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**NANOMATERIALS AND CONSUMER PROTECTION:  
THE ROLE OF RISK ASSESSMENT**

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***1. Introduction and objectives***

The recent development of techniques to manipulate matter at nano-scale is expected to play a major role in shaping the future of technology in a variety of sectors and applications, and to have an important positive impact on economies across the world. Policy makers are informed by experts that development and market penetration of such new technologies will be rapid and massive. Several hundreds products allegedly based on nanotech are reported to be already in the marketplace and figures of up to €1.9 trillion output for nanotech industry by 2014 have been mentioned by some economic researchers.

On the other hand, concerns have been repeatedly expressed by several scientists and scientific bodies, notably about the scarcity and inadequacy of the current scientific knowledge and of data for

identifying and assessing possible health and environmental risks associated with nanomaterials lifecycle.

Other reasons for concern, often mentioned by certain NGOs, pertain to ethical aspects, notably but not exclusively in relation with the health applications of nanotech.

As yet, public opinion, notably in the EU, does not seem to have fully and clearly seized the nanotechnology issue. According to opinion polls and other studies, the public has both positive expectations of nanotechnology benefits and generic concerns about its potential risks. Of course, the experience with other innovative technologies shows that any negative event bringing nanotech in the spotlight could have an immediate impact on public opinion and compromise the acceptance of nanotechnology products.

Significantly, the World Economic Forum has identified the "emergence of risks associated with nanotechnology" as one of the global risks in its 2007 "Global Risks Report" notably for the major economic consequences that the emergence of risks (real or perceived) might involve in this area.

Finally, regulators are in the process of analysing and discussing the adequacy of the existing regulatory and control systems in order to ensure safety on nanotechnology applications. No specific regulatory initiative for nanotechnology has been launched or announced so far.

Having said that, the objective of this paper is to analyse the role of risk assessment when supporting the successful and safe development of nanotechnology applications, notably in relation to consumer product, and to contribute to the discussion on a possible road map aimed at ensuring a collaborative approach in this area.

This paper largely refers to and builds upon the results of the work carried out in this area by the Commission Scientific Committees in particular SCENIHR, which is here extensively quoted. The aim is to present such results in a policy-oriented context and to reflect on how to build upon the scientific work in order to pave the way for targeted dialogue and collaboration on nanotechnology risk assessment matters, with a particular focus on consumer safety. In this respect, the DG Health and Consumer Protection of the European Commission is developing a collaborative approach with scientists, industry and other stakeholders in the policy areas under its responsibility, notably food safety.

## ***2. Background: the EU Strategy and Action Plan on Nanosciences and Nanotechnologies***

The European Commission established, in 2004-2005 respectively, a comprehensive strategy followed by an action plan on nanosciences and nanotechnologies, covering the period 2005-2009. The overall strategic objective of the Commission is a safe, integrated and responsible development of nanotechnology. In such strategy and action plan, safety is clearly indicated as one of the conditions for success of nanotechnologies in Europe. In that respect, the strategy states that public health, occupational health and safety, environmental and consumer risks of nanotech applications must be addressed at the earliest possible stage.

Early hazard identification and assessment of risks, notably consumer health risks, require the development and implementation of an appropriate strategy for knowledge development and application, fully integrating research activities, data production, risk assessment with product development and design. Such strategy should be designed to serve in particular the application by producers at the development/design stage of the relevant safety requirements, stemming from the regulatory framework, as well as the control and

enforcement needs of public authorities. Finally, it should be the basis for stakeholder dialogue and risk communication in this area.

### ***3. Key issues for the successful development of nanotechnology based consumer products***

It is vital to ensure competitiveness of industry's activities based on nanotechnology, which in fact encompass many sectors and are among the most promising knowledge-based new industrial developments.

Even dismissing some "hype" about nanotechnology, according to experts, it is indeed likely that consumers and society greatly benefit in many areas from such new technological development if nanotechnology keeps at least part of its promises. Nevertheless, the experience with other new technologies shows that such development can be hindered if the assessment and management of safety aspects and risks, real and perceived, in all their various dimensions including risk communication, are not fully integrated with technology and market developments at a very early stage.

This involves some basic conditions, which all point to the need for developing and applying at an early stage a common, effective risk assessment framework, with the necessary support from research activities and data production:

- nanotechnology products must prove to be safe since their first introduction on the market, based on appropriate, specific criteria. This requires identification and assessment of any specific risks by producers and integration of results obtained at the design stage;
- between all relevant stakeholders there must be clarity on, and a common understanding of the way in which the regulatory framework applies to nanotechnology products, including in particular requirements on testing and assessment. This calls for

dialogue and collaboration between stakeholders, authorities and scientists;

- appropriate information and instruments must be available to the authorities, and must be consistently and effectively implemented by them, notably for market surveillance and for product testing and verification, in order to provide solid guarantees to the public about full compliance with substantive safety requirements and to deter/neutralise "free riders" before they can damage the reputation of nanotechnology;
- there is a need for a consistent, collaborative approach on nanotechnology safety at international level, based on a consistent approach when identifying and assessing potential risks, in order to prevent divergent standards and requirements, which would damage technological, industrial and market development of nano-based products, confuse consumers and possibly lead to trade disputes.

A common road map for the assessment of potential risks of nanotechnology-based products is therefore vital to their safe and successful development.

#### ***4. Background: The EU regulatory framework for consumer safety***

Consumer product safety is comprehensively regulated in the EU by Community law, both in the food and non-food areas. A recent review made by Commission services of the adequacy of existing EU legislation to cover potential risks of nanotechnology based products has not shown major gaps in the applicability of basic safety requirements irrespectively of size.

This analysis also confirmed that the EU legislation does not include specific requirements for nanomaterials, notably as far as testing and assessment provisions are concerned.

Therefore, in certain cases, specific supporting instruments (guidelines, criteria, technical standards, test protocols etc) may be necessary in order to guide the producer on how to ensure the safety of nanotechnology products, to allow effective and consistent assessment by risk assessment bodies and to ensure that control authorities have the necessary information to carry out control and verification.

Once again, these results confirm that a key pre-condition to the compliance with the relevant safety provisions of EU product safety legislation is the availability of specific data on the nano-materials used, the resulting exposure, the toxicological characteristics as well as on the appropriate application of testing and assessment methods, which take account of the specific characteristics of nanomaterials.

### ***5. What is special with the assessment of potential risks of nanotechnology-based materials and products***

The Commission Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) has examined in 2006 the appropriateness of existing risk assessment methodologies to assess potential risks associated with engineered and adventitious products of nanotechnologies<sup>1</sup>.

It emerged that the approach based on hazard identification, hazard characterisation, exposure assessment, risk characterisation is applicable to nanomaterials, but that the current methodologies need

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<sup>1</sup> [http://ec.europa.eu/health/ph\\_risk/committees/04\\_scenihhr/scenihhr\\_cons\\_01\\_en.htm](http://ec.europa.eu/health/ph_risk/committees/04_scenihhr/scenihhr_cons_01_en.htm)

adaptation in practice in order to deal with the hazards associated with nanotechnology.

In short, the main issues identified in that respect were:

- Need for a case by case approach

SCENIHR observed that "there is insufficient data available at the present time to allow the identification of any systematic rules that govern the toxicological characteristics of all products of nanotechnology. It follows therefore that risk assessment will need to be made on a case by case basis. In order to perform a risk assessment for the application of nanotechnologies, identification of the methodological issues requires consideration of both the exposure and the hazard."

It may be expected that this conclusion may hold at least for some time and possibly be related to some intrinsic characteristics of nanomaterials like in particular the unpredictability and variability with size of the characteristics of nanomaterials. Therefore, a strategy for safe nanotechnology should take into account the need for a case-by-case approach in a feasible and proportionate manner.

- Need to use the appropriate metrics and take into account surface phenomena and particle characterisation

Normal mass-based approaches may not be appropriate for nanomaterials. Moreover, phenomena intervening between emission and biological interactions as well as proper characterisation of particles are essential. Besides, surface to volume ration may be more relevant than mass in establishing the appropriate metrics.

SCENIHR also concluded that "in considering the hazards associated with nanoparticles, the size, shape and composition, including surface charge and adsorbed species, of the nanoparticles are important. The phenomena of surface modification, aggregation and dissolution or degradation are also significant. Since nanoparticles that are readily soluble in the physiological environment lose their particle specific effects, they only remain of concern if they dissolve into harmful molecules. For particles that are essentially insoluble, there is the possibility of biopersistence, resulting in long term exposure and associated nanoparticle-specific effects. "

- Need to take into account possible specific biological behaviour of nanoparticles

Extrapolation from biological behaviour data for bulk material may lead to wrong conclusions.

SCENIHR observed that "There is little published data on the biological behaviour of nanoparticles, including the distribution, accumulation, metabolism and organ specific toxicity. Much of the data that is available concerns the respiratory system where there are experimental data to show that nanoparticles often exert greater toxic effects than larger particles of the same substance at the same mass concentration. Interactions of nanoparticles with biomolecules such as DNA, RNA or proteins are also more likely with decreasing particle size. Although no mechanisms unique to nanoparticles have yet been identified, a mechanism of toxicity for some nanoparticles is the induction of reactive oxygen species and the consequential oxidative stress experienced by cells."

On toxico-kinetics, SCENIHR noted that:

"Nanoparticle translocation can occur to a greater extent and to different sites than occurs with larger particles. There can therefore be a systemic distribution and accumulation of such particles. There is evidence that nanoparticles can translocate from their portal of entry and can reach other parts of the body, including the blood and the brain, although again very few studies have been performed and the extent and significance of this translocation is unclear. "

- Need to consider the specific aggregation state of nanomaterials

Not all forms of nanomaterials are expected to generate potential specific safety risks.

According to SCENIHR: "In considering the potential of adverse health risks associated with nanotechnology products, two separate types of nanostructure may be identified, those where the structure itself is a free particle, and those where the nanostructure is an integral feature of a larger object. Although all nanostructures may interact with living systems in ways that may be influenced by the nanoscale characteristics, it is not considered that these nanoscale features of larger objects (for example nanotopographical features on medical devices) pose any additional human health and environmental risks. The situation with free nanoparticles, including agglomerates, is quite different. It is the generation, application, distribution, persistence and toxicological characteristics of free nanoparticles that give rise to concerns over possible human health and environmental risks. These concerns include the physical, chemical or biological degradation of nanocomposites, which potentially releases nanoparticles. For environmental risk analysis,

these concerns imply the necessity for life cycle evaluation of these products."

- Need for adequate methods and data to assess human exposure

SCENIHR observed that "The principal route of human exposure is by inhalation in view of the presence of nanoparticles in air." However "The rapidly increasing use of manufactured nanoparticles in consumer products such as cosmetics, and pharmaceutical preparations and food technology implies that dermal, gastrointestinal, and parenteral routes of exposure are becoming more significant...There is an urgent need for exposure data on humans (consumers and workers)..."

Moreover, "The evaluation of exposure of individuals and the environment in general to nanoparticles, and therefore of the associated health risks, has been impeded by the difficulty of routine sampling, and of counting and measuring particles that are below the limit of detection by visible light. The use of mass concentration data alone for the expression of dose is insufficient, and number concentrations and surface area metrics are generally more relevant in exposure and risk assessment. This is not incorporated in current regulations. The development of methodologies and equipment that enables routine measurements in various media for representative exposure to free nanoparticles is an important priority."

- Need for specific toxicological studies and data

Again extrapolation of toxicological data from tests with bulk material may be inappropriate.

SCENIHR stated that "The safety evaluation of nanoparticles and nanostructures cannot rely solely on the toxicological profile of the equivalent bulk material. Nanomaterials need to be evaluated for their risk on a case by case basis for each preparation including the

intended use of the material. In carrying out the risk assessment for products of nanotechnology, new testing strategies will be required that will address the product specification, the intended use and the identification of potential exposure scenarios, both human and environmental. Conventional toxicity and ecotoxicity tests have already been shown to be useful in evaluating the hazards of nanoparticles. However, some methods may require modification and some new testing methods may also be needed. It appears that nanoparticles can exacerbate certain pre-existing medical conditions and may increase susceptibility to some diseases, which may require modification of testing strategies."

#### ***6. A case- by- case risk assessment approach***

The overall consideration that results from the above is that although the essential elements of the risk assessment and regulatory frameworks are in place and can be applied to nanotechnology-based products, the development of specific scientific knowledge and the provision of data to enable effective risk assessment and to support the practical application of the regulatory framework is a key and urgent priority. This is in particular the reason for the substantial and targeted research effort promoted by the European Commission on safety aspects of nanotechnology.

The main challenge is to ensure that the development of scientific knowledge and the identification and assessment of potential risks are coordinated in time with product development and marketing. Taking into account the expected rapid development of nanotechnology applications, a streamlined, co-operative approach seems to be both the most appropriate and the only feasible response in that respect.

A recent opinion of SCENIHR (on the appropriateness of the risk assessment methodology in accordance with the technical guidance documents for new and existing substances for assessing the risks of nanomaterials<sup>2</sup>) provides an extremely pertinent framework for cost-effective assessment, which would effectively support a case by case risk assessment approach.

This framework is intended to provide a basis for scientifically sound judgment on potential risks while minimizing the testing and assessment efforts. It involves a staged approach covering the following issues:

- whether human and/or environmental exposure can be expected in a life cycle perspective;
- the characterisation (nature, level, duration) of the expected exposure;
- hazard identification of materials to which exposure is expected;
- characterisation of relevant hazards and assessment of risk.

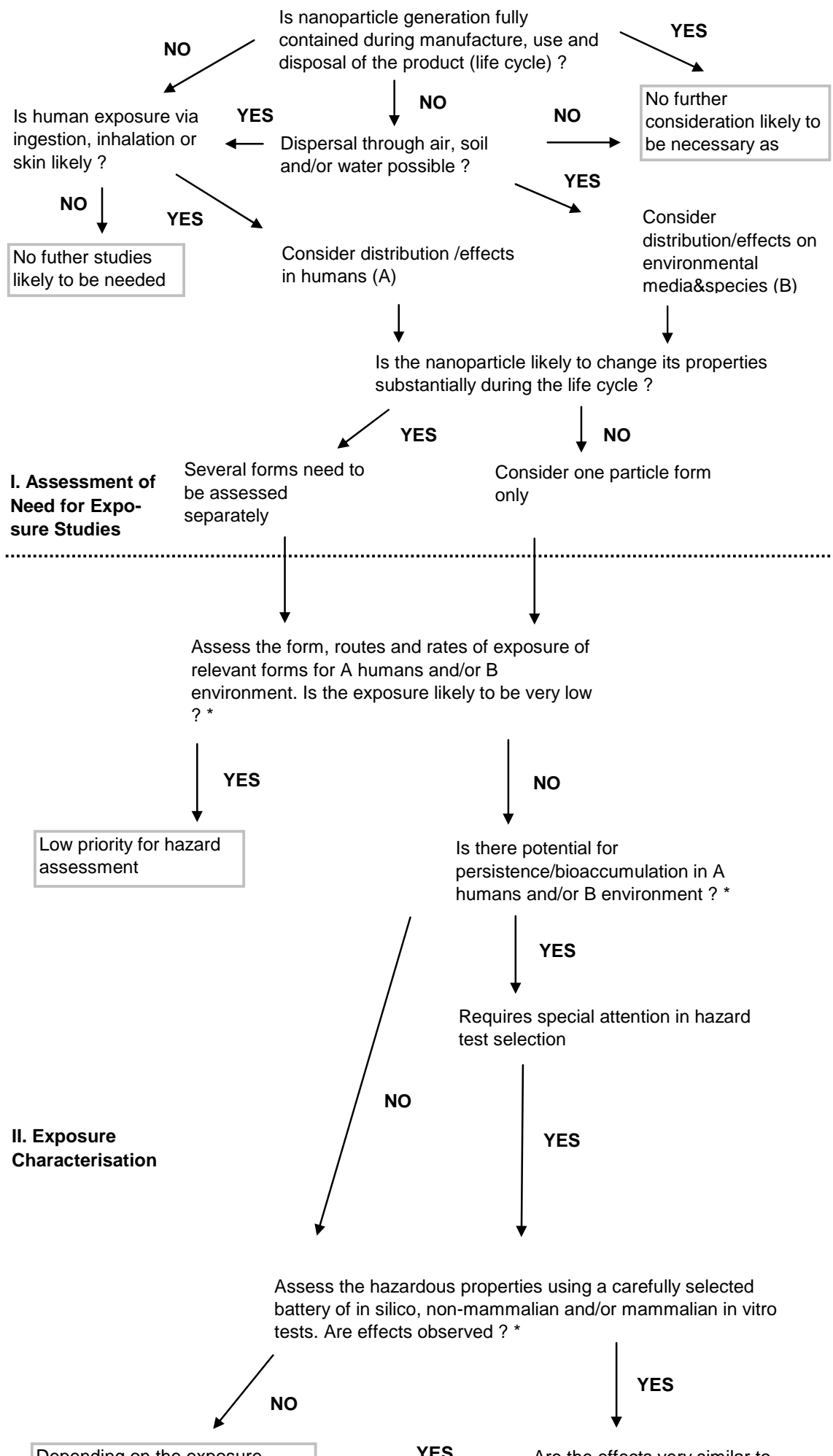
According to SCENIHR, while this framework would in theory streamline the risk assessment approach and ensure a high level of efficiency, its practical application requires significant further development on aspects like, in particular, dosimetry and development/validation of in vitro tests.

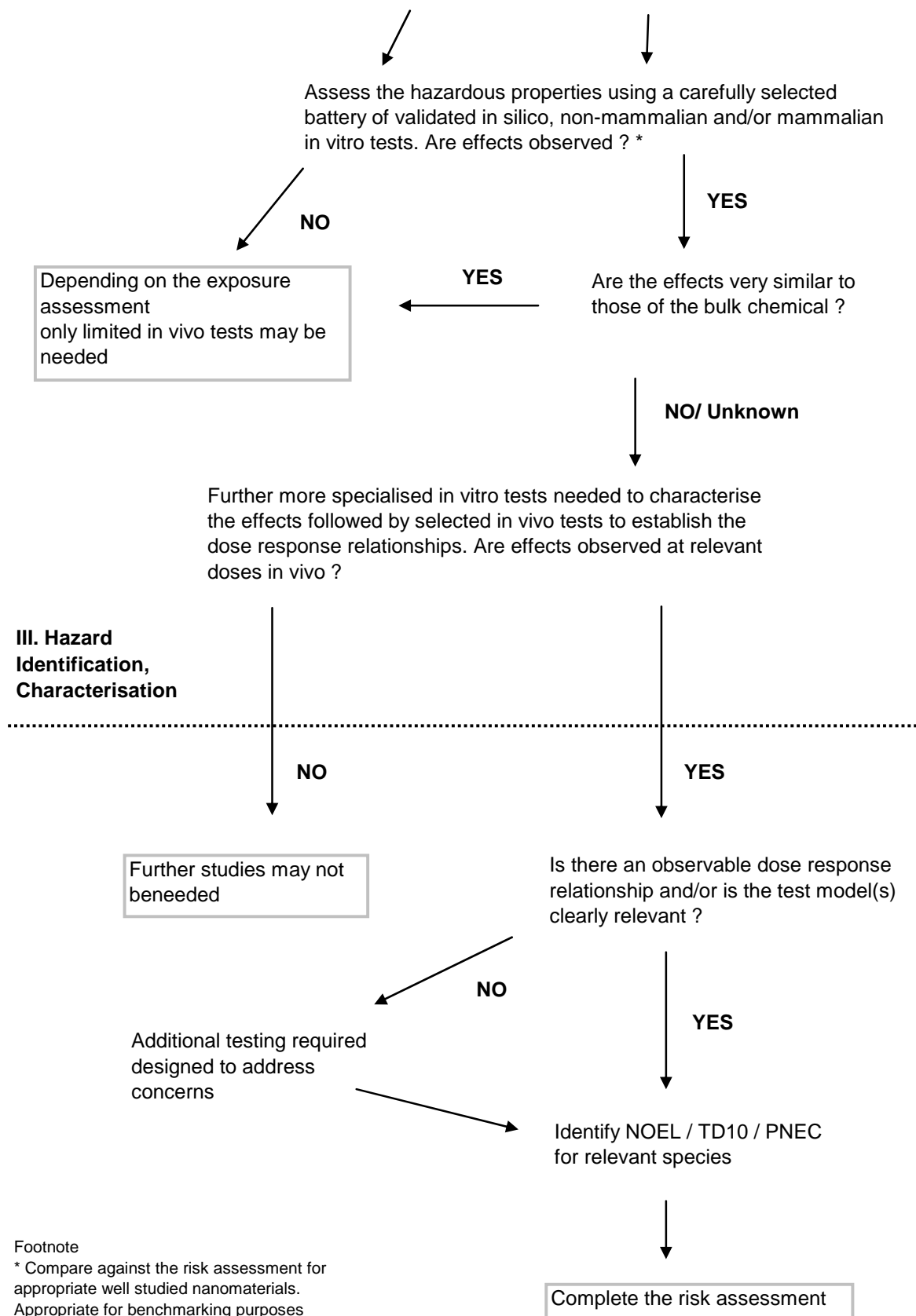
The proposed staged approach was graphically summarised by SCENIHR as in the following graphs:

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<sup>2</sup> [http://ec.europa.eu/health/ph\\_risk/committees/04\\_scenihhr/scenihhr\\_cons\\_04\\_en.htm](http://ec.europa.eu/health/ph_risk/committees/04_scenihhr/scenihhr_cons_04_en.htm)

**Outline of the staged approach to identifying the human and environmental risks from nanoparticles**





Footnote  
 \* Compare against the risk assessment for appropriate well studied nanomaterials. Appropriate for benchmarking purposes

## ***7. A road map to integrate risk assessment to nanotechnology development***

In light of the above, the effective and timely integration of risk assessment to nanotechnology-based product development would be highly facilitated by the establishment of a shared road map involving all the relevant actors, in particular scientists, researchers, industry experts and designers as well as regulatory/control authorities.

Ideally, such a shared road map should be developed taking fully into account the international dimension.

Given the extremely diverse applications of nanotechnology, in particular in the consumer area, a sectoral approach seems the most effective technique likely to deliver tangible results.

The road map, for a specific sector considered, might include the following steps:

- the establishment of a specific stakeholder forum for monitoring scientific, technological and market developments (a common radar screen) as well as consumer/public perceptions and concerns, and for stakeholder dialogue;
- a mechanism for prior identification and assessment by industry of the expected technological and market developments (which nanomaterials, which applications, perspectives for marketing of the corresponding products...)
- the development and implementation of a procedure for a validated preliminary analysis of the potential health risks for the applications considered (in particular in light of the methodological suggestions of SCENIHR, possibly further developed/adapted for the sector)

- the co-ordination between industry, research and risk assessment bodies in order to identify and fill in any significant knowledge gaps in light of the above-mentioned preliminary analysis and to complete or revise if necessary the assessment of potential risks.

Although much relevant work is already in progress in this area and countless initiatives are taken, there may be scope for trying to improve the productivity and efficiency of current efforts by facilitating targeted collaboration in well defined sectors, along the lines described above.

### ***8. The way forward***

Within the framework of the follow-up to the Commission Action Plan on nanosciences and nanotechnologies, the General Directorate for Health and Consumer Protection (DG SANCO) is continuing to promote the development of risk assessment methodology for nanomaterials. In addition to ongoing work of SCENIHR (and of SCCP for cosmetics), a mandate to the European Food Safety Authority (EFSA) is currently under discussion. Moreover, DG SANCO plans to promote the establishment of a network of nanotechnology risk assessors across the scientific bodies in the EU, with possible links at international level.

Moreover, DG SANCO plans to contribute to stakeholder and international dialogue and collaboration on nanotechnology along the lines mentioned above.

Since DG SANCO has in particular a direct policy and regulatory responsibility for food safety, and the food industry is one of the important sectors where nanotechnology-based consumer products are expected to make rapid market inroads, DG SANCO is launching a discussion with stakeholders in the food area on how to establish and apply a road map for safe development of nanotechnology in the

sector. In addition, DG SANCO is committed to dialogue on nanotechnology with the US-FDA and is prepared to provide a substantial input into future developments in the appropriate international fora.

An important development in respect of the stakeholder dialogue on nanotechnology safety is the 1<sup>st</sup> Annual Nanotechnology "Safety for Success" Workshop that will take place in Brussels on 25-26 October 2007 on nanotechnologies. It was organised as a follow-up to the International Conference of October 2006 in Helsinki in collaboration with the Finnish presidency of the EU.

## ***9. Conclusion***

In short, the main conclusions can be expressed as follows:

- the strategic potential of nanotechnology for our economies as well as its expected benefits for health and consumers should strongly motivate all stakeholders to take effective preventative risk assessment and management action to avoid the repetition of some negative past experiences with new technologies;
- early hazard identification and risk assessment are the key to the success of nanotechnology-based products;
- preliminary scientific analysis shows a need for a case-by-case risk assessment approach;
- the EU regulatory framework is largely adequate but there is a need for data, scientific knowledge, and specific instruments which may include guidelines, technical standards, test methods and protocols etc. in order to enable producers to ensure and demonstrate the safety of their products and to allow the

authorities to enforce and verify compliance with the relevant requirements;

- on the principle, the risk assessment methods are also adequate to cover nanomaterials, but their application may need to take into account the specific characteristics of nanomaterials. Furthermore, there is a serious lack of data to make effective assessments at this stage of development;
- a case-by-case risk assessment approach could be applied in an effective and proportional manner through the further development and the implementation in a specific, sectoral manner of the staged approach indicated by SCENIHR;
- the respective timing and co-ordination between research, data production, product design, identification and assessment of risks and market developments are the key to and the challenging aspects of the success of nanotech-based products;
- a joint approach involving industry, researchers and scientists, risk assessors, other stakeholders and the authorities seems the most appropriate way to effectively manage the challenges generated by risk assessment and management in the nanotechnology area. The international dimension needs to be fully taken into account;
- DG SANCO plans to test, in its policy domain, a structured approach along these lines with a view to contribute to best practices in this area.