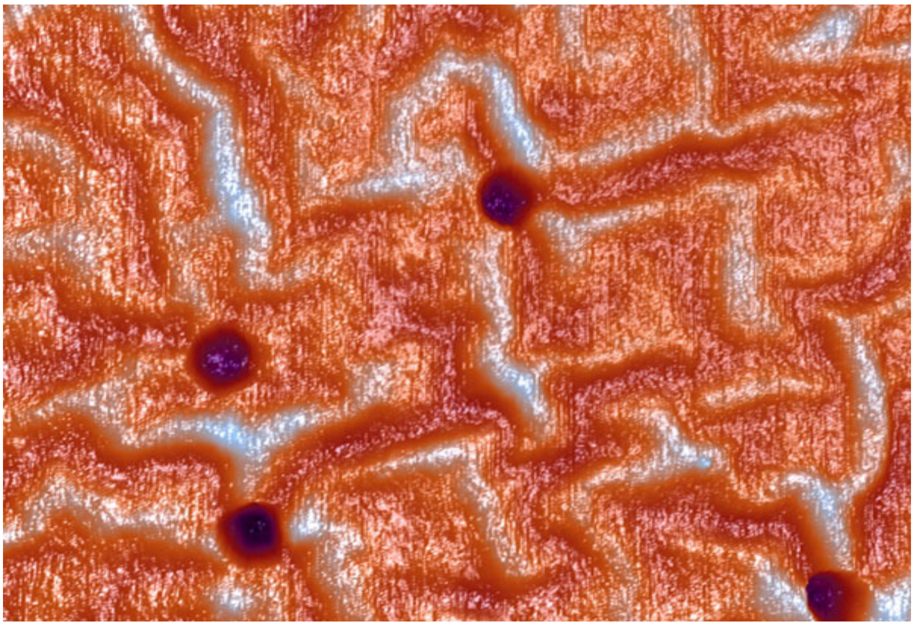
EuroNanoBio

Preparation of the Roadmapping Workshop in Milano

12. / 13. October 2009



Content:

Description of EuroNanoBio

Nanobiotechnology is a very specific field and it is essentially different from other areas of nanotechnology such as nano-electronics or nano-materials in many aspects. It is certainly the most complex sub-area of nanotechnology, because it simultaneously involves very distant scientific disciplines such as physics and clinical research, biology and mathematics, or engineering and immunology. From the industrial perspective, nanobiotechnology does not yet represent an industry by itself or an existing market. Due to this complexity, successful implementation of a European infrastructure in nanobiotechnology, the topic of this CSA project, depends critically on the successful matching, interface and cooperation of stakeholders who have little or no previous contact or knowledge of each other. The EuroNanoBio partners will use their unrivalled access to a wide panel of stakeholders in governments, industry, and academia to create a realistic roadmap for the construction of an European infrastructure in nanobiotechnology.

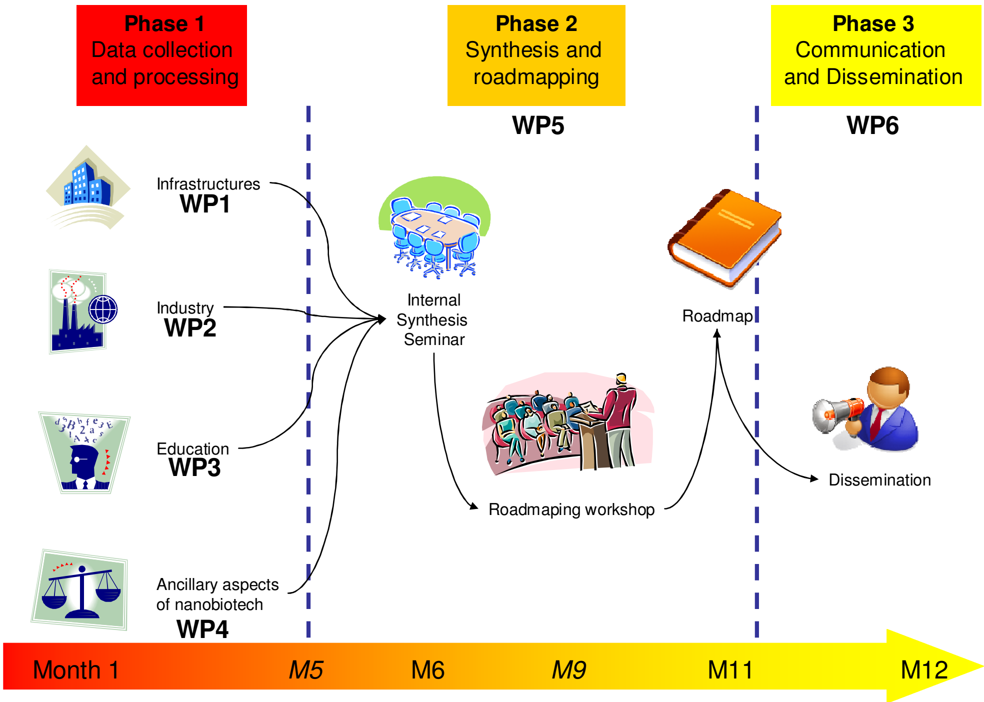
EuroNanoBio aims at defining the key features of a successful future EU infrastructure in nanobiotechnology and the roadmap to reach this goal. It will establish the features of the infrastructure, the role of the various stakeholders and the way to establish it.
This Support Action is divided into three phases:

1) An analytical phase where the existing data will be scrutinised and analysed to extract some success factors required for defining the EU infrastructure in nanobiotechnology. This analysis is conducted in four directions

- existing top class infrastructures or clusters inside and outside Europe
- modes of technology transfer from research to industry
- multidisciplinary education and training
- ancillary aspects of nanobiotechnology.

2) A building and consensus phase where many diverse stakeholders who play a role in the EU capacity in nanobiotechnology are invited to jointly define and adopt the key features of the infrastructure, and the way to build it.

3) A dissemination phase where the former results will be widely disseminated using internet, mailings and conferences.



The following reports of the four workpackages provided here constitute the basis for further discussion of the concept for implementation of European infrastructure in nanobiotechnology at the Roadmapping workshop in Milano.

WP1: Nanobiotechnology research infrastructures - Potentials and limitations of single-site facilities or distributed resources

We analysed the current situation of research infrastructure in Europe to establish definitions and evaluation criteria for Nanobio infrastructure and its impact on research and development. Aspects like activities, the efficient use of resources, regulation of access to the cluster and cluster alliances, but also interdisciplinary approaches including Nanomedicine, environment and food were considered.

One challenge is to validate the input (e.g. research & development, human resources, research equipments) and output (e.g. papers, patents, companies) of different initiatives because reports are often not specific and key people inside clusters are hard to identify. Nanobiotechnology activities are hidden under the term Nanotechnology, because Nanobio or Nanomedicine are not well defined. Presently, most clusters are only loosely organised and rarely managed by an agency, collaborations are occasional and unorganised. Clusters are often located at leading research centres with industry and hospital collaborations and shared facilities for spin-offs, but over all different cluster models vary widely.

Future recommendations for an improved research & development infrastructure:

Nanobio clusters need to be more tightly connected and organized at the EU level especially with regard to regulatory affairs, standardisation and access to clinical trials. Such well organised high quality clusters should combine research centres that join modern nanotechnology facilities in a multidisciplinary way. Additionally, managing agencies should connect clusters internationally and support the innovation processes so that translation of innovation to market and clinics becomes more efficient.

How can such an ideal situation be achieved?

Initially, different disciplines have to be integrated at a local level. The next step will be cluster or network management agencies that mediate between stakeholders and organise strategic meetings for academic institutions and between academia and industry. A complete directory of all nanobio partners and their collaborators as well as papers and patents and a characterization of research & development funding levels and outcomes would be required to create a successful network of organised Nanobio clusters. This network would help to build a knowledge exchange based community and ease the access to other markets or to clinical trials. The public acceptance of new technologies will have to be advanced as well as regulations introduced. A calendar of activities with plans for follow up on attendance, results and topics as well as funding for individual project can further promote the network.

Finally, a standardisation concept for Nanobio materials and a strategic plan for funding can be developed by the EU with advice from the cluster network.

Definitions of cluster, innovation cluster, research cluster, and cluster management agency applied in this document:

Cluster: Concentration in geographical space of all the partners (R&D centres, universities/departments, hospitals, industry, entrepreneurs/spin off companies, tech transfer advisers, technological foundries…) whose contribution is required for innovation to happen in a particular, interacting in an effective fashion, to bring new products/services into the market/hospital.

These interactions can be led and/or managed by an agency or office, with dedicated staff, or not. In Germany, and in some other European countries, the word "cluster" has become synonymous to that of "cluster management agency". However, the two should not be mistaken.

Moreover, a nanobio innovation cluster is built up around a nanobio research cluster. This is mostly due to its cross-disciplinary profile, which demands the effective interaction among scientists and engineers from very diverse expertise (materials science, microelectronics, photonics, cell biology, molecular biology, inorganic and organic chemistry, medicine…) for nanobio research to advance.

NOTE: Geographical size varies largely from one to another. Roughly, in most cases, it will imply one large city and a suburban radius of 100 kms.

WP2: From proof of concept to market – Analysis of nanobiotechnology-based industrial activities in Europe

Our objectives were to establish a representative panel of top level industrial managers with experience in nanobiotechnology based product and process commercialisation and the analysis of case studies of successful technology transfer or exploitation of nanobiotechnology. From this studies the critical needs of, and opportunities for, industry were to be deduced, especially for high-tech SME strong in nanobiotechnology research. An accomplished expert survey proved difficult to evaluate as the included companies differed widely in size, target market type and their level of experience or activity with Nanobiotechnology. Therefore, the responses varied and to yield a consensus opinion more experts will have to be asked.

It was found that a well-built nanobio infrastructure could significantly ease access for large and small companies to a range of expensive equipment. In general, companies would be willing to pay for infrastructure access, the rates depending for example on whether work was carried out as co-development or as licensable technology. Sharing equipment can make sense especially for SME´s as it helps them to save money and potentially can yield new collaborators. But while collaborating with other companies is considered advantageous, an important precondition for most companies is that the safety of intellectual property has to be guaranteed.

For major nanotechnology companies (MNCs) the situation is different than for SMEs. Large companies generally prefer to directly fund research & development and subsequently own resulting intellectual property or share it with an academic research providing organisation (RPO). Their expertise for regulatory issues and protection of intellectual property is usually in-house. On the other hand, SMEs often have to license intellectual property rights from a research organisation because of high costs involved, and could profit from the availability of external expertise provided by a Nanobio infrastructure.

Future recommendations:

The recognized gap in Nanobio expertise can be closed by a clear and defined roadmap that would include each Nanobiotechnology application area. This roadmap would foster collaboration not only among related companies within sectors of the nanobio industry, but by complementing industry requirements could also facilitate collaboration between industry and academia.

Through the creation of a critical mass of expertise and facilities within a nanobio infrastructure, industry and academia can be more efficiently linked leading to developments of innovative and converging technologies. Innovations could be brought to the markets much faster by such concentrated centres.

The often quite diverging agendas of the Nanobio industry can be met by a collective roadmap complemented with the parallel development of standards for existing and emerging nanobio products and processes.

Nanoparticles are core to many nanobio applications. There are issues about the reproducibility and precision for the synthesis processes of nanoparticles. There are also major challenges to be addressed with respect to nanoparticle toxicity. The potential to improve biocompatibility of some forms of nanoparticles may be an option in some situations. Combined, the issues and opportunities relating to nanoparticles need a multidisciplinary approach with a critical mass of expertise and facilities which can be logically provided in a Nanobio cluster with a large functional infrastructure. As an example, if standardisation of nanoparticle synthesis processes could be achieved comparable to the levels of semiconductor thin film processing, this could facilitate much more reproducible outcomes for nanoparticle applications. This challenge could be set as the key goal of European Nanobio development, as currently nanoparticle synthesis appears to be a limiting step for several nanobio products.

To create such *Nanobio Regions of Excellence* a large scale European initiative is required that is focussed on selected regions where the relevant critical mass in research capacity and expertise has already been reached. Collaborations between industry and academia should be large-scale and widespread and resources dedicated to promote these regions. Nanobio can provide a type of *cement* to enable collaborations among companies specialised in ICT, medical devices, pharma and biotechnology.

Within such *Nanobio Regions of Excellence,* there are greater opportunities for SMEs and MNCs to engage in mutually beneficial collaborations and to maximise the synergy from interactions of MNCs, SMEs and academic researchers. The SMEs can leverage IP opportunities from the MNC as well as gaining insights into new R&D opportunities, management practices, innovation cultures, and greater access to external knowledge and advice. In some cases, collaborations may lead to opportunities to recycle IP for new technologies / applications leading to regeneration of companies.

Through the added value of close links of MNCs with local companies and the facilities and expertise from academic research infrastructures, a basis can be formed for MNCs to leverage new investment from parent companies, and it can also lead to more commercially focussed researchers. This in turn creates an environment with potential for MNCs to become more deeply embedded in EC countries through local interactions with nanobiotech supply chain and multidisciplinary R&D collaborations.

WP3: Education towards a knowledge based nanobiotechnology economy

Our objective was to identify (1) the educational and training methods that are required to distribute information and awareness about nanobiotechnology in the communities of interest and (2) how to build a knowledge-based economy and infrastructure.

At present, there are already courses with nanobiotechnology content in 17 European countries. There are 4 master programs that fully focus on NBT but a larger number of programs in nanotechnology or nanoscience exist where NBT is only a certain track or specialisation, and there are also master programs that teach subfields of NBT (e.g. Medical Electronics, Cellular Biotechnology, biophysics and –informatics). While the total number is not high there is a great variety not only concerning the types of courses, including master degree programs as well as summer schools and continuing professional development, but also in the considerable range of curricula. This can be attributed to the fact that nanobiotechnology is not a clearly-bordered domain but a diverse and multidisciplinary field which can be considered a subfield of nanotechnology or an extension of biotechnology, as well as chemical or biological engineering. A strong necessity for a more precise and comprehensive definition of the field was identified which will help to define educational needs for NBT.

Does the current situation meet the requirements of different groups of stakeholders and how can NBT education be improved? Representatives from industry, academia and clinics were asked in a survey if their institutions would see an added value either by the possibility to hire M.Sc. specialised on NBT instead of on classical subjects (chemistry, biology, physics) or to train current employees in NBT specific short courses.

It becomes clear that the requirements and interests vary widely. Industry stakeholders often hire PhD level employees trained in classical subjects who are expected to adapt to new technological developments and areas e.g. at conferences with no need for additional training. On the other hand, for B.Sc. trained technical staff courses only on very specific techniques are required. Therefore, complete M.Sc. programs are not judged an added-value.

Academic stakeholders agree that interdisciplinary and theoretical knowledge about NBT should be part of any up to date curriculum in the classical subjects – but as a modular part within existing programs and as continuing professional education courses, not full NBT M.Sc.

The most positive responses came from clinical stakeholders. Added value is expected from overview courses as well as specific training courses concentrating on the clinical needs that can be addressed by NBT.

Future recommendations:

Our conclusion is that the most productive approach will be to incorporate Nanobiotechnology modules into already existing undergraduate and master level education in science and medicine instead of further investing in complete NBT M.Sc. courses. These modules should be designed in an individual way that suits the context of the course they are embedded in. Different technological perspectives have to be considered as well as the biological and clinical relevance.

There is furthermore demand for in-depth training on NBT which can be met by PhD graduate school programs. For clinical needs, partnerships with institutions strong in research will be most helpful for targeted education programs including short courses and continuous professional education.

To meet the educational requirements of an emerging and maturing field such as NBT appropriately, a clear definition of what NBT actually is and universal accreditation criteria that can be adapted to courses and modules will be of high priority.

WP4: Ancillary factors of nanobiotechnology

Different ancillary factors will significantly influence the success of a nanobiotechnology economy in Europe. Important prospective ancillary factors were found to be **ethical and social aspects, risk management and safety of products and methods, technology transfer, and communication**. After analysing the current situation problems and difficulties concerning the different aspects were identified and recommendations are made of the actions necessary to implement these areas in an EU nanobiotechnology infrastructure.

In new technologies **ethical and social thinking** and the further development of technology and science are not connected anymore. The current qualification system for scientists does not leave room for such considerations and presently only few nanobio programs even include any ELSA activities and most countries do not have designated programs for ELSA of nanotechnology.
But why are these activities still important?
Scientists will be required to address ethical questions in research proposals as funding agencies will increasingly ask for such considerations. Especially in nanotechnology application fields such as medicine or food awareness about ethical implications is crucial to meet critical sentiments about the potential dangers. While no nanotechnology specific issues have been identified yet it is essential to re-integrate ethical thinking into scientific research dealing with application areas such as medicine or food to ensure a responsible development. One practical approach would be to include ethic courses in engineering or life science studies and courses of relevant application areas. Besides, advice on ethical and social aspects of research projects needs to be made available for science and industry.

How can **risk management** be improved and a better **safety** of nanoparticles and research guaranteed?

Nanoproducts are “a thing without a definition” because the kind and amount of “nano” within a product varies widely. Today, there is little data that defines the risk and maximum levels of exposure to nanoparticles so potentially maximum risk has to be assumed. To meet the upcoming concerns about the safety of nanotechnology a precautionary approach of all stakeholders is needed that will encourage the generation of more data and the definition of potential risk.

To create a safe workplace and to balance risk and benefits existing safety officers in companies have to be trained and informed specifically about the properties of nanoparticles handled at their location. A European center for risk and safety management in nanobiotechnology providing information and advice would best serve the needs of SME´s and universities who cannot afford expensive risk management. To keep up with the speed of technology development a proactive regulatory partnership at all levels is necessary connecting ELSA, testing, training and communication aspects. In the long term a clear legal frame is inevitable describing how to handle nano objects.

Technology transfer of nanotechnology is a challenging task as nanotechnology is at the beginning of the value chain and additionally, university patents are mostly for a very early phase of a product – it takes a lot of time to reach the market. Scientists are interested in patents but the development of prototypes often takes too much time so that they drop out of the process. But patents are crucial for spin-offs as their main value, for collaborations of universities with industry, for university marketing, and prototype development.

The best way to facilitate technology transfer is to create transfer offices inside universities or research organisations with a good quality network of scientists, relevant companies or market experts. For development and growth of start-ups business incubators with local financial support are most suitable. However, not in every case start-ups will be the best way for technology transfer - scientists who lack “entrepreneurial spirit” could instead develop prototypes that are then bought by companies.

Communication is essential to engage with the public as early as possible for example with interactive experiments or science exhibits. Such usually well received events can make the development and application of nanotechnology as transparent as possible and help create a trustful atmosphere and a positive perception of nanotechnology.

Between scientists communication is well organized but should be improved among scientific disciplines, academia and industry at the regional, national as well as the European level. This can be accomplished by regional clusters that support the exchange of ideas and information not only inside but moreover between clusters. Connection of such clusters to a complementary alliance will be a crucial step for nanobiotechnology in Europe to be recognised at the global scale. Furthermore, such a cluster alliance can serve as a pool of professionals providing information for journalists, politicians and the public to communicate in a way understandable by non-scientists. The transparency and accessibility of data and stories can also help to attract funding and investments.

Future recommendations:

Connecting these findings it becomes clear that education in ethical and social values but also in science communication is crucial to deal with the increasing complexity of science and the impact of nanotechnology in areas such as medicine, food, cosmetics or environment. The different types of nanobiotechnologies and their applications have to be distinguished as well as the evaluation of their relevant risk potential. Clusters provide the organized communication platform for all stakeholders including the public to ensure a holistic proactive approach for responsible development of nanobiotechnology in a trusting environment.