



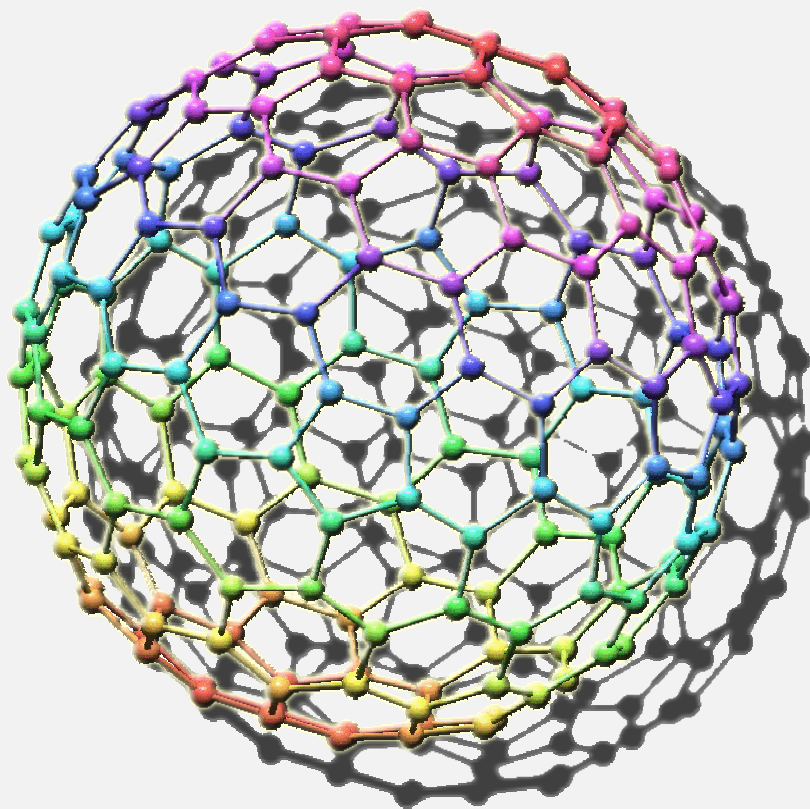
MEDITERRANEAN INFORMATION OFFICE
FOR ENVIRONMENT, CULTURE AND SUSTAINABLE DEVELOPMENT
the Federation of Mediterranean NGOs working on Environment and Sustainable Development

Nanotechnologies and Nanomaterials

Recommendations to safeguard their sustainable and responsible governance

Position Paper

December 2012



The Mediterranean Information Office for Environment, Culture and Sustainable Development (MIO-ECSDE) is a non-profit Federation of 126 Mediterranean NGOs for Environment and Development. MIO-ECSDE acts as a technical and political platform for the presentation of views and intervention of NGOs in the Mediterranean scene and plays an active role for the protection of the environment and the promotion of the sustainable development of the Mediterranean region and its countries.

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Buckminsterfullerene or buckyball (C60)

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Introduction

Modern synthetic chemistry has reached the point where it is possible to control and manipulate matter at atomic, molecular or macromolecular level and manufacture components at the 'nano'-scale (dimensions between 1 and 100nm). Nanotechnologies is an innovative enabling technology with the potential to develop novel materials able to introduce new nano-specific properties to products, devices and systems in wide-ranging professional and consumer applications, in almost all industrial sectors, including medicines, cosmetics, electronics, energy production, etc. Molecular manufacturing is promising and many prospective applications are claimed to be able to solve many of the world's current problems.

As nanotechnology moves rapidly from research and development to commercialization, concerns both among scientists and the wider public have grown on potential risks posed to the environment and human health due to the potential hazardous properties attributed to manufactured nanomaterials. Although commercialization of nanoapplications and nano-enabled products does not proceed as fast as predicted, the number of nano-enabled professional and consumer products on the market is steadily growing. Still, the information provided on nanomaterials included in the products and their potential release is either inadequate or insufficient. Consumers and workers are poorly informed and remain largely unaware.

MIO-ECSDE, based on the experiences gained through the European NanoCap¹ project on environmental, health & safety and ethical issues related to nanotechnologies has published a first position paper on the issue in 2009. The ongoing discussions in Europe involving different stakeholders including MIO-ECSDE and its members, the growing insight in potential hazardous properties of nanomaterials and the persistent inadequacy of information supply to the public advocated for the elaboration of an updated position paper on the issue.

MIO-ECSDE brings forward the consensus view and perspective of the Mediterranean civil society on emerging nanotechnology issues, many of which might have a significant influence on the sustainable development of the region. Key elements of this position paper are the operationalization of the Precautionary Principle, taking into account the full life-cycle of nano-enabled products; the adoption of an unambiguous definition of nanomaterials; the promotion of a transparent communication about the use of manufactured nanomaterials; the adaptation of the regulatory system(s) to the specific properties of nanomaterials, and the assurance that nanotechnological developments are driven by goals compatible to social and sustainable development demands.

1. Nano-: the great unknown

Nanotechnologies have certainly built up great expectations for overcoming some of the technological limitations and for providing solutions to some of the world's crucial problems. However, the 'invasion' of new nanomaterials and nano-enabled products into nearly every aspect of modern life, without prior preparation of the natural and social conditions, has also raised concerns and has sparked a tremendous amount of discussion and media coverage, while at the same time it seems to have won a place in the public policy agenda.

At present, after more than twenty years of intense research, relatively little is known about the environmental and human health impacts of nanoparticles. The general hazard and risk patterns of nanomaterials differ from other chemical substances. For nanomaterials the surface area, size, shape, charge, solubility and persistence are predominant factors, much more than their chemical composition per se, determining their fate and impact. The most prominent adverse effect of insoluble and biopersistent nanomaterials to living organisms, after exposure and uptake in the body, seems to be their ability to generate reactive oxygen species (e.g. hydroxyl radicals), which may lead to oxidative stress. Oxidative stress and oxidative damage to fundamental biomolecules and to antioxidant defenses of organisms may lead to adverse health effects, such as mutations and carcinogenesis. Many different nanomaterials may show these effects irrespective of their chemical composition and form (e.g. nanotubes, sphere-like nanomaterials, etc.). For rigid carbon nanotubes asbestos-like effects have been shown in animal and in vitro tests.

¹ NanoCap is the acronym for "Nanotechnology Capacity Building NGOs" NanoCap is the acronym for "Nanotechnology Capacity Building NGOs" European project, financed by the European Commission within the 6th Framework Programme (<http://www.nanocap.eu>).

Although scientific literature on nanotoxicology is constantly growing, information to fully assess the toxicity and risks of nanomaterials is still limited, fragmented and insufficient. There are still large gaps in knowledge relating to dose, composition, size, form and other physical-chemical properties of nanomaterials and therefore a far better understanding is needed in order to assess in a reliable way the potential environmental, health and safety risks related to nanotechnologies.

2. Policy recommendations to address shortcomings in existing regulatory systems and ensure a safe governance of nanomaterials

The rapid growth of nanomaterials' applications has by far outpaced information and data about the associated safety and health risks. The questions raised so far and the limits and gaps in information and data, pose serious challenges to regulation and policy makers.

2.1. The precautionary principle approach should be applied to the full life cycle of nano-enabled products, through appropriate operationalization practices.

Lack of data, uncertainties on impacts and/or preliminary scientific evidence indicating that there are reasonable grounds of concern regarding the potential risks of manufactured nanomaterials to the environment, human health and safety call for the application of the **precautionary principle**. Applying the precautionary principle requires the definition of workable operational practices applicable to the full life cycle of nano-enabled products. A radical but concrete building block towards making operational the precautionary principle in the field of nanotechnologies is the adoption of the principle “**no data, no market**” or “**no data, no exposure**”. This allows for provisionally avoiding the use of required (but lacking) hazard data and occupational exposure limits (OELs), and using precaution-based nano reference values (NRVs), which define levels for “concern characterization”. Similarly such an approach should be developed for nanomaterials in the environment, e.g. by developing environmental PM_{0.1} criteria (in analogy with the PM₁₀ and PM_{2.5}).

2.2. A commonly agreed, univocal, harmonized definition of nanomaterials should be applied to ensure a consistent approach to the regulation of nanomaterials across EU law.

In October 2011, the EC adopted the Recommendation on the definition of nanomaterials, according to which ‘nanomaterial’² is defined as *“a natural, incidental or manufactured material containing particles, in a unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1nm - 100nm. In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50 % may be replaced by a threshold between 1 and 50 %. [...]”*.

Even though this definition is rather ‘narrow’ and a safer upper-limit for the size of nanomaterials might have been the value of 300nm, thus ensuring the inclusion of larger agglomerates and aggregates, it is a solid starting point for further discussions. The requirement, that at least 50% of the number of particles should be in the size range 1nm - 100nm should also be further explored and take into account future scientific findings, in view of the definition review in 2014. In order to ensure the safe use of nanomaterials a commonly agreed definition, once established, should be incorporated in the relevant existing legislative frameworks, while specific amendments should be made to fill in any regulatory gaps.

It is worthwhile noting that according to the EC definition nanomaterials are not exclusively synthesized/manufactured nanomaterials. The term also covers particles originating from natural processes and heating/combustion processes (incidental nanoparticles), which may pose similar risks to human health and the environment. These “process-generated” nanoparticles which could form assemblies with manufactured nanomaterials and non-nanoparticulate pollutants should be taken into consideration in risk assessments.

²Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee. Second Regulatory Review on Nanomaterials. Brussels, 3.10.2012, COM(2012) 572 final.

2.3. Legislative loopholes related to the regulation of nanomaterials should be urgently ‘closed’ to secure a proper governance of nanotechnology applications.

So far REACH, the main legislative framework for regulating chemicals and their safe use, at European level, has no provisions specifically addressing nanomaterials. REACH deals with substances, in whatever the size, shape or physical state and thus in principle covers substances on the nanoscale. However, unless REACH is **amended to refer to the definition of nanomaterials** and the current **volume limits are amended to include nanomaterials with lower production volumes** (i.e. lowered to 10 Kg/year to take into account the increased reactivity of nanomaterials), nanomaterials will continue to “slip through”. Furthermore, the timeframe for registration of nanomaterials should be shortened, while at the same time the principle “no data no market” should be strictly applied. Manufacturers of nanomaterials should be obliged to develop a ‘**Nanomaterials Safety Report**’ (equivalent to the REACH Chemicals Safety Report) for all nanomaterial registrations brought in the market in volumes larger than 10kg/year). Similar amendments should be made to other relevant legislative frameworks such as the regulation on Classification, Labelling and Packaging (CLP) of products, the Occupational health and safety (OHS) related directives, etc.

2.4. A market surveillance instrument tracking nano-enabled products on the European market should be established and transparency should be ensured by appropriate labelling requirements allowing customers to make informed choices.

Currently there is no complete overview of nanomaterials and nano-enabled products on the European market, given the fact that there are no legal requirements to register or notify the use of nanomaterials in products. For example, the CLP Regulation that sets out the framework for compulsory communication of the identified hazards of substances or mixtures to actors in the supply chain, including consumers, is based on the identified toxicity of the involved substances. Given the lack of knowledge on nano-related hazards and the questionable suitability of testing protocols, communication on nanomaterials in nano-enabled products is insufficient. Consequently, a proper risk assessment and management cannot be made.

Cosmetics, biocides and food associated regulations have recently been adapted, so as to make labelling of nanomaterials used in a product obligatory, irrespective of their potential harm. However, for all other applications no labelling requirements are foreseen yet and none of the mentioned labelling requirements has yet entered into force.

In that respect, **a transparent communication of nanomaterials’** use in preparations and products should be made, through **mandatory labelling requirements** for all nano-enabled preparations and products. An **appropriate market surveillance instrument** should be established to supply the end user with relevant and reliable information regarding the reason for applying the nanomaterial(s) in nano-enabled products, the potential hazard involved and the way to apply the product in the most appropriate/safe way.

3. Research and development recommendations to address knowledge gaps and set directions for research and product development that reflect social values and needs.

2.1. Nano-research and technological applications should be driven by societal needs and priorities based on ecological, social and sustainability considerations. ‘Marketability’ itself should not be the driving force for nanotechnological research and development.

2.2. Research and testing is needed to fill the knowledge gaps related to nanotoxicology and minimization of risks from the hazardous nature of nanomaterials. In particular, there is an urgent need for additional toxicological and ecotoxicological studies, tests and protocols (all still very limited) to elucidate health and environmental impacts, as it has been shown that the ones available (targeted to bulk chemicals and substances) might not be suitable for the assessment of nano-risks. Relevant in this respect is to further operationalize the paradigm change in risk assessment from a mass-based approach towards a particles’ number based approach.

2.3. Public research programs need to play an important role in providing greater incentives and encouragement for nanotechnologies that support sustainable development and do not endanger humanity's well being in the long-term.

2.4. The recognized need to allocate substantial funding to risk assessment of nanomaterials should be high on the political agenda. The existing imbalance in funds allocated to nanotech research needs to be corrected

so that risk assessment and not only development come high in the agenda. Research into the potential hazards of nanomaterials should be a structural part of research projects carried out with public financial support and keep pace with new developments. Moreover, civil society and the public in general should be informed and actively involved in discussions directed to setting priorities for nano-research and application.

2.5. Appropriate directions for nano-related research and product development that reflect social values and needs should be jointly set through participatory processes and the active involvement of all stakeholders.

4. Recommendations specific to the non EU Mediterranean countries and beyond (developing countries) to ensure broad social benefits and reduce adverse impacts.

3.1. There is a need to connect the development of nanotechnologies with the development of poor nations and neighborhoods in order to meet internationally agreed poverty reduction goals, such as the Millennium Development Goals (MDGs). Millions of people lack access to safe water, efficient sources of energy, health care and education. Nanotechnologies may promise effective solutions in these areas. Yet, there appears to be little effort among technology steering authorities and stakeholders to act effectively in this direction. Although many industrial countries' governments and some governments in the developing world invest heavily in nanotechnologies, little of this investment is presently focused on the benefit of the poor, even in the countries where a large proportion of citizens are poor.

3.2. Governments should assure transparency and citizens' participation in steering and facilitating the development of emerging technologies. Priority should be given to the needs of the poor rather than at improving national corporate competitiveness in nanotechnologies. Universities and research institutes receive much of their funding for nano-research through government programs. However, much of this funding is focused on corporate interests. Universities should play a key role in managing innovation (patenting and licensing advances) to ensure that developing countries can reap the benefits from publicly funded nano-research.

3.3. Civil society organizations and the wider public should be involved setting priorities for nanotechnologies' related to research and development in order to ensure that these meet human needs in developing countries. A way should be found to balance monopoly privileges of nanotechnological development and marketing between developed (including multinational industries) and developing countries, thus avoiding to further deepen the existing divide.

3.4. Risk assessment over the full life cycle of nanomaterials and nano-enabled products should take into account specific risks occurring in developing countries due to their particular environmental and/or social conditions.



MIO-ECSDE Profile

The **M**editerranean **I**nformation **O**ffice for **E**nvironment, **C**ulture and **S**ustainable **D**evelopment, is a Federation of Mediterranean Non-Governmental Organisations (NGOs) for Environment and Development. MIO-ECSDE acts as a technical and political platform for the presentation of views and intervention of NGOs in the Mediterranean scene. In co-operation with governments, international organisations and other socio-economic partners, MIO-ECSDE plays an active role for the protection of the environment and the promotion of the sustainable development of the Mediterranean region and its countries.

ITS MAIN OBJECTIVES ARE ...

To protect the **Natural Environment** (flora and fauna, biotopes, forests, coasts, natural resources, climate) and the **Cultural Heritage** (archaeological monuments traditional settlements, cities, etc.) of the Mediterranean region. The ultimate goal of MIO-ECSDE is to promote **Sustainable Development** in a peaceful Mediterranean.

Major tools and methods used by MIO-ECSDE in order to achieve its objectives are the following:

- Promotion of the understanding and collaboration among the people of the Mediterranean, especially through their NGOs, between NGOs and Governments, Parliaments, Local Authorities, international organisations and socio-economic actors of the Mediterranean region at all levels.
- Assistance for the establishment, strengthening, co-operation and co-ordination of Mediterranean NGOs and facilitation of their efforts by ensuring the flow of appropriate information among relevant bodies.
- Promotion of education, research and study on Mediterranean issues, by stimulating collaboration between NGOs and scientific and/or academic institutions.
- Raising of public awareness on crucial Mediterranean environmental and social issues, through campaigns, publications, exhibitions, presentations, etc.

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