Report 2020:3

SweNanoSafe

Swedish National Platform for Nanosafety

Proposals for national measures for safe use, handling and development of nanomaterials

Foreword

SweNanoSafe is a national cooperation platform for nanosafety. The assignment stems from the government report "Safe development – a national action plan for the safe use and handling of nanomaterials" (SOU 2013:70) which, among other things, proposed measures for communication and collaboration. The platform was created in 2016 through an appropriation from the Swedish Ministry of the Environment and Energy and was initially hosted at SweTox. Since 1 January 2019 the platform has been located at the Institute of Environmental Medicine (IMM) at Karolinska Institutet (KI).

SweNanoSafe has been commissioned by the Swedish Ministry of the Environment to compile a report on possible national measures for the safe use, handling and development of nanomaterials. One starting point is the previous government report (SOU 2013:70), and focus has been placed on identifying obstacles and formulating concrete proposals for measures that can improve nanosafety. During the course of the work, opinions and viewpoints have been obtained from several different stakeholders, including companies, authorities and researchers, through workshops and conferences arranged by SweNanoSafe. In the section on laws and guidelines, focus has been placed on nanomaterials in the work environment and on waste management, as this has been highlighted as being particularly important by several stakeholders.

This report has been compiled by SweNanoSafe: Marika Berglund, Bengt Fadeel, Annika Hanberg, Klara Midander, Rune Karlsson (all at KI). Annika Nilsson (Lund University) contributed to the chapter on laws and guidelines. The expert panel at SweNanoSafe (chairman Bengt Fadeel) contributed to the chapter on research and development: Rickard Arvidsson (Chalmers), Maria Hedmer (Lund University), Alexander Lyubartsev (Stockholm University), Inger Odnevall Wallinder (KTH), Jenny Rissler (Lund University and RISE), Joachim Sturve (University of Gothenburg). Ulrika Carlander (SweTox) contributed to the section on education. Marie Beckman and Ann Catrin Lagerqvist (KI) contributed to the chapter on knowledge and information exchange. Heike Hellmold (SweTox) participated in the early stages of the work on the report. We would like to thank Lena Hellmér and Gregory Moore, KEMI, for their comments regarding the report. We would also like to thank Karolinska Institutet University Library (KIB) for the bibliometric analysis.

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Swedish National Platform for Nanosafety

Institute of Environmental Medicine, Karolinska Institutet

Address:

Box 210, SE-171 77 Stockholm

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Zinc oxide nanoparticles, Adobe Stock

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Abbreviations

AMM	Occupational and Environmental Medicine
AOP	Adverse Outcome Pathway
BAT	Best available technique
BREF	BAT reference document
CEN	European Committee for Standardization
CLP	Classification, Labelling and Packaging
CORs	Communities of Research
DG RTD	Directorate-General for Research and Innovation
EASAC	European Academies Scientific Advisory Council
ECHA	European Chemicals Agency
ECVAM	European Centre for the Validation of Alternative Methods
EHS	Environment, health and safety
ELSA/ELSI	Ethical, legal, and social aspects/implications
ENMs	Engineered nanomaterials
ERA-NET	European Research Area - Net
ERT	European Registered Toxicologist
ETPN	European Technology Platform on Nanomedicine
EUON	European Union Observatory for Nanomaterials
EURL	European Union Reference Laboratory
FORMAS	Research Council for Environment, Agricultural Sciences and Spatial Planning
FORTE	Research Council for Health, Working Life and Welfare
GLP	Good Laboratory Practice
IATAs	Integrated Approaches to Testing and Assessment
IKEM	Innovation and Chemical Industries in Sweden
IMM	Institute of Environmental Medicine
ISO	International Organization for Standardization
JRC	Joint Research Centre
KEMI	Swedish Chemicals Agency
LCA	Life cycle assessment
MISTRA	Foundation for Strategic Environmental Research
MOOC	Massive Open Online Course
NCL	NanoCharacterization Laboratory
NIVA	Nordic Institute for Advanced Training in Occupational Health
NNI	National Nanotechnology Initiative
MYNAK	Swedish Agency for Work Environment Expertise
NIOSH	National Institute for Occupational Safety and Health
OECD	Organisation for Economic Co-operation and Development
OSHA	Occupational Safety and Health Administration
QSAR	Quantitative Structure–Activity Relationship
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RISE	Research Institutes of Sweden
RIVM	Dutch National Institute for Public Health and the Environment
RRI	Responsible Research and Innovation
SDS	Safety Data Sheet

SIS	Swedish Institute for Standards
SOP	Standard Operating Procedure
SOU	Swedish Government Official Reports
SweTox	Swedish Toxicology Sciences Research Center
TC	Technical Committee
VR	Swedish Research Council
WG	Working Group
WHO	World Health Organization
WPMN	Working Party on Manufactured Nanomaterials

Summary

Nanomaterials, i.e. materials produced at a size of around 1 to 100 nanometres, have unique properties that make them useful for many different applications. However, these new properties could also give rise to adverse effects on human health and the environment. Tools are therefore needed to assess and manage risks associated with nanomaterials. This in turn enables the safe and sustainable development of nanotechnologies.

The government report "Safe development – a national action plan for the safe use and handing of nanomaterials" (SOU 2013:70) proposed several measures for the safe handling and use of nanomaterials that make the most of the potential of nanomaterials while also minimising health and environmental risks. The national cooperation platform SweNanoSafe was initiated in 2016 as a direct result of the aforementioned report.

This current report aims to identify obstacles to the safe use, handling and development of nanomaterials and to propose measures at national level. Building on the previous government report, this report has been produced by SweNanoSafe in dialogue with various parties from academia, industry, authorities and other stakeholders. Several national and international reports on nanosafety have also been used as a basis for this report. In addition, a bibliometric analysis of Swedish nanosafety research during 2001-2018 has been carried out.

This report covers the following main areas: (1) laws and guidelines relevant to nanomaterials; (2) research and development; (3) education, training and competence provision; (4) exchange of knowledge and information. However, this report does not address ethical aspects of nanotechnology. The report's proposals are summarised here, while a detailed description is provided in each chapter:

Laws and guidelines:

Measure 1. National guidance document for employers and workers regarding nanosafety in the work environment, and updating of guidance documents regarding safety data sheets.

Measure 2. Compilation of international recommendations regarding guidance values for nanomaterials in the work environment, and investigation of national recommended guidance values in the work environment.

Measure 3. Enforcement of nanomaterials in the work environment should be enhanced and coordinated between the responsible authorities and should be continuously updated as new knowledge about nanomaterials becomes available.

Measure 4. Mapping of major waste streams containing nanomaterials, and investigation of technical solutions that facilitate the safe recycling of waste containing nanomaterials.

Research and development:

Measure 5. Continued research is needed regarding basic toxicity mechanisms, although the research should also be directed towards regulatory relevance and validation of test methods for nanomaterials.

Measure 6. Knowledge is needed about the actual exposure to nanomaterials in both the work environment and the external environment, and a life cycle perspective should be applied to all nanomaterials.

Measure 7. Multidisciplinary research should be prioritised, and the research should be made more relevant to risk assessment; authorities should be mandated to coordinate research that meets regulatory needs.

Measure 8. State-funded research and development in nanotechnology should meet set requirements regarding safety and ethics, i.e. 'responsible research and development'.

Education, training and competence provision:

Measure 9. National network for the mapping, prioritisation and information of education and training in nanosafety – coordinated through the national cooperation platform SweNanoSafe.

Measure 10. Development of training and professional education regarding nanosafety in society, in particular in the work environment (in the short term) and integrated into academic programmes within nanotechnology (long term).

Exchange of knowledge and information:

Measure 11. Increased resources for dialogue and cooperation between national (and international) parties within nanosafety; transfer of knowledge between academia and industry.

Measure 12. Increased resources for dialogue and cooperation between national (and international) parties within nanosafety; transfer of knowledge between academia and authorities.

Overarching proposal:

Measure 13. Proposal for overarching measure for the safe use, handling and development of nanomaterials: a national nanotechnology strategy that includes nanosafety.

In summary, there is a need for increased *coordination* between various parties, as was also highlighted in the previous government report (SOU 2013:70). In this context the national cooperation platform can play an important role by bringing together relevant parties from academia, industry, authorities and other stakeholders. Furthermore, a national strategy for nanotechnology is needed whereby safety is integrated at an early stage of the innovation process. A flexible action plan is required, as nanotechnology and other technologies based on new materials are areas that are subject to constant development. Finally, international cooperation (e.g. within the EU, OECD and WHO) regarding nanosafety is of great importance.

Given our long experience of education, training and regulation in the field of chemical safety, and the range and quality of nanosafety research being conducted, Sweden has every opportunity to lead the way towards the safe handling, use and development of nanomaterials.

1. Introduction

1.1 Purpose of the report

SweNanoSafe is a national cooperation platform that aims to ensure the development and transfer of knowledge for the promotion of the work involving the safe handling and use of nanomaterials, and to facilitate cooperation between various parties such as authorities, industry and other stakeholders. Furthermore, the platform also aims to enhance nanosafety education and training within academia and for other stakeholders, and to increase knowledge about obstacles to the safe handling of nanomaterials and how such obstacles can be dealt with.

Building on the previous government report regarding the safe use and handling of nanomaterials (SOU 2013:70), the purpose of this report is to provide a brief description of the current situation regarding nanosafety work in Sweden, including an overview of international developments in this area, and to propose possible national measures for the safe use, handling and development of nanomaterials. Focus has largely been placed on nanomaterials in the work environment, as this has been highlighted by several stakeholders as being particularly important.

The platform's work falls within the framework of the environmental quality objective *non-toxic environment*, which aims to ensure that substances (chemicals, including intentionally produced nanomaterials) produced and used in society do not harm human health or biodiversity (KEMI, 2019). A prerequisite for the achievement of this objective is the availability of knowledge about the environmental and health effects of chemical substances for the purpose of risk assessment. It is, however, important to point out that nanomaterials have many desirable properties that make them useful in several areas, and that it is important to make the most of these opportunities while also minimising health and environmental risks, as was also highlighted in the previous report (SOU 2013:70).

1.2 Methodology

This report is based on the earlier government report "Safe development – a national action plan for the safe use and handling of nanomaterials" (SOU 2013:70). Furthermore, the IMM report on nanotoxicological research has constituted an important supporting document for this report (IMM, 2018).

Comments and viewpoints on relevant obstacles and measures have been obtained in connection with several meetings arranged by the platform during 2016-2019, as well as with the help of follow-up questionnaires, bibliometric analysis of Swedish nanosafety research (performed by Karolinska Institutet University Library), meetings with the platform's expert panel and collaboration council, and in dialogue with individual experts within academia, authorities and industry. Parts of the background material, such as the bibliometric results, are presented in the appendices to this report, while other background material can be found in the meeting reports published by the platform and downloadable from the website: swenanosafe.se. Finally, the steering group and project team for the project have worked on compiling the report (see Foreword).

1.3 Definition of nanomaterials

What are nanomaterials? ISO defines "nanomaterial" as a material with any external dimension in the nanoscale or having internal structure or surface structure in the nanoscale (ISO, 2010), and "nanoparticle" as a nanoobject with all three external dimensions in the nanoscale where nanoscale is defined as the size range from 1-100 nm (ISO, 2008). In 2011, the EU adopted a recommendation for a definition of the term 'nanomaterial' (2011/696/EU) (JRC, 2010):

'Nanomaterial' means 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.

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%.

However, these definitions are based solely on the size of the material and do not consider other properties. The European Commission's research unit Joint Research Centre (JRC) has recently published a report to clarify key concepts and terms used in the EU definition (JRC, 2019). In that report, focus is placed on intentionally produced nanomaterials, although knowledge about the health and environmental effects of nanoscale materials can also be obtained from studies of unintentionally produced particles, such as those found in traffic pollution (IMM, 2018). Nanoscale materials are covered by general chemical regulations for chemical products and goods, such as the REACH Regulation. It is important to note that the appendices to the REACH Regulation have recently been revised and that specific provisions on data requirements for nanoscale substances ('nanoform') have been introduced; the new provisions came into effect on 1 January 2020. Consequently, information is required about the ability of the nanoform to be absorbed into the body as well as its toxicological and ecotoxicological properties (www.kemi.se).

2. Laws and guidelines

2.1. Background

The dialogues between various stakeholders and SweNanoSafe have identified major needs for increased knowledge, information and education and training regarding health and environmental aspects of nanomaterials in the *work environment*, and in particular how the increasing handling of nanomaterials should be performed safely. Proposals relating to the legislative area of occupational health and safety, which has been highlighted by various stakeholders as being the area of greatest importance, are set out below. It is assessed that these measures can be implemented at national level in the relatively short or medium term. In the work environment area, focus is primarily placed on airborne nanomaterials and thus on health risks associated with inhalation of these materials.

When new technology is introduced, problems associated with waste management are usually identified last. This is also the case with nanotechnology: although nanomaterials are currently present in most product groups, there is a lack of knowledge about potential risks associated with the transition of these products into waste. *Waste management* is partly a work environment issue and partly an environmental issue, as nanomaterials can be spread in the external environment. Waste management must also be viewed in the context of the challenge facing society in terms of making the most of materials through reuse and recycling in an efficient and safe manner. The situation regarding waste management is generally more complex than at the manufacturing stage, partly due to the heterogeneous collections of materials that are being managed and the lack of information about what they contain. There is a major lack of knowledge about the types of nanomaterials that are present in waste streams and the exposure that occurs in relation to people and the environment.

EU chemicals legislation is essentially designed as regulations and applies as law in the Member States. The key provisions are contained in the chemicals regulation, REACH, and in the classification regulation, CLP, and these regulations also cover nanomaterials. Please see appendix 1 for additional background information about legislation relevant to nanomaterials.

2.2. Obstacles and measures

Measure 1. National guidance document for employers and workers regarding nanosafety in the work environment, and updating of guidance documents regarding safety data sheets.

Clear and user-friendly guidance documents regarding risk management measures form a key part of the work aimed at achieving increased nanosafety in the work environment. The lack of guidelines in Swedish focusing on nanosafety in the work environment has been pointed out by several stakeholders (authorities, companies, organisations and researchers) (SweNanoSafe, 2017:2; 2017:3). During 2019, the Swedish Work Environment Authority addressed some of these issues by publishing on its website a Swedish version of an information sheet from the European Agency for Safety and Health at Work, OSHA, regarding manufactured nanomaterials in the workplace, and this entails a clear improvement in the situation. However, in addition to the information material that is now available in Swedish, there are several other compilations containing guidance and information about nanomaterials in the work environment, in English and in other languages, which could contribute knowledge to Swedish work environment measures. Examples include material from OSHA and WHO and material from other EU Member States such as Denmark, Holland, Austria and Germany, as well as other countries outside the EU, not least the USA (NIOSH). Such documents should be compiled into one or more detailed guidance documents in Swedish. Several international documents contain similar recommendations. However, a certain amount of adaptation to Swedish conditions may be required. It is proposed that the primary responsibility for this compilation work should rest with the Swedish Agency for Work Environment Expertise (MYNAK). MYNAK, in consultation with the Swedish Work Environment Authority, KEMI and other stakeholders, should define the issues to be dealt with by the Swedish guidelines.

Furthermore, work is under way in the EU on the introduction of requirements regarding information about nanomaterials in safety data sheets (see appendix 1). It may be assumed that the European Chemicals Agency, ECHA, will update its guidance documents in accordance with these changes. KEMI, in cooperation with the Swedish Work Environment Authority and other stakeholders, could work to ensure the availability, in Swedish, of guidance documents that clearly address the issue of how safety data sheets should provide information about nanomaterials. KEMI could also provide information to manufacturers, importers and others responsible for developing and updating safety data sheets, to make them aware of the changes and the new requirements that are being imposed.

Measure 2. Compilation of international recommendations regarding guidance values for nanomaterials in the work environment, and investigation of national recommended guidance values in the work environment.

It is known that certain nanomaterials can cause harm to human health (IMM, 2018). There are, however, no binding hygienic limits for nanomaterials, due, inter alia, to shortcomings in scientific evidence and difficulties in assessing and measuring exposure (see chapter 3). In the absence of binding limits, *recommended guidance values* have been published for certain nanomaterials (OSHA, 2009; WHO, 2017). These recommended guidance values are based on the current state of knowledge and can serve as non-binding recommendations in the absence of hygienic limits, to better control the work environment risks associated with nanomaterials. MYNAK should compile the recommendations regarding guidance values for levels of nanomaterials in the work environment which have been developed by various parties, and which the Agency considers to have sufficient scientific grounds. These guidance values should be actively communicated with relevant stakeholders. The Swedish Work Environment Authority and MYNAK should investigate the needs, opportunities and obstacles associated with the introduction of national recommended guidance values for certain nanomaterials in the work environment, and on the basis of this investigation assess whether such guidance values should be introduced. Naturally, part of this work involves determining which nanomaterials are present in the work environment. SweNanoSafe has initiated a feasibility study regarding the presence of nanomaterials in the construction industry (SweNanoSafe, 2019:2), and this feasibility study should be followed up.

Measure 3. Enforcement of nanomaterials in the work environment should be enhanced and coordinated between the responsible authorities and should be continuously updated as new knowledge about nanomaterials becomes available.

There is continuous enforcement of the management of chemicals in workplaces and of safety data sheets. However, the enforcement work is divided between several authorities and sometimes overlaps:

- The Swedish Work Environment Authority is responsible for enforcement of chemical risks in the work environment and for certain issues under REACH (identification and application of risk management measures and ensuring compliance with the protective measures prescribed in safety data sheets).

- KEMI is responsible for enforcement in relation to primary suppliers' registration and release of chemical products on the market, their obligation to report chemical products to the product dossier, and ensuring that safety data sheets contain correct and complete information. KEMI is also responsible for ensuring that substances and mixtures are correctly classified according to CLP, and for enforcement of the release of goods on the market.

- The County Administrative Board, and in certain cases the local municipality, is responsible for enforcement in accordance with CLP and REACH of, inter alia, primary suppliers' management of chemical products and goods not entailing release on the market, as well as management of chemical products and management of goods not entailing release on the market by parties other than primary suppliers.

- Pursuant to the Swedish Ordinance on Environmental Supervision and Enforcement (SFS 2011:13), the County Administrative Board and local municipalities are responsible for enforcement of the management of chemicals in environmentally hazardous activities. The Swedish Environmental Protection Agency is the senior supervisory authority in relation to environmental and waste legislation (appendix 1).

Knowledge about risks associated with nanomaterials and how such risks should be managed is gradually increasing as related research makes progress. The supervisory authorities should place increased focus on nanosafety to ensure that new regulations and new knowledge are implemented in work environment measures. Coordinated supervisory measures do currently exist, although there is potential to further develop the level of cooperation between responsible authorities in relation to nanosafety, to ensure optimal use of information, methodology and documentation. SweNanoSafe also has an important role to play in this context as a *national cooperation platform* (see chapter 5). The Swedish Work Environment Authority and KEMI should develop supervisory guidelines that include nanomaterial-specific information for various relevant stakeholders. Specific supervisory measures should be targeted at businesses and activities dealing with nanomaterials in contexts where potential risks could exist.

Measure 4. Mapping of major waste streams containing nanomaterials, and investigation of technical solutions that facilitate the safe recycling of waste containing nanomaterials.

The rapid development of nanomaterials for widespread use in various industries is leading to the generation of waste containing nanomaterials. One problem that has been highlighted during the dialogue with the waste and recycling industry is the lack of information about whether waste contains or could generate harmful amounts of nanomaterials. Consequently, there is no possibility to implement measures for safe management in the work environment or assess risks to the external environment.

Studies should therefore be carried out into levels of nanomaterials in waste streams where various nanomaterials are likely to exist in large quantities. Examples of such waste categories may include building materials, textiles and packaging. The aim is to identify which groups/types of materials are likely to contain nanomaterials, and which nanomaterials are involved in relation to different product groups. Such information is needed to be able to prioritise measures targeted at types of waste where large quantities of potentially harmful nanomaterials may exist, and where measures may be needed to limit work environment and environmental risks. It is proposed that this is an appropriate assignment for academic researchers in collaboration with companies. Furthermore, it is important to improve knowledge about the content and presence of nanomaterials and potential risks to health and the environment associated with reuse, recycling, incineration and landfill. This work, in turn, borders on research into exposure and life cycle assessment (see chapter 3). The Swedish Environmental Protection Agency should play a leading role in this work, which should be performed in cooperation with KEMI, the Swedish National Board of Housing, Building and Planning and other authorities as well as the waste and recycling industry and relevant trade organisations such as the Swedish Waste Management Association.

A *long-term environmental objective* within waste management is to increase recycling of materials. Given the rapid pace of innovation in nanotechnology, the addition of nanomaterials to various materials and products can be expected to increase rapidly. In this context we are facing major technology and capacity challenges when it comes to producing recycled materials of desired quality from complex waste streams. Cooperation is needed between various stakeholders – authorities, companies, trade organisations and academia. Nanomaterials can undergo a transformation in the human body as well as in the external environment, i.e. nanomaterials can be broken down or otherwise modified so that their properties and harmful effects are affected (NIOSH, 2019). This should be considered in the work involving the handling and recycling of nanomaterials.

3. Research and development

3.1. Background

Knowledge exists about the adverse health effects of several commonly used nanomaterials such as silver nanoparticles and carbon nanotubes, but there is still largely a lack of information about exposure to nanomaterials in the work environment and in the external environment (IMM, 2018). It is particularly important to give consideration to occupational exposure, as those who work with the production and handling of nanomaterials run the greatest risk of exposure (see chapter 2); nanomaterial researchers can also be included in this category. It should, however, be emphasised that knowledge alone is not enough; the information must also be relevant for risk assessment purposes and, in addition, the knowledge must be communicated to the right stakeholders.

Swedish researchers have been successful in EU-funded projects and have, among other things, participated in FP7-NanoREG, a project with 85 partner institutes and thus the largest project of its kind in Europe. In Sweden, FORMAS (NanoSphere, 2009-2013) and MISTRA (Environmental Nanosafety, Phase I: 2015–2018, Phase II: 2019–) have made major investments in nanotoxicological research with focus on the external environment, while VR and FORTE (among others) have funded research regarding health effects. Please see appendix 2 for an inventory of nanosafety research at various Swedish universities and institutions during the period 2001-2018.

Nanosafety research over the past 15 years has resulted in a better understanding of how nanomaterials interact with biological systems. In addition, methods for mapping the biological effects have become increasingly sophisticated (Fadeel et al., 2018). Despite this, many questions remain, not least in relation to the degree of exposure to nanomaterials and risk assessment. An overall conclusion of the NanoREG project (2017) was that nanomaterial research during the past decade has been of an academic nature (*science-oriented*) rather than addressing issues relevant to risk assessment and regulation. In a summary of available risk assessment tools, RIVM (2014) noted that these need to be updated and proposed an 'adaptive' or flexible risk assessment approach to make it easier to assess new substances. A strategic research report on nanomedicine (ETPN, 2016) emphasised the importance of accelerating the regulation of nanomaterials for medical purposes to enable "a fast but safe track to innovation", i.e. nanosafety and innovation should go hand in hand. In addition, a life cycle perspective is needed: risk assessment must cover nanomaterials/products "from cradle to grave" (including waste management and recycling) (SOU 2013:70).

3.2. Obstacles and measures

Measure 5. Continued research is needed regarding basic toxicity mechanisms, although the research should also be directed towards regulatory relevance and validation of test methods for nanomaterials.

Toxicological studies of nanomaterials are of a higher quality today than 10 or 15 years ago, and most studies now include a careful characterisation of the nanomaterials being studied. However, there is still a need to standardise test methods and reference materials in nanotoxicological research (Faria et al., 2018).

In addition, endeavours are being made to move away from methods based on laboratory animals and instead develop alternative test methods; this applies to all toxicology and not just to the assessment of nanomaterials. There is a lack of validated *in silico* methods, i.e. computer-based modelling tools with which nanomaterials can be assessed and properties can be predicted; once again to reduce our dependence on animal testing. In accordance with the plan developed at the OECD Joint Meeting 2019 (with prioritisation of activities for the period 2021-2024), work on *alternative testing methods* should continue. KEMI is already involved in this work. We propose that Sweden should have representatives in several OECD working groups, to ensure that test methods and guidance documents are usable in the risk assessment of nanomaterials. In this context, SweNanoSafe and the newly established national research network (see appendix 2) should be able to play an important role by allowing experts to be nominated to the working groups. Access to validated test methods is crucial for the work of the authorities, and the OECD's internationally harmonised test methods (TG) are directly related to the EU's regulations and Sweden's environmental quality objective of a non-toxic environment. Validation of test methods is something that should be carried out by research institutes such as RISE or other appropriate parties, and in international cooperation under the auspices of the OECD or the EU (EURL/ECVAM). There are already infrastructure investments in nanosafety and nanomedicine within the EU (EC4SAFENANO and EU NCL), and Sweden can contribute with expertise in this area and at the same time take advantage of these networks.

Nanotoxicological research requires collaboration between materials science (chemistry/physics) and toxicological research, and funders such as VR, FORMAS, FORTE and others should support interdisciplinary projects to a greater extent. Basic research is needed to increase knowledge about how nanomaterials interact with biological systems – which in turn can form the basis for the development of adverse outcome pathways (AOPs) and IATAs.

Measure 6. Knowledge is needed about the actual exposure to nanomaterials in both the work environment and the external environment, and a life cycle perspective should be applied to all nanomaterials.

Nanotoxicological research has made great progress, but there are still gaps in knowledge regarding, for example, how nanomaterials interact with the body's cells or with other organisms in the external environment (EU NanoSafety Cluster, 2013). In addition, the research has mostly focused on hazard and has placed too little focus on exposure. There are shortcomings in the knowledge about exposure, and there is a lack of life cycle-relevant data for products containing nanomaterials, i.e. what happens to a product "from cradle to grave", and how does the hazard of the material or product vary from production to use and finally at the waste stage? In dialogue with various stakeholders it has emerged that a life cycle assessment perspective should be applied to all nanomaterials or products containing nanomaterials. We propose that requirements should be imposed on the consideration of a life cycle perspective in all publicly funded projects aimed at developing a nano-based product. Research councils should stimulate more research involving LCA.

Laws, regulations and guidelines (see chapter 2) aimed at minimising risks associated with nanomaterials must be based on scientific grounds. Consequently, continuous compilations of existing scientific knowledge about potential risks and risk minimisation in connection with the handling of nanomaterials constitute an essential basis for occupational safety and health. This includes potential health effects associated with the handling of nanomaterials in the work environment, and in this context a close collaboration between researchers and the relevant authorities is needed. MYNAK should be responsible for producing knowledge compilations in cooperation with the Swedish Work Environment Authority, KEMI and other relevant parties. Through the activities of SweNanoSafe, a research network has been developed with researchers involved in various forms of nanosafety at various higher education institutions (appendix 2). This network can facilitate contacts between experts in different fields and relevant authorities.

Furthermore, chapter 2 has already discussed the importance of mapping waste streams containing nanomaterials and developing technical solutions that facilitate the safe recycling of waste containing nanomaterials. This work requires knowledge about whether one or more nanomaterials are particularly harmful to health and the environment if they are spread in the work environment or to the external environment in connection with waste management, recycling or water treatment. The results of such a review should then form the basis for measures targeted at the nanomaterials identified as a possible risk. This could include, for example, measures to ensure that specific nanomaterials are traceable through the management chains down to waste and recycling management so that appropriate preventive measures can be implemented at that stage, or the avoidance or modification of the materials to limit the risks. The Swedish Environmental Protection Agency should play a leading role in this work, which should be performed in cooperation with KEMI, other relevant authorities and trade organisations, and researchers. SweNanoSafe's expert panel (chapter 5) should be able to contribute subject knowledge as well as guidance on how the review can otherwise be carried out.

Measure 7. Multidisciplinary research should be prioritised, and the research should be made more relevant to risk assessment; authorities should be mandated to coordinate research that meets regulatory needs.

There is still largely a lack of adequate supporting data for risk assessment of nanomaterials, despite the fact that large investments have been made in nanosafety, not least within the EU, with 50 or so research projects focused on nanosafety within FP7 alone, and continued investment within H2020 (www.nanosafetycluster.eu). In addition, several targeted investments in nanosafety have been made in the USA (www.nano.gov). But the knowledge about nanomaterials is often academic, and experiments are performed to highlight mechanisms while the experimental conditions are not realistic and thus not relevant to risk assessment. Common practice in Sweden dictates that government authorities do not have a mandate to direct research and thus do not have the possibility to prioritise research based on regulatory needs. We propose that authorities such as KEMI, whose assignment is to carry out risk assessment of chemicals and nanomaterials, be provided with a mandate and resources for *research coordination*. This does not mean that companies escape their responsibility for safety testing of new materials, but rather that the research can instead focus on developing new knowledge and methodology that is relevant to risk assessment. SweNanoSafe can contribute to this dialogue by coordinating researchers from academia, authorities and other stakeholders. A new "partnership" for risk assessment of chemicals is currently being planned within the next framework programme, Horizon Europe. The aim is to connect the research with the needs of the authorities. Regulatory use of test methods to investigate the health and environmental effects of nanomaterials could be included in this work, and it is an area to which Sweden should be able to contribute.

At present, national research funders primarily fund purely research projects within a limited area/topic such as toxicology, occupational exposure or material development. Few projects take in the entire breadth from material development to use of products containing nanomaterials; in addition, there is largely a lack of a life cycle perspective. There is a lack of research funding for small and medium-sized projects that could enable the performance of smaller nanosafety studies with focus on a specific issue within existing material development projects/research programmes. Not least, we are faced with the challenge of developing measurement methods for the detection of nanomaterials at low levels in the work environment and in the external environment, and there is often a lack of funding in this area. Research funders such as VR should be charged with the assignment of promoting small and large *multidisciplinary* projects with a clear connection between the development of new nanomaterials and safety (or risk).

Measure 8. State-funded research and development in nanotechnology should meet set requirements regarding safety and ethics, i.e. 'responsible research and development'.

The national report regarding the safe use and handling of nanomaterials (SOU 2013:70) highlighted the importance of making the most of the potential of nanomaterials to meet economic, medical, technical and environmental challenges while also taking into account possible health and environmental risks associated with these materials. An important aspect of this is the integration of safety aspects into the innovation process, otherwise referred to as *safety-by-design*. It should be noted that this is not just a question of weighing benefits against potential hazards, but rather a matter of considering safety aspects at an early stage of the material and product development process. However, SweNanoSafe's dialogues with various stakeholders have shown that *safety-by-design* is difficult to define in practical terms, and that it may primarily be viewed as a vision. A broader concept is *responsible research and innovation* or RRI, which means that societal aspects are considered at an early stage of the innovation process. RRI not only covers safety and ethical considerations but also regulation and risk management as well as other aspects such as gender equality. Responsible research and development should characterise all nano-related activities, and government-funded innovation projects (e.g. Vinnova-funded research) should require all applications to take this into consideration in the same way that all medical research must currently meet certain requirements in relation to issues concerning animal ethics or human ethics. VR should be charged with the assignment of developing guidelines for responsible research and development. Equivalent guidelines already exist at EU level, for example within nanomedicine (ERA-NET). SweNanoSafe could have a role to play in this work through the national network of researchers in the field of nanosafety (appendix 2).

4. Education, training and competence provision

4.1. Background

In order to ensure sustainable development in accordance with the global sustainability development goals and the Swedish environmental objectives, knowledge and skills are needed in the field of nanosafety. This chapter contains details of proposed measures that could be implemented at national level to facilitate the competence provision and enhance higher education in Sweden in the field of nanosafety.

The labour market is changing rapidly, and we are moving towards a more knowledge-intensive economy. Knowledge provides competitive advantages, although it also requires strategic investments in competence. In order to match the needs of the labour market and promote innovation, lifelong learning is required. This places demands on access to market-adapted education programmes and training courses developed in collaboration between various parties. The need for skills and knowledge in the field of nanosafety in Sweden has been highlighted in SOU 2013:70, both in relation to the work environment and in academic education within nanotechnology. Nanosafety should be included as a natural part of other areas of knowledge and expertise such as chemical safety/toxicology, environmental science, materials science, nanomedicine and nanotechnology where such education and training takes place (SweNanoSafe, 2019:1). Skills and knowledge in the field of nanosafety are also required in society outside of academia, for example within the activities of public authorities, industry, trade and labour market partners, as well as to interact with and pursue issues within the EU and other international organisations such as OECD and WHO. Specialist expertise in nanosafety is also needed to ensure the safe and sustainable development of Swedish innovations in nanotechnology. This is something that has been highlighted in the 'roadmap' for a Swedish nanomaterial-based industry developed by SwedNanoTech (SwedNanoTech, 2017).

A working group on education and training has recently been established within the EU NanoSafety Cluster. This working group is working on the development of strategies for the harmonisation of education and training measures in EU-funded projects, although to date there are few such activities in existence (www.nanosafetycluster.eu). There is a lack of equivalent initiatives in Sweden, although this is something that could take place within the framework of SweNanoSafe. During the period 2014-2018, SweTox worked on the coordination of educational and competence-enhancing measures regarding chemicals (including nanomaterials), health and the environment. SweTox felt that a permanent *national education platform for chemicals, health and the environment* would help to meet society's needs for education and training in this field in a coordinated and resource-efficient manner. They also emphasised the importance of interdisciplinary cooperation between universities and social actors to achieve the necessary competence provision.

4.2. Obstacles and measures

Measure 9. National network for the mapping, prioritisation and information of education and training in nanosafety – coordinated through the national cooperation platform SweNanoSafe.

Nanosafety is a multidisciplinary field requiring skills and knowledge in many different areas, such as materials science, toxicology and ecotoxicology, as well as risk assessment and regulation.

Cooperation is therefore needed to develop teaching in nanosafety. Those in need of education and training in this field are also spread throughout society at different types of companies, authorities and organisations and within academia. In order to be able to develop teaching that covers these needs, a focused discussion is required involving the interaction of all relevant parties.

The need for education, training and skills development in the field of nanosafety needs to be mapped and prioritised so that relevant measures can be planned and resources can be utilised in the best possible way. Such mapping and prioritisation can be achieved through collaboration between universities and other stakeholders such as authorities, industry and organisations. In addition, appropriate pedagogical methods should be discussed, for example, campus-based teaching versus web-based education. Distance learning in the form of e.g. e-learning, web-based courses and MOOCs (massive open online courses) provides the opportunity to reach out to many students/course participants, both nationally and internationally. This could also be an attractive form of education and training for professionals. With the help of new technical solutions, there are good opportunities to educate and train many course participants, and to facilitate the development of nanosafety-related courses and programmes. Given our experience of education and training within chemical safety and toxicology, Sweden is well placed to be able to initiate such courses and programmes.

There are currently a few programmes in chemical safety and/or toxicology, such as the Master's programme in Toxicology at Karolinska Institutet (KI), while nanosafety is included as part of other programmes such as the Master's programmes in Chemical Hazards in the Working Environment at KTH Royal Institute of Technology, Nanotechnology for Sustainable Development at the University of Gothenburg, and Nanotechnology for Industrial Applications in Life Science at Uppsala University. PhD courses in nanotoxicology are available at KI and Lund University. However, there is no collective information about programmes and courses that cover nanosafety. Teaching in the safe handling, use and development of nanomaterials is needed, not least, within the framework of programmes in engineering and materials science. In dialogue with various stakeholders, SweNanoSafe has identified a need for a *national network for education and training in nanosafety* (SweNanoSafe, 2019:1). SweNanoSafe can provide information about existing programmes and courses through the platform's website. National cooperation and a network between various relevant stakeholders increases the possibility of developing relevant and needs-based education and training, dissemination of knowledge and efficient use of resources. A national network for education and training can help to highlight the needs for training and professional education within nanosafety and can make it possible to more quickly achieve the implementation of relevant education and training measures at universities and colleges and through other actors.

Measure 10. Development of training and professional education regarding nanosafety in society, in particular in the work environment (in the short term) and integrated into academic programmes within nanotechnology (long term).

As new technologies develop, new risks to people and the environment may arise. To manage, eliminate or minimise these risks, relevant stakeholders (companies, authorities) may need to adapt their work methods. This often means that staff require training and skills development to understand the new materials and how to handle them safely. Just as fire safety training is mandatory in every workplace, training in nanosafety should also be mandatory. In order to increase skills and knowledge within the field of nanosafety in the long term, and to include safety aspects at an early stage of the development of new nanotechnologies (sometimes referred to as *safety-by-design*), it is important that nanosafety be included as a mandatory element of all education and training within nanotechnology and materials science. This requires the coordination of education and training resources, preferably through a national network for education and training (measure 9).

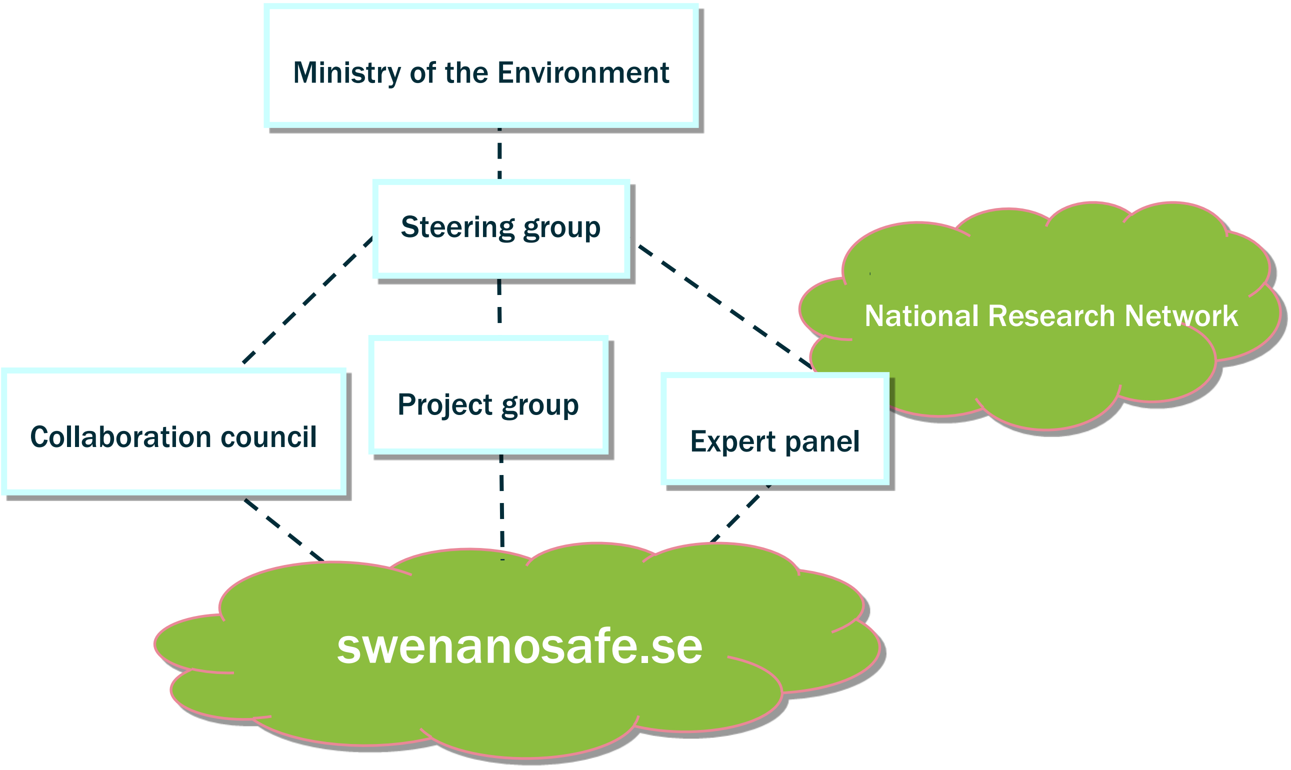
Knowledge about exposure levels, risks and risk management of nanomaterials in the work environment is growing rapidly (WHO, 2017; NIOSH, 2019). Consequently, there is reason to look at how this knowledge can be disseminated so that risks in the work environment can be managed in the best way possible. Proposals highlighted at various SweNanoSafe events include the importance of targeted investments in education, training and competence development for safety officers, occupational safety engineers, occupational hygienists, occupational health service personnel and individuals who develop and handle nanomaterials, for example in the construction industry (SweNanoSafe, 2017:2; idem, 2017:3; idem, 2019:2). The update of REACH concerning nanomaterials, which came into effect on 1 January 2020, may entail a need for training and professional education of personnel at relevant authorities. Just like other groups of professionals, toxicologists also need to regularly update their knowledge. European Registered Toxicologist (ERT) is a way to document the knowledge and skills of toxicologists. To achieve ERT certification, it is necessary to demonstrate broad and in-depth knowledge and skills in toxicology, where one of nine possible areas of specialisation is nanotoxicology. However, access to courses in nanotoxicology is very limited. NIVA (Nordic Institute for Advanced Training in Occupational Health) is one of the few organisations providing courses in nanosafety outside of academia. Consequently, there is a need for education and training in nanosafety that is flexible and can be adapted to the needs and level of prior knowledge of each participant. In order to achieve a wide spread of education, training and skills development, web-based courses should be developed. Comments and viewpoints should be sought and obtained from authorities, companies, organisations and academia, with the aim of adapting the courses to relevant needs and ensuring that the content is as up-to-date as possible.

Through targeted education, training and skills development measures regarding potential risks associated with nanomaterials, and through necessary protective measures, the risk of injury to workers is reduced. In addition, education, training and competence-enhancing measures within nanosafety can lead to more sustainable development of nanotechnology and thus provide Sweden with competitive advantages. With good knowledge about safety data sheets (see chapter 2) and how to design them, as well as guidelines for the safe handling of nanomaterials, manufacturers can disseminate accurate information to other parties in accordance with REACH, and occupational health and safety problems can be avoided.

5. Exchange of knowledge and information

5.1. Background

The report "Safe development – a national action plan for the safe use and handling of nanomaterials" (SOU 2013:70) contains proposed measures for communication and collaboration. Based on those proposals, a national platform for nanosafety (SweNanoSafe) was established. The platform was part of SweTox during the years 2016-2018, before being moved to the Institute of Environmental Medicine (IMM) at KI as of 1 January 2019. By way of government appropriation, KI was allocated funds to *"further develop a platform for the safe handling of nanomaterials that can contribute to the achievement of the environmental quality objective of a non-toxic environment and protect human health"*. The assignment involves communicating and disseminating knowledge about risks associated with nanomaterials to academia, authorities, industry and organisations, and identifying obstacles to the safe handling of nanomaterials. This report is one of the results of this assignment. The platform currently consists of a steering group that leads the work and a project group that, among other things, manages the website and arranges conferences and workshops; in addition, there is a collaboration council that brings together authorities, industry and other stakeholders, and a scientific expert panel with members from several different Swedish universities.



The Swedish platform has organised a series of meetings (workshops) with the aim of taking inventory of and discussing obstacles to the safe handling and development of nanomaterials within various areas, including as a basis for this report. Furthermore, a national nanosafety conference was arranged with focus on research and regulation of nanomaterials (SweNanoSafe, 2017:1), as well as a workshop at IMM on the topics of nanosafety and nanomedicine. In addition to assisting in the platform's work regarding identification of obstacles and measures, these meetings have also served as a forum for networking and the exchange of knowledge between various stakeholders (authorities, industry, organisations, academia). In 2018, SweNanoSafe established a national research network in the field of nanosafety, with 50 or so participants from various Swedish universities and research institutes (SweNanoSafe, 2019:1; idem, 2019:3). Plans are in place to establish an equivalent network for education and training, with the aim of mapping and highlighting education and training activities in the field of nanosafety (see chapter 4). SweNanoSafe collaborates with (among others) MISTRA Environmental Nanosafety, which is a consortium consisting of 5 Swedish universities with focus on the environmental impact of nanomaterials. The platform has also participated in international conferences such as EUROTOX (2019), where we took part in discussions regarding the establishment of a 'network of excellence' in the field of nanosafety (EC4SAFENANO). For 10 years now there has been a forum at EU level, the EU NanoSafety Cluster, which brings together all EU-funded nanosafety projects (www.nanosafetycluster.eu). The aim is to find synergies between various research projects. The platform was initiated by the European Commission's Directorate-General for Research and Innovation (DG RTD), but is led by the researchers themselves. Similarly, there is a platform for dialogue between European and American researchers in the field of "nanoEHS" (environment, health and safety) (www.us-eu.org). In turn, the National Nanotechnology Initiative (NNI) brings together 20 or so American authorities and aims to facilitate a cohesive strategy for research and development in the field of nanotechnology (www.nano.gov). NIOSH is the federal agency in the United States that conducts research and provides guidance on the work environment and on risks associated with nanotechnology (NIOSH, 2019). NIOSH has published several reports containing practical guidance on the safe handling of nanomaterials, for example in small and medium-sized companies (NIOSH, 2014; idem, 2016).

In order to facilitate and improve the exchange of knowledge, experience and information in the field of nanosafety and contribute to the implementation of nanosafety in society, cooperation is required between many different parties at several levels, nationally as well as internationally. The national platform for nanosafety, SweNanoSafe, has an important role to play in this context.

5.2. Obstacles and measures

Measure 11. Increased resources for dialogue and cooperation between national (and international) parties within nanosafety; transfer of knowledge between academia and industry.

The nanotoxicological research conducted during the past decade has largely been of an academic nature (*science-oriented*) rather than addressing issues relevant to risk assessment and regulation (NanoREG, 2017). However, in the dialogue with various stakeholders, SweNanoSafe has found that, when it comes to nanomaterials, both basic research and regulatory research is desirable. The basic research provides us with knowledge about how nanomaterials affect biological systems, while regulatory research - including validation of test methods - is necessary to provide support in the risk assessment of nanomaterials. In order to stimulate relevant research, there is a need for a *dialogue between academia and industry*, and the national cooperation platform SweNanoSafe can play an important role in this context. Knowledge often exists, but it also needs to be communicated (i.e. what do we know and what don't we know about the risks associated with nanomaterials?), while industry's needs also need to be verbalised so that the research within academia and at state research institutes such as RISE can be made more relevant. It is also important to participate in the dialogue at international level, e.g. through the EU NanoSafety Cluster, a European forum that is also open to national actors. The EU NanoSafety Cluster has developed a strategy for European nanosafety research (2013) along with several follow-up 'roadmaps' or strategy documents, for example on research needs of relevance to laws and guidelines regarding nanomaterials (2017). SweNanoSafe's business plan includes arranging a meeting with national platforms or equivalent in the field of nanosafety in Europe as a starting point for further collaboration. The continued development of the website (swenanosafe.se) is also of great importance.

Several international organisations are active in the field of nanosafety, including the OECD. As early as 2007, the OECD Working Party on Manufactured Nanomaterials (WPMN) launched a nanomaterial safety testing programme based on collaboration between health and environmental experts in the various Member States (OECD, 2019). This initiative has resulted in 90 or so reports to date. Sweden is involved in this work and should continue to actively participate in the development of methodology for both testing and risk assessment (SOU 2013:70). Increased resources should be allocated for this purpose, not only at relevant authorities such as KEMI, but also within academia and at various research institutes. ISO is working to develop standards within the field of nanotechnology, including standards for the safe handling of nanomaterials in the workplace. In Sweden, SIS participates in the two international networks, ISO and CEN. Sweden should take part to a greater extent in the standardisation work regarding nanotechnology and nanosafety, as standards are an important tool in the commercialisation of new products.

Measure 12. Increased resources for dialogue and cooperation between national (and international) parties within nanosafety; transfer of knowledge between academia and authorities.

The collaboration council that has been established within the national nanosafety platform represents an initial step in bringing together relevant Swedish authorities and other stakeholders regarding nanosafety issues. Lessons can be learned from the USA and the long-standing collaboration between several different authorities within the framework of NNI (NNI, 2014). Resources should continue to be allocated to support this dialogue; a secretariat is therefore needed at the national cooperation platform, to support the work of both the collaboration council and the expert panel. In addition, competence should be linked to SweNanoSafe to ensure that relevant knowledge regarding research, education and training, laws and guidelines (both national and international) is compiled, and to also ensure that this information is adapted to Swedish conditions (see chapter 2). To achieve such knowledge compilations, increased resources are needed. The members of the expert panel should contribute quality review, but additional resources are needed to produce these reports; the collaboration council, in turn, can contribute opinions and feedback about the areas that should be highlighted to facilitate the work on the safe handling, use and development of nanomaterials. One issue that should be examined is whether it could be possible to implement a joint Nordic initiative regarding knowledge compilations on nanomaterials. It may be possible for such an initiative to be funded by the Nordic Council of Ministers, and SweNanoSafe could undertake to lead the work. In Germany, projects regarding nanosafety are funded at federal level in collaboration with industry, to fill knowledge gaps and implement measures aimed at identifying and minimising the risks associated with nanomaterials. The German platform DaNa and the sequel DaNa2.0, which provides information about various nanomaterials, is part of this initiative (Krug et al., 2018). DaNa2.0 has, among other things, created a searchable database based on available scientific literature about the risks associated with nanomaterials (www.nanoobjects.info). In the Netherlands, RIVM contributes research regarding the risks associated with nanomaterials and information about nanosafety to relevant authorities, including by way of monthly newsletters. The European Commission recently launched an information portal on nanomaterials called EUON (European Union Observatory for Nanomaterials) (www.euon.echa.europa.eu). This portal enables parties interested in nanomaterials to obtain relevant information about, for example, use, exposure, possible toxicity, risks and legislation. The portal, which is operated by the European Chemicals Agency (ECHA), is currently under construction. However, the Swedish website (swenanosafe.se) fulfils an important function, in particular by reaching out with *quality assured* information adapted to Swedish conditions and needs. The website could also be used to provide increased visibility for relevant education and training activities (see chapter 4).

6. Overarching proposal

Measure 13. Proposal for overarching measure for the safe use, handling and development of nanomaterials: a national nanotechnology strategy that includes nanosafety.

The government report "Safe development – a national action plan for the safe use and handling of nanomaterials" (SOU 2013:70) was based on a committee directive on the development of a national action plan to fulfil the Swedish government's ambition regarding the safe handling and use of nanomaterials (Dir. 2012:89). The aforementioned report made many important proposals (SOU 2013:70), and this current report aims to build upon the conclusions of the previous report. However, in order to effectively implement an action plan on the safe use, handling and development of nanomaterials, a national strategy is needed. Vinnova (2010) developed a strategy for nanotechnology almost 10 years ago which stated, among other things, that "risk and innovation aspects should be linked together throughout the entire research and innovation process". A national platform was launched in 2016 with the aim of supporting the safe handling and use of nanomaterials by promoting cooperation between various stakeholders from academia, authorities, industry and organisations (swenanosafe.se). SwedNanoTech (2017) has emphasised the importance of establishing a national strategy for collaboration regarding nanotechnology and other new materials, and has also pointed out the importance of taking health and environmental aspects into account at an early stage of the innovation process. The fact remains that Sweden currently lacks a national strategy for nanosafety. One problem in this regard is that nanosafety is often dealt with in a vacuum, separate from innovation and development. With this report, SweNanoSafe wishes to highlight the need for a *national strategy for nanotechnology* in which nanosafety is included as a natural part, rather than having a separate strategy for nanosafety; such a national strategy should also cover education and training and coordination. A national strategy should be developed on behalf of the Swedish Ministry of the Environment and should ideally involve KEMI and other relevant government ministries and public authorities. The national platform SweNanoSafe can play an important role in this context by bringing together various parties from academia, authorities, industry and other stakeholders. Nanosafety should not be viewed as an isolated phenomenon – safety must be integrated into all use, handling and development of nanomaterials. There is a need for continued investment in national coordination of nanosafety, and this should take place in accord with other international initiatives.

Appendix 3 contains a summary of the proposed measures, together with an analysis of the benefits associated with each measure ("benefits") as well as the obstacles or challenges identified as factors that could hinder the implementation of these measures ("challenges"). The table in appendix 3 also contains an assessment of time perspective, i.e. the measures that can be initiated or implemented in the short, medium and/or long term.

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APPENDIX 1. Legislation regarding nanomaterials

Background

Chemical regulations mainly consist of EU regulations aimed at ensuring the proper functioning of the internal market and, at the same time, the protection of health and safety. They do not provide any real scope for divergent national rules. The regulations apply directly in the Member States, and a Member State may not make national decisions that are contrary to EU legislation. Sweden is actively collaborating with other Member States to bring about improvements in EU legislation on nanosafety. Legislation regarding occupational health and safety and waste (as well as environmental legislation) is decided by way of directives which specify *what* to achieve but leave it up to Member States to decide *how* it is to be achieved. These regulations also allow certain scope for national rules that provide more far-reaching protection. Within certain areas there is scope to impose more ambitious requirements on health and safety. Even regarding the more stringent regulatory frameworks, there is scope to act nationally within areas such as guidance and enforcement, to ensure that the stipulated level of safety is maintained. Through SweNanoSafe's dialogues with various stakeholders, measures have been identified that can be implemented at national level without conflicting with EU legislation. These measures are described in chapter 2. This appendix sets out an extended background on laws and regulations of relevance to nanomaterials.

Chemicals

EU chemicals legislation is essentially designed as regulations and applies directly as law in the Member States. The key provisions are contained in the chemicals regulation, REACH, and in the classification regulation, CLP.[1] For a summary of relevant legislation in Europe and other regions (USA, Korea and Japan), please see: Rasmussen et al. (2017).

Thus, substances and mixtures of substances manufactured or imported into the EU in quantities of at least one tonne per year must be registered pursuant to REACH (the regulation also covers goods to a certain extent). Information must be provided about the substance and its properties, and recommendations must be provided on how the substance can be handled safely. The level of information to be provided depends on the quantity registered. In principle, the information provided must cover all forms of the substance and the hazards they may entail, although specific information does not currently need to be provided about nanoforms. As of 1 January 2020, it is a requirement to also provide nano-specific information in the registration dossier. The revision of the REACH appendices is a step in the right direction and means that the chemicals legislation has now been clarified regarding nanomaterials. However, certain questions remain, for example, the extent to which different nanoforms may be consolidated into one and the same group of materials, which is crucial in relation to the issue of how much information that needs to be obtained when reporting each new nanoform (Clausen & Hansen, 2018).

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[1] Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals, and Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.

Substances and mixtures that are released on the market in the EU and have hazardous properties must be classified pursuant to CLP, irrespective of the quantity of the substance in question. Information about the classification must be included in the registration dossier as well as in the safety data sheet (see below). There are no explicit requirements that nanoforms must be classified separately. However, the classification must be made "in the form in which the substance occurs"; in other words, if the nanoform has properties that differ from the properties of the bulk material, it may need to be classified separately.

If substances are registered in quantities of ten tonnes or more, a chemical safety assessment must be carried out in accordance with REACH. In principle, the information provided must cover all forms of the substance and the hazards they may entail, although specific information does not currently need to be provided about nanoforms. As of 1 January 2020, it is a requirement to also provide nano-specific information.

For substances/mixtures meeting the criteria for classification as hazardous pursuant to CLP, or certain other criteria relating to hazard, a safety data sheet (SDS) must be delivered to professional users together with the substance/mixture. This applies regardless of the quantity involved. The safety data sheet must contain the information that the employer and the worker need about the substance/mixture, including the hazards it may entail and how the work environment risks can be minimised. Safety data sheets generally lack information about nanoforms. Although it is a requirement that information must be provided about (among other things) particle size, it is uncertain to what extent this provision is applied. The European Commission has put forward a proposal that information about nanomaterials must also be included in safety data sheets, and this is expected to come into effect on 1 January 2021.[2]

Work environment

The work environment should be a prioritised area for measures, as the risk of people being exposed to nanomaterials is more likely in the work environment than in other contexts. Waste management is also a work environment issue, as well as an issue of protection of the external environment. There is a major lack of knowledge regarding waste in relation to the issues of which nanomaterials are present in the waste, which ones could be harmful, and how best to dispose of them as part of the waste management process. In the EU, overall work environment issues are regulated in the framework directive for occupational health and safety, while issues relating to chemical safety are regulated in the directive on the protection of the health and safety of workers from the risks related to chemical agents at work.[3] These directives specify a minimum level of protection to be maintained in relation to occupational health and safety, and they allow scope for the implementation of more far-reaching national requirements. The provisions have been introduced into Swedish law through the Swedish Work Environment Act and through the Swedish Work Environment Authority's provisions on chemical hazards in the working environment.[4]

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[2] https://ec.europa.eu/environment/chemicals/nanotech/reach-clp/index_en.htm

[3] Directive 89/391/EEC on the introduction of measures to encourage improvements in the safety and health of workers at work, and Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

[4] The Swedish Work Environment Act (1977:1160), and the Swedish Work Environment Authority's provisions AFS 2011:19.

The employer must identify all chemical risks present in the workplace, the nature of the hazard in question, and whether there are guidance values or limits for the levels that may occur, or other specific rules and regulations. The risk of ill health or accidents must be assessed with consideration of the chemical risk factors that are present and how workers could be exposed. The assessment shall result in decisions regarding measures to be taken to limit the risks.

Waste

Waste is regulated through, inter alia, the EU Waste Framework Directive and the directive on industrial emissions.[5] The EU regulations specify a minimum level to be maintained by all Member States, although they also allow for the implementation of more far-reaching national requirements. The provisions have been introduced into Swedish law through the Swedish Environmental Code and the Swedish Waste Ordinance.[6] The regulations aim to protect the external environment and human health in general. Naturally, waste management also raises issues regarding the work environment and legislation concerning occupational health and safety. According to the EU waste hierarchy, the first step is to prevent waste from being generated. The second step involves recycling of materials or other recovery operations, such as energy recovery (generally incineration). Only if neither of those steps are possible or appropriate may waste be disposed of. Hazardous waste may not be mixed with other waste or materials. Permits are required for various waste management measures or operations. Common standards (BREF documents) have been developed within the EU for what should be considered to be best available techniques (BAT) for waste management.

It should be noted that the waste legislation does not contain any specific regulations regarding nanomaterials, meaning that such materials may be dealt with within the scope of the general regulation of waste management. The European Committee for Standardization (CEN) has developed a technical specification for guidelines for the management and disposal of waste from the manufacturing and processing of nanomaterials ('nano-objects'), which was provisionally adopted in September 2018.[7]

Enforcement

The responsibility for enforcement of legislation relating to chemicals and occupational health and safety is generally designed and applies in the same way, regardless of the form in which the substance or mixture occurs. Consequently, this section applies to enforcement in general, not specific enforcement of nanomaterials. The European Chemicals Agency (ECHA) is responsible for ensuring that registrants provide complete and accurate information at the time of registration. ECHA also has a senior guidance responsibility pursuant to the CLP Regulation. Responsibility for enforcement of compliance with REACH, CLP, occupational health and safety legislation and waste legislation at *national level* rests with the national authorities. In Sweden, KEMI, the County Administrative Board and the local municipality are responsible for enforcement of chemicals, while the Swedish Work Environment Authority is responsible for enforcement of occupational

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[5] Directive 2008/98/EC on waste, and Directive 2010/75/EU on industrial emissions.

[6] The Swedish Environmental Code (1998:808), and the Swedish Waste Ordinance (2011:927).

[7] CEN/TS 17275 Nanotechnologies - Guidelines for the management and disposal of waste from the manufacturing and processing of manufactured nano-objects.

health and safety. The Swedish Environmental Protection Agency is the senior (guiding) supervisory authority when it comes to environmental and waste legislation, and the County Administrative Board or the local municipality is the operational supervisory authority. The enforcement responsibility overlaps somewhat between the authorities, and the boundaries are not always entirely clear. For example, KEMI is responsible for ensuring that manufacturers and importers (primary suppliers) meet the requirements specified in chemicals legislation, while the Swedish Work Environment Authority is responsible for occupational health and safety issues in the same businesses/activities, and the County Administrative Board or local municipality is responsible for enforcement in relation to the external environment.

Miscellaneous

EU legislation largely covers nanomaterials, although it is only in recent years that the regulatory frameworks specifically state that they also regulate nanomaterials. The following is a brief account of such new or updated regulations.

Active substances intended for use in *biocidal products* must be authorised before they may be used. Such authorisation does not cover the nanoform of the active substance, unless this is explicitly mentioned. Nanomaterials are only permitted in biocidal products if there is a specially developed risk assessment. The biocidal product must be labelled with the name of each nanomaterial it contains, followed by the word "nano" in brackets. Furthermore, products containing nanomaterials cannot be subject to a simplified authorisation procedure.[8]

A fundamental requirement in relation to *cosmetic products* is that they must be safe for human health. Cosmetic products must be reported before they may be released onto the market in the EU. Comprehensive information must be provided about the product, including as a basis for assessing the safety of the product and enabling it to be traced up and down the supply chain. If the cosmetic product contains nanomaterials, additional information requirements apply. The product must also be labelled with information about the nanomaterials it contains, followed by the word "nano" in brackets. The European Commission shall publish and regularly update a catalogue of nanomaterials used in cosmetic products.[9]

All foods intended for final consumers or mass caterers must be accompanied by *food information.* The food information must be available and easily accessible. All ingredients must be clearly indicated in a list of ingredients. This also applies to all ingredients present in the form of engineered nanomaterials, which must also be followed by the word "nano" in brackets.[10]

Novel foods, i.e. any food that was not used for human consumption to a significant degree within the Union before 15 May 1997, must be authorised and included in a Union list before they may be placed on the EU market. If the novel food consists of or contains engineered nanomaterials, the tests carried out to demonstrate that the novel food does not pose a safety risk to human health must be scientifically appropriate for nanomaterials.[11]

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[8] Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products.
[9] Regulation (EC) No 1223/2009 on cosmetic products.
[10] Regulation (EU) No 1169/2011 on the provision of food information to consumers.
[11] Regulation (EU) No 2015/2283 on novel foods.

Substances to be included in *plastic materials intended to come into contact with food* must be authorised and included in a list of authorised substances. Substances in nanoform may only be used in such plastic materials if they are explicitly authorised and mentioned in specifications under the Regulation.[12]

Special attention shall be given to nanomaterials when *medical devices* are designed and manufactured. All risks linked to the size and the properties of nanoparticles which are or can be released into the user's body shall be reduced as far as possible. Products incorporating or consisting of nanomaterial belong to the highest risk class if they present a high or medium potential for internal exposure, and shall be subject to more stringent evaluation procedures than medical devices 'in general'.[13] For a summary of the laws and regulations applicable within nanomedicine, both in the EU and in other regions (USA and China), please see Marques et al. (2019).

[12] Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food.

[13] Regulation (EU) No 2017/745 on medical devices.

APPENDIX 2. Swedish nanosafety research

NATIONAL RESEARCH NETWORK

SweNanoSafe organised a workshop in June 2018 on research and education and training at Karolinska Institutet (SweNanosafe, 2019:1), and in connection with this workshop, a national network for researchers in the field of nanosafety was established. The researchers in the network can be divided into the areas of health, life cycle perspective, materials science, modelling, risk analysis, work environment, external environment and ELSA (ethical, legal and social aspects) (Figure 1).

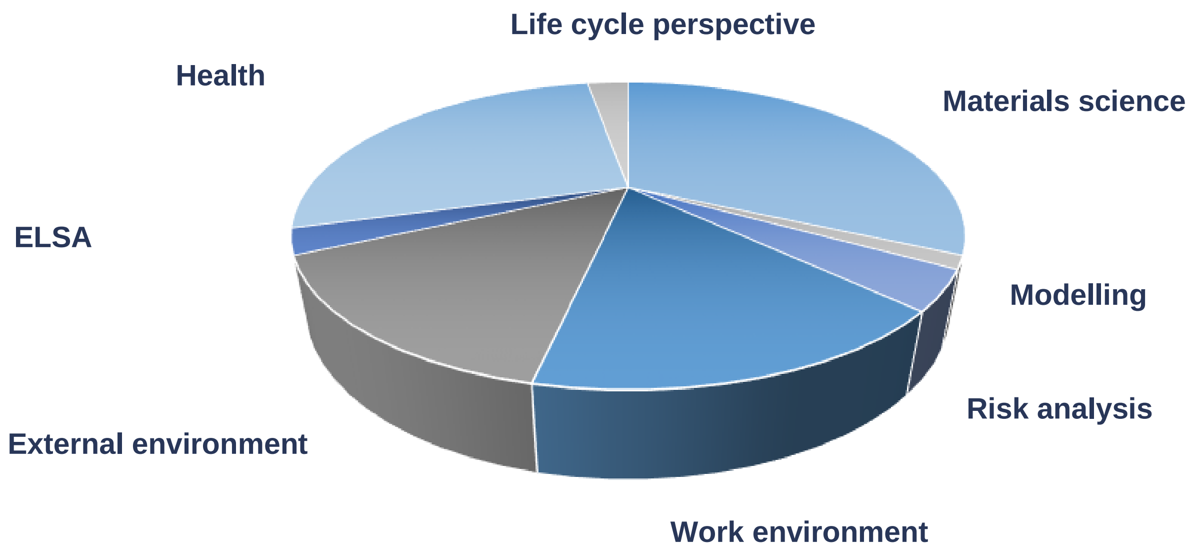

Figure 1. Nanosafety researchers in Sweden (n=75) divided into various research disciplines.

SWEDISH NANOSAFETY RESEARCH

In the summer of 2018, to map Swedish nanosafety research, SweNanoSafe gave Karolinska Institutet University Library (KIB) the assignment of carrying out a bibliometric analysis of research articles in the field. The keywords were defined by SweNanoSafe's expert panel.

Method

The bibliometric analysis was based on discussions between the project group, the expert panel and KIB aimed at achieving a common view on how bibliometric analysis should be carried out.

SweNanoSafe therefore gave KIB the assignment of performing a mapping of Swedish nanosafety research i.e. of carrying out a bibliometric compilation of the research at Swedish universities and research institutes, and of highlighting collaborations between them.

The bibliometric analysis was based on keywords relevant to the research field (see table 1) and was limited to Swedish universities and research institutes (table 2). Timewise the analysis was limited to the period 2001-2018. KIB chose to use Web of Science® as the search engine because it is more comprehensive than PubMed. However, Web of Science® differs from PubMed in that the keywords are not standardised. PubMed uses MeSH terms (medical subject headings), while Web of Science® is based on the article title and keywords specified by the author. This imposes demands on the ability to select keywords that cover different variations of the same word, including synonyms.

Results

KIB's first search (29/08/2018) resulted in 1,153 hits for the period 2006-2017. KIB based the search on terms that had been defined by the expert panel. KIB also added more terms that emerged during the work on the search. KIB chose not to include some terms because that they were too broad and did not address nanosafety. The terms in question were "mechanisms", "exposure", "characterisation" and "modelling". KIB made a special limitation in relation to the term "environment" since that it can be difficult to interpret. KIB therefore used more specific terms such as "ecology" and "environment" in combination with "impact" or, alternatively, focused on the publications found in subject categories related to the environment, such as "environmental sciences". KIB then reperformed the search in Web of Science® (03/12/2018) with additional keywords at the suggestion of the expert panel and the project group for the period 2001-2018. Some search terms were removed because they were considered to be specific to nanomedicine, such as "therapy", "diagnosis" and "theranostics". KIB also corrected some search terms and chose not to include certain terms which they deemed to be too broad. The new search resulted in 2,001 publications. A manual review performed by the project group (without the involvement of the expert panel) showed that many of the articles had nothing directly to do with nanosafety, but were instead about pure materials science and/or nanomedicine, and for this reason the articles in question were culled. A third search was performed on 04/03/2019 to capture all relevant publications for the year 2018. This search resulted in 2,018 publications for the years 2001-2018, of which 378 articles were deemed by the project group to be linked to nanosafety, and it is these articles that have been used in the further analysis.

Figure 2 below shows the total number of Swedish nanosafety publications per year during the period 2001-2018 for all universities and colleges. The figure shows an increasing trend: from five (5) publications in 2007 to (at least) sixty (60) publications in 2018.

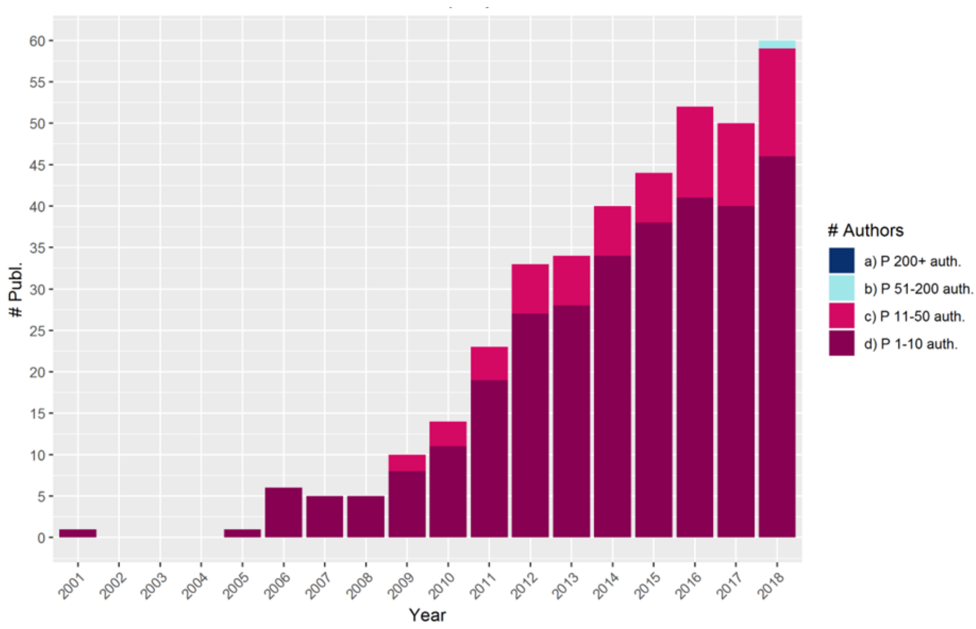

Figure 2. Swedish nanosafety publications per year for the period 2001-2018 (Web of Science®).

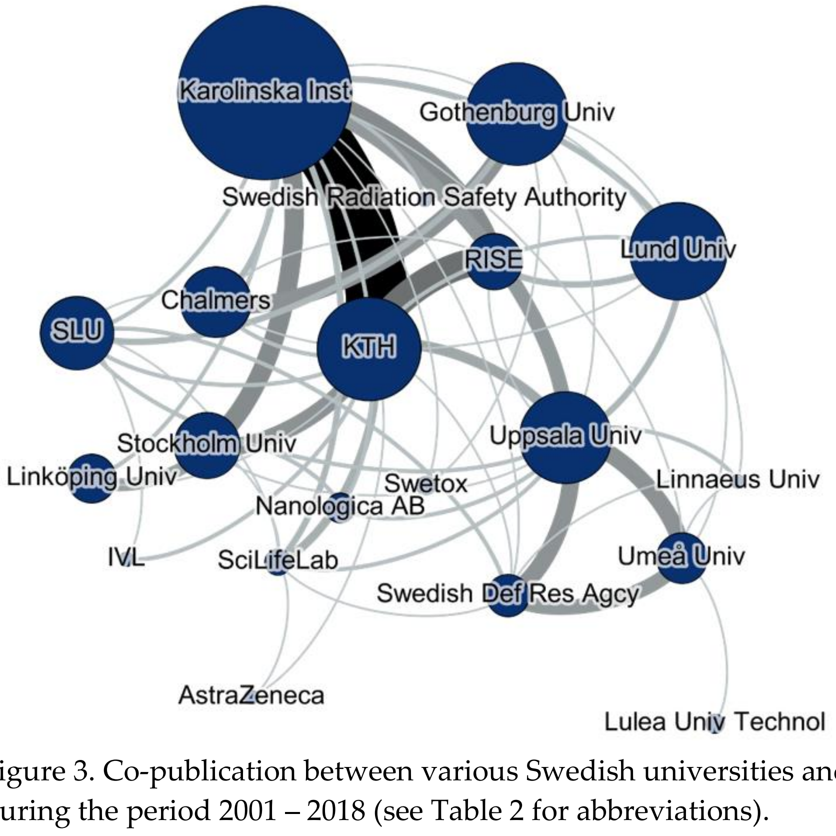

Figure 3. Co-publication between various Swedish universities and higher education institutions during the period 2001 – 2018 (see Table 2 for abbreviations).

KIB also analysed the articles regarding co-publication between various universities and research institutes (Figure 3). The size of the nodes in the figure corresponds to the number of publications for which the organisation is listed as a co-author. The thickness of the lines between the nodes indicates the collaboration between each organisation. As shown by the figure, the collaboration between Karolinska Institutet and KTH was most pronounced. Figure 4 (below) shows the network of researchers and the research areas during the last 10 year period.

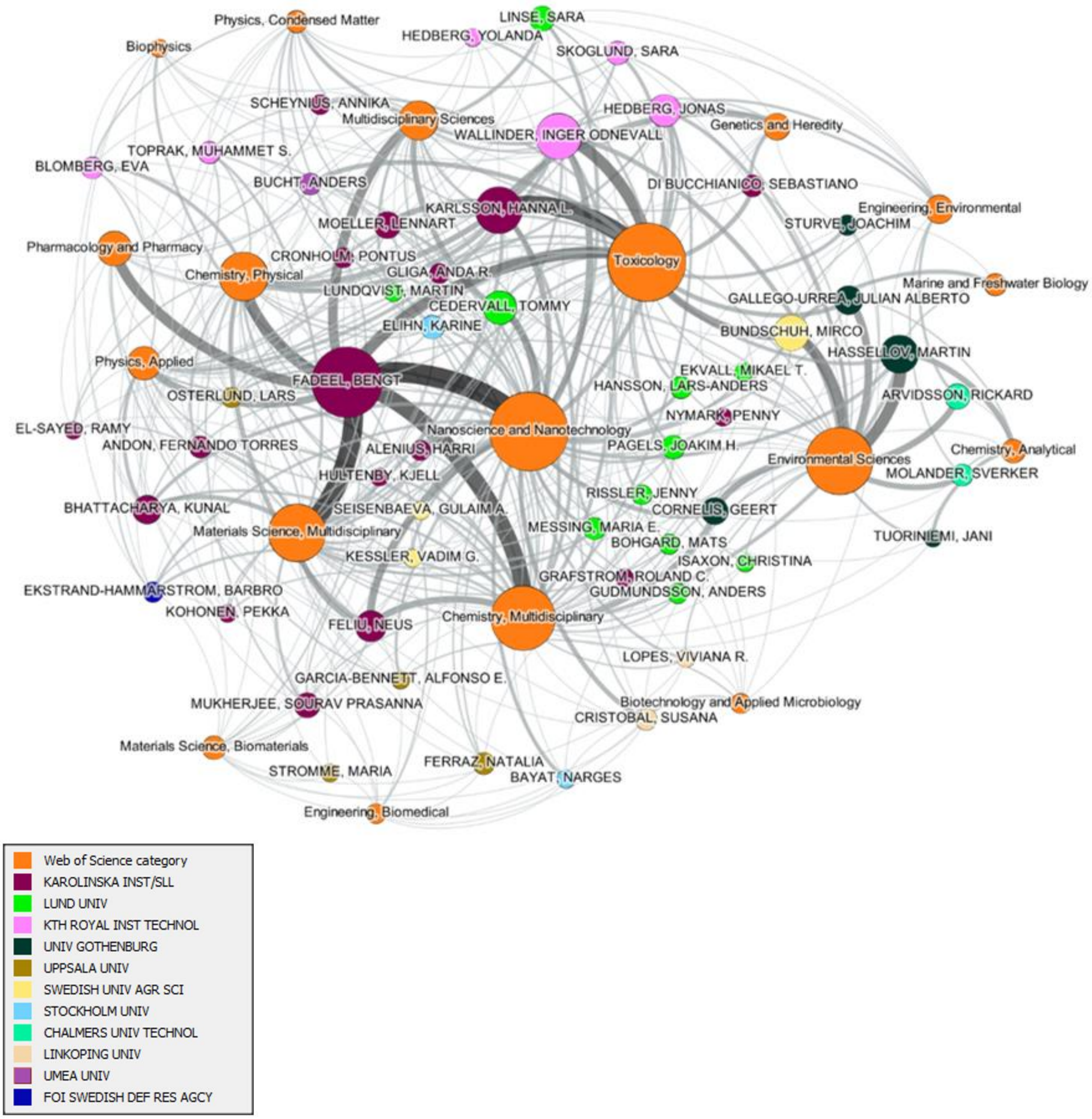

Figure 4. Network of nanosafety researchers based on publications during the period 2009 - 2018.

Table 1. Keywords used for searches in Web of Science®

Adverse outcome pathways (AOPs)
Airborne
Biocorona (or: corona)
Biomarkers
Carbon nanotubes/silver nanoparticles/nanosilica
Characterization
Ecotoxicology
Emission/emissions
Engineered nanomaterials
Environment
Exposure
Hazard
Human health/health effects
Impact
Inflammation
Life cycle assessment
Mechanisms
Metabolomics
Modeling/modelling
Nanomaterial/Nanomaterials
Nanomedicine
Nanoparticle/nanoparticles/ultrafine particles
Nanosafety/safety
Nanostructures
Nanotechnology
Nanotoxicity/cytotoxicity/genotoxicity
Nanotoxicology
Nanotubes
Occupational/occupational health
Physicochemical (or: physico-chemical)
Proteomics
Quantitative structure-activity relationships (QSARs)
Regulations
Release
Risk assessment/risk/risk management/risk perception
Synthesis
Systems biology
Systems toxicology
Toxicity/pulmonary toxicity
Toxicology
Transcriptomics
Waste

Table 2. Higher education institutions, universities and research institutes

Chalmers University of Technology
FOI Swedish Defence Research Agency
University of Gothenburg
Dalarna University
IVL Swedish Environmental Research Institute
Karlstad University
Karolinska Institutet
KTH Royal Institute of Technology
Linköping University
Luleå University of Technology
Lund University
Mid Sweden University
RISE Research Institutes of Sweden
Stockholm University
Swedish University of Agricultural Sciences
SweTox Swedish Toxicology Sciences Research Center
Umeå University
Uppsala University
VTI Swedish National Road and Transport Research Institute
Örebro University

APPENDIX 3. Summary of proposed measures

	Obstacles/Background	Proposed measure	Comments
1.	Clear and user-friendly guidance documents (in Swedish) form a key part of the work aimed at achieving increased safety in the work environment. There are compilations about nanomaterials in the work environment in English and other languages, and these should be compiled and translated (possibly adapted) into Swedish. At EU level (ECHA), work is ongoing to introduce requirements on nano-specific information in safety data sheets, although an adaptation to Swedish conditions may be needed in this case as well. Please see chapter 2 for a detailed description.	**National guidance document for employers and workers regarding nanosafety in the work environment, and updating of guidance documents regarding safety data sheets.** Responsibility: The Swedish Agency for Work Environment Expertise (MYNAK) in consultation with other actors such as the Swedish Work Environment Authority and KEMI. Time perspective: short term.	Benefits: Safer work environment. Challenges: Continuous updating is needed based on the prevailing state of knowledge nationally and internationally. The knowledge must be quality assured before it is translated into guidance documents.
2.	Certain nanomaterials can cause harm to human health (IMM, 2018). However, there are no binding hygienic limits for nanomaterials, due, among other things, to the lack of scientific evidence and difficulties in measuring exposure to nanomaterials in the work environment. Some recommended guidance values have been published (WHO, 2017) and these can serve as non-binding recommendations to better control the work environment risks associated with nanomaterials. Please see chapter 2 for a detailed description.	**Compilation of international recommendations regarding guidance values for levels of nanomaterials in the work environment, and investigation of the need for national recommended guidance values in the work environment.** Responsibility: MYNAK in consultation with the Swedish Work Environment Authority. Time perspective: short to medium term.	Benefits: Safer work environment. Facilitates exposure assessment. Challenges: Guidance values that cannot be complied with in the absence of measurement methods.

3.	The enforcement responsibility for chemical management partly overlaps between different authorities (see chapter 2 and appendix 1). Knowledge about the risks associated with nanomaterials and about how such risks should be managed is gradually increasing as related research makes progress. Enforcement is a consequence of new requirements regarding nanomaterials in the REACH appendices which came into effect on 1 January 2020. There is potential to develop the coordination between relevant authorities regarding enforcement and documentation of nanomaterials. The national cooperation platform SweNanoSafe can play an important role in this context. Please see chapter 2 for a detailed description.	**Enforcement of nanomaterials in the work environment should be enhanced and coordinated to a greater degree between the responsible parties and should be continuously adapted as new knowledge about nanomaterials becomes available.** Responsibility: The supervisory authorities. In addition, the Swedish Work Environment Authority, together with KEMI, should develop guidance documents with nanomaterial-specific information (in Swedish). Time perspective: medium term.	Benefits: Better enforcement. Safer work environment. Challenges: Requires coordination between authorities with enforcement responsibilities, i.e. national authorities, county administrative boards and local municipalities. Professional education and training is also needed.
4.	There is a lack of information about whether waste streams contain nanomaterials. Consequently, there is a lack of possibility to implement measures for the safe management of waste and an assessment of the risk of the spread of hazardous nanomaterials to the external environment. In the longer term, methods for the recovery of nanomaterials should be developed to ensure sustainable use of nanotechnology. Cooperation is needed between authorities, companies, trade organisations and academia. Please see chapter 2 for a detailed description.	**Mapping of major waste streams containing nanomaterials, and investigation of technical solutions that facilitate the safe recycling of waste containing nanomaterials.** Responsibility: The Swedish Environmental Protection Agency should play a leading role in this work, in cooperation with other relevant authorities such as KEMI and the Swedish National Board of Housing, Building and Planning, trade organisations and companies. Time perspective: medium to long term.	Benefits: Non-toxic environment. Sustainable development within nanotechnology. Challenges: Requires extensive technology and methodological development (although such investments represent a benefit in the long run). High demands on collaboration between various actors.

5.	Basic research regarding how nanomaterials interact with biological systems is needed and could form the basis for a better risk assessment of nanomaterials. It is important that priority be given to work involving alternative testing methods (i.e. alternatives to animal testing), in line with international work, for example within OECD. There is a need to standardise test methods and reference materials within nanotoxicological research. Please see chapter 3 for a detailed description.	**Continued research regarding basic toxicity mechanisms, although the research should also be directed towards regulatory relevance and validation of test methods for nanomaterials.** Responsibility: research funders and researchers at universities and research institutes (research, validation). Time perspective: long term.	Benefits: Better risk assessment. Reduction in animal testing. Challenges: Validation of new methods is time consuming, and international collaboration is needed.
6.	Research in the field of nanosafety has so far been focused on hazard and to a lesser extent on exposure. There is a lack of life cycle-relevant data about how nanomaterials interact with biological systems from "cradle to grave". There is a need for more knowledge about waste streams and whether certain materials are particularly harmful to health and the environment in connection with waste management, and how nanomaterials can be recycled. There is a lack of reliable methods for measuring nanomaterials in the work environment and the external environment. Please see chapter 3 for a detailed description.	**Knowledge is needed about the actual exposure to nanomaterials in both the work environment and the external environment, and a life cycle perspective should be applied to all nanomaterials.** Responsibility: MYNAK and other authorities (knowledge compilation); researchers (methods for exposure and recycling). Time perspective: medium to long term.	Benefits: Better risk assessment and risk management. Challenges: Requires method development and a reprioritisation of research funding to support exposure research/measurements.
7.	There is still a lack of adequate supporting data for risk assessment of nanomaterials. This is largely due to the fact that the research is not adapted to regulatory needs. It is common practice that Swedish authorities do not control resources or	**Multidisciplinary research should be prioritised, and the research must be made more relevant to risk assessment; authorities should be mandated**	Benefits: Better coordination and better risk assessment. Challenges: Multidisciplinary research imposes demands on collaboration. In addition

	have a mandate to direct and prioritise research. Funding for small and medium-sized research projects is insufficient. Few projects apply a life cycle perspective from material development to use of products containing nanomaterials. Please see chapter 3 for a detailed description.	**to coordinate research that meets regulatory needs.** Responsibility: government ministries and relevant authorities such as KEMI as well as research funders and researchers. Time perspective: short to medium term.	to academic researchers, other actors such as state research institutes should also be involved in regulatory research.
8.	The national report regarding the safe use and handling of nanomaterials (SOU 2013:70) highlighted the importance of making the most of the potential of nanomaterials while also taking into account possible health and environmental risks. It is absolutely crucial that safety be integrated at an early stage of the innovation process, something which is sometimes referred to as 'safety-by-design'. However, a broader grasp of safety along with other societal aspects is needed in connection with the development of nanotechnology (commonly referred to as "responsible research and innovation"). Please see chapter 3 for a detailed description.	**State-funded research and development in nanotechnology should meet set requirements regarding safety and ethics, i.e. 'responsible research and development'.** Responsibility: state research funders such as VINNOVA and VR who support innovation and development projects. Time perspective: can be implemented in the short term.	Benefits: Safer innovation process and safer products. Challenges: A lack of toxicological competence at small and medium-sized companies makes it difficult to implement safe/responsible innovation.
9.	Nanosafety is a multidisciplinary field that requires competence in several areas. Cooperation is therefore needed to develop teaching within the area. The need for education, training and skills development in the field of nanosafety needs to be mapped and prioritised so that relevant measures can be planned and resources can be utilised in the best possible way. There is a need for a national	**National network for the mapping, prioritisation and communication of education and training in nanosafety – coordinated through the cooperation platform SweNanoSafe.** Responsibility: SweNanoSafe, together with various actors within education and companies	Benefits: Enhancement of skills and knowledge in the field of nanosafety. Increased collaboration. Challenges: Educational activities within nanotechnology and nanosafety are spread out at several different universities, and those in need of such activities are also spread out

	network for education and training similar to the national network already established for researchers (appendix 2). Lessons can also be learned from SweTox which, among other things, strove for the coordination of education and training in the field of chemicals, health and environment. Please see chapter 4 for a detailed description.	and other actors with a need for education and training. Time perspective: can be initiated in the short term.	within different companies, authorities, etc. which places great demands on coordination.
10.	Personnel (including safety officers) need professional education and training and skills development to be able to assess and manage/eliminate risks associated with the handling of nanomaterials; just as fire safety training is mandatory in every workplace, training in nanosafety should also be mandatory. The update of REACH which came into effect on 1 January 2020 may entail a need for professional education and training at relevant authorities. Furthermore, safety/risk should be integrated into technical training related to nanotechnology and other new materials. Please see chapter 4 for a detailed description.	**Development of training and professional education regarding nanosafety in society, in particular in the work environment and integrated into academic programmes within nanotechnology.** Responsibility: SweNanoSafe and other actors such as education and training companies and universities. Time perspective: medium to long term.	Benefits: Enhancement of skills and knowledge in the field of nanosafety. Safer work environment. Challenges: It is difficult to influence the prioritisation of educational measures at various universities.
11.	A national cooperation platform within nanosafety (SweNanoSafe) has been established to promote cooperation between various stakeholders, including academia and industry. This work should continue, and the needs of industry must be made clear so that the research can be made more relevant. Furthermore, it is also important to	**Increased resources for dialogue and cooperation between national (and international) parties within nanosafety; transfer of knowledge between academia and industry.**	Benefits: Increased coordination and knowledge transfer within nanosafety. Challenges: There is a lack of incentive for researchers to engage in the dialogue with the surrounding society. Companies, on the other

	participate at international level, not least in the standardisation work (ISO, CEN), and to participate actively in the OECD's work regarding nanotechnology and nanosafety. Please see chapter 5 for a detailed description.	Responsibility: SweNanoSafe (on behalf of the Swedish Ministry of the Environment) together with relevant stakeholders. Time perspective: short term (the work is already under way).	hand, cannot share all information with other parties for competitive reasons.
12.	A national cooperation platform within nanosafety (SweNanoSafe) has been established to support the dialogue between academia and relevant authorities. SweNanoSafe should be given additional resources to ensure that existing knowledge at national and international level is compiled and adapted to Swedish conditions and the needs of Swedish authorities, and that the knowledge being communicated is also quality assured; the expert panel at SweNanoSafe (chapter 5) and the national research network (appendix 2) have an important role to play in this context. Please see chapter 5 for a detailed description.	**Increased resources for dialogue and cooperation between national (and international) parties within nanosafety; transfer of knowledge between academia and authorities.** Responsibility: SweNanoSafe (on behalf of the Swedish Ministry of the Environment) together with relevant stakeholders. Time perspective: short term (the work is already under way).	Benefits: Increased coordination and knowledge transfer within nanosafety. Challenges: There is a lack of incentive for researchers to engage in the dialogue with the surrounding society; focus is on the research itself, and science outreach is not viewed as a merit.
13.	In order to effectively implement an action plan (SOU 2013:70) on the safe use, handling and development of nanomaterials, a national strategy is needed. Sweden lacks a strategy for nanosafety and, in addition, nanosafety is often dealt with separately from innovation and development, despite consensus that safety/risk and innovation aspects should be consolidated. Please see chapter 6 for further background.	**Proposal for overarching measure for the safe use, handling and development of nanomaterials: a national nanotechnology strategy that includes nanosafety.** Responsibility: Swedish Ministry of the Environment. Time perspective: can be initiated in the short term.	Benefits: Safe development and handling of nanomaterials. Non-toxic environment. Challenges: Nanosafety may potentially be overshadowed by other aspects of a strategy on nanotechnology.