



Mapping research and development within the nanofield in Sweden

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Preface

The Swedish Chemicals Agency (KemI) has been assigned by the Swedish Government to produce a national action plan for a toxic-free everyday environment: Action plan for a toxic-free everyday environment 2011 – 2014 – protect the children better.

Efforts are now going on in several areas, both in Sweden, within the EU and internationally and often in cooperation with other authorities. Reducing chemical risks in the everyday environment is one step towards attaining the Swedish Parliament's environment quality objective A Non-Toxic Environment, which is the objective that KemI is responsible for.

Within the framework of the action plan, KemI compiles knowledge in KemI's report and PM series elaborated by experienced colleagues, researchers or consultants. In this way, KemI presents new and essential knowledge in publications which can be downloaded from the website www.kemikalieinspektionen.se

In the action plan, there is particular focus on health and environmental risks with nanomaterials. The main objective of this report was to identify research in Sweden regarding health and environmental risks and development of technology applications for nanomaterials. A large part of the work presented in this report was performed as a literature study of published scientific studies, regulations and reports from various agencies and organisations. Information on relevant research funding has been gathered from the webpages of the funding agencies. Finally, in order to get an overview of the innovations that are closest to be marketed a more detailed survey was carried out concerning companies working with nanotechnology and nanomaterials in Sweden.

The report was written by Linda Schenk, at the Division of Philosophy at the Royal Institute of Technology. Ebba Littorin, at the time also at the Division of Philosophy has made contributions to the survey of industry research and development. Project leaders and contacts at Kemi were Lena Hellmér and Maria Wallén. Others at KemI who have contributed to the work of this report are Emma Wikstad and Yvonne Andersson. Responsible for the project at KemI was Agneta Falk-Filipsson, Head of Unit, Risk Reduction and Support.

The views expressed in this report are the author's own and do not reflect necessarily the view of KemI.

Contents

Summary	7
Sammanfattning	9
List of abbreviations	11
1 Introduction	12
1.1 Scope and Aim	13
2 Nanotechnologies and nanomaterials: the Swedish perspective	13
3 Nanotechnologies and nanomaterials: an international perspective	15
3.1 The European Union research funding and strategies	15
3.2 Activities within the International Organization for Standardization (ISO)	16
3.3 Activities within the Organisation for Economic Co-operation and Development (OECD)	17
4 Definitions of nanomaterials for the purpose of this report	18
5 Areas of research	18
6 Academic publishing within the field of nanomaterials in Sweden	19
6.1 Nanomaterials world-wide: trends and topics	21
6.2 Nano-risk publications	21
7 Financing of nanotechnology and nanomaterials research in Sweden	22
7.1 Sixth and Seventh frame work programme.....	25
8 Industry research and development of nanotechnologies and nanomaterials	27
8.1 The non-nano companies	28
8.2 The nanotechnology companies	29
8.3 Products containing nanomaterials.....	31
8.4 Why use nano?	33
8.5 What are the needs of nanotechnology companies?.....	33
9 Risk research in Sweden	34
10 Emerging uses and potential exposures	38
10.1 Emerging uses	38
10.2 Potential exposures.....	40
11 Discussion	41
11.1 Concluding comments.....	43
12 References	44
Appendix A Analysis of research funding during 2010	48

Appendix B Identifying industry R&D.....	53
Appendix C Sponsorship arrangements for the testing of manufactured nanomaterials, as of March 2011	54
Appendix D Definitions from other organisations	56
Appendix E The questions sent out to Swedish nanotechnology companies	59

Summary

The objective of this survey was to map research and development activities on nanomaterials currently in progress in Sweden and to identify emerging uses of and potential exposures to nanomaterials. Research on risk to health and the environment was to be identified in more detail in this overview. The methods used were a bibliometric analysis, an analysis of granted research funding and a survey addressed to companies. The bibliometric analysis showed that a very small part of available publications on nanomaterials concern risks to health and the environment; only a few percent of the available scientific literature on nanomaterials concerns risks of these materials. The situation is the same in Sweden as world-wide. The three Swedish universities that have produced the highest number of publications regarding nanomaterials (applications, basic research as well as risk research) are Lund University, Chalmers University of Technology and the Royal Institute of Technology (KTH). When it comes to solely research on risks of engineered nanomaterials the Karolinska Institute is the most prolific. Considering research on non-engineered materials in nanoscale, also called ultrafine particles, Lund University was identified as the most productive. The kinds of engineered nanomaterials most commonly focused on in risk research were nanoparticles of metals and metal oxides and carbon nanotubes. Except for carbon nanotubes, nanomaterials with only one or two dimensions in the nanoscale have scarcely been treated at all by Swedish risk researchers.

It is also the universities that have been the most productive bodies with regard to academic publishing and were in 2010 the most successful in receiving research funding. This survey identified funding from twelve different Swedish agencies, amounting to nearly SEK 412 million. Less than five percent of this funding was targeted to research related to risks of nanomaterials or ethical, legal and social aspects of nanotechnologies. Only two of the twelve funding agencies allocated larger amounts to risk research. Funding within the European current and previous framework programme, , is a major contributor to Swedish research on nanotechnologies. However, it has not been possible to quantify the amounts within the scope of this report.

The company survey had a somewhat different scope compared with the other two analyses, as the starting point was research within nanotechnology rather than only research on nanomaterials. In total, 48 responses from companies within the target group were received. Being a nanotechnology company does not necessarily imply the use of nanomaterials, as nanotechnology is defined as the manipulation of matter at nanoscale, not by the actual use of nanomaterial. Nonetheless, in this survey four out of five responding companies reported they do use nanomaterials. An additional 35 companies were identified through information posted on the Internet as active within nanotechnologies and among these at least 28 also work with nanomaterials.

The companies in this survey are of varying sizes, with a majority being small and medium sized and approximately one third large enterprises. The identified 82 companies also operate over several sectors; the most common were life science and medicine (21), energy and clean tech (18) and electronics (10). From this limited number of respondents it is difficult to provide a simple overview of the Swedish nanotech industry. Within life science and medicine the development activities mainly concern medical devices and pharmaceuticals. Within energy and clean tech, solar harvesting methods, light emitting techniques and energy

storage are important applications. It is somewhat more common that Swedish companies themselves produce the nanomaterials used than purchasing them. The kinds of materials that companies seem to focus on in their research and development activities are mainly metals and metal oxides having one or more dimensions in the nanoscale. Carbon nanotubes are also used in numerous applications. The results from this survey indicate that the development activities thus concern a larger span of nanomaterials than is covered by risk research in Sweden. In addition, companies' risk assessment efforts seem according to our survey to have been relatively limited. A large share of the responding companies are still in the development phase, neither producing nor importing products that contain nanomaterials. Twenty companies stated to produce consumer products or components of consumer products. The main share of these products was reported to belong within the sectors of electronics, pharmaceutical and health and automotive.

An attempt to extrapolate the results from the performed company survey will by necessity be both crude and associated with a large degree of uncertainty. A large share of the applications described by the respondents to our survey were within the area of electronics, pharmaceuticals and medical devices, light emitting techniques and solar panels. According to the responding companies, medical devices and solar panel development have in some instances reached the stage of a final consumer product, while light emitting techniques have not. Due to the regulatory requirements for pharmaceuticals, there is a long time from first development efforts to release on the market. One can obviously expect occupational exposure in the manufacturing of these applications, and in the case of medical devices and pharmaceuticals also exposure of consumers. Concerning electronics, solar panels and future light sources the environmental exposure at the products' end of life might perhaps be of larger concern than the exposure of consumers. It is also appropriate to raise the question whether e.g. thin films or nanoparticles, nanowires and nanotubes bound in matrices, and the question of what happens to these when products become waste, should be considered as reasons for concern or not.

Thus, Swedish nanotechnology is not one industrial sector; rather nanotechnologies are used in various ways and to different extents in different sectors. This report is one step towards investigating the diversity of the Swedish nanotechnologies actors. This will be a necessity in order to optimally prioritise and intensify human health and environment risk research as well as to develop Swedish technical innovation in the nano area in a responsible and sustainable manner. Further efforts towards the aim of interweaving risk and innovation research are needed.

Sammanfattning

Syftet med undersökningen presenterad i denna rapport var att kartlägga svensk forsknings- och utvecklingsverksamhet gällande nanomaterial, samt att identifiera kommande användningsområden och möjliga exponeringsvägar för nanomaterial. Särskilt forskning om risker för hälsa och miljö skulle identifieras mer detaljerat i denna kartläggning. De metoder som har använts var bibliometrisk analys, analys av beviljade forskningsmedel samt en enkät riktad till företag. Den bibliometriska analysen visade att en mycket liten del av tillgängliga publikationer gällande nanomaterial behandlar risker för hälsa och miljö. Detta förhållande gäller för publikationer från Sverige såväl som från övriga världen. De tre svenska universitet som har publicerat flest vetenskapliga publikationer om nanomaterial (applikationer, grundforskning såväl som risk forskning) är Lunds universitet, Chalmers tekniska högskola och Kungliga Tekniska Högskolan. När det gäller enbart publikation av forskning om risker med tillverkade nanomaterial är Karolinska institutet mest produktivt. Gällande forskning om ej avsiktligt tillverkade nanomaterial, så kallade ultrafina partiklar, identifierades Lunds universitet som mest produktivt. Den typ av avsiktligt tillverkade nanomaterial som oftast fokuseras på inom riskforskningen är nanopartiklar av metaller och metalloxider och kolnanorör. Utöver kolnanorör så har nanomaterial med enbart en eller två dimensioner i nanoskala har knappt behandlats av svenska riskforskare.

Det är också de universitet som har varit mest produktiva i fråga om vetenskaplig publicering som under 2010 var mest framgångsrika i att bli beviljade forskningsmedel. Denna undersökning identifierade finansiering från tolv olika svenska forskningsmedelsgivare, sammanlagt delades dessa ut nära 412 miljoner kronor under 2010. Mindre än fem procent av dessa medel riktades till forskning om riskerna med nanomaterial eller etiska, regulatoriska och sociala aspekter av nanoteknik. Endast två av de tolv finansiärerna avsatte större mängder av medel mot riskforskning. Finansiering inom det Europeiska ramprogrammet, såväl nuvarande och tidigare, har varit och är en viktig bidragsgivare till svensk forskning om nanoteknik. Dock var det inte möjligt att kvantifiera de aktuella summorna inom ramen för denna rapport.

Företagsundersökningen hade en något annorlunda inriktning jämfört med de två andra analyserna, utgångspunkten i denna var forskning inom nanoteknik och inte bara forskning om nanomaterial. Totalt inkom 48 svar från företag inom målgruppen. Att nyttja nanoteknik innebär inte nödvändigtvis användning av nanomaterial, eftersom nanoteknik är definierat som hantering av materia på nanoskala och inte som hantering av nanomaterial. Dock uppgav fyra av fem företag i denna undersökning att de använder nanomaterial. Ytterligare 35 företag, utöver de som svarade på enkäten, identifierades som verksamma inom nanoteknik genom information på hemsidor. Av dessa arbetar minst 28 även med nanomaterial.

Svenska nanoteknikföretag som deltog i denna studie är av varierande storlek, en majoritet är små och medelstora medan ungefär en tredjedel är stora företag. De identifierade företag (n = 82) delas också över flera sektorer av vilka de vanligaste var life science och medicin (n = 21), energi- och miljöteknik (n = 18) samt elektronik (n = 10). Med det begränsade antalet svarande företag är svårt att ge en enkel översikt av den svenska nanoteknikindustrin. Inom life science och medicin rör utvecklingsverksamheten främst medicintekniska produkter och läkemedel. Inom energi och miljöteknik, är solfångare, ljuskällor och energilagring viktiga tillämpningar. Det är något vanligare att svenska företag själva producerar de nanomaterial som används än att köpa in dem från en extern tillverkare. De typer av material som företagen tycks fokusera på i sin forskning och utveckling är i huvudsak metaller och metalloxider som

har en eller flera dimensioner i nanoskala. Kolnanorör används också i många tillämpningar. Utvecklingsverksamhet gäller alltså en större spännvidd av nanomaterial än vad som täcks av riskforskning. En stor del av de i studien ingående företagen är fortfarande i utvecklingsfasen, och varken producerar eller importerar produkter som innehåller nanomaterial. Tjugo företag uppgav att de producerar konsumentprodukter eller komponenter som används i konsumentprodukter. Huvuddelen av dessa produkter rapporterades tillhöra kategorierna elektronik, läkemedel och hälsa samt bil och verkstad.

Ett försök att extrapolera resultaten från denna kartläggning av nanoteknikföretag kommer oundvikligen vara grovkornigt och befast med stora osäkerheter. En stor andel av de applikationer som är beskrivna av enkätrespondenterna faller inom områdena elektronik, läkemedel och medicin-tekniska produkter, ljuskällor och solpaneler. Enligt de svarande företagen har medicin-tekniska produkter samt solpaneler i vissa fall kommit till skedet färdig konsumentprodukt, emedan ljuskällor inte har det. På grund av de regulatoriska kraven på läkemedel har dessa en lång tid mellan utvecklingsfas och marknadsföring. Det kan förväntas att det kommer förekomma yrkesmässig exponering inom tillverkningen av dessa applikationer, och i fallet av medicin-tekniska produkter och läkemedel även konsumentexponering. Vad gäller elektronik, solpaneler och framtida ljuskällor kommer möjligtvis miljöexponeringen vara mer bekymmersam än konsumentexponering. Det är också relevant att ta upp frågan om huruvida tunnfilmer eller nanopartiklar, nanotrådar och nanorör bundna i matriser, och vad som sker med dessa när produkterna blir avfall, bör betraktas som potentiella problem.

Sammanfattningsvis, svensk nanoteknik är inte en ensam bransch, utan nanoteknik används på olika sätt och i olika utsträckning inom olika sektorer. Denna rapport är ett steg mot att kartlägga mångfalden av svenska nanoteknikaktörer. Detta kommer att vara en nödvändighet för att på bästa sätt prioritera och intensifiera forskning om hälso- och miljörisker samt utveckla svensk teknisk innovation inom nanoområdet på ett ansvarsfullt och hållbart sätt. Det finns behov av ytterligare satsningar för att sammanväva risk- och innovationsforskning.

List of abbreviations

ELSA: Ethical, Legal and Social Aspects

ERA-NET: European Research Area Net

FAS: Swedish Council for Working Life and Social Research

FORMAS: Swedish Research Council for Environment, Agricultural Sciences and Spatial Planning

FP6: The 6th framework programme for research and technological development

FP7: The 7th framework programme for research and technological development

ISO: International Organization for Standardization

KAW: Knut and Alice Wallenberg Foundation

KemI : Swedish Chemicals Agency

KVA: Royal Swedish Academy of Sciences

MISTRA: The Foundation for strategic environmental research

NIC: Nordic Innovation Center

NMP: Nanotechnologies, Materials and Production Technologies

OECD: Organisation for Economic Co-operation and Development

SCENIHR: Scientific Committee on Emerging and Newly Identified Health Risks

SEA: Swedish Energy Agency

SKEP: Scientific Knowledge for Environmental Protection

SSF: Swedish Foundation for Strategic Research

STINT: Swedish Foundation for International Cooperation in Research and Higher Education

Vinnova: Swedish Governmental Agency for Innovation Systems

VR: Swedish Research Council

WPMN: Working Party on Manufactured Nanomaterials

WPN: Working Party on Nanotechnology

1 Introduction

The manipulation of materials at molecular and atomic scale, is a young research area, or more correctly a collection of new research areas. Nanotechnologies have a potential to bring benefits to society offering unique opportunities for novel applications, ranging from more energy efficient and faster computers and mobile phones, to stronger and more durable materials, more efficient energy harvesting and storage devices, applications based on antimicrobial or self-cleaning properties and nano-medicine. The word nano has its origin from the greek word *nanos* which means dwarf, and is used as a prefix indication of a billionth (10^{-9}). A nanometer thus corresponds to a billionth of a meter. A football to the earth is a commonly used analogue used to describe how small the nanoscale is; a nanoparticle compared with a football is the same as the football compared with the earth. The smallest structures a human eye can discern are about 10 000 nanometres. The nanometer scale has become accessible both by application of new physical instruments and procedures and by further diminution of present microsystems. Working in the nanoscale is not just working with small materials, it is also working with different materials as the nanoscale also changes the properties and characteristics of materials. The nanoscale properties are the basis for a variety of technical applications in medicine, electronics, biomaterials and energy production.

In 2005 the European Nanobusiness Association performed a survey in order (ENA 2005) to map the attitudes of European businesses to questions such as business impact, the effects of regulation, public perception of nanotechnologies. The results showed that 90 per cent of companies expected nanotechnologies to have an influence on their business, and 58 per cent thought this would happen within three years. The impact might not have become as thorough as expected a few years ago, and most of the potential applications of nanotechnologies are currently still in the research and development stage and are expected to appear on the market in the coming years.

According to the Woodrow Wilson initiative's database there are more than 1,300 consumer products containing nanomaterials on the market. In particular nanoforms of silver, titanium, cerium and carbon nanotubes have been found (www.nanotechproject.org/inventories/consumer, 2012-05-14). A report focused on the European market was recently published by the Dutch National Institute for Public Health and the Environment (Dekkers et al. 2010). A survey focused on the Swedish market has been published by the Swedish Chemicals Agency (KemI 2009a). A few hundred different products were found on the Swedish market. These were of the same kind as those found in similar surveys in other European countries, with the possible exception that products containing antibacterial nanosilver were found to be somewhat less common in Sweden. It was estimated that the introduction of new products containing nanomaterials on the Swedish market would be modest in the coming years, as Swedish actors were reported to find the current regulatory uncertainties too high. The easy access to products via Internet based trade, and the resulting private import, was mentioned in both the KemI and Dekkers et al. surveys as a problematic factor for obtaining a fully comprehensive overview.

Regulatory concerns regarding the use of nanotechnologies and more specifically nanomaterials originate in lack of knowledge on their use and potential effects. The nanoscale properties that make nanomaterials so appealing for the development of new applications could also imply a new set of risks to health and the environment, as the toxicological properties of the nanoscaled substance most likely also will change compared with the bulk material. More than a thousand products containing nanomaterials are currently available

commercially, a situation which clearly necessitates investigation of the exposure and toxicity of these materials in the near future. Currently it is unclear how regulatory agencies will handle nanomaterials from a risk management perspective. Existing regulations on the protection of human health and the environment were as a rule issued before attention was paid to engineered nanoscaled materials on the market. The existing national and international regulatory frameworks for chemicals in their different applications, e.g. industrial chemicals, pharmaceuticals, cosmetics, food and food contact materials, are considered also to cover nanomaterials by the European Commission (EC 2008b). Further, it was stated by the Commission (EU 2008b), that it is unclear how applicable the current regulations, such as REACH, are for management of potential risks posed by engineered nanomaterials. There are several reports that identify and list knowledge gaps that need to be filled for risk assessment purposes (SRU, 2011; Gustavsson et al. 2011; van Zijverden & Sips 2009; EU OSHA 2009). Among the commonly occurring themes are lack of information on exposed populations, areas of application, possible toxicity and proper dose descriptors. An additional issue is that the nanoscale might interfere with the applicability of available test methods, which have been developed for toxicity testing of bulk substances and, in most instances, have not been validated for nanomaterials. The lack of adequate testing methods for nanomaterials further complicates the situation as the scientific and regulatory community currently lacks the tools to fill these identified knowledge gaps.

1.1 Scope and Aim

As was presented in the previous section, there are a variety of products on the market containing nanomaterials, for example consumer products such as cosmetics, household appliances and food contact materials. It can be established that there is a consumer exposure, also including exposure of children. There is, however, a large degree of uncertainty as to which extent and to which nanomaterials. Authorities responsible for protection of human health and the environment have very limited means to identify the nanomaterials found on the market, and the kinds of products containing these. One way to work towards gaining such knowledge is to target current development activities, in order to identify what might become available on the market. Such an approach would also facilitate the identification of current and future research needs regarding potential risks to health and the environment.

The overall aim of this project is to map research and development activities regarding nanotechnology and nanomaterials in Sweden and to identify emerging uses and potential exposures to nanomaterials. For the purpose of this report a number of different methods have been used for the identification of companies, universities and research institutes. This report encompasses a bibliometric analysis, an overview of recent research funding and a questionnaire study targeted to nanotechnological research and development companies. The different methods are presented briefly in the main body of this report and in detail for two of the analyses in appendices A and B.

2 Nanotechnologies and nanomaterials: the Swedish perspective

Nanotechnologies are not new areas of research in Sweden, for instance the Nanometer structure consortium in Lund founded in 1987 was among the first of its kind internationally. However, this early start has not been followed up from a policy perspective, as for instance Sweden still lacks an overarching national strategy for nanotechnologies. In comparison,

many of the other countries within the EU and the OECD have established a nanotechnology policy several years ago. In 2007, the Swedish Governmental Agency for Innovation Systems, Vinnova, described the Swedish nanotechnology innovation system and the potential for creating nanotechnology innovations (Vinnova 2007). It was concluded that Sweden had a potential to become an internationally leading country on nanotechnological research. However, at the time the efforts within academia, research financing and risk capitalists were scattered which presented an obstacle to the realisation of that potential. This report also mentioned the problem with legitimacy for the technology due to a lack of knowledge of environmental and health risks. The report expressed a concern that uncertainty concerning the effects has led to a negative attitude towards nanotechnologies. The debate at the time mentioned the negative effects that nanoparticles could have. But the diversity of innovations in the field and the different properties depending on size, material and structure makes a general risk analysis difficult. Therefore the authors called for “a genuine risk debate” in parallel to technological development. Since the uncertainty is considered to be an obstacle to the creation of innovations legitimacy is needed for long-term economic growth.

In 2009, Vinnova, was assigned by the Swedish Government with the task to, in consultation with the Swedish Research Council (VR) and after consulting the Swedish Research Council for Environment, Agricultural Sciences and Spatial Planning (Formas) and the Swedish Chemicals Agency (KemI), develop a proposal for a Swedish national strategy for the nanotechnology area. Nanoscience and nanotechnologies were identified as a potential growth area for Swedish industry with the opportunity to benefit society not only with increased industrial competitiveness and job creation, but also in the area’s potential to improve life quality and contribute to a cleaner environment. The strategy emphasised “that nanotechnology affects many areas and that it is not desirable to coordinate all aspects under a single ‘nano policy’ ”. No national strategy has so far been developed.

Also in 2009, KemI was assigned the task to perform an analysis of the need for regulation or other measures within the EU in order to achieve a good evaluation of risks to the environment and health posed by nanomaterials. The results from this analysis include a number of recommended measures (KemI 2010), of which the first recommendation was to work towards an internationally accepted definition. In order to increase the knowledge of nanomaterials on the market, an EU mandatory notification system for products containing nanomaterials was suggested. In order to identify the potential effects on environment and health from nanomaterials further work on the development of test methods as well as increased funding to such research activities was recommended. A regulatory review of the REACH and Classification, Labelling and Packaging (CLP) regulations was also identified.

Previous surveys by KemI has covered the use and occurrence of nanomaterial containing products in Sweden (KemI 2009a) and an inventory of which measures that have been taken in order to identify and assess risks associated with nanomaterials (KemI 2009b). In 2007, an overview of available knowledge concerning nanomaterials and risks to health and environment was compiled identifying knowledge gaps and developing suggestions on how to target these (KemI 2007). The use of nanomaterials falls under the jurisdiction of several Swedish regulatory authorities, a short overview of 17 Swedish Agencies’ activities on nanomaterials is given in KemI (2012). Swedish funding activities, both from governmental agencies and a selected number of private research funders are described in section 7 of this report.

3 Nanotechnologies and nanomaterials: an international perspective

In the following sections research strategies within the European Union, and activities within the ISO/TC229 group and the OECD will be briefly described since their activities have a substantial influence on Swedish activities. European activities up to 2009 have been summarised in a previous report from KemI (2010). As the main objective of this report is to cover research activities, section 2.1 will thus focus on EU level research funding and more recent EU funding strategies. A more broad international perspective is also available in a recent report on developments and activities in a number of countries and organisations (OECD 2011a).

3.1 The European Union research funding and strategies

The 7th framework programme for research and technological development (FP7) has a total budget of €50 billion and is an important source of funding for nanotechnologies and nanomaterials related research. The FP7 started in 2007 and will continue until 2013. The research that is and will be funded by FP7 will be carried out within ten different themes, one of which is the theme *Nanotechnologies, Materials and Production Technologies* (NMP). This programme is targeted at developing knowledge for new products, processes and services and to strengthen the competitiveness of European Industry. It is also stated that this theme aims towards creating conditions for innovation while meeting safety and environmental requirements. Over the duration of FP7 the NMP theme has a budget of €3.5 billion. The European expert advisory group NMP published a position paper on future research and technology development for 2010-2015 (NMP EAG 2009). It emphasises the importance of the area for Europe's economic growth, job creation and also the potential solutions to major challenges that it can bring. However, it is also concluded that the true potential has not yet been exploited. The expert group identified investments to be appropriate and competitive to those of other industrial countries but the scale should be maintained and concentrated on areas of particular strength. Nonetheless, future investments were estimated to become lower than those in Asia and North America. Regarding research on environmental, health and safety risks, the US annual investments were found to be three times the size of EU investments in the field during the years 2008 to 2010. One priority issue identified by the expert advisory group was therefore to maintain or increase investments in risk research in order to secure a competitive role for the EU when it comes to global regulations. It is also pointed out that public acceptance is a prerequisite for an "economically viable nanotechnology industry". As consumer confidence and public acceptance can be established when accurate information is available it is important for governments to sponsor independent research. Gaining knowledge at an early stage of the development process would be beneficial also for industry (NMP EAG 2009).

The NMP advisory group has also performed an analysis of the research needs on environmental, health and safety risks. Research priorities should be given to five areas; *Instrumentation, Metrology and Analytical Methods* which incorporates for instance creating methods for identifying and measuring parameters and creating databases for the characterisation of nanomaterials. The goal of *Nanomaterials and Health* is to understand nanomaterials in relation to the biological system, *Nanomaterials and the Environment* with focus on the effects on species and the ecosystem, *Human and Environmental Exposure Assessment* focuses on development of methods to detect nanomaterials in biological

matrices, the environment and workplace should be emphasised, and finally, developing *Risk Management Methods* in order to identify and handle risks(NMP EAG 2009).

Research applications and the safety of nanomaterials are not limited to the NMP theme of FP7. An initiative to collect projects related to nanomaterials safety is the *European NanosafetyCluster* (www.nanosafetycluster.eu, 2012-05-14). The objective of this cluster is to collect nanosafety related research in order to create possibilities for synergies and also avoid duplication of research efforts. This cluster is comprised of completed and ongoing projects that are funded within the NMP theme as well as other programmes under FP7 and FP6.

The ERA-NET collaboration was introduced under FP6, and was a separate framework for increasing collaboration between national and regional funding partners. Under the ERA-NET scheme, national and regional authorities identify research programmes they wish to coordinate or collaborate in. The Micro and Nano Technologies ERA-NET (MNT ERA-NET) was launched under FP6 in 2004 and continued its activities under the FP7 until 2011. The objective has been to support research and development in micro and nano technologies that are close to market. (www.mnt-era.net/MNT/, 2012-05-14). The ERA-NET Materials (MATERA) is targeted at materials science and engineering in Europe, and several projects concerning nanostructured materials have received funding (www.tekes.fi/info/matera/, 2011-11-05).

EuroNanoMed is a network aimed at developing applications of nanomedicine and has up to date had two calls for research projects (www.euronanomed.net/, 2012-05-14,). The Scientific Knowledge for Environmental Protection (SKEP) collaboration is aimed at improving the European capability of environmental protection. Although not specifically targeted towards nanotechnologies, the SKEP ERA-NET third call's theme was the challenges and opportunities of emerging technologies for environmental regulation, under which a nanomaterials oriented project was funded. The SKEP network is since June 2009 a completely self-funded network (i.e. no longer under a FP), and a fourth call, possibly concerning better regulations is being discussed (www.skep-network.eu, 2012-05-14).

In order to support the OECD sponsorship programme on the Testing on Manufactured Nanomaterials, the European Commission's Joint Research Centre (JRC) has launched a nanomaterials repository (see below). In connection to this repository, a database for hosting and managing information on nanomaterials relevant for risk assessment, was developed and launched in 2009. This database is compatible with the database used for REACH registration IUCLID (www.nanohub.eu, 2012-05-14).

3.2 Activities within the International Organization for Standardization (ISO)

The International Organization for Standardization (ISO) develops and publishes international standards. It is a non-governmental organisation consisting of the national standards institutes of 162 countries (www.iso.org, 2012-05-14). Within the ISO, the subcommittee technical committee on nanotechnologies (TC 229) was established in 2005 to work with standardisation in the field of nanotechnologies. Specifically the objective of TC 229 is to develop standards for:

- Terminology and nomenclature
- Metrology and instrumentation

- Specifications for reference materials; test methodologies
- Modelling and simulations
- Science-based health, safety, and environmental practices.

Up to date the subcommittee has published 16 standards, including terminology and definitions of nanotechnology related terms (see the section on definitions) and technical reports on how to classify nanomaterials, characterisation in different contexts as well as how to perform risk evaluations. More information can be found on the ISO website which has a section dedicated to nanotechnologies (www.iso.org/iso/hot_topics_nanotechnology, 2012-05-14).

3.3 Activities within the Organisation for Economic Co-operation and Development (OECD)

The Organisation for Economic Co-operation and Development (OECD) is an organisation of 34 member states from the industrialised world. The objective of this organisation is to “improve the economic and social well-being of people around the world” (www.oecd.org, 2012-05-14). Two working parties are assigned to the issues of nanotechnologies and nanomaterials.

Working Party on Manufactured Nanomaterials (WPMN)

The OECD Chemicals Committee Working Party on Manufactured Nanomaterials (WPMN) was established in 2006, as a subsidiary group to the OECD Chemicals Committee. The WPMN is working on international co-operation in health-related and environmental safety-related aspects of manufactured nanomaterials. Towards this aim the WPMN performs projects such as:

- OECD Database on Manufactured Nanomaterials to Inform and Analyse Environmental, and Human Health and Safety Research Activities
- Safety Testing of a Representative Set of Manufactured Nanomaterials
- Manufactured Nanomaterials and Test Guidelines
- Co-operation on Voluntary Schemes and Regulatory Programmes
- Co-operation on Risk Assessment
- The role of Alternative Methods in Nanotoxicology
- Exposure Measurement and Exposure Mitigation
- Environmentally Sustainable Use of Manufactured Nanomaterials

Within these projects up to date 28 different reports have been published in the series *Safety of Manufactured Nanomaterials*. Of specific interest is the Sponsorship Programme on the Testing on Manufactured Nanomaterials which was launched by the WPMN in 2007, the objective of the programme is to gather expertise and to fund the safety testing of specific manufactured nanomaterials. The nanomaterials tested, sponsors and contributors within this sponsorship programme are listed in Appendix C. More information about the work of the WPMN, as well as the OECD’s publications regarding safety issues of nanomaterials, are available at www.oecd.org/env/nanosafety.

OECD Working Party on Nanotechnology

The OECD also established a Working Party on Nanotechnology (WPN) in 2007 to advise upon emerging policy issues on science, technology and innovation related to the responsible development of nanotechnologies. It is a subsidiary group of the Committee for Scientific and

Technological Policy. The WPN activities have so far resulted in a number of workshops, round tables and the following reports:

- Fostering Nanotechnology to Address Global Challenges: Water (2011)
- The Impacts of Nanotechnology on Companies: Policy Insights from Case Studies (2010)
- Nanotechnology: An Overview Based on Indicators and Statistics (STI Working Paper 2009/7)
- Inventory of National Science, Technology and Innovation Policies for Nanotechnology 2008

The reports are available on the Internet (www.oecd.org)

4 Definitions of nanomaterials for the purpose of this report

The terms nanomaterial and nanotechnology/ies have been widely used, up until recently there have been no officially recognised definitions of nanotechnologies and nanomaterials. A very recent recommendation of a definition of the term nanomaterial was published in October 2011 by the European Commission. As a result of the previous lack of such an EU level definition different EU regulations have presented different definitions for the purpose of their implementation. For further discussions of definitions for regulatory purposes see e.g. Lidén (2011), Malkiewicz et al. (2011) and the JRC reference report by Lövestam et al. (2010).

When this project started the Commission definition (EC 2011) had not been published and thus a tentative definition of nanomaterials was suggested for the purpose of this work:

- Intentionally manufactured nanomaterials or nanostructures
- Usually at least one, inner or outer, dimension below 100 nm
- The nano-dimension gives rise to new properties compared with the substances' bulk form or single molecules of the substance.

The sole purpose of this definition was to act as guidance for the responding companies (section 8), and is by no means a regulatory definition, nor an opinion regarding the development of such.

The tentative definition draws upon suggestions and definitions from other organisations that were available at the start of this project. A summary of these, as well as the Commission definition are given in Appendix D.

5 Areas of research

As has been previously mentioned, there are many areas of research that have branches into nanotechnologies. A bibliometric analysis aimed at understanding and tracking the evolution of scientific disciplines identified 32 research areas within the category of nanoscience and materials through a co-citation analysis (Igami & Saka 2007). Nanoscience is an overarching term that includes nanotechnologies as well as basic research of phenomena at the nanoscale. A report from the European Commission Research Directorate published in 2006 identified four major subareas: *nanomaterials*, *nanoelectronics*, *nanobiotechnology* and *nanotools* (Hullmann 2006). The European Patent Office uses a division of nine sub-categories when

classifying nanotechnology patents: *nanobiotechnology or nano-medicine, nanotechnology of information processing, storage and transmission, nanotechnology for interacting, sensing or actuating, nano-optics, nano-magnetism, nanotechnology for materials and surface science, methods or apparatus for measurement or analysis of nanostructures, manufacture or treatment of nanostructures, and subject matter not provided for in other groups* (EPO 2011). A report from the OECD also lists six different subfields to nanotechnology: *electronics, optoelectronics, medicine and biotechnology, measurements and manufacturing, nanomaterials and environment and energy* (Igami & Okazaki 2007). As is suggested by the above presented category titles, these are not concordant between the different actors. These divisions of the nanotechnologies should thus not be seen as exhaustive lists, nor as fixed as there are many interactions between these areas in the currently performed research.

For the purpose of this report, mainly sections 7 and 8, nanotechnologies and nanomaterials research have been divided into three different categories depending on the purpose of the research activities rather than the scientific branch. The first is research aimed towards *applications of nanotechnologies or nanomaterials*. The second is *basic research* that is aimed at the understanding of phenomena at the nanoscale without the outspoken purpose of finding a certain function of application. The third is *risk research and Ethical, legal and social aspects of nanotechnologies and nanomaterials (ELSA)*, which also is the main topic of section 9. Risk research is a combination of nano(eco)toxicology, concerning effects on both human health and the environment, and measurements for the purpose of e.g. exposure assessments or the development of measurement methods for such purposes. ELSA has a wider scope than solely (eco)toxicological risks, although an obvious ethical and regulatory concern is the protection of health and the environment. To exemplify, ELSA also concerns the applications and uses of nanotechnologies, as well as the fairness of distribution of benefits harvested from nanotechnological advances. Risk research and ELSA were combined into one category, rather than kept apart due to the fact that not much of Swedish research covered by this report concerns ELSA.

6 Academic publishing within the field of nanomaterials in Sweden

In order to get an overview of Swedish research related to nanomaterials a search on *Web of Science* was performed. The search terms used were the same as in Linkov et al (2009) (see also box 1) and will in the following sections be referred to as the *nano search string*. In contrast to the methodology in the Linkov et al. (2009) the search was not limited to articles only, also proceedings papers and conference abstracts were included. This search string could underestimate the number of publications, as not all kinds of nanomaterials might be identified by these search terms. However, identifying all kinds of nanomaterials in all available publications would require a different search method involving a time-consuming close reading of a large number of publications. The current method is judged to sufficiently approximate the number of publications and allows for a comparison between different actors. The records yielded by the nano search string were further analysed using the filter functions in Web of Science and also by adding “risk” to the nano search string. Again, simply adding risk to the search string probably underestimates the number of available publications. The numbers presented in the following sections should therefore be seen as indicative of the amounts and proportions, rather than the exact amount of published research. The decision to use Web of Science rather than any other scientific indexing service was based on its broad

Box 1 The nano search string

Search string for identification of nanotechnology related scientific publications, as also used in Linkov et al. (2009)

quantum dot OR nanostruc* OR nanopartic* OR nanotub* OR fulleren* OR nanomaterial* OR nanofib* OR nanotech* OR nanocryst* OR nanocomposit* OR nanohorn* OR nanowir* OR nanobel* OR nanopor* OR dendrimer* OR nanolith* OR nanoimp* OR nanoimp* OR dip-pen

scope. Since it comprises several separate indexing services within the natural sciences, social sciences as well as arts and humanities, it covers a wide range of scientific fields. The filter options provided by this Web of Science also allow identification of funding agency, national affiliation and scientific area.

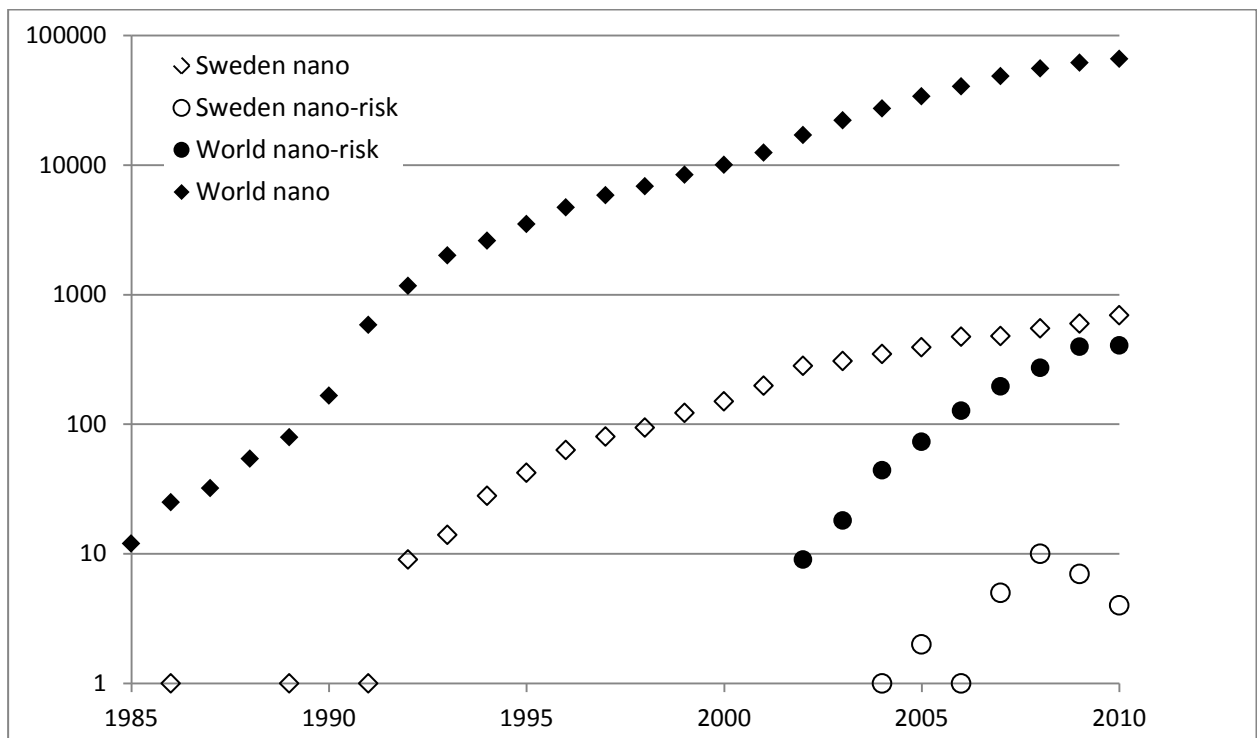


Figure 1 Nanomaterial publications per year between 1985 and 2010. Note that the scale on the y-axis is logarithmic. Sweden: one or more authors have stated a Swedish affiliation, nano: publications returned by the nano search string (see box 1), nano-risk: publications returned by the nano search string AND risk.

Table 2 The top five countries, measured in number of papers with one or several authors affiliated in that country.

Nano publications (all)	Nano risk publications
1. USA	1. USA
2. Peoples Republic of China	2. Germany
3. Japan	3. Peoples Republic of China
4. Germany	4. United Kingdom
5. South Korea	5. Switzerland
33. Sweden	19. Sweden

6.1 Nanomaterials world-wide: trends and topics

Entering the nano search string in the “topic” field yielded 476 093 records of which 418 858 are articles, 67 473 proceedings papers and 15 811 meeting abstracts. Of these 5 447 records had one or several authors affiliated to a Swedish university, research institute or company (5 017 articles, 789 proceeding paper, 165 reviews). As can be seen in figure 1 the publication rate for papers on nanomaterials has increased much during the last 25 years. Swedish researchers have published research papers in the nanotechnology field since 1986, and currently nearly one thousand publications per year have one or several authors with a Swedish affiliation (figure 1). According to this bibliometric analysis USA is the most active country within the field of nanotechnology, followed by China and Japan (table 2). The most prolific universities in Sweden are listed in table 3

Table 3 Most published Swedish universities.

Lund University (including the Hospital University and Faculty of Engineering)
Chalmers University of Technology
Royal Institute of Technology
Uppsala University (incl the Hospital University and Ångström Laboratory)
Linköping University
Göteborg University

The most common subject categories as defined by Web of Science are listed in table 4. Nanotechnologies and nanomaterials are of a multidisciplinary nature. More publications are sorted under branches of material science, physics and chemistry than the category specifically concerning nanoscience and nanotechnology. The comparison of the rankings presented in table 5 might indicate that Swedish research has been proportionally somewhat more focused on physics. The most notable difference in ranking is that a somewhat larger proportion of Swedish publications fall within the category of atomic, molecular, chemical physics, since this category ranked seventh of Swedish publications and eleventh world-wide.

Table 4 The top ten subject categories (as defined by web of science) measured in number of nanotechnology publications world-wide. Numbers in parentheses indicate the ranking based on Swedish publications.

1. Materials Science multidisciplinary (1)	6. Nanoscience and nanotechnology (5)
2. Applied Physics (2)	7. Polymer science (9)
3. Physical Chemistry (3)	8. Electrical electronic engineering (10)
4. Chemistry multidisciplinary (6)	9. Multidisciplinary physics (8)
5. Condensed matter physics (4)	10. Optics (11)

6.2 Nano-risk publications

In figure 1 also the number of publications returned by a search on the nano search string AND risk are plotted. These nano-risk publications are significantly fewer in number (n=1935) than the total amount of nanomaterial publications, and the first nano-risk publications also came several years later than the first nanomaterial publications. It should be noted that the Y-axis in this figure is logarithmic, at first sight it might be easy to underestimate the differences in number of publications. The nano-risk publications constitute less than 1 % of the total number of nanomaterial publications worldwide (0.05% in 2002 and 0.61% in 2010).

A very small number of nano(eco)toxicology or ELSA publications with at least one Swedish author were found through this analysis. In total, some 40 publications were identified, including non-article publications such as conference abstracts using the nano search string AND risk. Some of these publications concerned ultrafine particles or air pollution, in total 34 Swedish researchers were identified as active within risk related research on engineered nanoparticles. In order to get a more comprehensive overview of the Swedish publications in the area of nano(eco)toxicology and ELSA a follow up analysis using these authors was performed. A snowball approach using the Web of Science Database was applied, which means that searching for all articles by each identified author, and from that filter out articles that concerned aspects of nano-risks. This procedure was repeated for each identified Swedish co-author of the papers. This resulted in some 70 published articles treating risks of engineered nanomaterials and having one or several authors with a Swedish affiliation. The most prolific Swedish university in this category is the Karolinska Institute. As the area of nanotoxicology has its origin in research on ultrafine particles (Oberdörster et al 2005) the same procedure was performed on the authors of articles on ultrafine particles. These amount to approximately the double number of papers, with Lund University as the most prolific. The areas of research presented in these publications have been compiled together with the results from the financing analysis (section 7) in section 9.

7 Financing of nanotechnology and nanomaterials research in Sweden

Two larger Swedish research programmes have been launched in Sweden aimed solely at nanotechnology research, *Nano-X* which was funded by the Swedish Foundation for Strategic Research (SSF) and *Green Nano* which was funded by Vinnova. The Nano-X programme had a total budget of SEK 80 million between the years 2006 and 2010 and funded five different programmes by SEK 12.5-15 million each. All Nano-X projects concerned the research area of materials science. The purpose of Green Nano, launched in 2008, is aimed at innovative nanotechnology applications which should reduce the environmental load. Five projects of two to five years each were awarded SEK 37.5 million for the development of lighting technology, solar energy harvesting, fuel cells and nanostructured cellulose. The programme *Designed Materials Including Nanomaterials-Industrialisation* is also funded by Vinnova and has in 2009 awarded some SEK 26 million to 15 different projects ranging from

Box 2. Abbreviations used for the funding agencies presented in figures 2 and 3

FAS: Swedish Council for Working Life and Social Research

FORMAS: Swedish Research Council for Environment, Agricultural Sciences and Spatial Planning

KAW: Knut and Alice Wallenberg Foundation

KVA: Royal Swedish Academy of Sciences

MISTRA: The Foundation for strategic environmental research

NIC: Nordic Innovation Center

NMP: Nanotechnologies, Materials and Production Technologies

SEA: Swedish Energy Agency

SSF: Swedish Foundation for Strategic Research

STINT: Swedish Foundation for International Cooperation in Research and Higher Education

Vinnova: Swedish Governmental Agency for Innovation Systems

VR: Swedish Research Council

materials for use in infrared cameras to antibacterial prosthetics and solar cells. No similar calls have been made for research aimed at investigating risks to health and the environment or ELSA.

Previous overviews of nanotechnologies related research funding have been presented by Vinnova (2007) and Vinnova (2010). According to Vinnova 2007 the investment in nanotechnologies research in 2005 amounted to at least SEK 234 million. This number only includes four major Swedish foundations and EU FP6. Vinnova (2010) presented a somewhat more detailed analysis of public research funding and estimated the amount of funding from public financiers in the year 2008 to be approximately SEK 280 million (see also appendix A). The amount of funding from the same agencies as presented in Vinnova (2010) amounted in 2010 to SEK 374.5 million. The ranking in amount of funding has stayed the same between the years, with the Swedish Research Council (VR) as the largest funding agency followed by the SSF and Vinnova. The other identified funding agencies all give substantially less to nanotechnologies research than these three (figure 2). The overview presented in figure 2 also includes private research funding and the total amount for all nanotechnologies research funding that has been identified amounts to SEK 411.6 million.

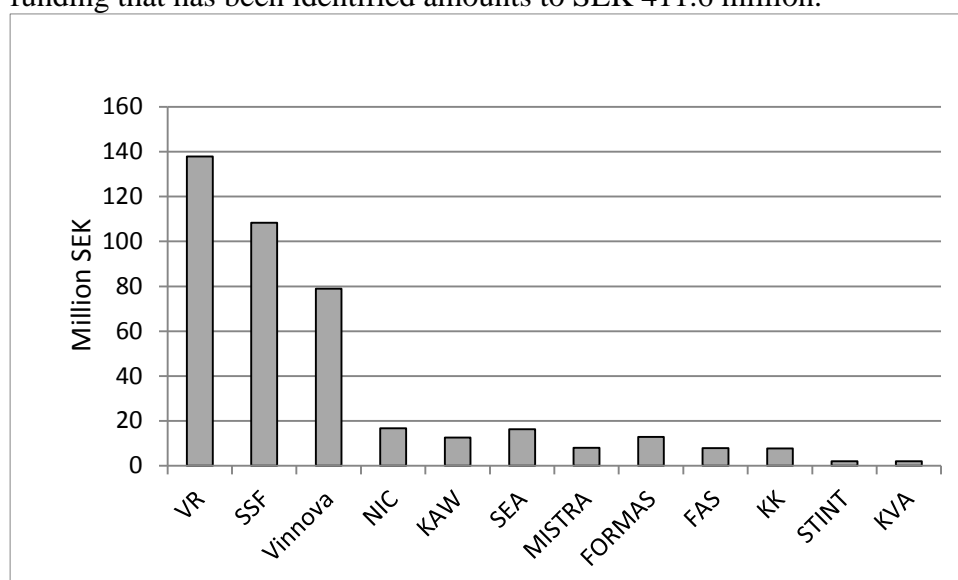


Figure 2 Total amount of funding to nanotechnologies related research during 2010 in million SEK. Abbreviations are explained in box 2.

For the purpose of this overview also private research foundations have been included, these have been identified through the bibliometric analysis. It should be noted that the Alice and Knut Wallenberg foundation (KAW) has provided extensive funding to nanotechnologies research in the form of grants for the procurement of research equipment and instruments. According to an estimate provided by the KAW the foundation has funded the purchase of equipment used in nanotechnologies research in Sweden with SEK 473 million in total.

Not surprisingly the largest part of the funding, 86% (SEK 354 million), was received by universities, 6% was received by research institutes (SEK 25 million) and 8% by companies (SEK 33 million). Of the funding awarded in 2010 the largest part was dedicated to research on applications or innovations of nanotechnologies, approximately 75%. In figure 3 the research on applications and innovations has been clumped together with basic research as it was often difficult to distinguish between these. Basic research is estimated to comprise 6 to 7%. Research on risks to the environment and health comprises projects such as exposure

assessment methodology, eco- and toxicological research. Only one project classified as ELSA was been identified and that concerns the innovation system of nanotechnologies and was funded by Vinnova. In total, only 4.5% of the research funding was given to projects concerning risks to environment and health, less than 0.1% was targeted to ELSA.

Table 5 The amount and kind of Swedish research funding in 2010.

	Share of funding 2010	Average per grant 2010 in million SEK	Average number of years per project (median)
Applications, innovations and basic research	76.7%	1.2	3.2 (3)
Infrastructure	18.7%	2.9	NA
Risks to environment and health and ELSA	4.5%	1.4	2.8 (3)

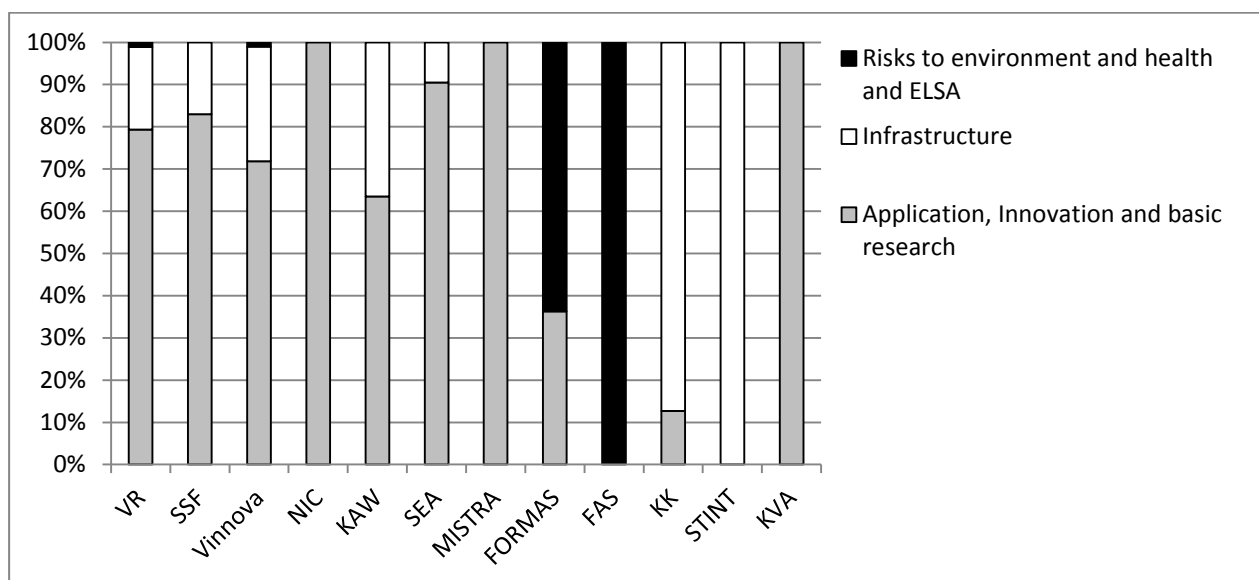


Figure 3 Division of funding in percent between research focused on risk to the environment and health or ELSA and basic research or research focused on nanotechnologies applications and innovations. Abbreviations are explained in box 2.

Almost 20 per cent of the total amount of funding was given to activities such as funding of networks, the organisation of workshops and equipment, which has been labelled as infrastructure. It should also be noted that the majority of the infrastructure funding is targeted at research groups working with applications and innovations. Average funding for the different areas of research and or infrastructure are presented in table 5. Figure 3 presents an overview of the proportions given to the different causes per funding agency. Only four funding agencies support any nanotoxicology or ELSA research, and only two of these in larger proportions, namely Formas and the Research Council for Working Life and Social research (FAS).

Chalmers and Lund University received the largest amounts of funding, and Lund University the largest amount of individual grants (figure 4). In the previous overview presented by Vinnova (2010) 15 universities, or 14 since Kalmar and Växjö have merged into Linné

University, received funding for nanotechnologies research during 2008. In this compilation of funding for 2010 the number of universities has increased to 19. However, the large amounts are still dedicated to the same Universities as in 2008, although the amounts has changed somewhat. Five of the universities received funding for nano(eco)toxicological research: Göteborg university (SEK 7.1 million), Lund University (SEK 6.5 million), Karolinska Institute (SEK 0.9 million), Royal Institute of Technology (SEK 0.8 million) and Luleå University of Technology (SEK8.2 million). More information about the research areas in these and other Swedish universities active in (eco)nanotoxicology or ELSA is given in section 9.

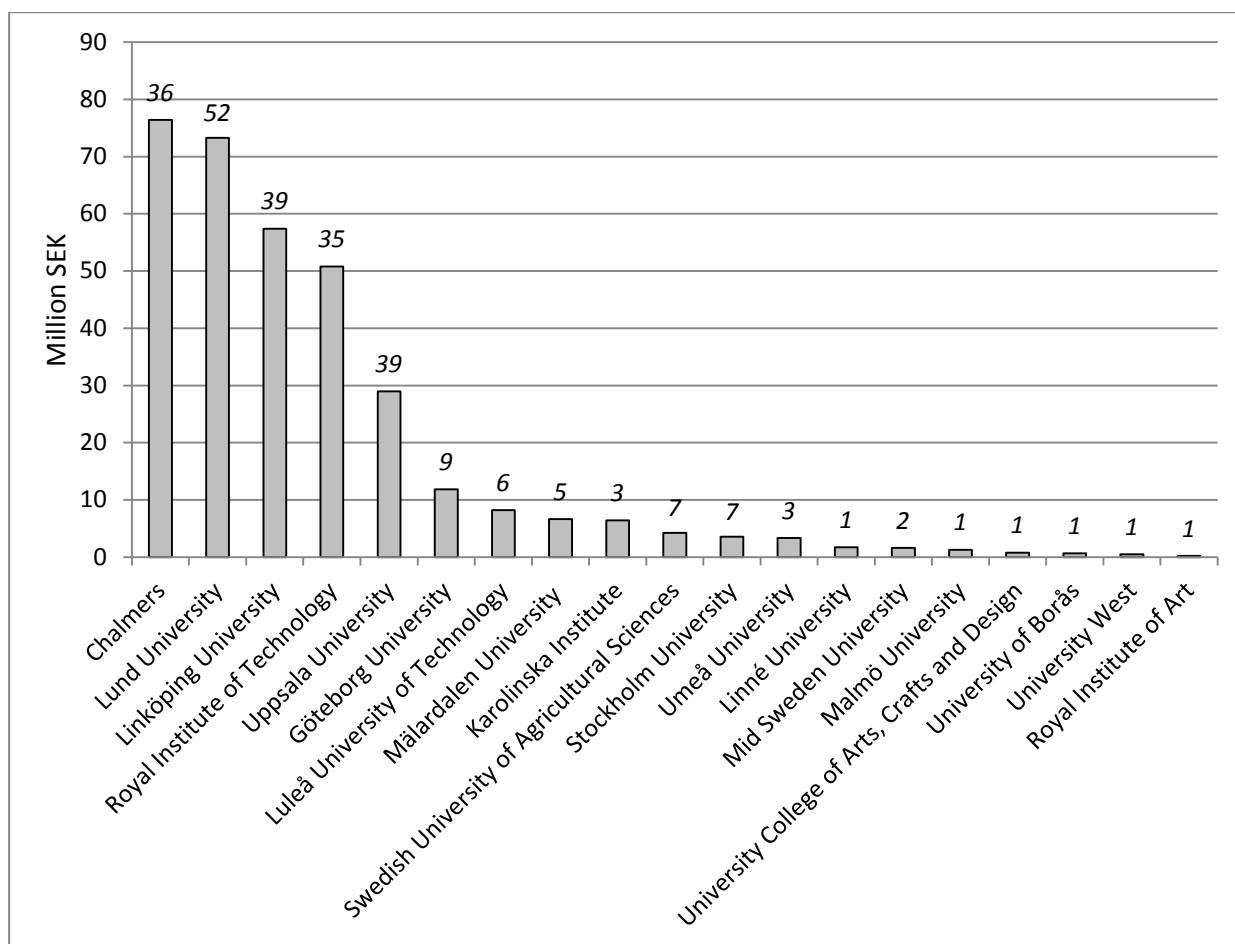


Figure 4 Amount of funding per university in 2010. The numbers above the bars indicate the number of grants the funding is distributed over.

7.1 Sixth and Seventh frame work programme

The bibliometric analysis (section 6) was also used to identify funding agencies of the published research, showing that the EU FP6 and FP7 are and have been very important sources of funding for Swedish research. As described in section 2.1 the FP 7 has specified a theme specific to nanotechnologies, NMP; which of course does not exclude that nanotechnologies or nanomaterials related research can be granted funding also within the other themes. Also under the FP6 there was a NMP priority, *Nanotechnology and nanosciences, knowledge-based multifunctional materials and new production processes and devices*. The budget set aside for this FP6 priority was, however, smaller than that under FP7, €1.4 billion versus €3.5 billion.

Table 6 Nanosafety projects under FP6 and FP7 including Swedish partners.

Project acronym and duration	Coordinating Institute	Swedish partners	Objective
Nanommune 2008-2011	Karolinska Institute	Uppsala University and Royal Institute of Technology	assess whether engineered nanomaterials interfere with the immune system
NanoSustain 2010-2013	Nordmiljö AB	Nanologica AB	develop new solutions for the sustainable design, use, re-use, recycling and final treatment and/or disposal nanomaterials
NanoValid 2010-2015	Nordmiljö AB	Nanologica AB	develop and validate new innovative methods for the life cycle impact assessment of engineered nanoparticles
MARINA 2011-2015	Institute of Occupational Medicine, UK	Karolinska Institute	develop reference methods for managing the risk of engineered nanoparticles and nanomaterials
Nanodevice 2009-2013	Finnish Institute of Occupational Health	Stockholm University and Lund University	develop methods for characterisation and measurement of airborne nanoparticles that can be used in workplaces.
Nanofate 2010-2014	Centre for Hydrology and Ecology, UK	Göteborg University	investigate the fate and effects of engineered nanoparticles in the environment.
QNano 2011-2014	University College Dublin, Ireland	Uppsala University	nanomaterial safety testing
NanoInteract 2007-2008	University College Dublin, Ireland	Lund University	understanding interactions between nanoparticles and organisms

Within each of these framework programmes some 20 projects are or have been coordinated by a Swedish institution. The number of projects that have Swedish partners has not been possible to identify through the Cordis project database for FP6. Within FP7 in total close to one hundred projects are funded with either a Swedish coordinator or partner. In terms of number of coordinated projects the Royal Institute of Technology has been the most successful Swedish Institute within both FP6 and FP7. This is, however, not necessarily indicative of the success in terms of funding. Under the FP6 the European Research Area Networks were also initiated of which two projects have been identified as especially relevant for Swedish research on nanotechnologies and nanomaterials. The ERA-NET initiative EuroNanoMed is aimed at developing applications of nanotechnologies to medicine and health. It comprises 24 partners from Europe and has up to date awarded €18.4 million to

research projects divided over two calls, one in 2009 and the second in 2010. In total, 16 projects are funded, four of which are coordinated by Swedish researchers. In the ERA-NET Scientific Knowledge for Environmental Protection, financed by FP6, one project, coordinated by KTH, concerning the applicability of the REACH regulation to nanomaterials has been funded (reported in Malkiewicz et al. 2011).

The *European Nanosafety Cluster* (www.nanosafetycluster.eu) has gathered over 30 nanosafety related projects that are funded within EU FP6 and FP7. Three of these projects are coordinated by Swedish researchers and an additional five have Swedish partners. Table 6 lists the Nanosafety projects including one or several Swedish partners. Unfortunately it has not been possible to quantify the amount of research funding to each Swedish actor within the time-frame of this report.

8 Industry research and development of nanotechnologies and nanomaterials

Companies were identified in a multistep procedure using *Appendix A* in Vinnova (2010) as a starting point. Additional companies were identified through searching for “nano” in company names, patent applications and on the webpage of the Swedish technology publication *Ny teknik* [New technologies], consulting the websites of Nano Connect Scandinavia and the conference Update 2011, searching for scientific publications on Web of Science and granted research funding. In total, 197 companies were identified as possibly active within nanotechnologies or nanomaterials research through these means, 117 of these through Vinnova (2010). It should be noted that the scope of this survey does not include the majority of the retail of consumer products as the target group was companies active within nanotechnologies or nanomaterials research and development. All 197 identified companies were asked to confirm research and development activities within nanotechnologies and fill in a questionnaire concerning these activities (see also appendix E)

The questionnaire covered the following topics:

- Background information about the company
- Confirmation regarding the company’s involvement in nanotechnological research
- Sector of research, if applicable.
- Use and nature of nanomaterials
- Nature of products, if any, on the market, level in value chain and sector

The reason for sending a questionnaire to companies is that information about their research activities is not as publicly available as can be expected by university research which focuses on academic publishing and sources of funding which publish information about research grants.

The companies were primarily contacted via e-mail, or through forms on their webpages if no suitable e-mail address was available. Thirtyfive companies did not have a webpage or a listed e-mail address. These companies were contacted by phone if a telephone number was available in order to retrieve an e-mail address. Four companies had merged with other companies included in the list, three are no longer active and one has moved its operations outside of Sweden, an additional 15 companies were not possible to reach by phone or e-mail.

In total, 176 companies were contacted, although it should be noted that due to the many different means of identification it was expected that not all of these would be within our target group of currently active. For instance the use of “nano” in company names does not necessarily refer to the nanoscale or nanotechnologies. In total 48 responses from companies within the target group were received. An additional 35 companies replied that they were not active within nanotechnologies or nanomaterials research and development. In some instances the company representatives reached through telephone confirmed nanotechnological activities but declined to answer the questionnaire due to shortage of time. Three companies replied that they could not find a suitable person to answer questions about potential nanotechnological activities. By consultation of the companies’ websites (when available) and the summaries of applications for research grants it was concluded that of the companies not responding at least 35 work with nanotechnologies and of these at least 28 work with nanomaterials according to the definition used for the purpose of this report. Information about year of registration, location, line of business and, when possible, type of nanomaterials was collected using Internet based sources of information and added to the analysis presented below. For more information see appendix B.

The excerpts of quotes presented in the following sections have been translated into English and modified to protect the confidentiality of the respondents.

8.1 The non-nano companies

Of the companies that did reply to our query 43% replied that they were not nanotechnology companies. A few of these companies replied that they were not using or researching on nanomaterials at the time, but were considering a future expansion to that area. A common theme was that the companies seemed to prefer to be described as belonging to the ‘conventional’ branches of natural science such as biology and chemistry rather than nanotechnologies subdivisions within these branches. One argument for identifying the company as active in e.g. biology rather than nanotechnology was that working in the nanoscale is not new to all scientific branches. Also, several companies replied that their major focus was on the micrometer scale, and that very little or no efforts were taken to bring the operations into the nanoscale. Nor did several companies working with optical measurement methods identify themselves as nanotechnology companies.

Of the 35 companies replying that they were not active in nanotechnologies 25 had previously been identified as nanotechnology companies by Vinnova (2010), only one of these specified that their previous line of research had been within a field of nanotechnologies. There were also other instances where a company was identified as active within nanotechnology through one or several steps in our identification procedure, but when contacted directly replied that they would not define themselves as active within nanotechnologies or nanomaterials research. This large proportion of different judgements regarding what constitutes nanotechnology is perhaps not surprising considering the historic lack of an accepted common definition.

When companies work together with university researchers or research institutes on development and innovation, it can also be difficult to draw the line on whether to label the company as active within nanotechnology or not. The companies were contacted with follow up questions, in order to clarify why they do not consider themselves to use nanotechnologies. However, most of these companies denied further participation in the survey. Many of the approached companies are small enterprises and, although unfortunate for the purpose of this report, it is understandable that their time and resources for this kind of requests are limited.

8.2 The nanotechnology companies

As was also shown in Vinnova's survey (2010), most nanotechnology companies are located in or near the large academic centers of nanotechnologies, Lund, Gothenburg or Stockholm/Uppsala. The companies are active within a large number of different sectors of which the most common are Life sciences and medicine (21), Electronics (18) and Energy and clean tech (18), see also figure 5.

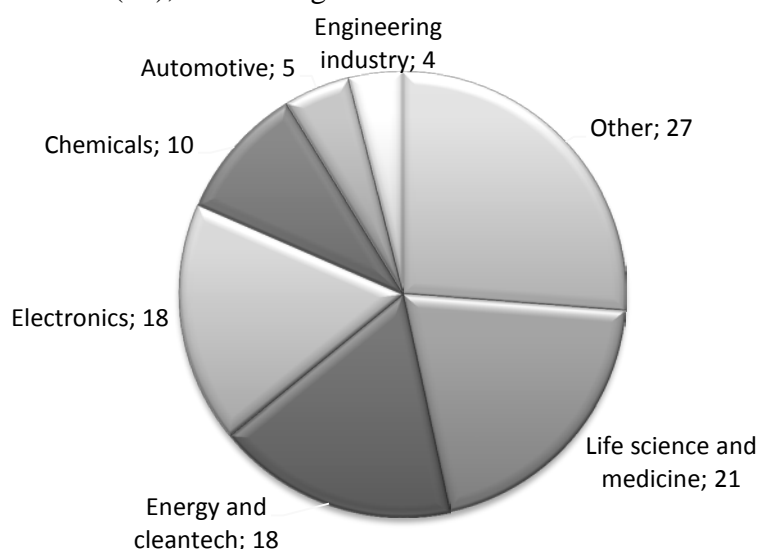


Figure 5 Sectors within which the 82 nanotechnology companies are active. Each company could select several sectors. Sectors to which only three or fewer companies belong are listed as "Other".

As can be seen in figure 6, the number of companies has increased steadily since the 1990s. Among the companies there are both those that had previous research and development on materials in the bulk scale and those that have taken their origin in nanotechnological applications. The earliest a company reported to have started with developing applications of nanomaterials was in 1979. Being a nanotechnology company does not necessarily mean that research and development utilises nanomaterials, however, 38 out of the 48 replying companies specified that they work with research and development of applications of nanomaterials. Only one company out of the 48 stated that they perform research regarding risks of nanomaterials.

Table 7 Size of nanotechnology companies, in number of employees

Number of employees	Number of companies
0	1
1-5	12
6-50	19
51-250	3
>250	13

A majority of the responding companies are small or medium sized, about one third is large companies (table 7). Of the companies larger than 250 employees, twelve have been founded before 1990, and only the one established later started research into nanomaterials the same year it was founded. Half of the companies working with nanomaterials started their research

and development activities on nanomaterials the same year as the company was founded. Of the companies that perform research and development activities on nanomaterials more than 60 % (23 companies) produce the nanomaterials themselves. Nanomaterials are also bought from five other Swedish producers and producers outside of Sweden; eight within the EU, seven outside of the EU).

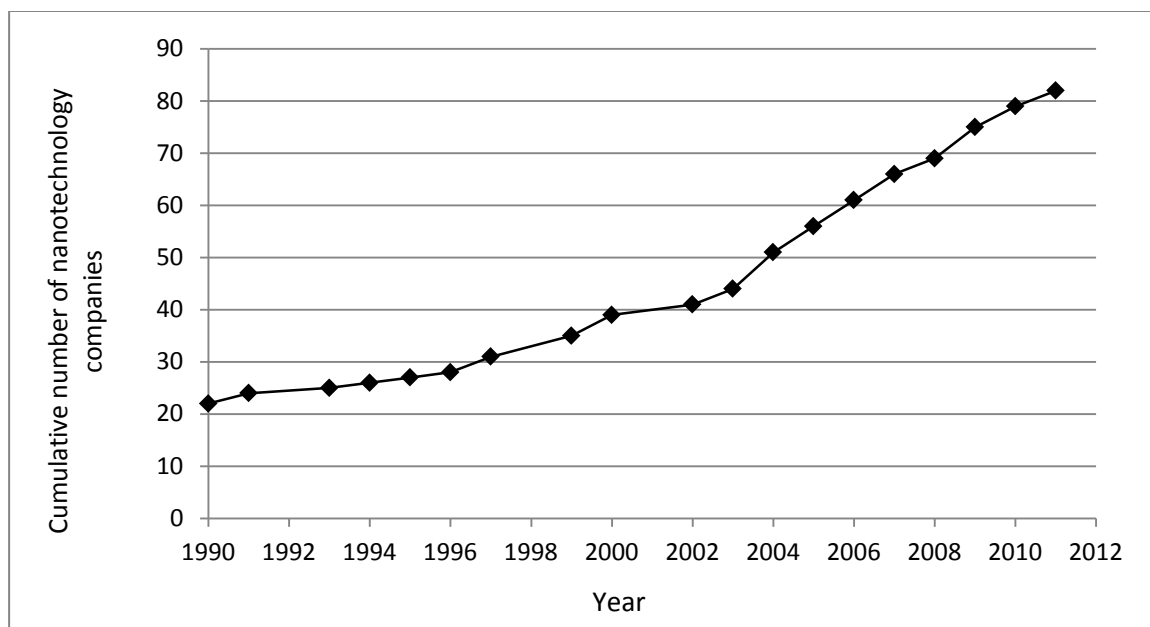


Figure 6 Cumulative number of nanotechnology companies in Sweden since 1990 (82 companies). Please observe that the earliest a company started research on nanomaterial applications is 1979, and only eight companies had started research and development activities on nanomaterials before 1990.

Table 8 overview of materials used, listed in ascending order depending on number of user companies.

Materials	Structures
Metals and metaloxides	17 Nanoparticles and chrystals 12
Carbon based	10 Thin film 12
Composites	7 Nanowires and nanotubes 6
Polymers and dendrimers	7 Nanofilters 2
Silica sol	2 Mesoporous materials 1
Nanoclay	1 Microfibrills 1
	Quantum dots 1

The companies could specify several different combinations of each.

Forty-two companies gave an estimate of how large proportion of their research budget that is targeted at activities on nanotechnologies or nanomaterials. Half of these companies (21) target less than 25% on research towards these areas, eleven companies target more than 75% of the budget. The nanomaterials used varied, the overview presented in table 8 gives some indication that metal, metal oxides and carbon based materials are most commonly used. It was also attempted to gain a similar overview of nanomaterials used by the non-responding companies through the reporting on their respective websites. The trend seems similar, metals and metal oxides are most commonly used, and the forms most often mentioned are nanoparticles, followed by thin films and nanowires and nanotubes. However, no specification of the amount of material has been collected, which could significantly alter the ranking in the table. Also, not all companies offered specific information about the kind of

nanomaterials they use, in some cases they explicitly stated that they were unable to do so. Several specified that they also use doped nanoparticles; i.e. intentionally adding other substances in controlled amounts in order to alter the properties of the nanoparticles. The respondents did not give further specifications of the nature of the doping.

Regarding risk assessment activities performed by the companies, 21 replied that they had performed some kind of safety evaluation of the nanomaterials they use. In most cases it has not been specified what was encompassed by such an evaluation. The specifications given of product safety evaluations were for pharmaceuticals and health products. One company specialises in research and consultant activities regarding risk assessment. Seven of the 21 companies specified that they follow routines for safe working conditions in the lab, or that the employees have been specially educated for lab work. Two of the companies answered that no safety evaluation had been performed, and 15 companies did not reply at all to this question.

Table 9 Do the companies produce or import products containing nanomaterials?

No	20
Components and materials for other industry or research	18
Consumer products	10
Equipment	7
Several product categories possible	

8.3 Products containing nanomaterials

A large proportion of the companies working with nanomaterials seem still to be in the development phase regarding the nanomaterial applications, as 20 companies have specified that they neither produce nor import products containing nanomaterials (table 9). It should be noted that not all of the 44 companies that replied to this question specified that they use nanomaterials. The 20 companies that produce consumer products, or components that are used in consumer products were also asked about the kind of product categories.

Some examples of specific uses of nanomaterials are to make materials and surfaces harder or stain resistant using e.g. nanoparticles of silica or carbon nanotubes. Light emitting diodes or solar panels can contain nanowires of metal oxides. Thin films of metals or metal oxides are commonly used in electronic applications and in solar panels, and in medical products (also polymer thin films). Besides pharmaceutical and medical applications developments of light emitting or light/energy harvesting techniques constitute the most common uses of nanomaterials. Such applications have been specified within several sectors, for example electronics, automotive, energy and clean technology. The development of light emitting diodes or electrochemical cells seems to be in a less mature state than that of solar panels as none of the development companies working with such applications produce consumer products or components for consumer products.

Table 10 Categories of consumer products containing nanomaterials

Electronics	6
Pharmaceuticals and health products	4
Products for the automotive sector	4
Products used in construction	2
Packaging	2
Office supplies	2
Solar panels	2
Paint and glue	2
Textiles	1
Tools	1
Sports articles	1
Foodstuffs and additives	1

The companies could specify several different categories, and as is shown in table 10 electronics and products for the automotive sector are the most common. The kinds of materials that were reported by the responding companies to be used in the three most common product categories are presented in table 11. This table is not to be considered exhaustive as an investigation into the websites of the 28 non-responding companies, also identified as nanomaterial users, specifies the use of a wider range of materials within these categories. For instance ceramic nanomaterials and nanoporous materials can be used as carriers of the active pharmaceutical ingredient in pharmaceutical and health products. Future developments are expected to broaden the range of nanomaterials found in consumer products. Respondents active within electronics, but not producing consumer products have also specified that they use e.g. carbon nanotubes.

Table 11 The kinds of nanomaterials found in the more common consumer product categories, as specified by the replying companies.

Material or structure	Product categories
Nanoparticles and nanocrystals	Automotive Electronics Pharmaceuticals and health
Nanoporous materials	Electronics
Nano filters	Automotive
Nanotubes	Automotive
Thin films	Electronics Pharmaceuticals and health
Nanocomposites	Automotive Pharmaceuticals and health
Carbon based	Automotive Electronics
Metals and metal oxides	Automotive Electronics
Polymers and dendrimers	Electronics Pharmaceuticals and health

This list should not be considered an exhaustive list of materials that are found in these product categories.

8.4 Why use nano?

The companies were also asked to give a short description of the specific advantages and benefits of using nanomaterials or nanotechnologies in their research and development activities. Nanomaterials and nanotechnologies might create opportunities for completely new applications, as well as improving the performance of materials or applications already used. As expected the new properties of nanoscaled materials as compared with the bulk material is an important benefit for research and development companies. Some of the comments exemplifying the new properties were “opens up new opportunities”, “physical benefits from surface effects”, “possible to create meta-materials”.

It is, however, not always the new properties in comparison with the bulk material that are the main focus of applications used by these companies. The nanoscale obviously allows miniaturisation of applications and processes, and is useful towards the aim of “as thin as possible”. Thus, in some instances it is the smallness rather than changed physico-chemical properties that is the major benefit; “no benefit from being nanotechnology in itself”.

Durability is a commonly mentioned benefit. By working in the nanoscale materials can become e.g lighter, smaller or keep transparency and still be more durable than previously used materials. Several also state cost efficiency to be an additional benefit, and according to one company the most prominent benefit. Not all of the companies have found useful and working applications yet, and some of these seem to be in a relatively early stage of research and development. Some of the companies have phrased the benefits in terms of potential benefits. Many of the offered explanations are given using terms as “could”, “might” and “can sometimes”. The survey also received comments indicating that specific benefits have not been found. In summary, the large variety of testimonies regarding the benefits on nanotechnologies and nanomaterials also emphasises that nanotechnology is not a separate branch of science and there are many different motivations for working in the nanoscale.

8.5 What are the needs of nanotechnology companies?

The final question of the questionnaire had the objective to allow the companies to comment on the use of nanomaterials, business conditions and how governmental agencies should work with such issues. Of the 48 responding companies 28 had chosen not to give any comment on this question. The comments have been structured into three different themes and subthemes, and are presented and illustrated by quotes.

The first theme was that the companies identified a *need for regulatory action*, and this need was not necessarily put in relation to the companies' needs; “products that reach the consumer market should not include new nanomaterials before health- and environmental effects have been investigated. Labelling, both voluntary and mandatory was suggested as a risk management, because “it should be clear if a product contains free nanoparticles”. Some of the suggestions made were less specific but relatively strict such as “agencies should demand a zero-risk”.

The second identified theme takes its origin in the needs of the companies, and more specifically the *need for information and support* concerning both issues related to risk management and business conditions in Sweden. Agencies are pointed out as having an “important role” in the establishment of safe use of nanomaterials. The lack of definitions and regulations are pointed out as problematic and “clear rules” are sought after, as well as are “well documented risks” and coherent information. The information from agencies should

also be “brief”, “accessible” and offered on a regular basis. An authority based “help desk which can answer to questions concerning risks of nanomaterials” is also requested. It was also mentioned that both financial and regulatory support is needed in order to promote innovation. Several point out that companies need less regulations, and that regulations should be “easy to follow”.

The third theme conveys some criticism towards how different stakeholders have used and defined the term nanomaterial. The criticism is aimed at the lack of proper and/or meaningful definitions, and identifies a tendency to *overemphasise the importance of size*. Respondents find that “nanotechnology is today often used very carelessly” and that a “twisted media hype” conveys “the image that it is a completely new field of research which is not the case”. It is also emphasised that the “substances used is not an issue, rather the safety of those substances” and “it should really be pretty obvious that size does not mean everything to the material’s properties, for example its toxicity”.

The three themes presented above could be divided into two different sets that convey almost the opposite messages. The first of these is the companies that ask for support from the governmental authorities, their comments are about the need for guidelines on how to perform risk assessment and risk management, but also the need for research activities that produce knowledge about risks and regulatory overviews. Much responsibility for the future safe use of nanomaterials is put on regulatory agencies, rather than on the actors that develop these materials. The other set of themes include rather critical opinions on the role of the governmental agencies and their past performances as well as criticism on the intentions of the governmental agencies. However, it should be noted that less than half of the respondents chose to comment and that this low response rate reduces the possibility to generalise these opinions. Why companies choose not to comment on this specific question could be due to a variety of widely separate reasons, such as the respondents being content with the current situation as well as perceiving it as without meaning to use this channel of information. As the question was the last on the questionnaire perhaps respondents chose to skip it for reasons of time-constraints. A few answers also indicated that the companies did not have any comments to this question because they did not consider themselves to be very affected by the actions of regulatory agencies.

9 Risk research in Sweden

As has been shown in the previous sections on available publications and research funding the amount of resources spent on risk research is considerably smaller than that spent on research into applications of nanomaterials. The word risk is in this section used as in risks to health and the environment. The research areas and projects briefly presented in this section were identified through the bibliometric analysis and the analysis of financing presented above. Additional data on finished and ongoing research projects have been collected from FAS, Formas, Mistra and the framework programmes FP6 and FP7 (including Swedish partners only). For FAS, Formas and Mistra the searches have been complemented by a search for projects concerning ultrafine particles (using the search phrase “ultrafin*”). In table 12 an overview is presented of Swedish actors and areas of research that can be of importance for nanomaterials risk research. References are foremost given to research project acronyms or registry numbers, through which these projects can be found on the granting agency’s webpage. As a considerable part of the risk research in Sweden is publicly funded, it is expected that information about finished research as well as ongoing research will be

Table 12 Swedish research related to nanotoxicology or ELSA. References to publications are only given if the area of research complements those covered by the identified research projects.

	Areas of research	Examples of projects and sources of funding*	Other notes
Universities			
Chalmers	Exposure modelling of nanoparticles in aquatic environments		Arvidsson et al., 2011
	Science based innovation, sustainability and social robustness of nanotechnologies	<ul style="list-style-type: none"> • Mistra Nanoroboust 	
	Methods to reduce exposure to ultrafine particles in indoor air	<ul style="list-style-type: none"> • FORMAS 2007-1583 	
Göteborg University	Methods for measurement of nanoparticles in the environment	<ul style="list-style-type: none"> ○ FORMAS 2009-1696 	
	Environmental toxicity testing of nanomaterials	<ul style="list-style-type: none"> ○ FORMAS 2010-921 ○ FORMAS 2009-1696 ○ FORMAS 2007-1562 	
	Exposure scenarios, e.g. for prioritisation purposes	<ul style="list-style-type: none"> ○ FORMAS 2009-1696 	
	Size-dependent surface adsorption on nanoparticles	<ul style="list-style-type: none"> ○ FORMAS 2010-748 	
	Size-dependent skin sensitisation properties of lipid vesicles		Simonsson et al., 2011
Karolinska Institute	Biological decomposition of carbon nanotubes	<ul style="list-style-type: none"> ○ FORMAS 2011-955 	
	Modelling of toxicokinetic properties of nanoparticles.	<ul style="list-style-type: none"> ○ FAS 2010-0702 	
	Effects of nanomaterials on human health: the immunesystem.	<ul style="list-style-type: none"> • Nanommune (FP7) • FAS 2007-0285 • FAS 2004-1363 	
	Effects of nanomaterials on lung cells.	<ul style="list-style-type: none"> • FORMAS 2006-626 	
	Traffic-related airpollution and respiratory effects in children and adolescents	<ul style="list-style-type: none"> ○ FORMAS 2010-701 	
<ul style="list-style-type: none"> • Research project completed ○ Research project still ongoing in October 2011 			

Linköping University Hospital	In vitro tests of pyrogenic potential of ambient ultrafine particles	Jayawardena U. et al., 2009
Lund University	Exposure to and health effects of nanoparticles and ultrafine particles	○ FAS 2009-1291 ● FAS 2006-0803
	Interaction nanoparticles and biological fluids: protein corona	● FORMAS 2008-597
	Sampling techniques and dose estimates for ultrafine particles	● FAS 2001-0194 ● FORMAS 2007-1223
	Characterisation of nanoparticles	● FORMAS 2008-1467 ● FORMAS 2006-938
Örebro University	Exposure assessments of ultrafine particles	○ FAS 2004-1122
Royal Institute of Technology	Ethics of nanotechnologies and science communication	● NanoBio-RAISE (FP6)
	Applicability of REACH to nanomaterials	● Nanomaterials on REACH (SKEP ERA-NET FP6)
Stockholm University	Effects of metal nanoparticles on lung cells.	○ FORMAS 2010-968
	Exposure assessments of ultrafine particles	○ FAS 2004-1122
Swedish University of Agricultural Sciences (SLU)	Analysis and health effects of particulate air pollution	● FORMAS 2007-984
Umeå University	Health effects of engineered metal oxide nanoparticles	● FORMAS 2008-1375
	Air pollution and cardiovascular disease	● Swedish Heart Lung Foundation Mills et al (2011)
Uppsala University	Neurotoxicity of metal nanoparticles	Sharma et al (2012)

● Research project completed

○ Research project still ongoing in October 2011

Research institutes

FOI Swedish Defence Research Agency	Health effects of engineered metal oxide nanoparticles	<ul style="list-style-type: none">○ FORMAS 2008-1375● FAS 2007-1520
SP Technical Research Institute of Sweden†	Characterisation of nanomaterials	<ul style="list-style-type: none">○ CO-NANOMET (FP7)

Trade and enterprise

Nord Miljö AB & Nanologica AB	Environmental hazard characterization and impact assessment	<ul style="list-style-type: none">○ NanoSustain (FP7)
Nord Miljö AB	Develop new reference methods for hazard identification and risk assessment	<ul style="list-style-type: none">○ NanoValid (FP7)

- Research project completed

- Research project still ongoing in October 2011

* More information about the research projects is available via the funders' websites:

www.fas.se, www.formas.se, cordis.europa.eu/fp7/projects_en.html,

cordis.europa.eu/fp6/projects.htm

†The research performed at SP has as a primary objective to support European industry

available through the funding agencies. This overview includes both risk research on engineered nanomaterials and unintentionally produced materials in the nanoscale. What has been labelled as risk research in this section is a rather diverse set of projects ranging from exposure measurements at work places to modelling of toxicokinetic properties and the development of criteria for the design of studies in order to make them more useful for risk assessment purposes. Research concerning ultrafine particles in air pollution has also been included in table 12, as it concerns the nanoscale although not intentionally engineered materials. Examples of ultrafine particles covered by the presented research projects are diesel exhaust, welding fumes, and soot from candles. Research on ELSA has been performed in the area of sustainable innovation, applied ethics and regulatory analyses.

The risk research covers a wide array of different kinds of engineered nanomaterials. The environmental risk research is mainly performed at Chalmers, Göteborg University and within the two FP7 programmes coordinated by NordMiljö AB (table 12). Göteborg University is also a partner in the FP7 project NanoFate (table 6). The nanomaterials that have been or are intended to be tested within these research programmes are nanoparticles of silver, gold, copper, palladium, titanium dioxide, cerium oxide, zinc oxide, copper oxide, silica, nanocellulose, single- and multi-walled carbon nanotubes and fullerenes.

A larger number of research projects focus on risks to human health compared to environmental research (tables 6 and 12). Much of this is however related to research on ultrafine particles. Examples of publications or research projects focusing on engineered particles have been found originating from Göteborg University, Karolinska Institute, Lund

University, Stockholm University, Swedish University of Agricultural Sciences, Umeå university, Uppsala University, and the Swedish Defence Research Agency. Nanomaterials that have been identified as either tested or intended to be tested are found among the metals, metal oxides, single- and multi-walled carbon nanotubes and polymers. Some more specific examples are copper oxide, titanium dioxide, iron oxides (Fe_2O_3 and Fe_3O_4), zinc oxide, cerium oxide, silica, polystyrene, poly N-isopropylacrylamide nanoparticles and mesoporous silica.

A comprehensive overview should also take into consideration the size distribution investigated as different properties also can be found within the range of the nanoscale. Also crystal structure has been shown to affect the properties of the nanomaterial, one example is that of TiO_2 , which generally occurs in several different polymorph types the most common of which is anatase and rutile. Studies from the Swedish Defence Research Agency have shown that even when size distribution is similar different TiO_2 polymorphs show very different uptake of kinetics and inflammatory response. This effect is caused by differences in agglomeration properties, e.g. the strength of the bonding within the agglomerates, growth direction and the resulting shape of the agglomerate (Andersson 2011).

10 Emerging uses and potential exposures

Economy and commerce is global, and emerging uses of nanomaterials in products need to be viewed from this perspective. The presented overview so far has identified ongoing development projects concerning e.g. energy storage and harvesting, light emitting device, electronics and façade coatings. Future products on the Swedish market will, however, not be limited to these areas. Nanotechnologies may, and with all certainty, be implemented in a broad scale of sectors and applications. It would be hard to identify sectors that most certainly will not be affected by nanotechnology developments within the coming decade. In the following two sections some areas of research and development will be described further and a brief overview of the available knowledge of exposure scenarios provided.

10.1 Emerging uses

Technological maturity varies between as well as within the different areas of nanotechnology. Efforts on mapping nanotechnological developments in Europe are ongoing, for instance within the EU FP7 funded project ObservatoryNano. The Scandinavian network Nano Connect is an initiative for strengthening cross-border cooperation on nanotechnology. Within this network efforts are amongst other things directed at connecting academia and industry, highlighting the potential of nanotechnologically enabled solutions (www.nano-connect.org, 2012-05-14). The network publishes information brochures providing an overview of the research group partners (NanoConnect 2011a), but also of specific areas of applications and potential nanotechnological solutions within these (NanoConnect 2011b;c;d). Up to date three brochures on applications have been published, for energy, life science and electronics and sensors. This section mainly draws on such previous efforts by the above mentioned actors (ObservatoryNano 2011a;b; NanoConnect 2011a;b;c;d), but also the consulting of webpages of Swedish research centres or networks mentioned below.

Thin films can have a variety of uses and forms the basis for a large range of nanomaterial applications. At Linköping University the FunMat Center (Functional Nanoscale Materials)

was established in 2007. This research and innovation center is jointly funded by Vinnova, Linköping University and industrial partners and focuses on surface engineering (thin film deposition). FunMat focuses on three fields of applications. First, high-temperature-stable materials for coating cutting tools, chemical and biological sensors, and new nanoscale materials. Second, electrical contacts for electronics and power transmission, and for gas and chemical sensors. The third area is low friction resilient surfaces. (www.liu.se/forskning/funmat, 2012-05-14)

There are many Swedish actors active within the area of nanomedicine, this was shown by the company survey presented in section 8 and another indication the Swedish Medical Nanoscience Center at Karolinska Institute which was formed in 2009. Up to date there are a few nanotechnology enabled products on the market within the area of nanomedicine, and some are currently undergoing clinical trials. Most potential applications are, however, still undergoing development. Nanotechnologies will provide future solutions to diagnostics, one example would be glowing or magnetic nanoparticles that attach to cancer cells and can be used to identify tumours. Home-pregnancy tests containing colloidal gold nanoparticles are on the market (e.g. testlagret.se, 2012-05-14). Current developments indicate that other home-diagnostic tests or simple and cheap multi-parameter tests will be enabled by nanotechnology applications. Tumour specific nanoparticles can be used to identify and diagnose, but also to treat. Targeted drug delivery is another application within the area of nanomedicine, dendrimers, liposomes and micelles are other structures in the nanoscale that can be used for this purpose. Within regenerative medicine nanotextured surfaces can improve the bonding between natural and artificial tissue. In addition prosthetics can be made lighter and more durable using for instance nanocomposite materials.

As seen in the company survey, a variety of nano-enabled energy applications are currently being pursued. Some applications are already on the market and many are under development. Solar cells and low energy light emitting diodes or electrochemical cells have already been mentioned in section 8. In addition, lightweight nanocomposites low friction coatings and nanolubricants are expected to reduce energy usage of e.g. vehicles. In construction nanoporous materials, aerogels, can be used for improved thermal insulation. Also for use in construction, and already available on the Swedish market are sealing tapes, for insulation, and surface sealing products, for reduced cleaning needs, containing (unspecified) nanoparticles (<http://byggkatalogen.byggjtjanst.se>, 2012-05-14). Nanomaterials such as carbon nanotubes and polymer nanocomposites also hold promises for replacing copper as the preferred material for energy transmission. Although still in the early research phase nanostructured electrodes are developed for use in batteries, the hope is to reduce charging life and improve battery life length.

Nano-enabled functional textiles is an area in which European research and development is strong. Nanotechnologies can enable lower weight, improved protection and also multifunctionality. Such features can improve the currently available protective clothing in many ways, thermo insulating properties will be enhanced at a lighter weight utilising titanium dioxide, silicon dioxide, nanoclays and aerogels. Research is also going on in novel functions such as protection from toxic chemicals by including nanoparticles of magnesium oxide, dendrimers or gold. Textiles that are stain resistant water repellants and/or with antimicrobial activity are already on the market. These properties are produced using for instance nanosilver, nano titanium dioxide, plasma nanocoatings. According to Som et al. (2011) nanoscaled silver, titanium dioxide, silica, zinc oxide, alumina, layered silica, carbon black and carbon nanotubes are currently used or being investigated for use in textiles.

Wearable smart textiles, such as clothing items with printed electronic circuits on them are still in the early research phases. In Sweden, the Smart Textiles center located at Borås University serves as an arena for collaboration between different partners from academia and industry (www.smarttextiles.se, 2012-05-14). Within Smart textiles both basic research and needs driven development activities are ongoing. Solutions under development that involve nanotechnological applications are lightweight electrically conductive fibres and nanofiber textiles for sound care products.

10.2 Potential exposures

As described in the previous section there are many potential uses of nanomaterials and accordingly a wide array of future products are imaginable, besides the current uses. The presented examples also show that most nanomaterials can be used in several product categories, fulfilling similar or different functions and purposes. The potential exposure patterns from these applications are thus difficult to predict. In addition, the exposure will not only depend on the product category, but on the specific uses, as the nano-enabled solutions probably also will extend the uses outside the traditional applications (such as geotextiles or future conceivable multifunctional textiles). In applications where the nanomaterials are embedded in the product (e.g. genome sequencing devices employing quantum dots attached to DNA polymerase molecules) human exposure will at use stage probably be of little significance. However, at the production stage occupational exposure could be expected, and potentially also environmental exposure. The waste stage is however expected to present the largest challenges for environmental exposure. Other product categories such as nano-enabled functional textiles could implicate exposures also for consumers, in addition to the occupational and environmental exposures.

In 2008 an effort of mapping use of nanomaterials in consumer products indicated that the presence of nanomaterials on the Swedish market was scarce, with the exceptions of carbon black and the area of electronics (KemI 2008). Inventories such as the Woodrow Wilson Initiative indicates that the by far most commonly used nanomaterial in consumer products is nanosilver. Considering the antibacterial function of silver it is hardly surprising that most products in this inventory also are found within health and fitness applications. Within this category one can find personal care products, clothing items, cosmetics and sporting goods. A majority of the products originate from the US. Also titanium dioxide has been pointed out as a nanomaterial that is widely used and might become increasingly so. According to an OECD overview of national information gathering schemes on nanomaterials titanium dioxide was the nanomaterial reported by most countries (seven out of eight responding countries) and companies/institutions (OECD 2011b). In the OECD survey the surveyed companies mostly report to use nanomaterials in quantities of less than 10 kg per year. Nanomaterials identified as used quantities above 1 000 kg per year by at least one company were titanium dioxide, carbon black, silicon dioxide, aluminum oxide, zinc oxide, iron oxide and cerium oxide.

Aschberger et al (2011) present estimates of environmental concentrations of fullerenes, multiwalled carbon nanotubes, nano-titanium dioxide, nano-zinc oxide and nano-silver. These nanomaterials were used as case studies in the EU FP7 funded project ENRHES which was finalised in 2009. The lack of available data necessitated the use of assumptions in the exposure modelling and thus considerable uncertainties adhere to the resulting estimates. Nevertheless, the results indicate that apart from surface water, also soils and sediments could be environmental compartments of concern due to the nanomaterials' accumulation.

Wear and tear differs between applications. Silica nanoparticles leaking from façade coatings through corrosive action of air pollution can be expected to significantly differ from silica nanoparticles leaking from textiles during washing and wearing. This could mean that even if the same kind of nanomaterial (same size, crystal structure or functionalisation is incorporated in two different products, the resulting wear and tear nanomaterials reaching the environment (or humans) will differ. Also ageing, agglomeration and aggregation change the nanomaterials' chemico-physical characteristics.

Different schemes aimed at gaining information about nanomaterials in consumer products have been launched. One example is the Voluntary Reporting Scheme developed by DEFRA in the United Kingdom. Such voluntary reporting schemes have proved insufficient, either due to failed reporting or incorrect reporting, Oomen et al (2011). A mandatory reporting scheme might thus be required in order to obtain an acceptable level of confidence. This is also one of the recommendations of KemI (2010). On the request of the DG Environment Wijnhofen et al (2010) have developed a methodology to identify consumer products containing nanomaterials. This method was also tested by developing a sample database, which is suggested as a potential basis for a future EU level database of consumer products containing nanomaterials. The authors also note that industry needs to play an active role in the work towards such an inventory, because industry alone can provide reliable data on nanomaterial presence in products. It was concluded that an inventory of products with only voluntary nano-claims would probably become limited in scope and thus be of limited use for assessing actual human and environmental exposure.

11 Discussion

Current understanding of the toxicity of nanomaterials, engineered or not, is severely limited as toxic properties of nanomaterials might differ from bulk materials depending on factors such as size, shape and surface area. The properties and risks of a nanomaterial thus also can differ substantially between different nanomaterials of the same chemical composition. These aspects add a new dimension to toxicological and ecotoxicological research regarding nanomaterials and how such studies should be used for risk assessment purposes. The research community has only just recently begun to address these issues, and many basic questions such as how to measure nanomaterial exposure and how to deliver the doses in controlled experiments are still not resolved. As has been previously mentioned, several recent reports identify and list knowledge gaps (SRU, 2011; Gustavsson et al. 2011; van Zijverden & Sips 2009; EU OSHA 2009; KemI 2007; 2010), such as lack of information on exposed populations, areas of application, possible toxicity and proper dose descriptors. Research on the toxicology of nanomaterials is thus critical for ensuring a safe handling. Nonetheless, repeated analyses of the distribution of research funding, including the one presented in this report, have shown that only a very small part, usually around 5 per cent, is directed towards research on ELSA and risks to health and the environment, and that the majority goes to research on applications of nanotechnologies and nanomaterials.

One of the objectives of this report was to get an overview of research and development activities in Swedish companies, and to have information on whether risk assessment activities are included in these companies' work. It seems as somewhat more than half of the companies working with nanomaterials have performed some kind of risk assessment or safety evaluation, although the specifications offered in most cases gave at hand that such risk

assessments have been relatively simple and targeted at the occupational aspects in the research and development phase, with the exception of pharmaceutical developers. It seems as the focus on consumer safety is more explicit for pharmaceutical companies. Close to 40 per cent of companies using nanomaterials did not give any answer to the question about risk or safety assessments, which probably implies that no such assessments have been performed, or that there is poor knowledge within the company of such activities. That risks to health and environment are not prioritised by Swedish nanotechnology companies has been indicated in previous studies. In a series of interviews with nanotechnology companies Dahlöf (2010) investigated perception of nanotechnology and health risks in ten different companies using nanotechnology of some kind. The companies for the study were selected to represent different steps in the value chain as well as different technical applications and different sizes. The results from the study indicate that the companies do not perceive any health or environmental threat from their use of nanotechnologies or nanomaterials. According to Dahlöf, the companies interviewed emphasised that free, and especially airborne nanoparticles do pose a threat to human health, however, it was also pointed out by all Dahlöf's respondents that their company's products did not contain free nanoparticles or nanoparticles that can come loose during use of the product. In line with the results regarding risk perception, the companies in the Dahlöf study were not very active in research on risks to health and the environment, although some projects were undertaken with regard to the REACH legislation. Also in the present study a lack of free nanoparticles, in research activities or in applications, could be a factor behind companies perceiving no or only a limited need for risk and safety assessment activities.

One of the obstacles to work presented in this report has been the lack of a definition of nanomaterials previous to October 2011. A tentative definition was used for the purpose of data collection for this report, which also included internal structures in the nanoscale as a criterion (e.g. nanoporous materials). The fact that the Commission's definition also includes non-intentionally manufactured materials is not expected to affect the outcome of the company survey as research and development as a rule concerns engineered nanomaterials. One example of the definition issue is that the results from this mapping differs to some degree from that presented in Vinnova (2010). When contacted for the purpose of this survey 25 of the companies identified by Vinnova replied that they did not consider themselves to be nanotechnology companies. The Vinnova mapping is admittedly inclusive rather than exclusive, and not all companies were included by direct communication with company representatives. Had there been a well-established and generally accepted definition available the differences would perhaps have been smaller. Also of potential importance is the commissioner of the survey. Vinnova is the government agency responsible for innovation and growth while KemI is a supervisory agency that regulates the use of substances. The incentives to be identified as a nanotechnology company might differ depending on the context.

It has previously been hypothesised that companies see it as a risk to be identified as nanotechnology companies for regulatory reasons, for instance by Dahlöf (2010). Several of the specific comments given in the questionnaire also confirm that there is a concern that regulations applied to nanomaterials will become too strict. Several companies also seemed to find that the major responsibility on the investigation of potential risks associated to nanomaterials lies on Swedish authorities rather than on developers themselves. The questions and voiced concerns will need to be addressed by future policies and communication efforts.

There might be a potential gap between the risk research and the development of application regarding materials in two or fewer dimensions. The kinds of materials that companies seem to focus on in their research and development activities are mainly metals and metal oxides having one or more dimensions in the nanoscale. Carbon nanotubes are also used in numerous applications. It seems as the risk research in academia and research institutes has aligned itself to a similar material selection, although focusing on nanomaterials with three dimensions in the nanoscale and carbon nanotubes. This is hardly surprising as the voiced concerns regarding effects on especially human health have been targeted at nanoparticles. Silver nanoparticles seem to be the one material where more concern and research effort are targeted on the environmental risks rather than human health.

An attempt to extrapolate the results from the performed company survey will by necessity be both crude and associated to a large degree of uncertainty. To a large extent the applications described by the respondents to our survey were within the area of electronics, pharmaceuticals and medical devices, light emitting techniques and solar panels. According to the responding companies, medical devices and solar panel development have in some instances reached the stage of a final consumer product, while light emitting techniques have not. Due to the regulatory requirements for pharmaceuticals, it takes a long time from first development efforts to release on the market. Occupational exposure in the manufacturing of these applications can clearly be expected, and in the case of medical devices and pharmaceuticals also exposure for consumers. Concerning electronics, solar panels and future light sources the environmental exposure at the products' end of life might perhaps be of larger concern than the exposure for consumers. It is also appropriate to raise the question of whether e.g. thin films or nanoparticles, nanowires and nanotubes bound in matrices should be considered as reasons for concern or not, and what happens to these when products become waste.

11.1 Concluding comments

Regulating use of nanomaterials as well as developing policies to stimulate nanotechnological innovations will be a challenging task. The companies included in this study are very diverse, they are of different sizes and have different origins and histories. As can be seen in section 10 the companies belong to different sectors, as well as to different steps in the value chain. Swedish nanotechnology is not one industrial sector; rather nanotechnologies are used in various ways and to different extents in different sectors. It might in a policy perspective be difficult to frame all aspects of nanotechnologies into one strategy. This conclusion has also been drawn by OECD (2010), who recommends that strategies and policy instruments need to acknowledge the multiplicity of approaches and to be adapted to the specific sub-fields of nanotechnologies.

This report is one step towards investigating the diversity of the Swedish nanotechnologies actors. This will be a necessity in order optimally to prioritise and intensify human health and environment risk research as well as to develop Swedish technical innovation in the nano area in a responsible and sustainable manner. Further efforts towards the aim of interweaving risk and innovation research are needed.

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Appendix A Analysis of research funding during 2010

The research funding bodies to be included were identified using the analysis presented in Appendix A of Vinnova (2010) and through the publication analysis presented in section 7 of this report.

A1 Public funding

The Foundation for Strategic Environmental Research (MISTRA)

MISTRA is a part of the Swedish innovation system aimed at sustainable development and funds research that is aimed at providing solutions for environmental issues. The webpage sections on ongoing and performed research were searched (www.mistra.org, 2011-10-07), projects judged as likely to include nanotechnology were investigated more in depth for instance by reading the annual reports also published in the webpage.

The project Marine Paint amongst other potential solutions investigated the efficiency of metal oxide nanoparticles as antifouling booster biocides. The programme was funded SEK 84 million during 2003 to 2010. The project Macrospheres for hydrogenstorage was awarded SEK 4.5 million during 2006 to 2010. The project E4 MISTRA Energy efficient reduction of exhausts from vehicles among other things investigated the potential to reduce emissions using nanostructured materials. This programme is hosted by Volvo Technology AB and has been granted SEK 20 million during the years 2006-2014. Two additional programmes also use nanotechnology based tools (personal communication Christopher Folkesson Welch); however, these are not included in this overview. MISTRA has also co-funded the ProEnviro program (see the Swedish Foundation for Strategic Research) together with SSF.

When calculating the amount of funding during the year 2010 the program budgets have been divided by the number of years. No consideration has been taken to the fact that the research into nano applications might constitute only a part of the project.

The Knowledge Foundation (KK)

The knowledge foundation (www.kks.se) funds research in 17 of Sweden's (the new) universities and colleges, under the condition that this research takes place in collaboration with industry. It is also required that each to each project of the the industrial partners contribute with an amount of funding that is equal to the Foundation's funding. Within the investment of *Advanced Competence Development* one sub-programme is the **minST** programme (micro and nanotechnology) designed to give mechanical engineering companies access to micro- and nanotechnology. The programme was started in collaboration with Mälardalen University in 2004 and the Knowledge Foundation supported it with SEK 15 million during an initial two-year-period. The project was granted continued funding of SEK 40 million until 2011.

The Swedish Energy Agency (SEA)

Projects were identified through the project database using the general search function and the term 'nano' (<http://energimyndigheten.se/sv/Forskning/Projekt databas/>, 2011-10-05). Nineteen projects were identified as ongoing during 2010.

The Swedish Foundation for International Cooperation in Research and Higher Education (STINT)

Projects funded by STINT were identified through reading the news from 2002 to 2011 (www.stint.se, 2011-10-05)

The Swedish Foundation for Strategic Research (SSF)

The SSF supports research in natural science, engineering and medicine. The objective is to promote development of research settings of the highest international standard and of importance for Sweden's future competitiveness (www.stratresearch.se, 2011-10-05). The SSF project database was searched for nanotechnology related research through reading the project titles. 31 projects receiving funding during the year 2010 were identified.

The Swedish Research Council (VR)

VR is a government agency that provides funding for basic research in all disciplinary domains. By searching the project database (<http://vrproj.vr.se/default.asp?funk=s>) using the term "nano" 157 projects funded during 2010 were identified.

The Swedish International Development Cooperation Agency (SIDA)

No relevant projects were found through a search on "nano" on the webpage (www.sida.se, 2011-10-07). Travel grants are not specified by title or project description and it was thus not possible to include these in the analysis.

The Swedish National Spaceboard

Searching for "nano" on the webpage yielded no hits relevant for the purpose of this project. At least some of the research funded by the Swedish National Spaceboard probably includes micro- and nanotechnologies, however, it was not possible to identify any such research in the project database as this only specifies the main applicants' name and amount granted.

Vårdal Foundation

Searching for "nano" on the webpage (www.vardal.se, 2011-10-05) did not yield any relevant hits.

Swedish Environmental Protection Agency

The webpage was searched for "nano" and "granted" (beviljade), however, no research grants concerning nanotechnology or nanomaterials were identified. Calls for funding were also scrutinised identifying two calls with potential for covering nanomaterials. The first concerned health effects caused by road traffic (Hälsoeffekter av vägtrafik) which was announced in collaboration with the Swedish energy agency. The other concerned the system of environmental quality standards (Forskning om systemet med miljö kvalitetsnormer). Both are considered to more likely concern non-engineered nanoparticles. The granted funding within these calls was not found on the webpage (www.snv.se, 2011-10-06).

Swedish Governmental Agency for Innovation Systems (Vinnova)

Vinnova is Sweden's innovation agency, and the aim is to increase the competitiveness of Swedish researchers and companies. Vinnova funds needs-driven research and the development of effective innovation systems, investing €220 million in new and ongoing projects each year. In 2010, 68 nanotechnology related projects were funded by Vinnova. These were identified by searching the project database (<http://www.vinnova.se/sv/Resultat/Projekt/> , 2011-10-05) for “nano”.

A2 Private foundations

AFA Insurance

AFA Insurance is owned by Sweden's labour market parties. The main operation is within insurance, but the organisation also funds research aimed at improving work environment and occupational health. The project catalogue was searched for projects concerning nanomaterials or ultrafine particles (www.fas.se, 2011-10-05). No relevant projects were found.

Crafoord Foundation

Through the bibliometric analysis the Crafoord foundation was identified as a relatively important funding agency for nanotechnological research. However, as the grants are only specified through applicant and university, and not project name or project description, it was difficult to discern what would be grants to nanotechnology research. Thus, this foundation was not included in the analysis of funding.

Riksbankens Jubileumsfond (RJ)

RJ is an independent foundation with the goal of promoting and supporting research in the Humanities and Social Sciences (www.rj.se, 2011-10-07). Searching the project database for “nano” yielded no hits.

The Royal Swedish Academy of Sciences (KVA)

It is the Royal Swedish Academy of Sciences that awards the Nobel Prizes in Physics and Chemistry, as well as the Sveriges Riksbank Prize in Economic Sciences in Memory of Alfred Nobel (www.kva.se). The Academy also awards a number less well-known personal prizes for research accomplishments, of which a few have been awarded to scientists from Chalmers and KTH, active in the field of nanotechnology for many years. These personal prizes have not been included in the analysis of research funding. The Academy also awards research funding in a few instances, for instance granting five years for research for young researchers. One such grant is included in the analysis of grants during 2010, and it has been estimated to SEK 1000 000, as the exact sum was not revealed by the press release published on the webpage. The funding has been identified through searching the webpage for “nano” (2011-10-06).

A3 Complementary tables and figures

Table A1 Summary of identified research grants in 2010

Funding agency	Number of grants	Average amount SEK per grant during 2010
VR	157	878 229
Vinnova	68	2 468 775
SSF	32	1 592 914
SEA	19	859 006
FORMAS	8	1 610 375
FAS	4	1 991 667
STINT	4	506 250
KK	3	2 602 222
MISTRA	3	2 699 074
KAW	2	6 300 000
KVA	2	1 000 000
NIC	2	8 350 000

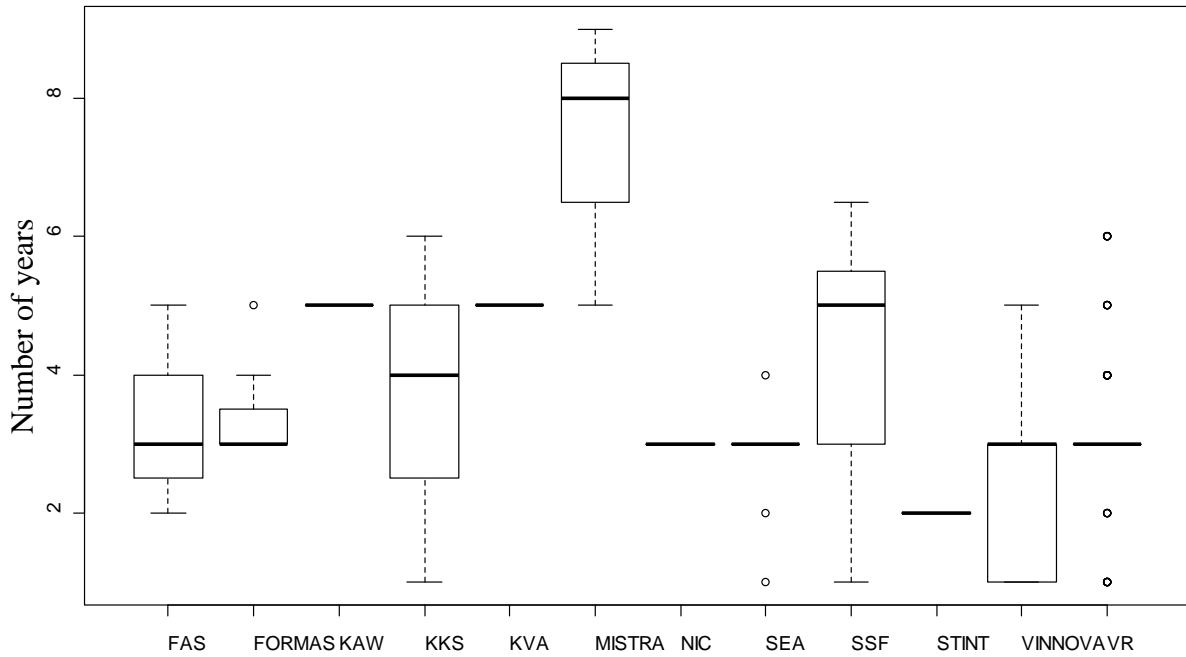


Figure A1 Number of years for projects (when applicable, i.e. excluding infrastructural grants) for the different funding agencies.

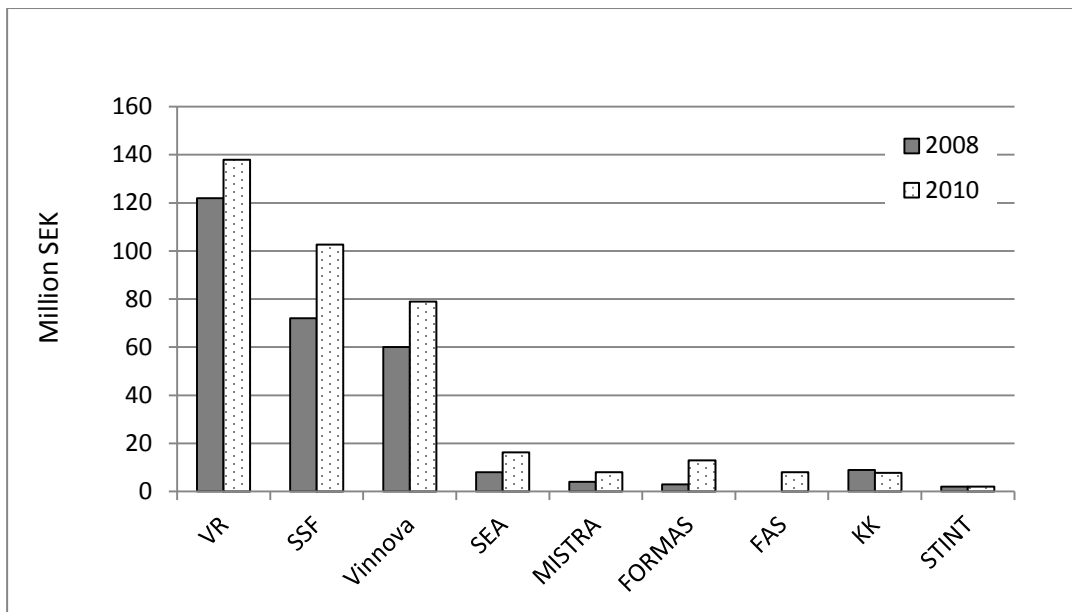


Figure A2 A comparison of funding between the years 2008 and 2010. Data from 2008 is collected from Appendix A in Vinnova 2010.

Appendix B Identifying industry R&D

Companies were identified in a multistep procedure using *Appendix A* in Vinnova 2010:1 as a starting point. This appendix presents an update of a previous Vinnova report (2007) which also included an overview of Swedish companies using or developing nanotechnology. Through Vinnova (2010) 117 companies were included.

Additional companies were identified through the following means:

Searching for companies with “nano” in the name in the registry of Swedish companies (UC), companies unlikely actually to be nanotechnology companies were sorted out after consulting the listed SNI-codes (Swedish Standard Industrial Classification defined by Statistics Sweden and provided by UC) or company websites (if available).

Consulting the list of companies presented on the website of the network Nano Connect Scandinavia, <http://www.nano-connect.org/a-dynamic-region/nanotech-companies2>, the search was performed on 2011-08-05.

Searching the webpage of the conference Update 2011 for Swedish participants: <http://www.b2match.eu/update>, the search was performed on 2011-08-05.

Searching on “nano” in the patents database (www.prv.se), only patent application submitted later than 2006 were reviewed as the Vinnova (2010:1) analysis is based on patent analysis using nanomapper (which lists patents up until 2006). The patent applications which had been submitted by companies were read in order to identify whether the company was Swedish and whether the application did concern nanotechnology or nanomaterials. The definition presented in section 4.3 of the main report was used.

Reading articles concerning nanotechnology and nanomaterials published on the webpage of the Swedish publication “Ny teknik” [New technologies] (www.nyteknik.se, the search was performed on 2011-08-08) which states to cover technology developments and innovations in the sectors such as IT, telecom, energy and biotechnology.

The publication analysis is presented in section 6 of the main report.

The analysis of research grants is presented in section 7 of the main report.

Combining this exercise with the 117 companies identified by Vinnova, 197 companies were found. As the decision criteria for inclusion were designed to be inclusive it was expected that not all these companies would identify themselves as nanotechnology companies. In order to get a more accurate count as well as collect information for the analysis a questionnaire was distributed to all companies possible to contact through e-mail or telephone. E-mail was used as a primary means of contact.

The companies were given two weeks to fill in and return the questionnaire, after which time those who had not responded were reminded by telephone if possible or e-mail.

Appendix C Sponsorship arrangements for the testing of manufactured nanomaterials, as of March 2011

This table has been updated based on agreements made at the 8th WPMN. The order in which the nanomaterials are listed in the table is not indicative of the priority. These nanomaterials have been selected by the WPMN mainly taking into account those materials which are in commerce, or close to commercial use. Other criteria included for instance production volume and the likely availability of such materials for testing.

Manufactured Nanomaterial	Lead sponsor(s)	Co-sponsor(s)	Contributors
Fullerenes(C60)	Japan* United States*		Denmark China
SWCNTs	Japan* United States*		Canada France Germany European Commission China BIAC
MWCNTs	Japan* United States*	Korea BIAC	Canada France Germany European Commission China BIAC
Silver nanoparticles	Korea United States	Australia Canada Germany Nordic Council of Ministers	France Netherlands European Commission China BIAC
Iron nanoparticles	China	BIAC	Canada United States Nordic Council of Ministers
Titanium dioxide	France Germany	Austria Canada Korea Spain United States* European Commission BIAC	Denmark Japan*† United Kingdom China
Aluminium oxide			Germany Japan*† United States
Cerium oxide	United States* UK/BIAC	Australia Netherlands Spain	Denmark Germany Japan*† Switzerland European Commission
Zinc oxide	UK/BIAC	Australia United States BIAC	Canada Denmark Germany Japan*† Netherlands Spain European Commission

Silicon dioxide	France European Commission	Belgium Korea BIAC	Denmark Japan*†
Dendrimers		Spain United States*	
Nanoclays	BIAC		Denmark United States European Commission
Gold nanoparticles	South Africa	United States	Korea European Commission

BIAC- Business and Industry Advisory Committee to the OECD

* Indicates that integrate alternative test methods being performed.

† Indicates that only alternative methods are being performed.

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http://www.oecd.org/document/47/0,3343,en_2649_37015404_41197295_1_1_1_1,00.html

Appendix D Definitions from other organisations

Table D lists summaries of definitions of the terms nanotechnology/ies and nanomaterials drawn upon for the purpose of this report and the Commission definition of October 2011. The list is not exhaustive as preference was given to definitions proposed by the European Commission or the European Union, ISO and the OECD.

There are a variety of different elements like scientific evidence, technical feasibility, economic consequences that impact the discussion on whether and how to discriminate between the bulk and nanoforms of a material. From a scientific point of view there is no substantiation for a clear cut-off based on the spatial scale, however, basing the definition on “new properties” will be technically difficult and the regulatory applications might become, or be perceived as arbitrary. Hence, most of the provisional or adopted, definitions of nanotechnology/ies and nanomaterials that have been published previously are based on the spatial scale.

In a resolution of 24 April 2009 the European Parliament urged the Commission to strive for an internationally harmonised definition of the term nanomaterial. In December the following year the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) of the European Commission proposed a working definition for the term “nanomaterial” for regulatory purposes (SCENIHR 2010). As previously mentioned the Commission recommended a definition of nanomaterial in 2011 (EC 2011). Notable differences between the Commission recommendation and the SCENIHR recommendation are the consideration of external versus internal dimensions in the nanoscale and the percentage of particles in a size distribution that defines a material as a nanomaterial (table D). Also, SCENIHR included only engineered materials while the Commission recommendation also includes unintentionally produced materials. Definitions on the EU level have also been given previously in the Cosmetics Product Regulation (EU 2009) and have been suggested in, a proposal for a new Novel Foods Regulation (EC 2008a, at present on hold as the Parliament voted against due to the cloning item.) and in the proposal for a regulation concerning the placing on the market and use of biocidal products (EU 2010). The Cosmetics Product Regulation includes an obligation to specify products containing nanomaterials. Accordingly this regulation also presents a definition of nanomaterial (see table D). It is also stated in the same regulation that this definition should be subject to future revisions and will be adapted to technical and scientific progress. It should be noted that on 29 March 2011 the final conciliation meeting on updates to novel foods rules failed, meaning that the current Novel Foods Regulation, adopted in 1997, will remain in force.

The term “nanotechnology” was first used by Taniguchi (1974) referring to the ability to engineer materials precisely at the nanometer level. It has since then often been pointed out that nanotechnology is not a single and well defined area of research, rather there are a number of research areas that have developed subareas in the nanoscale region (see also section 5). Thus, as for instance the Royal Society (2004) has put it, it would be more correct to talk about *nanotechnologies* than *nanotechnology*. In the same report the following definition was also proposed “the design, characterisation, production and application of structures, devices and systems by controlling size and shape at the atomic scale” A few years later the ISO also proposed a working definition for nanotechnology, and currently a number of definitions related to nanotechnology and nanomaterials can be found in the ISO Concept Database (cdb.iso.org: login as guest). Like Taniguchi (1974) many definitions of

nanotechnologies take their point of departure from the nanometer level. In addition, such definitions might include the term *nanoscale*, as for instance the definition by ISO, which in turn also requires a definition (see footnotes to table D).

Table D Proposed definitions of nanotechnology/ies and nanomaterial.

Source	Nanotechnology/ies	Nanomaterial
European Commission, 2011		a natural, incidental or manufactured material containing particles, in an 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 1 nm-100 nm /.../ fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanomaterials
ISO/TC 229, 2010	application of scientific knowledge to manipulate and control matter in the nanoscale† (2.1) in order to make use of size- and structure-dependent properties and phenomena, as distinct from those associated with individual atoms or molecules or with bulk materials (manipulation and control includes material synthesis)	material with any external dimension in the nanoscale† or having internal structure or surface structure in the nanoscale (including nano-object and nanostructured material which are also defined by ISO)
US EPA, Stewardship program under the Toxic Substances Control Act, 2010		particle, substance, or material that has been engineered to have one or more dimensions in the nanoscale‡ /... / The term “engineered” is intended to mean that the material is 1) purposefully produced and 2) purposefully designed to be a nanoscale material
EU SCENIHR, 2010		a material that consists of particles with one or more external dimensions in the size range 1 nm - 100 nm for more than 0.15% of their number <i>and/or</i> has internal or surface structures in one or more dimensions in the size range 1 nm – 100 nm <i>and/or</i> has a specific surface area by volume
EU proposal for a regulation concerning the placing on the market and use of biocidal products, 2010		any intentionally produced material that has one or more dimensions of the order of 100 nm or less or is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic of the nanoscale§.

EU Cosmetics Products Regulation, 2009		an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm
EU Novel Foods Regulation, 2009 <i>At present on hold as the Parliament voted against due to the cloning item.</i>		any intentionally produced material that has one or more dimensions of the order of 100 nm or less or is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic to the nanoscale§
OECD, 2007		material which is either a nanoobject or nanostructured. (nanoobject is defined as a material confined in one, two or three dimensions at the nanoscale; nanostructured is defined as having an internal or surface structure at the nanoscale¶)
Royal Society, 2004	the design, characterisation, production and application of structures, devices and systems by controlling size and shape at the atomic scale	
US National Nanotechnology Initiative, 2004	the research and technology development at the atomic, molecular or macromolecular levels, in the length scale approximately 1-100 nm; the creation, use of structures, devices and systems that have novel properties because of their small size; and ability to be controlled or manipulated on the atomic scale	

*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 %.

†size range from approximately 1 nm to 100 nm (notes: Properties that are not extrapolations from a larger size will typically, but not exclusively, be exhibited in this size range. For such properties the size limits are considered approximate. 2) The lower limit in this definition (approximately 1 nm) is introduced to avoid single and small groups of atoms from being designated as nano-objects or elements of nanostructures, which might be implied by the absence of a lower limit.)

‡generally, but not exclusively, below 100 nm and above 1 nm

§ (i) those related to the large specific surface area of the materials considered; and/or (ii) specific physico-chemical properties that are different from those of the non-nanoform of the same material
¶typically between 1 nm and 100 nm

Appendix E The questions sent out to Swedish nanotechnology companies

This is a copy of the original questions, in Swedish, as sent out to the companies.

Frågor till svenska nanoteknikföretag gällande forskning och utveckling av nanomaterial

Ert företag har blivit identifierat enligt en eller flera av dessa vägar:

- Vinnovas rapport *Nationell Strategi för Nanoteknik 2010:01*
- Analys av svenska patent (med utgångspunkt i en sökning på 'nano' i Patent och registreringsverkets databas)
- Sökning på UC Affärsinformation (sökord 'nano' i företagsnamn)
- Sökning av webbsidor: www.nano-connect.org samt www.nanowerk.com

Det finns för närvarande ingen allmänt vedertagen definition på nanomaterial. Följande aspekter är vanligt förekommande i föreslagna definitioner och kan användas som vägledning för dessa frågor:

- Avsiktligt framställda nanomaterial eller nanostrukturer
- Vanligtvis med minst en, inre eller yttre, dimension under 100 nm
- Nanodimensionen ger upphov till nya egenskaper jämfört med ämnets bulkform eller enskilda molekyler av ämnet.

FÖRETAGET

1. Uppgifter om företaget:

Företagets namn:

Verksamhetsort:

Webbsida:

År för företagets grundande:

Företagets storlek:

1-5 anställda

6-50 anställda

51-250 anställda

mer än 250 anställda

2. Är företaget ett tillverkningsbolag, forsknings- och utvecklingsbolag eller service-/konsultbolag?

3. Inom vilken sektor eller bransch är företaget verksamt? Använd gärna de kategorier som finns i inforutan nedan, flera alternativ är möjliga.

- Detaljhandel
- Läkemedel och life science
- Elektronik
- Energi- och miljöteknik
- Verkstadsindustri
- Skogs- och jordbruk
- Bygg
- Kemi
- Skönhet och hälsa
- Stål- och gruvindustri
- Fordon
- Förpackning
- Annan, specificera gärna:

FORSKNING/UTVECKLING

4. Bedriver ert företag miljö- och hälsoriskforskning och/eller utveckling av tekniska applikationer av nanomaterial?

5. Fokuserar er forskningsverksamhet helt och hållet eller enbart till viss del på nanoteknik? Uppskattningsvis hur stor andel av forskningsverksamheten, baserat på företagets totala forsknings och utvecklingsbudget, fokuserar på nanoteknik?

Mindre än 25%

26-50%

51-75%

76-100%

6. Vilket år började företaget med forskning/utveckling om nanomaterial?

7. Vilken typ av nanomaterial använder företaget i forskning/utveckling? Använd gärna de kategorier som finns i inforutan nedan, flera alternativ är möjliga.

Typ av nanomaterial

- Kolbaserade
- Metaller och metalloxider
- Polymerer och dendrimerer
- Kompositmaterial
- Annat material, specificera gärna (t ex dopade/ ytbehandlade material):

Typ av nanostruktur

- Nanopartiklar (ex kristallina nanopartiklar; kvantprickar)
- Nanokompositer (fasta blandningar av olika material; nanolera)
- Nanostavar (ex nanorör, nanostavar och nanotrådar)
- Nanoytor (ex tunn film eller ytbeläggning).
- Nanoporösa material (där materialet innehåller hålrum i nanostorlek)
- Annan typ av struktur, specificera gärna:

8. Tillverkar ni nanomaterialet själva eller köps det in, i det senare fallet är det från en svensk producent eller en utländsk producent inom eller utanför EU?

9. Kan ni ge en kort beskrivning av de specifika fördelarna med att använda nanomaterial/nanoteknologi i er forskning och utveckling?

10. Ge gärna en kort kompletterande beskrivning av er forskning:

TILLVERKNING

11. Tillverkar ni eller importerar ni en eller flera produkter med nanomaterial i sig?

Vad för typ av produkter är det?

Utrustning åt annan industri eller forskning

Komponenter och material åt annan industri eller forskning

Slutkonsumentprodukt

Annat, specificera gärna:

12. Om ni tillverkar slutkonsumentprodukter, eller komponenter till slutkonsumentprodukter, till vilken eller vilka kategorier hör dessa slutkonsumentprodukter? Använd gärna de kategorier som finns i inforutan nedan, flera alternativ är möjliga.

- Bil och verkstad (bränslekatalysator, bilvax)
- Kläder och textil (fläckfria tyger, antilukt)
- Kosmetik- och hygienprodukter (hudkrämer, schampo)
- Elektronik (batterier, displayer)
- Livsmedel och livsmedelstillsatser (kosttillskott, energidryck)
- Hushållsartiklar (möbler, hushållsapparater, rengöringsprodukter)
- Läkemedels- och hälsoprodukter (bandage, plåster, mediciner)
- Sportartiklar (golfklubbor, cyklar, skidvalla)
- Leksaker och barnartiklar (mjukdjur, sugnappar)
- Kontorsartiklar (papper, färg till skrivare)
- Förpackningar
- Annat, specificera gärna:

13. Har ni i samband med er forskning gjort en risk- eller farobedömning (hälsa och/eller miljö) av era produkter med avseende på det nanomaterial som används?

14. Slutligen, har ni några kommentarer kring användande av nanomaterial, företagens förutsättningar och myndigheters arbete kring detta?



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