

RESPONSIBLE DEVELOPMENT OF NANOTECHNOLOGY: TURNING VISION INTO REALITY

BIAC Nanotechnology Committee – Vision Paper

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INTRODUCTION

Sustainable economic growth is an overarching strategic challenge for the 21st century. Innovative technological change plays a key role in helping to ensure this growth. It raises living standards, improving quality of life, and offering global society new or improved means by which to enhance, for example: energy security, healthcare, water treatment, food production and storage, environmental protection, and information and communications. Fundamental to this effort, our scientific understanding has significantly advanced, allowing for the design and manipulation of materials at the atomic scale. This results in the expansion of nanotechnology (the ability to engineer materials at the nano-scale) in a growing number of economic sectors with enormous potential to improve a broad range of human activities.

As nanotechnology continues to rapidly develop and change a wide range of activities, growing numbers of governments and international organisations have focused on how to stimulate its development

while considering environment, health and safety issues. BIAAC believes that the OECD is proving to be the most effective multi-stakeholder forum within which to explore the right policies for addressing this balance.

The goal of this vision paper is to identify the strategic priorities from the perspective of the OECD business community. It is meant to serve as guidance to both the private and

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the public sectors as international nanotechnology policy is debated and formulated. Relying on BIAAC's formal role with the OECD, this paper will pay particular attention to those areas where the OECD can and should take action in order to help achieve the goal of the responsible development of nanotechnology.

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PRESENT AND FUTURE OPPORTUNITIES

Nanotechnology is an enabling technology that already impacts almost all existing industry sectors and harbours the potential to enable the creation of entirely new economic sectors. In many cases, products that contain or are produced using nanotechnology are not new to the marketplace, as nanotechnology is already used in many mass-market consumer products, such as scratch-resistant and protective sunglasses, “self-cleaning” coated windows, and personal care products. At the same time, it is expected that major forthcoming benefits of nanotechnology will be reaped from its giant potential in helping to increase energy security, improve food security, counter disease, provide clean water, enhance information exchange and communications, and remediate pollution. Nanotechnology provides a growing range of tools for industry to improve product performance beyond what could normally be achieved using conventional technologies. The contribution of the following applications, while by no means an exhaustive list of applications or uses within a specific sector, should be considered in the debate on nanotechnology:

Energy

Nanotechnology holds great potential towards helping to meet the world’s energy needs in environmentally-friendly ways. For example, nanotechnology-based products can be used to reduce energy consumption through better insulation systems, the introduction of more efficient lighting (e.g. using LED technology), highly energy-efficient information and communication technology products (such as nanowires), and by the use of lighter and stronger

materials in transport vehicles. Similarly, nanotechnology is being employed for the design of more efficient combustion engines due to improved catalysts. The use of cost-effective “ultra-capacitors”, which allow for the storage of large amounts of energy, could furthermore come to play a key role in

“It is expected that major forthcoming benefits of nanotechnology will be reaped from its giant potential.”

engine design. Nanotechnology can also be further harnessed for cost-effective production of more efficient solar cells and hydrogen-powered fuel cells.

BIAC welcomes ongoing work by the Working Party on Nanotechnology on sustainable energy as well as new work on the contribution of nanotechnology to green growth.

Food and Agriculture

The complete chain from food production to consumption could be significantly influenced by nanotechnology developments. Society can expect to reap the benefits from higher quality, more sustainable food production due to applications of nanotechnology. Such benefits could include:

- Increased yields through smart fertilisers that react to environment conditions such as temperature or humidity;

- Reduced overall fertiliser consumption due to more timely and targeted use, rendering agricultural production more environmentally friendly;
 - Improved food quality monitoring with nanosensors, making it possible to effectively detect minimal decay or contaminations at an early stage;
 - Higher bioavailability of food ingredients such as essential vitamins and minerals;
 - Longer shelf life, increased pathogen control and reduced spoilage.
- Developing delivery systems that enable the slow and continued release of a therapeutic dose of a drug;
 - Building the scaffolds that support tissue growth, enabling oxygen delivery to cells, as well as nutrients and the removal of waste products;

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Healthcare

Nanotechnology holds enormous potential to revolutionise healthcare, with possible applications including diagnostic imaging agents, drug delivery systems, thermal therapy delivery agents, body sensors, displays, high performance X-ray tubes, tissue engineering, microfluidics, pathogen detection systems and compact electronic systems. The size and physical properties of nanoparticles permit the production of advanced materials as well as the possibility to enter cells and pass through physiological barriers. Nanomedicine, focusing on nano-scale interactions within individual cells and biomolecules, aims to detect changes and problems at the molecular and cellular levels, and has the potential to treat them, *before* symptoms express themselves. Ways in which nanotechnology can significantly enhance current healthcare include:

- Designing delivery vehicles that can improve the circulatory presence of drugs to reach the treatment sites;
- Reducing systemic toxicity by using lower doses of highly targeted drugs and chemotherapeutic agents;

- Using magnetic or paramagnetic nanoparticles in conjunction with Magnetic Resonance Imaging (MRI) to track the movement of nanomedicines towards target sites, thus providing advanced medical imaging;
- Using single-domain magnetic nanoparticles in conjunction with high-frequency alternating magnetic fields to treat inoperable tumours.

Infrastructure costs for the incorporation of nanotechnology into healthcare applications are expected to be high, and intellectual property protection could be complicated as different sub-systems are integrated (for example, in the combination of different drugs in drug delivery vehicles). As nanotechnology develops, it will also be key to update medical education so that healthcare professionals understand and introduce new applications.

Water Treatment

Nanotechnology has the potential to play a significant role in making pre- and post-consumer water treatment available in places where treatment is not currently possible. Nanomaterials are therefore currently being tested for their effectiveness in water treatment in the following areas:

- Removal and/or remediation of contaminants in drinking and waste water, such as trace heavy metals and organics;
- Improving membranes to enhance flux and selectivity in membrane-based separations;
- Developing nano-surfaces to increase the surface area for reactions, thus reducing friction.

Significant investment will be required in the near future to develop nanotechnology applications for water treatment that are decentralised, clean, safe and affordable solutions. BIAC welcomes the publication of the report on *Fostering Nanotechnology to Address Global Challenges: Water* by the OECD Working Party on Nanotechnology.

Information and Communication

As in other sectors, the implications of nanotechnology on the future of electronics and information and communication technologies (ICT) are impossible to predict

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fully, but nanotechnology will be critical to solving challenges faced by the ICT industry. ICT platforms are currently pushed to their fundamental physical limits. Traditional approaches to reduce feature size and increase functionality are becoming prohibitively difficult and expensive. The incorporation of nanomaterials in ICT systems allows extension of conventional ICT platforms and enables new innovations and technologies beyond the current platforms.

For example, nanowires can be used to create devices that are even more minuscule than the current microelectronics, resulting in millions more transistors being packed onto a microprocessor, and computers that are dramatically smaller and faster. Moreover, nanotechnology will lead to a revolution in smart sensors, novel semiconductor devices, logic elements and computer chips, memory and storage devices, optoelectronics, molecular electronics, quantum computing, and other applications and technologies. These will spearhead the creation of new products, services, and economic growth, and new channels of global communication, interaction, and collaboration. Advanced nanotechnology manufacturing processes and new nanomaterials will be essential to meet the future electronics and ICT needs.

Pollution Remediation

The use of nanotechnology has made substantial contributions to improving the efficiency of waste disposal site clean-ups, removal of air pollutants, and wastewater treatment technology. These improvements will continue as nanotechnology is incorporated further into existing environmental remediation technology, and as new technologies are investigated and commercialised. The use of nanotechnology in site remediation technology includes:

- Nano-scale iron particles to oxidise organic contaminants;
- Heavy metal separation (mercury, lead, arsenic) using nano-porous materials;
- The use of dendrimer polymers to separate and trap pollutants; and
- Nano-scale colloids to treat dense non-aqueous phase liquids (DNAPL) or high concentrations of adsorbed chlorinated volatile organic compounds (CVOC).

Other innovative uses include new approaches to providing clean drinking water, the synthesis of single wall carbon nanotubes by laser vaporisation of diesel soot, the use of ceramic-based nanomaterials in fuel additives to improve fuel efficiency and reduce air pollutants, and nano-scale metal catalysts to improve the efficiency of catalytic converters.

Transport

Demand for mobility and transportation services has increased significantly over recent years, a trend that is expected to continue. This rising demand leads to increased fuel consumption and has thus direct environmental implications. The tire industry accounts for part of this impact,

through the use of natural resources and fuel consumption due to tire rolling resistance. Through nanotechnology, the industry can help address these challenges in a proactive and effective manner. The use of more advanced nanomaterials is expected to increase rubber reinforcement and decrease energy dissipation, so that tires become lighter and even more fuel-efficient. The tires industry is engaged in an active dialogue with the OECD to address potential challenges and reap the benefits of opportunities offered by the use of nanotechnology.

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PRESENT AND FUTURE CHALLENGES

Hand in hand with the above-mentioned nanotechnology applications and their far-reaching benefits is the discussion about their potential impacts and factors that may limit the development of nanotechnology. International cooperation is critical for addressing these issues effectively. The OECD is in a prime position to help lead the way in international research and cooperation about both the potential benefits and the potential challenges associated with nanotechnology development. The following key challenges, identified by the OECD business community as some of the issues that will increasingly affect nanotechnology

development in coming years, should be duly considered in future OECD work:

Environment, Health and Safety Issues

A major challenge facing the stimulation of nanotechnology development is its potential impact on environment, health and safety (EHS) issues. Public interest in EHS issues related to nanomaterials continues. This, in part, leads to a significant increase in public and private funding for research and development both in EHS issues as well as in developing new nanotechnologies.

Business is making a constructive contribution to the nano-EHS dialogue and will continue to do so in the future. Research efforts are focused on identifying,

“BIAC calls upon OECD policy-makers to foster consensus-based risk assessment approaches.”

understanding and managing the risks that may be associated with nanotechnologies and nanomaterials in order to provide a framework for responsible development of safe and sustainable nanotechnologies. Identifying and adapting internationally accepted risk assessment methodologies should be fostered through achieving consensus on the appropriate scientific principles and technical requirements. Scientifically sound risk assessments, in turn, should inform protection of workers, consumers, the public and the environment.

BIAC calls upon OECD and policymakers to help facilitate such efforts by fostering consensus-based risk assessment approaches, enabling access to sound scientific data and other relevant information, and increasing coordination of activities concerning nanotechnologies and nanomaterials among OECD member states and interested non-governmental organisations.

Responsible Development

Enabling technology innovation and application, while identifying and addressing EHS concerns, requires an oversight system that utilises all viable options in an integrated manner. Business supports the need for a sound and enabling regulatory framework, which is an essential part of an overall policy mix. At the same time, it

should be noted that there exists a range of options to provide appropriate oversight for the responsible development of nanotechnologies, including both voluntary initiatives and government regulation. Due to strong variation in the defining characteristics of nanomaterials and their related EHS impacts, business-led initiatives will continue to play an important role in coming years towards developing guidelines and practices that are tailored to suit different types of nanomaterials, industrial processes, applications, and economic sectors. This is particularly essential in cases where regulation may currently be unsuitable or simply lacking in certain jurisdictions. The private sector will thus continue to develop and implement appropriate product stewardship actions, including the sharing of relevant information throughout value chains in order to ensure effective risk assessment and management of EHS issues.

A key issue remains as to whether existing legal frameworks can be used to adequately assess the risks of the use of nanomaterials, or whether separate legislation is needed to ensure the safe management of nanomaterials. Governments around the world are addressing this issue. Examples include:

- The European Commission, in its communication on regulatory aspects of nanomaterials, has made it clear that EHS risks of nanomaterials are in principle covered by EU regulatory frameworks. For example, although there are no specific provisions for nanomaterials, the Registration, Evaluation and Authorisation of Chemicals (REACH) requirements apply to nanomaterials. The EU Commission has established a working group comprising Competent Authorities of EU Member States, industry representatives and other non-governmental organisations to examine how

nanomaterials can be dealt with under REACH. Additionally, some EU member states are discussing with industry how to improve the transparency of the use of nanomaterials in commercial products close to the consumer.

- Meanwhile, the United States Environmental Protection Agency (EPA)

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has determined that nano-scale materials that are new chemical substances are covered under existing chemical regulations and are subject to pre-marketing notification rules. EPA has also announced that it is utilising its existing authority to develop regulations concerning nanomaterial testing, information disclosure, and the evaluation and approval of “significant new uses” of nano-scale forms of existing chemicals (i.e. those already on the U.S. chemical inventory). EPA is also exploring options for managing nano-scale materials used in pesticide products.

- The Australian Government, Department of Health & Ageing - National Industrial Chemicals Notification Scheme (NICNAS) has issued a set of adjustments to its new chemicals processes for industrial nanomaterials, accompanied by guidance on new chemical requirements for notification of industrial nanomaterials.

For the responsible development of nanotechnology, BIAC calls upon policymakers to consider the range of public and private-led initiatives that are currently in operation in different countries, and to

consider the effectiveness of such approaches in different national and international contexts.

Human Resources

In addition to a sound framework for the responsible development of nanotechnology, industry requires highly-skilled labour for the continued development of the technology. However, the vast interdisciplinary, cross-sector and emergent nature of nanotechnology development poses a challenge for the academic community to train students with the necessary knowledge, understanding, and skills to interact and lead the research and development of nanotechnologies. Skills shortages for nanotechnology development could significantly diminish the opportunities that stand to be gained from the technology vis-à-vis global challenges, such as water and food availability, climate change and

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energy security. Similarly, skills shortages could limit international understanding about related EHS issues and potential risks.

In order to avoid such skills shortages, BIAC calls upon OECD policymakers to support work towards measuring and forecasting labour markets’ needs for nanotechnology development. The OECD, together with business, trade unions, academia and other stakeholders, can also work together to develop common understanding as to which skill competencies should be fostered within educational institutions for careers in nanotechnology.

Intellectual Property Rights

International cooperation, both public and private, will help accelerate the responsible development of nanotechnology. At the same time, it is critical that high quality patent and other intellectual property rights (IPR) continue to protect innovation in the nanotechnology area. Intellectual property protection creates incentives for investment in the costly R&D necessary to bring new nanotechnology products to market. Universities and research institutions conducting basic research in chemistry, physics and materials science license their patents to emerging companies, fuelling entrepreneurship and job creation.

Meanwhile, balancing the protection of regulatory data with the need for transparency is likely to become an increasingly important challenge for the responsible development of nanotechnology, given its newly-emergent nature. The ability of large enterprises to protect their discoveries enables these organisations to take risks on unproven technologies. The OECD business community therefore reminds policymakers that without effective and high quality intellectual property protection, incentives for innovation would be greatly reduced and technical advancement in this burgeoning field would suffer.

Marketing and Consumer Issues

Industry is committed to maximise transparency and foster public trust by informing the public about the outcome of the risk assessment of their new products. More and more products which are manufactured using nanotechnology processes are on the market. But as with any new technology, public trust in industry to fulfil legal and ethical requirements must

be gained. Therefore, in addition to existing product stewardship processes and practices, industry is gathering hazard data, assessing possible risks and recommending, where necessary, appropriate risk management measures for the handling, transportation, use, and disposal of nanomaterials.

Consumers also want assurance that the products they buy are worth buying. Product enhancement aspects need to be clearly communicated to the public. BIAAC stands ready to further engage with the OECD on the crucial issues of marketing and consumer concerns.

Measurement

The emerging and enabling nature of nanotechnology also suggests that a broader approach to measurement may be needed in order to ensure a level playing field within this highly competitive business sector and between the economic regions, which should eventually also facilitate a broad-based comparison of enabling technologies.

In 2010, the International Council of Chemical Associations (ICCA) approved core elements of a risk-based definition of “manufactured nanomaterials in a regulatory context”, which constituted a major step forward.

However, on October 18, the EU Commission published a recommendation of a definition for nanomaterials (OJ L375/38) which will broaden - based upon size alone - the number of nanomaterials already commercially available significantly.

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PRESENT AND FUTURE ROLES FOR BIAC AND THE OECD

It is clear from this paper that nanotechnology has enormous potential for helping to address many of the global challenges of the 21st century, and its current rapid development should therefore be actively encouraged. At the same time, the development of nanotechnology needs to be carried out in a responsible manner in order to more fully understand its impacts and the factors that limit its development. In

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our view, this responsible development of nanotechnology on an international level constitutes the best way forward for the realisation of its full potential.

The OECD Working Party on Nanotechnology and the OECD Working Party on Manufactured Nanomaterials are at the forefront of international efforts to improve global understanding of the responsible development of nanotechnology. Their comprehensive programmes of work lead to policy recommendations and information sharing for policymakers and other stakeholders. BIAC actively participates in both working parties and remains committed to provide the OECD with business expertise and guidance.

In order to address current and possible future opportunities and challenges with respect to nanotechnology development, BIAC calls upon the OECD to address the following priorities in future programmes of work:

- Continued high support and attention for the OECD Sponsorship Programme for the Testing of Manufactured Nanomaterials with specific view to a thorough review of results from Phase 1 of the Programme and the development of a subsequent informed scope of Phase 2 of the Programme;
- Development of thorough case studies that demonstrate the important contributions of nanotechnology towards addressing selected global challenges;
- Development of globally harmonised hazard and risk assessment procedures for manufactured nanomaterials;
- Pro-active collaboration with ISO in order to standardise agreed hazard and risk assessment approaches and methods;
- Continued research into the safe handling of manufactured nanomaterials in the workplace;
- Assessment of the framework conditions necessary and conducive for the development of nanotechnology;
- Increased inclusion of nanotechnology in future works on the implementation of the OECD Green Growth Strategy, analysing specific examples where nanotechnology can make or has made an effective contribution;
- Development of adequate protection of intellectual property rights in association with the responsible development of manufactured nanomaterials;
- Focus on the issue of convergence with other technologies, such as ICT and biotechnology, where nanotechnology is affecting innovation and different sectors

in a fundamental way. We encourage the OECD to consider the role of nanotechnology in related policy discussions on convergence.

In view of limited resources, OECD activities should generally focus on areas that are widely supported, where the Organisation has clear added value and that lead to tangible outcomes. Duplication of work within the OECD or with other organisations should be avoided. We have noted that different working groups have taken up or are planning to deal with nanotechnology issues, for example in the area of waste management. We urge the OECD to ensure that the two OECD working parties that have dedicated nanotechnology experts take the lead so that the OECD messages and policy recommendations concerning the challenges and opportunities related to nanotechnology remain consistent and benefit from the input of the right experts.

OECD business will continue to promote the responsible development of nanotechnology

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by: supporting global research schemes; promoting harmonised global safety testing standards; assessing the value and limitations of existing legal frameworks; and ensuring that sound science forms the basis for efficient and proportionate regulations. Fully aware of the importance of EHS issues and public acceptance, OECD business will maintain a strong focus on maximising transparency and stakeholder engagement towards reaping maximum benefits from

uses of nanotechnology to address global challenges and thus sustain economic growth. In cases where new and accepted evidence demonstrates that additional oversight for the products of nanotechnology is needed, the OECD business community will support its implementation.

BIAC calls upon the OECD leadership to continue to offer strong support for the ground-breaking work that the OECD is carrying out with respect to nanotechnology. OECD business will take every effort to support the work of the OECD towards creating a policy environment that fosters the full potential of nanotechnology, hence turning the responsible development of nanotechnology from a common vision into a global reality.

About BIAC

The Business and Industry Advisory Committee to the OECD (BIAC) was constituted in March 1962 as an independent organisation officially recognised by the OECD as being representative of business and industry.

BIAC's primary objectives are to:

- positively influence the direction of OECD policy initiatives,
- ensure business and industry needs are adequately addressed in OECD policy decision instruments, and
- provide members with relevant and timely information on OECD policies and their implications for business and industry.

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