Säker utveckling!

– Nationell handlingsplan för säker användning och hantering av nanomaterial

Betänkande av Utredningen om nationell handlingsplan för säker användning och hantering av nanomaterial

Stockholm 2013

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Summary

The technology used to intentionally produce and use nanomaterials is called nanotechnology. The term "nanomaterials" usually refers to very small materials with at least one dimension in the size range of 1 and 100 nanometres. A nanometre is one millionth of a millimetre.

Nanomaterials are not special substances but very small forms of substances that often occur in larger forms. A large number of ordinary substances may exist as nanomaterial. Metals and metal oxides are examples of such substances. Carbon occurs in many different forms, including in the forms of carbon nanotubes, graphene, and fullerenes. Fabrication of nanomaterial can be made by starting with larger materials and pattering down to make nanoscale structures or by starting at the atomic scale and building the desired nanomaterial from even smaller materials e.g. molecules and atoms. Nanomaterials are also unintentionally formed in our surroundings, in the smoke from forest fires or when a volcano erupts, for example. This report, however, deals with nanomaterials that are intentionally produced.

Because of their small size, these substances can take on different properties to those the same substance has when it occurs in a larger form. Materials are produced on a nanoscale for exactly that reason, i.e. the substance has properties that are different to the ones it has when occurring in bulk form. These differing properties can be electrical, optical, magnetic, chemical or mechanical (strength, pliability, etc.) Graphene, which consist of a single layer of carbon atoms, is stronger than any other carbon material but still light and flexible. It can therefore combine electrical and optical properties in an exceptional way. The nano form of titanium dioxide is transparent, instead of white, giving it cosmetic advantages in e.g. sunscreens. It is special properties like these that are so sought-after

and that are the basis of nanotechnology's potential for innovation and development.

Nanotechnology is normally referred to as an "Enabling Technology". It forms the basis for technological development and innovation in a broad spectrum of technical and scientific areas, and this development is expected to continue in the foreseeable future.

Nanomaterials and nanotechnology have many different areas of application. Nanomaterials can, for example, be used in environmental technology, e.g. by helping us to make more efficient use of sustainable energy sources as well as controlling emissions. New smaller and more effective sensors based on nanotechnology are, for example, used in vehicle security and control systems. Nanomaterials can also be used to create targeting drugs and carry out better diagnostics. ICT technology is one of the areas developing rapidly with the help of nanotechnology, e.g. computers are getting faster and have ever-greater capacity. Nanomaterials are used in many different types of products, such as paint and other surface treatment products, cosmetics, textiles, sports equipment and electronics.

Nanomaterials and nanotechnology are therefore already contributing, and may well contribute even more in the future, to the development of better and smarter technical solutions that benefit society.

There is huge economic potential here. Nanotechnologies global turnover 2009 was 250 billion dollars. Prognoses suggest an increase to 3000 billion dollars by 2020. The value of nanoproducts on the market has grown with 25 % between 2000 and 2008. Nanotechnology is expected to have generated 600 000 new employments by 2020, which is 15 times as many as in 2008.

But the changed properties of nanomaterial can also change the affect the materials have on humans and the environment and thereby create new or different risks to health or the environment compared to what "normal" chemical substances create Risk assessments and safety routines are needed to ensure that both the materials and the products are managed as safely as possible. Tests have shown that certain nanomaterials can be assimilated, spread and behave in the body and in the environment in a different way to other substances. Materials on a nanoscale can also cause harmful effects that are different to those caused by other substances. In order to perform reliable risk assessments, tailored methods for measurement and testing need to be developed and made available,

not the least for regulatory purposes Many countries, both inside and outside the EU have developed action plans and strategies in order to be able to utilise the development potential of nanomaterials in a safe way. These strategies often deal with the same types of questions, even if they receive varying degrees of emphasis in different countries.

The strategies stress that safety research and innovation research must be integrated. They cover aspects such as research and technical development, knowledge about the potential risks for humans and the environment and the fact that the legislation must be adapted to nanomaterials. The debate about the responsible development and management of nanomaterials from a lifecycle perspective also includes ethical and social considerations as well as knowledge transfer and dialogues among various stakeholders. Many national strategies contain a plan for achieving open and transparent communication about the opportunities and safety aspects of nanomaterials. Most countries have also established some form of national forum to promote and coordinate issues relating to nanomaterials and nanotechnology.

In this report measures are proposed for a national action plan for the safe use and management of nanomaterials. These measures utilise the opportunities that nanomaterials provide while simultaneously minimising the risks to human health and the environment.

An action plan for the safe management of nanomaterials

Measures to build knowledge about health and environmental risks

The measures proposed under this heading aim to increase our knowledge of the potential health and environmental risks of nanomaterials.

To be able to assess the risks associated with nanomaterials and just as with “normal” chemical substances, knowledge is needed as to the effects different concentrations of the substance can cause. Knowledge is also needed about how the substance is released, spread and converted in the human body and in the environment. Furthermore, a clearer understanding is needed as to which groups of humans or which ecosystems can be exposed to the substance and

at what levels. This information is then compiled and considered in a risk assessment.

Collecting the knowledge needed to perform a risk assessment of nanomaterials requires methods for detecting, testing, measuring and evaluating them. Such methods are still to a large extent conspicuous by their absence.

Even a great deal of very basic knowledge about the effects of nanomaterials on humans and the environment, and how they interact with their surroundings, is missing. Without such knowledge, it is difficult to make risk assessments of nanomaterials.

Safe management of nanomaterials requires not only awareness about their individual health and environmental risks in special management situations but also a broader overview of how each material is used in society. We need knowledge about nanomaterials potential risks in a lifecycle perspective, including risks with waste management and possible recycling of products containing nanomaterials.

The need for method development and for research into the risks posed to humans and the environment is therefore very considerable when it comes to nanomaterials. Furthermore, the funding set aside for risk research is in general rather limited in comparison to the funding set aside for research into the development of nanotechnology and nanomaterials.

Those working with nanomaterials on a daily basis are particularly exposed to the potential risks. It is therefore important to put special focus on protection in the work environment.

Standards and methods for testing and risk assessment need to be harmonised internationally to deliver comparable results. This is why much of the development of testing and risk assessment methodology is taking place under the auspices of the OECD. Standards are also being developed in the International Organization for Standardization (ISO) and in the European Committee for Standardization (CEN). In order for Sweden to be able to contribute to and influence development, the country must take a greater role in international work.

The committee's proposal

- Swedish agencies to participate actively in prioritised programmes for the development of testing and risk assessment methodology within the EU and the OECD.
- Substantially increased funding to be set aside for research and development of testing and risk assessment methodology.
- Targeted, and substantially increased, funding to be set aside for research into the health and environmental effects and safety aspects of nanomaterials and for research into the ethical and social consequences of utilising nanomaterials and nanotechnology. The risks in the work environment to be given particular focus.
- The risks are to be considered from a lifecycle perspective.
- Investments in research and development to set a focus on innovation and consideration of the potential health and environmental effects of nanomaterials in an early stage.

Measures for an overview and dispersion of knowledge concerning the health and environmental risks of nanomaterials

The measures proposed under this heading aim to give a better overview of the existing knowledge and improve coordination in order to develop new knowledge.

An inventory of the current state of knowledge, as regards the health and environmental effects as well as the ethical, legal and social aspects of nanomaterials, should be established and continuously maintained. Such an inventory will ensure that the Government, Swedish agencies, researchers and other stakeholders have up-to-date knowledge prior to decisions on priorities and measures.

Good communication among research groups will help to disseminate knowledge systematically, and open doors to cooperation on common problems among different research areas. Researchers already communicate and cooperate to a large extent, but there is good cause to take measures to facilitate and bolster such activity, particularly aimed at providing better conditions to ensure that development in the nano field is also safe from a health and environmental perspective.

The innovation and risk perspectives should go hand in hand in all nanomaterials and nanotechnology training and education. This will help to create awareness among students and young researchers of the importance of integrating environmental and health aspects into development and innovation work.

The agencies are already taking measures to continuously improve the skills of and provide in-service training for their staff. Since the nano field is developing rapidly, and the issues coming to the fore are often both complex and complicated, there is still reason to place particular emphasis on the need for such measures concerning nanotechnology and nanomaterials. Furthermore, arranging joint education and training activities for the relevant agencies may also contribute to a greater consensus among them.

The committee's proposal

- An inventory of the current state of knowledge to be carried out and continuously updated as regards the health and environmental effects and the ethical, legal and social aspects of nanomaterials.
- Measures to be taken to facilitate and strengthen cooperation and knowledge transfer among Swedish research groups.
- Measures to be taken to promote development in higher education nanomaterials programmes, so that knowledge about the health and environmental effects and the ethical aspects is conveyed in parallel with and tied to the technical knowledge all the way through all higher education nanotechnology programmes in Sweden.
- The relevant agency staff to receive training and continuous in-service training on nanomaterials and nanotechnology and their potential health and environmental risks.

Measures for communication and cooperation

The measures proposed under this heading are aimed at creating better conditions for communication and cooperation, both within and among different stakeholder categories.

Good communication improves both coordination and efficiency. Clear communication and a healthy dialogue are important for several reasons. Dialogue between business and research is important for product development and can help to implement innovation and safety research in parallel. Good communication about both benefits and safety concerns is necessary to ensure the general public's trust in, and acceptance of, the new technology. Good communication and coordination among different actors and stakeholders are important to be able to implement preventive measures and deal with any crises that may occur. Businesses require information about legislation on nanomaterial. It is also important for agencies to be able to pursue dialogue with each other to convey a uniform message to nanomaterials users and to exchange information. The development of rules in connection with a dialogue with all stakeholders provides greater democratic legitimacy and increases the likelihood of compliance.

The committee's proposal

- Increased resources to strengthen knowledge transfer among researchers and enterprises concerning the health and environmental safety of nanomaterials and how such aspects can be integrated into the technological development of enterprises.
- Central agencies to pursue a dialogue with enterprises, organisations and other stakeholders concerning the design of guidance documents and rules regarding nanomaterials and nanotechnology.
- Greater resources to be invested in communication and dialogue with the general public, enterprises, environmental and consumer protection organisations, agencies and other stakeholders about the advantages and potential risks of nanomaterials and nanotechnology.
- A forum to be established for greater and stronger knowledge transfer, communication and dialogue between researches and enterprises, between governmental bodies and with the general public, and other stakeholders concerning health and environmental safety on nanomaterial.

Measures for the development of the EU's regulatory framework

The measures proposed under this heading are aimed at adapting the EU's regulatory framework concerning products and chemicals so that it is more applicable to nanomaterials, and so that the appropriate knowledge on nanomaterials is available and can be conveyed to the relevant agencies, downstream users and consumers.

Since nanomaterials can have properties that differ from the properties of regular chemicals, they have to be treated separately in some instances as far as the various regulatory frameworks are concerned. Several regulations and directives from the EU now contain specific rules pertaining to nanomaterials, including the Cosmetics Regulation, the Biocides Regulation and parts of European food legislation. Other regulatory frameworks cover nanomaterials but, for the present, have no explicit rules governing them.

For example, the European chemicals regulation, REACH, applies to nanomaterials, but the rules do not take the special conditions that apply to them into consideration. The basis of the requisite registration is the chemical symbol of the substance. Nanomaterials can therefore be covered by the registration and evaluation rules pertaining to the larger form of the substance despite them potentially having radically different properties. The amount of information required when registering a substance varies depending on the volume covered by the registration. The tonnage limits are not adapted for nanomaterials, which are, with few exceptions, manufactured and marketed in small volumes. The limits are so high that many nanomaterials probably never reach them and therefore need not be registered at all. REACH, along with the European Regulation on Classification, Labelling and Packaging of Chemical Substances and Mixtures (CLP Regulation), provides the ground rules to ensure that the information necessary to be able to apply other regulations to nanomaterials is forthcoming. It is therefore of the utmost importance that REACH being adapted to nanomaterials.

The knowledge developed on nanomaterials in the data collections and the assessments that are to be carried out also needs to be conveyed to downstream users and consumers effectively. It should also be possible to trace products especially if they prove to be problematic from a health and environmental perspective. Some regulations require nanomaterials to be labelled and allow financial actors to submit information on the supply chain. Several regulatory frameworks do, however, need to be reviewed and revised in these

respects in order to ensure that any potentially problematic nanomaterials can, in the future, be traced and taken care of.

Regarding the European Regulation on Novel Foods and Novel Food Ingredients, the Council of Ministers and the European Parliament have agreed on a revision proposal in order to better adapt the regulatory framework to novel foodstuffs that contain nanomaterials. This proposal is currently dormant, however, as a result of disagreement on other issues. Sweden should make vigorous efforts to ensure the proposal is adopted as soon as possible.

The committee's proposal

- The Government and relevant agencies shall work to bring about a revision of REACH, the European chemicals regulation:
  - Nanomaterials are to be registered as a separate substance.
  - The tonnage limits are reduced for nanomaterials.
  - The information to be submitted when registering nanomaterials include supplementary data on their physic-chemical properties and, when necessary, other relevant information.
  - The obligation to register products containing nanomaterials is extended.
  - The rules regarding information to downstream users are to be revised so that they also include relevant details on nanomaterials.
- The Government and relevant agencies shall work to bring about a revision of the European legislation on chemical substances and products:
  - The regulatory frameworks ensure that the data submitted and the assessments made are relevant to the substance in the form it occurs.
- Manufacturers, importers and distributors of products containing nanomaterials should be able to declare the preceding and subsequent links in the distribution chain.
- The proposed amendments to the regulation on novel foods, aimed at clarifying the regulations on nanomaterials, are to be adopted as soon as possible.

Measures to increase knowledge about nanomaterials on the market

The measures proposed under this heading aim to improve knowledge as those products on the market in which nanomaterials are present.

This knowledge is important for several reasons. So that it is possible to make a risk assessment of the substance, knowledge is needed as to *whether* humans and the environment are exposed to it, *how* this exposure occurs and *the relevant volumes*. Enterprises need to know *which* of the products they use contain nanomaterials so that they can employ safety routines to protect their employees and the environment against the potential negative effects. Consumers also need to have such knowledge in order to be able to make informed choices and weigh the product's benefits against possible drawbacks.

Agencies responsible for regulation and risk control in areas connected with nanomaterial and nanotechnology need to know which nanomaterials occur on the market, their volumes and in what way the products are used. Such information is needed in order to allocate well-founded priorities when working to limit the risks and when improving regulatory frameworks. Furthermore, a greater number of agencies need knowledge and an overview in order to take decisions on which products to choose from a health and environmental perspective.

The introduction at the EU level of a register for nanomaterials has been discussed. The European Commission has so far rejected the idea of such a register. France, Belgium and Denmark, along with Norway, have instead decided to introduce national nanomaterial registers. What is registered and what demands are placed on enterprises vary among these countries, however.

Considering the major knowledge gaps and the lack of adequate legislation identified by the committee, it is our assessment that measures also need to be implemented in Sweden to increase knowledge about nanoproducts on the national market.

The committee's proposal

- The Swedish Chemicals Agency to be given the task of investigating how an obligation to submit information on the occurrence of nanomaterials when registering products in the product register might be worded.
- An inventory of products on the market that contain nanomaterials to be performed.

Measures for implementation: Platform for coordination

The measures proposed under this heading are aimed at ensuring that the proposed measures are implemented in an integrated, coordinated and resource-efficient manner, and at establishing and further developing good channels of communication between relevant actors and the general public.

The committee has identified a very great and varied need for communication and cooperation, both within and among many different stakeholder categories.

Therefore, the committee suggests that a "Nano Council" and a "Nano Centre" are established to function as a platform for coordination.

It is entirely possible to organise the various separate needs for communication channels by means of a number of separate and well-defined solutions. The proposals presented above are hence not dependent on the establishment of a "Nano Council" or "Nano Centre", but can be implemented independently.

Such a strategy would, however, not solve the basic problem: the lack of overview and horizontal, vertical and diagonal coordination of a large number of research and societal areas in "Nano-Sweden". What is fundamentally requested and needed is a "spider's web", in which contact threads can run in different directions and between different levels in society.

Such a network would considerably improve the scope for communication, coordination and overview compared to the option of choosing separate solutions for delimited problem areas. In addition, it would achieve this in a much more resource-effective manner since relevant actors are in place in the organisation and can be incorporated into different constellations as required.

The committee has therefore chosen to put forward a proposal for the establishment of a special body, the Nano Council, which will be given the overarching responsibility for concretising and prioritising which additional measures are needed and will function as a unifying forum for the extensive activities that are proposed in this action plan for the compilation and conveyance of knowledge, communication and cooperation for the safe management of nanomaterials and nanotechnology. The Nano Council also needs a secretariat and executive arm, and sufficient funding, to oversee the concrete measures and projects that are to be implemented.

The committee's proposal

- A Nano Council to be established and given the overarching responsibility for the further development of strategies and for prioritising measures for the safe management of nanomaterials.
  - The Nano Council to be organised as an independent council under the Government.
- A Nano Centre to be established as a secretariat and operative arm of the Nano Council.

The consequences of the proposals

Consequences of not implementing the proposals – the status-quo alternative

The economic consequences of not taking any action to improve the conditions for the safe management of nanomaterials are difficult to assess. In a worst-case scenario, knowledge gaps regarding the health and environmental risks may lead to a situation that result in both major costs and great suffering, as has occurred in the case of asbestos.

It can be ascertained from a socioeconomic standpoint that knowledge-building and the development of testing and risk assessment methods will continue to be slow and that the continued imbalance as regards investment in safety research and in innovation research respectively will persist, resulting in new materials, applications and areas of application in which there is a lack of knowledge being developed regarding the potential risks. Further-

more, the lack of cooperation and coordination is also likely to persist and the regulatory framework will continue to be inadequate and not at all applicable to nanomaterials.

The consequences of implementing the proposals

The majority of the measures proposed by the committee have a high level of ambition when it comes to improving coordination among the relevant actors in order to create better conditions to build up, disseminate and utilise knowledge, and to develop rules and other measures to ensure the safe management of nanomaterials. The measures – apart from the proposal for the establishment of a Nano Council – are not precise enough to be able to calculate their costs or to analyse them quantitatively.

The majority of the proposals can be financed by redistributing funding within the relevant sectors.

The cost to the business sector on grounds of the suggestions here presented is likely to be only negligible. When the revised regulatory frameworks are in place, additional costs may be incurred for assessment of products and information transfer. It is not possible, however, to assess the extent of such costs until more precise proposals have been developed.

The socioeconomic benefits of implementing the proposals are deemed to be considerable. Greater knowledge about the health and environmental risks of nanomaterials improve the conditions for both their safe management and their safe future technological development. Increased communication and cooperation give nanomaterials and nanoproducts greater legitimacy and promote safe technological development and innovation. This is also considerably beneficial for a business economics point of view since it means that risks can be avoided to a greater extent, and products that are assessed as safe will have a better chance of gaining legitimacy on the market.