2021:6

SweNanoSafe

Swedish National Platform for Nanosafety

Toward Safe and Sustainable Nanotechnology Innovation

Executive Summary

Foreword

Through a mandate from the Ministry of the Environment and the Swedish Chemicals Agency, SweNanoSafe maintains a national platform for the safe handling of nanomaterials, to contribute to the achievement of the environmental quality goal of a non-toxic environment and to protect human health. The platform aims to disseminate knowledge and provide advice and support to authorities on issues related to the safe handling and use of nanomaterials. SweNanoSafe brings together academia, authorities, industry, and organisations in a joint dialogue on nanosafety. This also includes identifying needs for the safe handling of nanomaterials and contributing solutions and concrete measures that meet the needs, as well as actively promoting improved nanosafety.

Since 2019, SweNanoSafe has been hosted by the Institute of Environmental Medicine at Karolinska Institutet. The platform is comprised of a Steering Board, Operations Coordination Group, Scientific Expert Panel, Government Agency Council, Research Network, and Education Network, and conducts activities such as workshops and meetings, and communication *via* a website (www.swenanosafe.se).

SweNanoSafe welcomes questions, comments, and proposals regarding nanosafety, through swenanosafe@swenanosafe.se.

Many stakeholders are involved in activities such as research, development, production, use, recycling/final disposal processes, and regulatory management throughout the life cycle of engineered nanomaterials. One important aspect is to promote the integration of safety early in the innovation process. Through our stakeholder workshops, we have found that understanding and assessment are absent with regard to current practice for the governance needed for rapid learning and responsible nanomaterial innovation. There is also a lack of examples as to how Responsible Research and Innovation (RRI) is managed in practice (safe by design, precautionary principle, etc). Furthermore, we identified a need to develop an understanding of the current experiences of the various stakeholders on how to innovate responsibly. As a result, SweNanoSafe commissioned a preliminary study to address these issues, and the assignment was carried out by Action Research Center for a Resilient Society (Gothenburg, Sweden). Rune Karlsson at SweNanoSafe authored the present executive summary based on the study report by Sari Scheinberg and Sverker Alänge at Action Research Center.

Stockholm, 21 December 2021

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Pixabay

This report can be downloaded from www.swenanosafe.se

Stockholm, December 2021

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List of abbreviations

BPR	Biocidal Products Regulation
Cefic	European Chemical Industry Council
ChemSec	International Chemical Secretariat
CLP	Classification, Labelling and Packaging (EU Regulation: EC 1272/2008)
CNT	Carbon nanotube
EC	European Commission
ECHA	European Chemicals Agency
EEA	European Economic Area
ENM	Engineered nanomaterial
EU	European Union
FP	Framework Programme
GLP	Good Laboratory Practices
ISO	International Organization for Standardization
KEMI	Swedish Chemicals Agency (Kemikalieinspektionen)
KIR-nano	Risks of Nanotechnology Knowledge and Information Centre
LV	Swedish Medical Products Agency (Läkemedelsverket)
NDA	Non-disclosure agreement
NGO	Non-governmental Organisations
NM	Nanomaterial
OA	Open Access
OECD	Organisation for Economic Co-operation and Development
PPP	Public-Private Partnership
RATA	Risk Analysis and Technology Assessment
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals (EU Regulation: EC 1907/2006)
R&I	Research and Innovation
RIVM	Dutch National Institute for Public Health and the Environment
RRI	Responsible Research and Innovation
SAAMs	Swedish Association of Advanced Materials
SDS	Safety Data Sheet
SIN	Substitute It Now!
SiO_2	Silica (silicon dioxide)
SME	Small and Medium-sized Enterprise

1. Introduction

Responsible Research and Innovation (RRI) was developed as an approach by the European Commission (EC) about 10 years ago and involves "societal actors working together during the whole research and innovation process in order to better align both the process and its outcomes, with the values, needs and expectations of European society" (1). Other organisations have also adapted RRI-terminology with slightly different meanings or definitions, but all agree that societal challenges should be the primary focus of scientific research, and agree on the methods to be used to achieve this goal (2).

RRI proposes to change research and innovation (R&I) systems through more transparent, participatory, and reflective processes calling for the co-responsibility of different actors in deciding R&I agendas. Awareness and implementation of RRI principles can potentially lead to functional engineered nanomaterials (ENMs) already being risk-optimised from the start of the value chain.

The backstory for RRI begins during the Fifth Framework Programme (FP5, 1998–2002) with the EC's publication in 2001 of its White Paper on governance (3). The RRI approach was put firmly on the European policy agenda in 2012 and positioned as a cross-cutting concept that would support a then future eighth Framework Programme (FP8) called "Horizon 2020" (4). With the introduction of a ninth programme (FP9) "Horizon Europe" (2021–2027), RRI remains an operational objective (5).

To date, there is a lack of knowledge as to the extent RRI is carried out in Sweden within the area of ENM – development and how RRI is handled in practice, for example in terms of concepts such as the precautionary principle and safe by design. The participation and representation of key stakeholders in core activities regarding RRI in the various processes during the life cycle of ENMs is not clear, how each stakeholder views the value they bring, the roles and responsibilities they have, the relations and dynamics they contribute to, and what they need from the other stakeholders.

One way to address RRI was recognised in a SweNanoSafe report from 2020: Proposals for national measures for the safe use, handling, and development of nanomaterials (6) by suggesting "…research and development in nanotechnology should meet set requirements regarding safety and ethics… (measure 8)".

A study was commissioned by SweNanoSafe together with researchers (Sari Scheinberg and Sverker Alänge) from the Action Research Center to contribute to knowledge and understanding, to create new ways of meeting, and gather information on how stakeholders work with nano innovation and nanosafety today, through in-depth interviews and by identifying those who may be interested in participating in a national collaboration to create better RRI processes. A key question, among others, within the scope of the study, was: How can we create and maintain a sustainable workflow in industry, government, and academia that strengthens and integrates a safe and responsible process of research, innovation, and utilisation at all stages of the ENMs life cycle?

Several participants from different stakeholder groups participated in discussions to identify/develop a process that would contribute to the improved implementation of an RRI approach. The study has shown the urgency of establishing collaboration between stakeholders about nanosafety practices in the form of a "safety network" involving all stakeholders to shorten the time to market for safer substances, chemical products, and articles.

2. Method

Action research has its background in two different traditions. The first is related to education and views action research as research-oriented towards the enhancement of current practice (7), while the second describes action research as a systematic collection of information that is designed to bring about social change (8). Booth seeks advances through the simultaneous processes of action and research that are linked by critical reflection.

In this project, primarily associated with the first tradition "enhancement of current practice", main stakeholders were identified and invited, committing to a long-term iterative process aiming to jointly study and learn and thereby contributing to innovative and safer ENMs. The project was conducted from November 2019 to March 2021.

2.1 Sample information

The sample was obtained by identifying relevant organisations through discussion with colleagues at SweNanoSafe and Swedish Association of Advanced Materials (SAAMs) (formally known as SwedNanoTech), the reviewing of research papers and reports, and through web searches. Organisations identified were large companies, start-ups and SMEs, government (agency, authority), academia, research institutes, foundations, funders, and NGOs. In the end, representatives from 26 organisations were invited to be interviewed, of which all accepted (see Table 1). In total, interviews were conducted with 33 respondents, four of them representing two organisations.

2.2 Data collection

Among the interviewees, eleven companies were producing ENMs, providing services or applications, based on the use of ENMs. The interviewed organisations included one large company with decades of experience in silica (SiO_2) production. Except for this well-established company, the sample included start-ups and other SME companies. Five of the interviewed start-ups were focusing on graphene: Two start-ups produced graphene, including graphene-based metal oxide nanocomposites. Other applications of graphene included graphene in coatings and paint, graphene reinforced concrete, and graphene for cooling electronic devices.

Among the non-graphene start-ups, one was producing long polymer nanofibres that mimic structures in the human body, with applications in tissue engineering. A few could be classified as service providers, offering collaboration on R&D and/or nanosafety testing. A few SMEs provided applications based on ENMs such as carbon nanofibres catalytically grown on surfaces for use in electronic devices, nanostructure capacitors, and nano release material (acting as a non-sticking surface). The sample included two biotech companies, one providing nanoparticle delivery for single-cell biology, the other a technique of nano-sized membrane vesicles for intracellular delivery of antibodies.

Table 1: Distribution of stakeholders in different categories.

Categories of stakeholders	Sum	SiO_2	Graphene	CNT	Research	Service provider	Biotech	Other
Start-ups, other SMEs	10	-	5	1	-	2	2	-
Large companies	2	1	-	-	-	-	-	1
Research Institutes	2	-	-	-	-	-	-	2
Foundations	1	-	-	-	-	1	-	-
Universities	5	-	-	-	5	-	-	-
Nanosafety platforms	2	-	-	-	-	-	-	2
Research funding bodies	1	-	-	-	-	-	-	1
Government agencies	1	-	-	-	-	-	-	1
NGOs	1	-	-	-	-	-	-	1
Business associations	1	-	-	-	-	-	-	1
Total	26	1	5	1	5	3	2	9

2.3 Interviews and workshops

The research questions were selected based upon the purpose and principles that were driving the project and subsequent actions. An interview guide (9) with six main questions (Table 2) was created to lead the interviews and thereafter adjusted to meet the needs and perspectives of the various stakeholders interviewed. The key method of collecting data was through individual, semi-structured interviews along with interview questions that were formatted as the discussion developed.

Interviews were conducted by Sari Scheinberg and Sverker Alänge in Gothenburg, Linköping, Lund, Stockholm, and Uppsala either in-person or online. Rune Karlsson participated in most of the interviews. In addition, an online interview was accomplished with a representative from a Dutch research institute. In total, interviews were carried out with 33 interviewees from 26 organisations.

In addition to the interviews, two online feedback workshops (10 June 2020 and 9 September 2020) were conducted. The purpose was to confirm the initial analysis with the participating interviewees, the collection of any missing data, and ultimately, the validation of the findings to create an overall picture of consensus. Also, to get all voices and perspectives into the discussion, generate priorities and ideas for improvement, and formulate any concrete next steps.

Table 2: Main research questions addressed in the present study.

	Research questions
1	What are the current practices regarding RRI?
2	How does regulation and policy guide and support RRI?
3	How do work culture and moral code support and hinder safe innovation?
4	How do stakeholders work and collaborate?
5	What are the ideas for improvement?
6	What is important when we explore these questions together?

3. Summary of findings

3.1 Access to scientific journals and databases

Academic results are often published in journals that are restricted and are written for other academics, that are not primarily for industry utilisation or public consumption. While some SMEs, including start-ups, have connections at the university that can give them access to scientific-technical literature and databases, many lack this opportunity. Also, for small companies, a subscription often comes with a very high cost (10). This makes it difficult and expensive for SMEs to access databases such as Scopus, Web of Science, ScienceDirect, and research papers. However, there is an Open Access (OA) movement providing the end-user with more and more data, for example within Horizon Europe (11).

Several of the interviewed SMEs suggested that they would like to collaborate in order to promote the broadest level of availability to valuable information tools at a reasonable cost. One way proposed, would be to form a consortium, giving individual members preferrable desktop access to full-text scientific journals, databases of scientific journals, books, and conference proceedings at a reduced price.

As a result, a need to accelerate the work towards opening up access to literature sources and databases for all SMEs and other stakeholders was identified. These findings from the interviews, that journal and database costs are a potential barrier to knowledge transfer and R&D, are supported in the literature. Unquestionably, open access mandates have been shown to have a positive impact on innovation activity (12).

3.2 Early warning signals and rapid learning cycles

The interviewed company representatives agreed that a solid risk assessment during the entire innovation process is important so that they can show that the material is safe. In addition, from a business perspective, it is important to obtain early warning signals when developing new materials and thus avoid potential risks to human health and the environment. Several of the companies had already realised in order to speed up the innovation process, information regarding any possible material hazard needs to be included in the business risk calculation.

Business risk is the exposure a company or other organisation must factor in that will lower its profits or lead it to fail. Anything that threatens an organisation's ability to achieve its financial

goals is considered a business risk. For a company putting a product on the market that contains potentially hazardous substances implies a business risk. If the product is proven unsafe, the company may face a sales ban, withdrawal from the market, meet compensation claims, besides a bad reputation.

Today, many companies are applying "Rapid Learning Cycles", a concept taken from Agile software development, including systematic experimentation, risk reduction, and knowledge capitalisation (13), implying a new approach to product development. This means, speeding up the innovation process by also including the chemical risk perspective.

It was also considered important to involve regulators in the process, for example by discussing any future changes to the chemical legislation, such as REACH (Registration, Evaluation, Authorisation, and Restriction of Chemicals).

3.3 Nanosafety in practice

Companies' representatives asked questions about acceptable risks in their daily operations, possible risks of nanoproducts they put on the market, and information requirements to comply with the regulation. SMEs don't often have their own in-house competence in risk assessment and knowledge of the regulations to assess risk so they must rely on the hiring of expert services.

What is possible to do in terms of nanosafety depends on competence and methods available, but also on the attitude and code of ethics within the organisations. Several examples of code of ethics were provided, including the use of the precautionary principle in practice in the industry, for example deciding not to use CNT because of similarity to asbestos fibres at a point in time when only limited research was available concerning the safety of CNT.

All interviewees responded by focusing on chemical safety in their laboratories and the working environment for their employees. The interviewees were generally aware of how to manage risks in the laboratory and during production. All steps in the life cycle (synthesis, production, distribution, use, and recycling/waste management) should minimise the potential for exposure and related risk to humans and the environment. One way mentioned to address this, was to use a closed production process, where virtually nothing can be leaked out to the surroundings. In high volume production, manual handling could be almost totally avoided and replaced by automatic processing only, thus minimising exposure.

Further, if the nanoparticles (NPs) are contained in a liquid it was considered better than in a dry powder as it is easier to control and eliminate exposure from a liquid. It is even better when NMs are bound in a matrix or at the surface, individual NPs cannot then be released except from possible wear.

While the interviewees provided good examples of waste management, it can also be a challenge. One step mentioned was the cleaning of equipment used for NMs that increased employees' exposure also in laboratory and production environments that to a large extent were closed and automatic. Another area mentioned was recycling, which needs to be further considered. One example given was the collection of nano waste (liquid) at a research laboratory that was sent abroad for processing. To date, there are no standards that relate specifically to the safe disposal or recycling of ENMs (14).

Safety data sheets (SDSs) are an essential tool mentioned to mitigate risk as they are a communication tool between suppliers and customers/users. The interviewees emphasized the educational component of the SDS contributing to the rapid diffusion of safety knowledge. SDSs are intended for everybody in workplaces. Employers hold most of the responsibility for occupational health and safety, but also supervisors, and workers, have obligations when it comes to workplace safety.

An issue commented upon by several interviewees and workshop participants is that industry needs to find out from agencies what tests are needed to be regulatory compliant and to be able to make decisions on acceptable risks in their daily business operations.

3.4 Substitute it Now! list

The SIN (Substitute It Now!) List (15), developed by the NGO International Chemical Secretariat (ChemSec) is a list of hazardous chemicals that are used in a wide variety of articles, products, and manufacturing processes. ChemSec claims these chemicals should be removed as soon as possible as they pose a threat to human health and the environment. Primarily, it is a tool for companies along the supply chain that want to identify substances for substitution to more sustainable and non-toxic chemicals.

In comparison, ECHA's regulatory strategy sets criteria for identifying substances of very high concern (16) and defining how to further regulate them. The process starts by screening information that companies have submitted (REACH registration dossiers and classification and labelling notifications) and looking at external sources, such as other lists of substances of concern published by regulatory bodies, agencies, trade unions, and NGOs. Unlike the SIN list to select substances of most concern, ECHA relies on both hazard concern and potential for exposure.

In November 2019, ChemSec decided to add all CNTs to the SIN list with reference to the precautionary principle. Although some types of CNTs have been classified as hazardous, others have not to date been found to be associated with hazards and thus the SIN list has been criticized for grouping all CNTs into the same class (17). Some of the companies interviewed, specifically the ones using graphene, were concerned about this ruling. Both CNTs and graphene can be seen as classes of carbon-based compounds and consequently, graphene could potentially also be added to the SIN list. The companies thought that if this is going to happen, it would stifle their innovation efforts.

3.5 Collaborations between stakeholders on nanosafety

This project identified several ongoing collaborations between industry, academia, and research institutes. Many companies expressed an interest to work with stakeholders on safety practices, waste management, and regulatory questions. Some companies were already partners in national or EU-nanosafety projects, for example, Mistra Environmental Nanosafety II, GRACIOUS, NanoSolveIT, and NanoCommons. Others were involved or part of other constellations, such as technical competence centers (2D-TECH), supply chains (SDSs are the primary means to communicate information on hazards and safe use), material manufacturers (the Graphene Council), associations (SAAMs), and life science research parks (Medical Village, Lund).

These already ongoing collaborations and associated contacts were suggested to be the foundation

for a network of main companies, focusing on nanosafety practices and issues. It was suggested that SweNanoSafe should take the lead for such a collaboration.

3.6 Publication bias: underreporting of negative findings

In academic research, positive (statistically significant) findings may be more likely to be published than null or negative findings (18). Negative findings (statistically non-significant) are more often overlooked, discouraged, or simply not put forward for publication.

The underreporting of negative results introduces bias into meta-analysis and therefore misinforms researchers, policymakers, funders, and other professionals. Resources are potentially wasted, for example, on already disputed research that remains unpublished, and therefore unavailable to the scientific community (19). Also, industry funding is a key source of bias that can affect research at multiple stages, such as in the design, conduct, and publication (20).

The present interview study indicated that academic (and industry) researchers are primarily focused on publishing articles with positive results and editors of research journals are more likely to accept manuscripts showing such data.

Interviewees from SMEs expressed the view that they would like to have access to the complete findings, including the negative. For example, statistically non-significant toxicity results could be very useful to direct industry's innovation efforts, and some interviewees are of the opinion that the current scientific publishing model is not based on the needs of industry. One SME commented that it would be of great benefit if we could determine wheather there were any null toxicity findings for a specific nanomaterial (graphene) that we consider were included in our processes.

Incentives to publish negative findings based on scientific recognition and/or financial compensation (such as from research funding bodies), were suggested by SMEs. More importantly, journal editors should be made further aware of the importance of disseminating negative and positive findings alike.

3.7 Dutch and German examples on safety and innovation

Some of the SMEs commented that it would very valuable if a national strategy for safe innovation of ENMs was implemented which they could relate to, thereby directing their efforts in the area.

One of the interviewees represented the Risks of Nanotechnology Knowledge and Information Centre (KIR-nano) at the Dutch National Institute for Public Health and the Environment (RIVM). KIR-nano was established in 2007 to effectively identify and evaluate the potential risks to human beings and the environment (21). Nationally, the centre informs and advises Dutch ministries, provides information to professionals, and other interested parties on the potential risks of ENMs. Internationally, it represents the Netherlands in various frameworks such as ISO and OECD working group(s) on the safety of ENMs and participates in several European activities, for example via the EU NanoSafety Cluster.

This RIVM-participant pointed to other relevant safety and innovation programmes in the Netherlands and Germany. NanoNextNL (22) was a Dutch Innovation programme (2011-2016, €250

million), showing that a simultaneous focus on applications and top science, is very well possible. For example, it resulted in more than 1250 publications and 127 unique patents. The programme is seen as a successful formula for the provision of societally relevant innovation through public-private partnerships (PPP) in technology. The programme integrated risk analysis and technology assessment (RATA) in research plans, business plans, and innovation models in a stage-dependent way.

The coordinated collaboration among seven federal ministries in Germany, including the Federal Ministry of Education and Research, and the Federal Ministry of Health, that started in 2006 has made a significant contribution to the promotion of safe nanotechnology. Both the use of nanotechnology applications and the possible impact of NMs on humans and the environment have been investigated under the umbrella of an action plan, to establish the basis for responsible use of nanotechnology. The third and most recent Nanotechnology Action Plan 2020 was adopted in the autumn of 2016 (23).

In conclusion, experiences from the Netherlands and Germany could be seen as an inspiration for a Swedish action plan on nanotechnology that includes nanosafety.

3.8 Chemicals' legislation and relations with regulators

Concerning access to competence with regards to compliance with the EU's chemicals legislation such as CLP and REACH, the question for start-ups/SMEs is to consider to what extent in-house expertise is needed in relation to external input which can be provided by different kinds of consultants or service providers. The impressions gathered from interviews of SMEs were that there is a significant lack of knowledge as to how the legislation works. For example, knowledge about KEMIs Helpdesk was limited. Several companies lack in-house expertise on how to apply legislation. However, most companies are searching for assistance to find the right information via consultants, etc.

According to CLP, manufacturers, importers, and downstream users of a substance or mixture are required to gather and assess any existing available information related to the hazardous properties of a substance or mixture. CLP does not normally require new testing.

REACH applies to manufacturers and importers that put more than 1 ton of a substance or mixture on the EU/EEA market. REACH registration requires information on the intrinsic properties of a substance. Information can be generated from new tests, which may be contracted out to a specialised company (laboratory/contract research organisation). The methodology of the test needs to be appropriate, and the test must be relevant to your substance. For tests on environmental or human health properties, the tests should be performed according to GLP, while for physicochemical characteristics this is not needed. Companies registering the same substance (a consortium) need to agree on the data for their joint REACH registration.

The interviews showed that an important issue for companies was that they would like a dialogue with authorities regarding future regulation. For example, if REACH would be applicable at lower tonnage limits, i.e., at grams rather than tonnes, that would be an issue of specific concern in the nano area. Currently, drafts of upcoming regulations are generally open for comments by all stakeholders.

3.9 Experience of REACH among the interviewees

In general, SMEs knew that ENMs are included in the existing REACH and CLP definition of a substance, and provisions set by both regulations apply. It was recognised that as effective from 1 January 2020, explicit legal requirements under REACH, as outlined in the annexes, apply for companies that manufacture or import nanoforms. These reporting obligations address specific information requirements, outlined in revised annexes to the REACH regulation.

REACH was considered not to have an impact on most of the start-ups, other SMEs according to the interviews. A primary reason provided was that REACH only concerns bulk production of 1,000 kg or more per year and most of the companies interviewed only produce or handle very limited amounts per year.

Many interviewees gave the impression that even if they had to comply with REACH, test procedures are not available yet (CLP still applies and companies are responsible for the safety of their products). This is/was partly true, and presently there is no full overview of the availability and suitability of methods needed to fulfil the new nano-specific requirements in REACH.

The opinion of the interviewees is partially confirmed by the European Chemical Industry Council (Cefic), arguing that there is a lack of fully developed test methods to fulfil the nano-specific requirements (24). This places nanomaterial producers and users in a challenging situation when compiling all required information for the registration dossier.

ECHA acknowledges the challenges that registrants face to provide the necessary data. However, the agency has stated that it has adopted a temporary approach for endpoints where an internationally agreed test method does not exist and that the lack of certain test methods should not be an obstacle in the registration process (25).

Experience from registration of REACH information requirements for nanoforms as of 1 January 2020, and general assessment of REACH fitness, may sometime in the future lead to the review of current tonnage limits. There have been discussions within international collaborations (the Graphene Council) of changing the weight limit to include companies using grams of NMs.

The current project showed a general need and recognition to understand and apply the regulation in industry, especially among small companies.

3.10 Views on the roles and responsibilities of regulators

Concerning The Swedish Chemicals Agency (KEMI), responding stakeholders considered that its role is to enforce the chemical legislation for the placing of products on the market through primary suppliers. These are companies that manufacture or import chemical products, articles, or pesticides into Sweden and resell them. With regards to articles that are placed on the market by retailers and wholesalers, KEMI and the municipalities have a shared supervisory responsibility.

KEMI provides a national helpdesk including Q&As as the first point of contact for questions related to the CLP, REACH, and BPR (Biocidal Products Regulation) regulations. KEMI also provides support by answering questions concerning responsibilities and obligations within the agency’s field of chemicals legislation. According to the agency's governmental assignment, KEMI cannot provide direct advice to individual companies on how to proceed, such as how to respond to inquiries about the contents of individual products or how to assess the risk of a particular use of a product. Nevertheless, KEMI can enter into a dialogue concerning issues of interest for the

companies, for example, by providing reference to previous decisions concerning similar topics and it may refer to previous rulings for similar products. The agency also emphasizes that companies need to have access to expertise themselves either in-house or via consultants.

The Swedish Medical Products Agency (Läkemedelsverket, LV) is the national agency responsible for regulation and surveillance of the development, manufacturing, and sale of pharmaceuticals and other medicinal products, ensuring that the patient, health care, and veterinary care have access to safe and effective products and that they are used appropriately and efficiently. LV is also the national regulatory body for cosmetics.

To enable an open dialogue about the development work with new pharmaceuticals, LV provides, for example, scientific advice on regulatory issues to the pharmaceutical industry and other actors based on the applicant's documentation. It can apply to all types of pharmaceuticals, regardless of the choice of procedure for approval. The fee amounts to SEK 45,000 per counseling session of 90 minutes.

A frequently asked question by the SMEs, was whether future obligations of KEMI could also include similar advisory services (for a fee) as provided by LV? The discussions with SMEs pointed to a lack of knowledge as to how medical legislation is applied in comparison to chemical legislation. Companies require more in-house competence (or they need to know when to outsource) regarding legislation. Medical legislation, in general, is more flexible than chemical legislation with regard to how methods and procedures should be applied and provides more room for a case-by-case assessment of risk and benefit.

4. Conclusions

4.1 Main recommendations

The recommendations identified in this project include proposals for action on sustainable ENM development, safe innovation, and safe handling of ENM (Table 3).

Table 3: Main conclusions and recommendations of the project.

	Recommendations
1	Enabling online access for SMEs to full-text scientific journals, as well as databases of peer-reviewed literature, books, and conference proceedings. Moreover, aiding SMEs to access research data for any specific nanomaterial, also statistically non-significant.
2	Supporting rapid and safe innovation through effective dissemination of safety research and preparedness for regulatory changes.
3	Enhancing dialogue between industry (SMEs) and government (KEMI) regarding safety issues, services provided, and coming regulation and legislation (regulatory preparedness).
4	Guiding and advising SMEs on safe handling of ENMs, safety testing, and implementation of the regulation.
6	Investigating the prospect of realising a national strategy for safe nanotechnology development.
7	Training should be available for companies to increase their knowledge and skills, such as how to comply with the regulation and how to identify and manage the risks linked to the ENMs they manufacture and/or market.

4.2 Suggestions for improvement

A "Safety network" was suggested by interviewees, that would contribute to sharing knowledge and experiences relating to safety when working in the laboratory (chemical safety) and production (occupational health), safety testing, and complying with chemicals legislation (CLP, REACH). Stakeholders may include industry (competitors could also join by signing non-disclosure agreements (NDAs), academic researchers (industry, institutes), and regulators. One important component mentioned was that companies would have opportunities to learn safety practices from each other. SweNanoSafe could initiate and facilitate such a network.

Start-ups/SMEs are often not aware of the current legislation which prolongs time to market. Several companies face similar problems and there is a need to share this knowledge on safety and how to register in practice with others (including competitors). Consequently, there is a need for education among industry, especially for smaller companies on how to comply with regulations. SweNanoSafe has initiated a network in order to improve education in nanosafety, the aim being, to facilitate a greater understanding and compliance with regulations.

The newly published strategy for Safe(r) Innovation Approaches is recommended as a basis for national improvement in the area (26). The approach entails suggestions on the development of so-called Trusted Environments in support of open communication between industry and regulators.

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