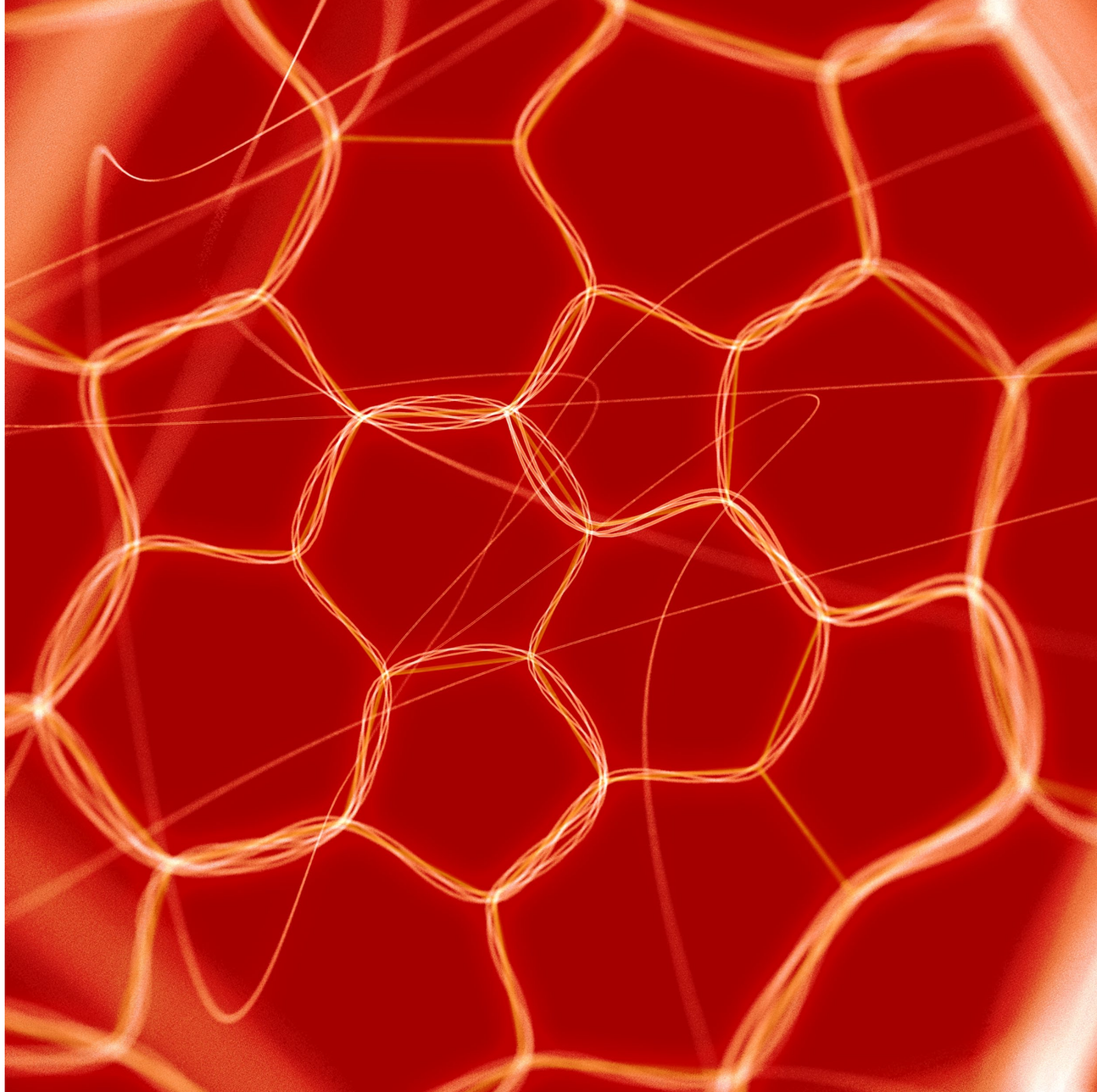
In January 2009, it was widely reported that Canada was to become the first country in the world to introduce a mandatory safety reporting scheme for companies producing or importing nanomaterials of more than 1kg. Companies, it was claimed, would be required to submit information on physical and chemical properties, toxicological data, and methods of manufacture and use[9]. However, as of mid 2009 details of this scheme have as yet not been published in the “Canadian Gazette”, hence no such scheme exists at present.

The Californian Department of Toxic Substances Control Department has become the first jurisdiction to make mandatory the information provision on carbon nanotubes, including information regarding test methods, fate and transport in the environment and other relevant information. It is now in the process of expanding this mandatory information call to other nanomaterials[10]. In particular the Californian DTSCD has added nanosilver, nano zerovalent iron and cerium oxide to a list of potential materials of interest.

Risk Governance Frameworks – enabling discussion?

A key player in developing risk governance for emerging, systemic global risks such as climate change, nanotechnology and energy technologies is the International Risk Governance Council (IRGC). IRGC is an independent, not-for-profit organisation that aims to bring governments, industry and NGOs together to further the understanding and management of emerging global risks impacting human health and safety, the environment, the economy and society. IRGC is supported financially by a number of governments, insurance and electricity companies. The IRGC has developed a generalised risk governance framework that aims to conceptualise all aspects of risk governance from pre-assessment, appraisal of risk, tolerability and acceptability judgment to risk management. This approach claims to go beyond the traditional risk assessment paradigm as it includes societal concerns, ‘early warning’ signs, inclusion of all stakeholders and integrated risk communication [11].

Through a series of international conferences, surveys and reports the IRGC has applied this framework to nanotechnology. Nanotechnology development is viewed by IRGC as consisting of four phases: passive, active nanostructures, integrated and heterogenous nanomolecular systems (the latter two not yet developed, only conceptualised). Each of these will require separate and distinctive governance responses and risk governance is expected to become progressively more complex as apart from health and environmental, new ethical, political, security and societal issues and risks arise[12].
The actual act of assembling the nanotechnology specific IRGC risk governance framework has undoubtedly brought together many of the key stakeholders for discussions, but it is difficult to envisage how the framework can be applied in practice. The IRGC clearly plays an influential role in framing how particular risks are viewed and is engaged in bringing together, frequently in an informal manner, key governmental and industry decision makers. The role these informal meetings play in setting the overall risk governance agenda is unclear, but is probably substantial and influential. NGO representatives are often invited to speak at IRGC conferences, and a conscious effort is made not to exclude stakeholders.
Other examples of risk management and monitoring systems are the DuPont/Environmental Defence Nano Risk Framework[13] and CENARIOS[14]. These efforts are less ambitious in scope and reach when compared to the IRGC framework and seemed to have achieved little traction within the industry.



2. European nanoregulation

In its attempt to avoid the regulatory mistakes made in the management of earlier technological developments, the European Commission recognised the need for regulation of the risks from nanotechnologies in its "Communication on Nanotechnologies" as early as 2004[15]. The EU continued to respond to the nanotechnology challenge by issuing additional action plans, research strategies, international engagement and a code of conduct for European research. The independent scientific committees of the Commission also published a list of opinions on various aspects of nanomaterials and nanotechnologies (see Appendix 1 for a list).

However, for several years now the EU Commission has continued to insist that existing regulation would be sufficient to cover nanomaterials and products. For instance, it stated in a communication to the EU Parliament in 2008 that "it can be concluded that current legislation covers to a large extent risks in relation to nanomaterials and that risks can be dealt with under the current legislative framework. However, current legislation may have to be modified in the light of new information becoming available, for example as regards thresholds used in some legislation.[16]"

The main argument put forward by the Commission is that since nanomaterials are not explicitly excluded from regulations, they must be covered. However, it is clear that existing regulation needs to be made more explicitly "nano proof", particularly in relation to the trigger mechanisms for safety tests and safety data information. Possibly the most important question about regulation is how it can be enforced in the case of nanomaterials, which continue to go beyond the limits of traditional testing mechanisms. The main EU regulations are explained in more detail below.

Without such clarifications, the implied approach appears to be that no action will be taken by the authorities until a health hazard or environmental impact is identified. This will be very hard to observe and prove, as the materials are often difficult to characterise and measure and their toxicological profile remains largely unknown. Additionally, ill effects may take years to come to light or be relatively subtle in their expression. The precautionary principle, therefore, must be applied with care.

In response to the Commission's regulatory assessment on nanomaterials, the European Parliament provided its response in early 2009. Parliament disagreed that current legislation in principle covered nanomaterials and called on the Commission to revise relevant legislation such as REACH by the end of 2011, to establish a comprehensive "no data-no market" approach (as set out in REACH) and to introduce mandatory labelling of nanomaterials used in consumer products[17]. In two other recent votes, MEPs also backed revisions on regulations on cosmetics and novel foods so that nanomaterials are more explicitly dealt with.

While nanomaterials may have an impact on a number of legislative frameworks and directives (see Appendix 2 for a summary), the main regulations that have received some detailed scrutiny address chemicals broadly, food and feedstocks, and cosmetics.

REACH and nanomaterials

REACH is a new (2007) European Community Regulation on chemicals and their safe use, standing for the Registration, Evaluation, Authorisation and Restriction of Chemical substances. In chemicals regulation terms, REACH is ground-breaking because it reverses the burden of proof regarding the safety of a substance, requiring producers to provide such evidence and no longer requiring authorities to provide evidence of harm.

While there are no explicit provisions referring to nanomaterials, the Commission claims that nanomaterials are covered by the "substance" definition in REACH whereby manufacturers and importers have to submit a registration dossier (for substances manufactured or imported at or above 1 tonne per year) and a chemical safety report (for substances manufactured or imported at or above 10 tonnes per year). In addition:

- The European Chemicals Agency can require any information on the substance if deemed necessary
- When nanomaterial forms of bulk materials are introduced onto the market, the registration dossier will have to be updated including different classification and labelling of the nanoform and additional risk management measures will need to be described.
- These new risk management measures and operational conditions need to be communicated to the supply chain
- In order to address the specific properties, hazards and risks associated with nanomaterials, additional testing methods may need to be modified and/or information be supplied. Until these exist, testing will have to be carried out according to already existing guideline
- Current provisions, including quantitative triggers and information requirements may have to be modified if and when new toxicological data becomes available

The most recent work on nano in REACH takes place in the Competent Authorities subgroup Nano, where issues such as substance identification of nanomaterials, information requirements on intrinsic properties (incl. testing strategies), exposure assessment (including exposure scenarios, evaluation of risk management and mitigation measures and exposure estimation), as well as hazard and risk characterisation for chemicals safety assessment are being discussed among member states experts, industries', NGOs' and Commission representatives. The outcomes of these discussions serve as guidelines to CARACAL (Competent Authorities for REACH and CLP) where policy decisions on REACH implementation are being made.

Pesticides and biocides and nano-formulations

Products covered by the Pesticides and the Biocides Directives need to be assessed and authorised before use. As many pesticides are a source of surface and ground water pollution, they are also subject to the EU's Water Framework Directive. However, none of these regulations currently considers nanoscale products, or recognises nanomaterials to be new substances.

To adequately cover nano preparations of existing pesticides and biocides, and any new nanoformulations, additional safety assessment before authorisation for commercial use is clearly necessary and should be made mandatory.

Cosmetics and nanomaterials

Cosmetic products fall under the Cosmetics Directive which has been undergoing revision. In March 2009, agreement was reached on the revision which included nano-related elements, including the need to disclose nano-sized ingredients on the product ingredients list and mandatory notification for products containing nano-engineered materials. In the case that the Commission has doubts over the safety of a specific nanomaterial, it can demand the submission of nano-specific safety data, which would then be reviewed by the Commission's Scientific Committee on Consumer Safety (SCCS).

While a definition for nanomaterials has been included in the Cosmetics Directive, it is at odds with the definition proposed in the regulation on novel food, which is also undergoing revision. For cosmetics, a nanomaterial is defined as 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 [nanometres]". This clear and strict size limit potentially leaves room for manufacturers of certain nanomaterials above this size scale to escape these rulings. The proposed definition for Novel Foods is still being decided.

Food, food packaging and food contact materials and nanomaterials

The general safety article of the EU Food Directive requires all food for consumption to be safe. As an overarching safety article, it should of course also apply to foods and food packaging containing nanomaterials. However, so far European regulation does not recognise the critical issue of particle size. If a substance has already been approved for use in bulk form, there is no regulatory trigger to require a new safety assessment before a particle is used in nano-form in food ingredients, additives or packaging.

This could change with the new Novel Food Directive currently under revision. In March 2009 the European Parliament voted to include mandatory nano-specific safety testing and labelling of nano food products. As methods for nano-specific safety testing of food products still have to be developed, this would mean a de facto moratorium for nano food products. In a recent report, the British Royal Commission on Environmental Pollution (RCEP) estimated that it might take up to 15 years to develop test protocols for the safety assessment of nanomaterials[18]. Parliament's vote is part of the continuing revision of the Directive, which will continue to be discussed at EU level before going into final decision procedures in late 2009.

The EU Food Packaging Regulation covers all materials coming into contact with food such as a packaging, bottles (plastic and glass), cutlery, domestic appliances and even adhesives and inks for printing labels. Similar to the regulation on novel foods, it requires the establishment of a positive list of authorised food contact materials and an assessment of their potential toxicity or safety. However, its weakness is that once again the failure to identify nanomaterials as new substances means that nanomaterials of already authorised substances in bulk form will not be subject to new safety assessments.

A key scientific advisory body to the European Commission, the European Parliament and EU Member States in the area of food is the European Food Safety Authority (EFSA). EFSA's area of responsibility covers advice on risk management for food and feed safety, nutrition, animal health and welfare, plant protection and plant health. Since 2007 EFSA has convened an expert working group on nanotechnology involving people from national food safety authorities[1]. In February 2009, EFSA published a final scientific opinion on the potential risks related to the application of nanotechnology in food and feed safety and the environment, affirming that in their opinion the regulatory frameworks for food and feed are appropriate. However, EFSA acknowledged that methods still need to be developed to detect and measure nanomaterials in food, feed and biological tissues, and that a better understanding of exposure and toxicity is needed. Interestingly, the opinion also recommends the inclusion of a specific surface area as part of the definition of nanoscale materials, in addition to size[19].

EU Commission nanotechnology "milestones"

2004	Towards a European strategy for nanotechnology, COM 338
2005	Nanotechnologies Action Plan, COM 243
2007	Nanosciences and Nanotechnologies: An actionplan for Europe 2005-2009. First Implementation Report 2005-2007
2008	Recommendation on a Code of Conduct, COM 424
2008	Regulatory Aspects of Nanomaterials, COM 366
2009	Planned Second Implementation Report and second Nanotechnologies Action plan 2010-2015

3. Regulatory responses around the globe

United States

A number of different US Agencies are involved in nanotechnology regulation, including the FDA, the EPA, the Occupational Safety and Health Administration (OSHA), the Consumer Product Safety Commission (CPSC) and NIOSH. However, like the EU, the United States continues to avoid strict mandatory notification or overt forms of regulation of nanomaterials. US federal agencies have held public meetings, tried voluntary data programmes and published White Papers, yet manufacturers are still not required to identify nanoparticle ingredients on product labels, to conduct nano-specific safety tests on these ingredients, or to submit their products for approval prior to commercialisation. No US law is specifically designed or has been amended to regulate nanotechnology and nanomaterials.

One of the problems with the US food and agrochemicals regulation for instance is that it rests on the principle that an absence of evidence of chemical or product harm means that the product is considered safe, even if very little research has been conducted into its safety. This approach places a burden on the community to demonstrate that a product (nano or not) is harmful before regulators will control its sale, for example by requiring manufacturers to conduct new safety testing. This approach unfortunately may act as a commercial disincentive for companies to engage in comprehensive product safety testing before being obliged to do so.

A further and very serious weakness is that US regulators often focus on the marketing claims of product manufacturers, rather than the actual content of foods, packaging, pesticides, etc. Despite the authority of regulators to regulate products' content, if a manufacturer chooses not to make marketing claims about its product's nano content, there is a real possibility that a product could be treated as nano-free.

Much of nanotechnology regulation discussion in the US has focused on the applicability of the Toxic Substances Control Act (TSCA) to the regulation of nanosubstances as it broadly applies to all potentially toxic chemical substances. The TSCA contains many potentially useful aspects including reporting mechanisms, which permit the EPA to require manufacturers to notify them of new information regarding risks associated with a particular chemical. Critics point out however that the TSCA put enormous

burden on the EPA to prove that a 'new' chemical poses new risks, rather than that the manufacture proof a chemical is safe. In addition the Food, Drug and Cosmetic Act (FDCA) and the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)—both administered by the FDA—can potentially be used to regulate nanotechnology-based foods, drugs, cosmetics, and pesticides. Where nanomaterials are not covered by these other laws, TSCA applies[9].

Perhaps one of key nanotechnology regulatory battle in the US will revolve around the question whether a nanomaterial is 'new', even though it has previously existed in bulk format (such as gold, silver and titanium dioxide). Under the TSCA, chemicals are defined by their molecular structure and the EPA has stated it will determine whether or not a nanosubstance is new on a case by case basis. The first 'test' cases in this context revolve around carbon nanotubes, which are considered by the EPA a different and hence new chemical substance when compared to graphite and other allotropes of carbon, which are already listed on the TSCA Inventory.

The EPA is particularly interested in the shape, length, and wall thickness of particular carbon nanotube types. The EPA had started to impose conditions (Significant New Use Rules or SNURs) on carbon nanotube manufacture including developing toxicity data, requiring carbon nanotubes to be embedded in a polymer or metal structure, and requiring workers to use personal protective equipment [20]. However, the SNUR was temporarily withdrawn in July 2009 due to a potential legal challenge. At the time of writing this report, it was unclear how the situation would be resolved [35]. The SNURs would have also provided the EPA with an initial mechanism to evaluate the safety of nanoforms of existing substances.

The EPA was also obliged to invoke the Fungicide and Rodenticide Act (FIFRA) in 2007 to deal with the Samsung Nanosilver Washing machine and issued a decision that required the washing machine to be registered under the act as a pesticide. The EPA stressed that this decision was not in any way related to nanotechnology however because silver ions, not nanoform ions, were being released. Similarly, when the EPA fined ATEN Technology Inc $208,000 in 2008 for their failure to register several products being marketed as antimicrobial, the EPA claimed this fine was not related to nanotechnology but to unproven health claims and failure to register a product under FIFRA[9].

The US government is of course taking a leading role in many international efforts, including holding the chair of the OECD working group on nanotechnology for several years (now passed to a European representative), co-chair at the recent SAICM meeting that discussed nanotechnology, various joint projects with the WHO and is involved in many of the ISO working groups. Representatives of the FDA and EPA are frequently invited and speak at international conferences concerning nanotechnology regulation.
Of note in the US and international context, and highly influential in the nanotechnology debate, is the Project on Emerging Nanotechnologies (PEN). PEN is a US-based think tank established in partnership between the Woodrow Wilson International Center for Scholars and the Pew Charitable Trusts. PEN maintains a very comprehensive website on nanotechnology, including an inventory of consumer products and has published numerous informative reports on nanotechnology, including its regulation.

Canada

Canada also believes that its current regulatory regime can be applied to nanotechnology. It has not, however, excluded the possibility that "new approaches may be necessary in the future to keep pace with the advances in this area.[21]" The two most active regulatory departments on the nanotechnology policy to date have been Health Canada and Environment Canada. Health Canada has taken responsibility for developing a plan for the regulation of nanotechnology and coordinates its efforts with those of other federal regulatory departments and agencies. Like Europe, Canada generally envisages a precautionary approach to nanotechnology and the Federal Departments of Health and Environment have published a proposal in 2007 for a regulatory framework for nanomaterials under the Canadian Environmental Protection Act 1999 (CEPA).

The CEPA makes a distinction between new and existing chemical substances. All new chemical substances manufactured in or imported into Canada must be

scientifically assessed for their potential risks under the New Substances Notification Program. Importantly, regulatory oversight depends on the quantities released into the environment. The majority of Canada's regulatory activity to date has focused on the unique properties of products of nanotechnology in the context of chemicals management and environmental protection[9].

In 2007, the Canadian Federal Environment Department issued to manufacturers and importers an advisory note reminding them of their regulatory responsibilities for nanomaterials under the New Substances Notifications Regulations (Chemicals and Polymers)[22].This advisory note closely mirrors the EPA approach discussed above. The key issue will be the definition of what is and is not a new material. While manufacturers have a regulatory responsibility, it does not appear strictly mandatory. There have however been speculations in the press regarding a mandatory notification on nanomaterials, after a workshop on the "Proposed Regulatory Framework for Nanomaterials under the Canadian Environmental Protection Act, 1999" suggested mandatory notification as a solution. So far, no further official information on a mandatory scheme has been published.

Again similar to the EPA, Environment and Health Canada have recently begun using the Significant New Activity (SNAc) provision of CEPA to gather information on nanomaterials. However, neither a list of these nanomaterials has been published nor as explanation as to why particular substances have been chosen. The trigger for 'existing' nanomaterials has been set as quantities greater than 10 kg per calendar year, where the substance has a particle size between 1 and 100 nanometre.

Canada actively participates in intergovernmental activities such as the OECD and various ISO initiatives. Canada currently convenes the ISO Nanotechnology Technical Committee (TC229) Joint Working Group on Terminology and Nomenclature.

Japan

No direct regulation of nanomaterials has as yet been implemented in Japan. Similar to Canada, the Chemical Substance Control Law requires that manufacturers notify the regulators about nanomaterials if the regulators consider them to be new chemicals. In this context a number of notifications concerning fullerene derivatives have been submitted to the regulator under the small quantities exemption of the new chemical notification.

The Ministry of Economy, Trade, and Industry (METI) and the Ministry of the Environment (MOE) have established specific nanomaterial safety working groups and conducted a preliminary survey on the safety of nanomaterials in occupational settings. The results of this survey have been published and voluntary guidelines for the handling of nanomaterials and limiting release of nanomaterials into the environment have been published[23]. Additional guidelines on worker safety and on medical practices and pharmaceuticals using nanomaterials are under preparation[24]. Japan actively participates in the work of

4. International intergovernmental efforts

As discussed in an earlier report in this series, it is at present virtually impossible to construct a meaningful risk assessment for nanomaterials. Too much is unknown about their health and environmental impacts, but it has been established that at least some nanomaterials pose serious adverse effects. Given the globalised nature of our economies and hence the global level of production, transport and sale of nanomaterials and the concomitant dangers this may entail, international cooperation and action is urgently needed. A number of NGOs, for example the ETC Group and the Centre for Environmental Law (CIEL) have suggested that a global and legally binding framework for nanotechnology is desirable and necessary. This would need to be:

- Built on the precautionary principle
- Broadly participatory and transparent
- Comprehensive in the scope of the risks addressed and
- Apply to the whole lifecycle of nanomaterials[25]

At present no such framework exists and its creation is currently almost unimaginable. However, a number of international organisations have started to engage with nanomaterials and nanotechnologies in general. Here we will briefly review the activities of the OECD, ISO and UNESCO and discuss some other international "players".

Standardisation – the role of the International Standards Organization

The International Standards Organization (ISO) is an NGO that aims to provide a bridge between the public and the private sector and plays an important role in setting international industrial and commercial standards. While ISO is legally an NGO, its standards often become law (via treaties and national standards) and can be defined as a consortium of interested parties with strong links to governments and major corporations.

While fulfilling an important role in society, the purpose of standards is to facilitate business and industry operations rationalisation of production processes. This may at times be difficult to reconcile with public policy measures. Standardisation may also have a tendency to intervene in areas where other regulatory approaches may be more appropriate. Given the key stakeholders of ISO, the public interest as such is usually not taken into account, especially in relation to environmental issues. ISO only provides very limited avenues for input for public interest stakeholders such as unions, NGOs or consumers[26].

In response to the increased use of nanotechnologies in industry, ISO has established the Technical Committee TC 229 "Nanotechnologies" which is comprised of four working groups. These are meant to address issues relating to the governance of nanotechnology, notably:

- Terminology and nomenclature (definitions)
- Measurements and characterisation
- Health, safety, and environment
- Materials specification

While it is uncontested that universally valid and internationally accepted definitions and terminology will assist research and industry, there are many unresolved issues.

The recently agreed size-based definition (i.e. 1-100nm) for nanoparticles (ISO 27687), which is scheduled to be adopted by many governments, provides a good example. The size range within which ISO has defined nanoparticles will have significant implications for health and safety regulation at national level. However, the current definition requires further discussion and perhaps amendment to ensure the best outcome not only for industry and science, but for the public good. It is not unusual for standards to be amended over time, as new information comes to light.

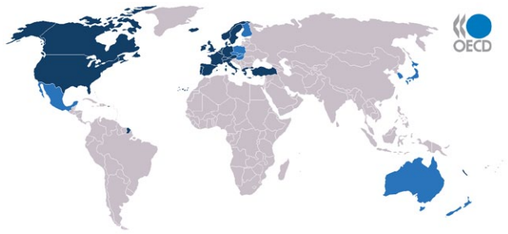
If, for instance, governments decide that nanoparticles will be regulated as new chemicals, then the use of an arbitrarily defined size range to act as an index of novel properties is problematic. Particles that fall outside the

size range deemed to encompass nanoparticles – even if they are not much bigger and also exhibit novel, nano-specific behaviour - will not be assessed as new chemicals and will not trigger new health and safety assessments where substances have previously been approved for use in the bulk form. Inappropriate metrics that apply to larger particles will be used to measure exposure or commercial use quantities. This makes it particularly important not to set too narrow a size-based definition of nanoparticles.

Unsurprisingly, many industry proponents have argued for such a narrow nanoparticle definition (1-100nm). Given early evidence that some particles up to a few hundred nanometres in size also behave like nanoparticles[27], [28], civil society groups have called for the size-based definition to be larger. The United Kingdom's Soil Association's new organic standard excludes particles smaller than 200nm in size; Friends of the Earth groups in Australia, Europe and United States and the European Environmental Bureau have called for particles up to 300nm to be treated as nanoparticles for the purposes of health and safety assessment.

The above is an example of issues being addressed in creating a standard. ISO members frequently believe that they are engaged in a value-free, scientific and objective activity when creating definitions and terminology, that the standard they are defining is disconnected from other influences (like regulations, industry interests, etc.) and that they are engaged in uncovering the truth, rather than creating it. Due to the one country, one vote decision making procedure, it is very difficult for dissenting voices (e.g. including public interest groups as voting members) to be heard or to make an impact.

While it may sometimes appear that ISO is the only international body concerned with standards relevant to nanotechnologies, this is not entirely the case. The International Electrotechnical Commission (IEC) is an international standards body that prepares and publishes International Standards for all electrical, electronic and related technologies. Like ISO, it is an NGO and operates in a similar manner. It concerns itself with the standardisation of nanomaterials and nanotechnologies, but only in respect to electrical and electronic products and systems.



OECD work on nanotechnology

The Organisation for Economic Cooperation and Development was created in 1960 by a number of countries in Europe and North America as well as Turkey to extend an existing organisation for economic cooperation which operated only in Europe until then. According to the OECD, the organisation "brings together the governments of countries committed to democracy and the market economy from around the world to:

- Support sustainable economic growth
- Boost employment
- Raise living standards
- Maintain financial stability
- Assist other countries' economic development
- Contribute to growth in world trade

The Organisation provides a setting where governments compare policy experiences, seek answers to common problems, identify good practice and coordinate domestic and international policies. [29]"

The OECD has two nanotechnology-focused bodies; the Working Party on Nanotechnology (WPN) and the Working Party on Manufactured Nanomaterials (WPMN). The WPN was established in 2007 and its objective is "to advise on emerging policy-relevant issues in science, technology and innovation related to the responsible development and use of nanotechnology" while the WPMN was established in 2006 to further governmental cooperation in the OECD on policy issues relating to the development of nanotechnology. The OECD brings together "government experts" from OECD countries, the European Union, and representatives from Brazil, China, Russia, Singapore and Thailand. Also intermittently present are observers from UNEP, the World Health Organisation, the International Standards Organisation, and representatives of industry organisations (BIAC), the Trade Union Advisory Committee to the OECD (TUAC) and environmental NGOs.

The OECD's nanotechnology webpage states: "Nanotechnologies pose new opportunities and challenges to governments. Nanotechnologies are likely to offer a wide range of benefits, including in helping address a range of societal and environmental challenges, e.g. in providing renewable energy and clean water, and in improving health and longevity, as well as the environment. However, unlocking this potential will require a responsible and coordinated approach to ensure that potential challenges are being addressed at the same time as the technology is developing[30]."

Working Party on Nanotechnology (WPN)

The WPN was established in March 2007 to advise upon emerging policy issues related to the responsible development of nanotechnology, as well as promote international co-operation that facilitates research, development, and responsible commercialisation of nanotechnology.

The WPN has six project areas:

1. Develop statistics and indicators for nanotechnology
2. Monitoring and benchmarking nanotechnology developments
3. Addressing challenges in the business environment specific to nanotechnology
4. Fostering nanotechnology to address global challenges
5. Fostering international scientific co-operation in nanotechnology
6. Policy roundtables on key policy issues related to nanotechnology (including risk governance)

Working Party on Manufactured Nanomaterials (WPMN)

The WPMN is focused on eight main areas of work (projects), managed through separate Steering Groups, with different timelines and objectives:

1. Development of a database on human health and environmental safety (EHS) research
2. EHS research strategies on manufactured nanomaterials
3. Safety testing of a representative set of manufactured nanomaterials
4. Manufactured nanomaterials and test guidelines
5. Co-operation on voluntary schemes and regulatory programmes
6. Co-operation on risk assessment
7. The role of alternative methods in nanotoxicology and
8. Exposure measurement and exposure mitigation[30]

Project 3 "safety testing and representative sets of nanomaterials" selected and agreed on a 'representative' set of fourteen manufactured nanomaterials for environmental health and safety testing. These are:

- Aluminium oxide
- Carbon black
- Cerium oxide
- Carbon nanotubes
- Dendrimers
- Fullerenes
- Iron nanoparticles
- Nanoclays
- Polystyrene
- Silicon dioxide
- Silver nanoparticles
- Titanium dioxide
- Zinc oxide

Unfortunately, government funding for OECD activities is mostly in the form of staff time, so a limited budget means that important and/or commonly used nanomaterials were omitted from the list including quantum dots, boron nanotubes, gold nanoparticles, and cadmium telluride. For each nanomaterial chosen, only one or two nano forms are being investigated. Given that nanomaterial properties, and hence safety assessments, are dependent on surface, structure, presence or absence of functional groups etc., it is questionable if such a limited reference set will provide policy-relevant results. Nonetheless, the work is providing useful information that would not have otherwise been collected at such an international level. Findings from this research are to be made publicly available only around 2011.

The OECD working party has recently made publicly available the OECD Database on Research into Safety of Manufactured Nanomaterials which collects research projects addressing environmental, human health and safety issues of manufactured nanomaterials. The database's purpose is to help identify research gaps and to assist researchers in future collaborative efforts. The working party has also begun publishing a number of documents, for example, on exposure measurement and mitigation.

While in principle the OECD working parties appear a good idea, in practice they are very problematic. Civil society is not properly represented as civil society organisations have limited funds to attend and participate in these kinds of fora, nor is the public interest its paramount driving force. Since the OECD does not have global coverage, some country voices are lacking, particularly developing countries. The OECD's main driver and commitment on nanotechnologies, in line with its over-arching aims, appear to be the economic potential of nanotechnologies and nanomaterials and to nano industry expansion. Calls for the application of the precautionary principle in responding to risks are also not part of the OECD's framing of nanotechnology. The OECD working party appears to have taken the defacto lead as an intergovernmental organisation that influences regulatory responses to nanotechnologies. This clearly cannot substitute for a global framework of cooperation, partly because many of the OECD objectives such as boosting employment, supporting sustainable economic growth, contributing to growth in world trade, and maintaining financial stability, may run counter to ensuring the safe and precautionary development of nanotechnologies[25].
On a truly international level chemicals are managed through the United Nations Environment Programme via SAICM (Strategic Approach to International Chemicals Management). See below for more information.

INTERNATIONAL EFFORTS

UNESCO

In recent years a number of international organisations have taken interest in nanotechnologies. For instance, in 2006 UNESCO (United National Educational, Scientific and Cultural Organisation) conducted a number of expert consultations in the area of nanotechnology and its ethical and political implications, culminating in a brief publication[31]. Importantly, the publication raises broader ethical and political issues such as intellectual property rights, secrecy and legitimacy of scientific results, the potential for a knowledge divide.

FAO/WHO

More recently, the FAO/WHO (Food and Agriculture Organisation and the World Health Organisation) held an expert meeting in mid-2009 on "Food safety implications of nanotechnology applications in the food and agriculture sectors". Unfortunately NGOs were not offered a seat at the table. A report on this meeting has not yet been made publicly available.
The WHO Collaborating Centres for Occupational Health are engaged in research collaboration on nanomaterials, with a focus on identifying and evaluating occupational and environmental exposure and risks and developing guidelines for the assessment of safety measures. Part of the collaborating centres global research priorities for 2009-2012 is to encourage practical research on emerging issues, including nano-materials, with a particular focus on low- and medium income countries in regards to safety measures to ensure workers' health.

UNEP

One of the aims of the United Nations Environment Programme's (UNEP) Chemicals Branch of the Division of Technology, Industry and Economics (DTIE) is to promote sound management of chemicals worldwide. These efforts are mostly focused around specific chemicals such as mercury, lead and cadmium as well as persistent organic pollutants. UNEP has not taken a very active role with respect to nanotechnologies, but has published in its GEO 2007 Yearbook a chapter on the emerging challenges of nanotechnology with respect to the environment. UNEP proposed more systematic research and sector-specific policies, as well as cooperation with international partners and stakeholders, as well as the SAICM approach as a useful platform for such an undertaking[32].

SAICM

SAICM (Strategic Approach to International Chemicals Management is a policy framework to foster the sound management of chemicals globally. It is a multistakeholder approach, which includes governments and non governmental organisations. SAICMs goal is for sound chemicals management by 2020; is of multi-stakeholder and multisectoral character; emphasizes chemical safety as an issue of sustainability and; and is formally endorsed or recognitized by the governing bodies of key intergovernmental organizations.
The regular International Conference on Chemicals Managements is part of SACIM's action plan. During the second session of 2009 conference "nanotechnology and manufactured nanomaterials" was nominated by the Intergovernmental Forum on Chemical Safety (IFCS). Additionally the Inter Organisation Programme for the Sound Management of Chemicals (IOMC) nominated "Manufactured nanomaterials" an Japan nominated the "sound management of specific substances - nanomaterials" as emerging issues of importance. All three nominated nanotechnology/nanomaterials because of the new challenges posed to health and safety, and the new emerging risks associated with it.

Intergovernmental Forum on Chemical Safety (IFCS)

The Intergovernmental Forum on Chemical Safety (IFCS) brings together representatives from twelve intergovernmental organisations (IGO) and representatives from thirty-nine non-governmental organisations (NGO). The purpose of IFCS is to bring together a wide range of stakeholders to discuss issues in the area of sound management of chemicals. It was established in 1994 at an Intergovernmental Conference on Chemical Safety convened by the ILO, UNEP and WHO, in response to a recommendation adopted at the United Nations Conference on Environment and Development – UNCED, held in Rio de Janeiro, Brazil, in 1992.
For the first time in September 2008 the IFCS considered nanotechnology and released the Dakar Statement on manufactured nanomaterials (September 2008). Possibly the most important sentence in the Statement is the recommendation that:
"governments and industry apply the precautionary principle as one of the general principles of risk management throughout the life cycle of manufactured nanomaterials[33]."
The statement also recommends continued dialogues with all stakeholders and wide information sharing with all stakeholders on key aspects of nanonmaterial. Importantly, the statement asks for civil society involvement to be strengthened and to particularly take vulnerable groups such as children and pregnant women into account when assessing risks. It of course recommends worker exposure to be minimised[33].

5. NGO RESPONSES AND INITIATIVES

Partly as a response to the lack of national and international progress in governance of nanotechnologies, a broad coalition of over 80 civil society, public interest, environmental and labour organisations published a declaration on Principles for the Oversight of Nanotechnologies and Nanomaterials in 2007[34]. This coalition brings together a diverse range of NGOs, spanning from environmental groups, workers' unions, consumer interests groups, groups focused on Southern and global justice issues, indigenous groups and ones concerned with technology developments.

This declaration sets out eight fundamental principles that the signatories believe "must provide the foundation for adequate and effective oversight and assessment of the emerging field of nanotechnology, including those nanomaterials that are already in widespread commercial use[34]". The principles are:

- Regulation based on a precautionary approach
- Mandatory nano-specific regulations
- Health and safety of the public and workers
- Environmental protection
- Transparency
- Public participation
- Inclusion of broader impacts
- Manufacturer liability

A key demand of the joint NGO "Principles for the oversight of nanotechnologies and nanomaterials" is for the burden of proof of safety to be placed with nanotechnology product manufacturers and distributors, for nanomaterials to be classified as new substances for assessment purposes, and for mandatory nano-specific legislation.

At European level, the European Environmental Bureau has been coordinating an international network of environmental NGOs and contributing to policy discussions. Its members provide contributions to both national and EU level discussions. Below are key points from positions developed on what actions are needed at EU level.

6. What kind of policy framework do we need for nanotechnologies?

The safe and responsible development and application of nanotechnologies requires a dedicated nanotechnologies-specific regulatory framework that provides a credible, coherent and comprehensive approach to its governance. Such an approach would enable the research community and industry to better target future applications within publicly agreed sustainability parameters. Key provisions of such a framework need to include the following aspects:

6.1 A pre-market registration and approval framework for nanomaterials

The fast-moving development of the types and uses of nanomaterials requires a regulatory framework that can anticipate the safe management of future applications in advance of their availability on the market. Such a framework would help to better identify future developments in these materials and their uses, either at early research stage or in later near-market stage. To enable these goals a regulatory framework requires:

- Registration of public and private research
- Test-based assessment of nanomaterials
- Approval of near-market uses of nanomaterials

The above information needs to be available to the public in an easily accessible inventory.

6.2 Public consultation on technological innovation, including nanotechnologies and nanomaterials

Most policy attention has been devoted to encouraging technological innovation rather than social innovation. Social innovation must include public participation in decision-making and the development of more democratic decision-making procedures. In light of increasing focus on innovation, and eco-innovation in particular, more efforts are needed at EU and national levels to legitimately incorporate public opinion in political decisions even if this opinion runs counter to industry interests. For example, public opinion should be sought systematically on the needs for many technological innovations.

6.3 Assessing technology for social purposes and benefits

It is generally assumed that new technological innovations will also deliver greater social advantages which are then used as an argument to justify greater risk exposures. This assertion is seldom tested, but the introduction of a so-called ‘fourth hurdle’ could serve to test the social purpose and social benefit of technological innovations, especially those that are government funded. Nanotechnologies and their products provide an ideal testing ground to develop such forms of public interest driven technology assessment.

6.4 Adequate legislation before further market penetration of nanomaterials

Given that there is disagreement over the adequacy of existing legislation to address the potential impacts of nanomaterials, it is clear that the European Commission’s regulatory assessment conclusions are unsatisfactory and do not provide a solution to closing the regulatory gaps. Experience from REACH has already shown the limitations of this legislation in dealing with nanomaterials, and that current implementing tools (e.g. test methods, test results needing to be communicated, etc.) do not apply to the nano level.

Taking the approach of amending existing legislation is already leading to fragmented and incoherent governance, best illustrated with the current revisions of the Novel Foods Regulation and the Cosmetics Directive. Given that nanotechnologies and nanomaterials can be used in many different ways and in different types of products, a policy and regulatory framework which can address these various applications coherently and comprehensively is needed. Such a comprehensive and coherent policy and regulatory framework would need the following:

- An immediate review and revision of existing legislation relevant to nanomaterials
- The urgent and strict application of the REACH no data, no market” approach to products containing manufactured nanomaterials that could lead to exposure of consumers or the environment
- Required pre-market approval for all applications of nanotechnologies and nanomaterials as a central element of the policy and regulatory framework
- Provide the necessary implementation tools for the coherent and comprehensive management of these technologies and materials. Particular focus and priority is needed on the development of testing methods to identify human health and environmental impacts
- To develop robust safety assessment standards while recognising the serious limitations of our existing scientific capacity and knowledge to identify potential impacts
- Clarity and coherence on the key aspects of nanomaterials definition, with focus on:
  - Size being defined from 0.3nm to 300nm
  - Substances having nanomaterial-like properties to be included, even though they fall beyond the official size range
  - All nanomaterials to be included in regulation, not just those that are insoluble or bioaccumulative, as well as aggregates and agglomerates
- To immediately start work on the establishment of a mandatory EU label as an identification tool to be placed on products containing manufactured nanomaterials which could lead to exposure of consumers or the uncontrolled release in the environment

6.5 Prioritise research funding on the environmental, health and safety impacts of nanomaterials

Currently, the vast majority of EU nanotechnology research funding focuses on technological development, aimed at enhancing economic competitiveness and growth. This is unacceptable given the continuing unknowns about nanomaterials and that current product and safety testing does not extend to the nano level. EEB therefore calls for reprioritisation of funding and the majority of research being directed to environmental and human health aspects, and to strengthening social innovation on public participation in decision-making.

Appendix 1: European Commission and Scientific Committees Opinions regarding Nanotechnology

EU Commission or Committee	Opinion relating to	Date of publication
European Food Safety Authority (EFSA)	The Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety	10.02.2009
Scientific Committee on Consumer Products (SCCP)	Statement on Zinc oxide used in Sunscreens	21.01.2009
Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)	Risk Assessment of Products of Nanotechnologies	19.01.2009
European Commission (EC)	Nanomaterials in REACH: Follow-up to the 6th Meeting of the REACH Competent Authorities for the implementation of Regulation (EC) 1907/2006 (REACH)	15.12.2008
European Commission (EC)	Regulatory aspects of nanomaterials (Communication from the Commission to the European Parliament, the council and the European Economic Committee)	17.06.2008
European Commission (EC)	Commission Recommendation "On a code of conduct on responsible nanosciences and nanotechnologies research"	07.02.2008
Scientific Committee on Consumer Products (SCCP)	Opinion on Safety of Nanomaterials in Cosmetic Products	18.12.2007
Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)	Opinion on the scientific aspects of the existing and proposed definitions relating to products of nanoscience and nanotechnologies	29.11.2007
Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)	The Appropriateness of the Risk Assessment Methodology in Accordance with the Technical Guidance Documents for new and existing Substances for Assessing the Risk of Nanomaterials	21.06.2007

For all SCENIHR opinions see: http://ec.europa.eu/health/ph_risk/committees/04_scenihr/scenihr_opinions_en.htm#nano
For SCCP opinions see: http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_123.pdf
EU nanotechnology communications see: http://ec.europa.eu/nanotechnology

Appendix 2: Summary of key regulatory instruments affected by nanotechnologies and possibly covering nanotechnologies

Regulation/Directive	Purpose	Does it cover nanomaterials?
REACH - Registration, Evaluation, Authorisation & Restriction of Chemicals	Applying to the manufacture, placing on the market and use of substances on their own, in preparations or in articles	No explicit provisions referring to nanomaterials, but nanomaterials are covered by the "substance" definition in REACH.
Directive 98/24/EC –Health and safety of workers	Protection of the health and safety of workers from the risks arising from exposure to chemical agents at work	Not explicitly
Directive 67/548/EEC Packing & Labeling	Packaging and labeling of dangerous substances	Not explicitly
Directive 98/8/EC Biocide Directive	Production & marketing of biocidal substances and products	Not explicitly
EU Framework Directive 89/391	Occupational safety and health of workers at workplaces	Not explicitly
Council Directive 98/24/EC	Protection of the health and safety of workers from the risks related to chemical agents at work	Not explicitly
General Product Safety Directive	Health and safety of consumers, workers, patients and users – any products not covered by specific product legislation	Not explicitly
Cosmetics Directive	Applicable to cosmetic products	A nanomaterial has been included and is defined as either "insoluble or biopersistent" and in the 1-100nm size range
The general safety article of the EU Food Law Regulation 178/2002	Food safety	
Directive 2006/12/EC Waste Directive	How to deal with waste	Not explicitly
Integrated pollution prevention and control (IPPC)	Pollution prevention and control	Not explicitly
Council Directive 96/82/EC (Seveso II Directive)	On the control of major-accident hazards involving dangerous substances	Not explicitly
Water Framework Directive	To improve the aquatic environment and to reduce the pollution	Not explicitly, Member States will have to establish quality standards including nanomaterials

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