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Horizon-Scanning and Identification of Emerging Risks among Nanotech Companies in Denmark

Steffen Foss Hansen* and Henrik Vejen Kristensen**

Abstract

In order to understand how companies identify and handle emerging risks related to nanomaterials, we completed more than 15 in-depth interviews with key personnel in various Danish companies. Companies varied greatly in regard to number of employees and overall R & D capacity and health and safety personnel, but also in regard to level of which, they already used/produce products that contain nanomaterials. Surprisingly, very little research has been done on: 1) How companies identify emerging risks, 2) Collect and analyze data on these risks, 3) how they communication results of their analysis internally and externally, 4) how they complete their analysis of management options and subsequently implementation of these management options and finally, 5) what the implications of action taken has been.

Blue-color employees noting "that something might not be right" as well as the media rumors turned out to be the two main sources of identification of emerging risks, whereas ad hoc personal and non-formal networks and meetings with academics and health care officials also played a role. In most cases, various sources were used in obtain more factual information including: Google; Newsletters from the National Research Centre for the Working Environment; chemistry databases and scientific articles, but the information gathering process itself was somewhat unsystematic and seems to be completed ad hoc over time. Internal data analysis was performed by occupational health personal within the companies in constant consideration of resources available, priorities, possible management options, etc. unless health personal "felt like it" putting far more effort into it. Very often independent external experts were consulted in order to learn more and get outside confirmation of key internal findings and interpretations of the available literature.

The selection of management options often involved a pro et con analysis of various options considering various technical and operational barriers whereas implementations often followed a process of: 1) Double-checking that company is in compliance with existing legislation and guidelines - often non-NM specific; 2) Initial mapping of NM R & D within the company; 3) Initiation of a capacity building process; 4) Mapping of NM exposure (sometimes very extensive); 5) Mapping of health effects among employees (again sometimes very extensive) and 6) Mapping and implementation of possible management options. Overall, very few options had been implemented about mostly "easy", "low-hanging fruit" - PE-options and administrative controls. Results were mostly communicated internally via intranets or internal workshops with health representatives.

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Externally communications included publication of scientific papers, posting of information on company websites, but surprisingly involve no or very limited dialogue with authorities as this was considered irrelevant at best and potentially a source of additional confusion and bureaucracy. Overall, implications of action taken within the companies have had little impacts, but in generally company representatives noted that they had gotten an improved knowledge about NM risks; that there was a general alertness regarding risks related to airborne NPs and – in some companies - that there was an increased dialogue between workers and leadership.

1. Introduction

Identification of an emerging technological risk is a prerequisite for any kind of risk assessment and risk management and safe handling. Nanomaterials constitute the one of the most recent case of emerging technologies and associated risks. In order to understand how companies identify and handle emerging risks related to nanomaterials, we completed 15 in-depth interviews with key personnel in various Danish companies. Companies varied greatly in regard to number of employees and overall R & D capacity and health and safety personnel, but also in regard to level of which, they already used/produce products that contain nanomaterials.

To the best of our knowledge there is no definition per see on "emerging technological risks", but the term "emerging technologies" has been defined in many ways. Day et al. (2000) suggest that emerging technologies are defined as "science-based innovations that have the potential to create a new industry or transform an existing one." Similarly, a publication National Institute on Occupational Safety and Health on emerging technologies and the safety and health of working people state that "Emerging technologies exist where the knowledge base is expanding, the application to existing markets is undergoing innovation, or new markets are being tapped or created." (NIOSH 2006).

Identification of emerging technologies and materials and their potential risks is a vital first element of any proactive strategy on OHS. In some countries, public and/governmental agencies already are set up to be on the outlook for and alert to emerging technologies and materials and potential risk. For instance, the Department for Environment Food and Rural Affairs (DEFRA) in the U.K. launched a Horizon Scanning and Futures Programme in 2002, and the government has committed itself to the establishment of a Centre of Excellence in Horizon Scanning, which aims in part to spot the implications of emerging science and technologies. In Denmark, potential regulatory aspects and risks of emerging technologies such as information and communications technologies (ICT), biotechnology and nanotechnology were originally discussed under the heading of green innovation. In 2006, the Green foresight project by Jørgensen et al. (2006) reviewed and discussed the future environmental challenges and possible environmentally related competitive advantages related to nanotechnology, biotechnology and ICT. The Danish Ministry of the Environment and the Environmental Protection Agency as part of an environmental innovation strategy from 2002-2003 that focuses on green products and materials. Hence it was not focused on identifying emerging technological risk per see.

 Often new and emerging technologies and materials are first invented, explored and used in R&D labs and production facilities of universities, SMEs and larger companies. Surprisingly, very little research has been done on: 1) how companies identify emerging technological risks; 2) Collect and analyze data on these risks; 3) how they communication results of their analysis internally and externally; 4) how they complete their analysis of management options and subsequently

implementation of these management options and finally, 5) what the implications of action taken has been.

In the following we first provide a description of how we identified the companies that we interviewed and how the interviews were completed after which we describe our findings. Finally we discuss their implications and provide a number of recommendations.

2. Methodology

In Denmark the industrial uptake of nanomaterials has been driven by users of nanomaterials and products based on nanomaterials in sectors like healthcare and cleaning services, auto- and transport services, public laboratories polymer composites, insulation and other industrial manufacturing plants. To our knowledge, only a limited number of Danish companies actually produce nanomaterials. Since much research and risk management guidance today has been focus on R&D and productions of nanomaterials, we have included a wide range of user-companies to explore the practice, challenges and need of governance support in this latter stage of the value chain. With reference to both the ISO and EU definitions of nanomaterials and objects, we have included companies using primary nanomaterials, nanostructured materials and companies facing challenges with incidental nanomaterials to cover the complex issue of defining and dealing with nanomaterial related risks (European Commission 2011).

Companies were first identified via network and then via use of snowball method i.e. asking the first OHS-representatives that we interviewed to suggest 2-3 other potential relevant companies or OHS-representatives to interview and then repeating this process until we have talked to most of the same names and companies that were mentioned. In-depth interviews with user companies were supplemented with interviews with public research laboratories; OHS consultants, union and trade representatives and OHS regulative authorities to evaluate the current options for governance support and identified the need of support in the governance system as a whole.

When completing the interviews, we used a qualitative responsive evaluation design (Stake 1990) in order to build empirical ground for recommendations at the company level and governance system level. We did focus group interviews using a semi-structured qualitative interview guide when interviewing central OHS and R&D representatives from companies and organizations. The guide allowed the respondents to provide an historical account of their work related to nanomaterials – from first awareness of risk issues to implementation of policies or/and new safety measurements. It also allowed the interviewer to bring examples of challenges and solutions for former interviews in the study in for validation and elaboration in new organizational contexts.

3. Results

In the following, we will present our findings. In order to support our observations, we include selected citations from the OHS-personnel that we interviewed. It should be noted that there might be a risk of over interpretation of individual statements when they are taken out of the interview context and that these statements were originally made in Danish and hence have been translated into English here.

3.1 Identification of emerging risks

Blue-color employees noting "that something might not be right" as well as the media rumors turned out to be the two main sources of identification of emerging risks, whereas ad hoc personal and non-formal networks and meetings with academics and health care officials also played a role.

In the case of the company that deals with issues of exposure to incidental nanomaterials from combustion processes, the worker union representatives had been alerted sporadically over the course of some years in the late 90s: "my wife says that I smell like of work despite just having showed"; "there is something in the air"; "I think that there are too many case of cancer in the section that I work in"; "…fertility problems…"; "…high abortion rates…", "…retired people die too early" according to the Union representative that we interviewed.

Another OHS-representatives from a major R & D university department noted something similar for nanomaterials: "lab technicians had been the first to come to her expressing concern about the safety of nanomaterials and asked questions".

Many OHS-representatives got the initial notion of nanomaterials are an emerging risk through the media. For example, one said: "I do not know for how long we have been working with it, but I caught my attention through the media." Similarly, one of the global manufacturing company explained that lots of media attention on nanorisk related issues did provide at first source of "alerts" along with suppliers using the prefix "nano" in their marketing made OHS-representatives eerie to the fact that there might be a risk or an issue that they needed to look into.

Other ways in which to identify emerging risks that were mentioned were for instance to 1) study all safety resumes prepared by the safety sections in the different R & D departments of the company and use these actively to identify emerging issues and of course, learn more about them and 2) participates actively in workshops and seminars held by national and international research projects that tries to includes multi-stakeholder aspects thereby hear and learning about emerging risks.

3.2 Collection of data, information and knowledge

In most cases, various sources were used in obtain more factual information including: Google; Newsletters from the National Research Centre for the Working Environment; chemistry databases and scientific articles, but the information gathering process itself was somewhat unsystematic and seems to be completed ad hoc over time. One OHS-representative by himself mentioned that: "information comes from a diffuse range to sources".

Several OHS-representatives from different companies explained that whenever time permits, they systematically visits the homepage of the Danish National Research Center for the Working Environment, search university libraries, read EU research reports on nanomaterials and use Google to search for news related to the issue. Using Google turned out to be key element: "We try to figure something out and there is no literature on OHS-issues. We Google." Only one OHS-representative that we interviewed said that the OHS-unit had a series of databases that they would always use and search for information before using Google to find additional sources of information: "We assume that it is as a carcinogen and advise people to work in closed systems. The precautionary principle will always prevail. We do not only rely on guidance documents. Is it dangerous? Has it been investigated? We google everything on all the substances that we buy, look at the toxicological information in the workplace risk assessment, which lies in prolongation of the work what we already do on chemicals and we would never trust the information provided by the supplier". Both the two global manufacturers told us that they often asked suppliers to provide the safety information that they had access to and that they communicate very clearly to their suppliers, what it is that they want and do not want, which the supplier actually seem to appreciate.

Several interviewees also pointed out that network and access to resource personal was key to data collection. As one OHS-representative stated: "Network is gold worth" explaining that they draw on past colleagues from a former workplace that now works with the Danish environmental protection agency and Danish Industry, respectively. Similar, one said that they relied on a "more

diffuse data collection via intellectual networks" e.g. "People meet in different forum and try to articulate the issues at hand". "Personal networks, contact, all kinds of contacts are our sources of information".

Only two aspects were highlighted by all interviews and the first of these was the importance and relevance of the information, newsletter and website provided by the Danish National Research Center for the Working Environment: "NRCWE does a lot of really good stuff with summaries of key reports, news appetizers and they are extremely helpful and they can always put you in connection to someone that know more about it and they are able to explain it in a manner that we understand".

The second aspect that was highlighted by all interviews was that the Danish Environmental Protection Agency and the Danish Working Environment Authority were not very helpful. One OHS-representative stated that: "You will not get any freaking answer, if you ask them and if you do, it will a formal answer, engulfed in legal mumbo-jumbo. The website of the Danish Environmental Protection Agency is not very good and it seems as if as you are suppose not to find what you are looking for and if you ask them a question that you have thought just a little about, they go completely into a deadlock and no one wants to touch it". Similarly, critique was directed towards the Danish Working Environment Authorities: "Taking contact to the authorities, would be like "sending a folk of headless chickens that did not know anything into the factory and ask them to make decision and it will not be the right decision – they do not know anything more than we do - instead we have to trust that the people that work with it and that they will look at the risks".

3.3 Analysis of information and knowledge by OHS-personnel

Internal data analysis was performed by occupational health personal within the companies in constant consideration of resources available, priorities, possible management options, etc. unless health personal "felt like it" putting far more effort into it. Most often independent external experts were consulted in order to learn more and get outside confirmation of key internal findings and interpretations of the available literature.

One of the global manufacturers used a very formalized process to analyse the data collected. First, they investigated what happens when the nanomaterials is prepared and compared it with a similar product, determined particle release and found no significant difference in all process where nanoparticles were generated. An independent toxicologist reviewed all reports prepared and the internal company doctor has been very proactive in the regard to initiating this process i.e. having reports developed and independent toxicologist evaluated the reports. And the worker union actually used the same approach in order to have an outside expert consultant analyse and comment on the OHS data published and used this expert in the dialogue with employees.

3.4 Communication internally and externally

Results were mostly communicated internally via intranets or internal workshops with health representatives. Externally communications included publication of scientific papers, posting of information on company websites, but surprisingly involve no or very limited dialogue with authorities as this was considered irrelevant at best and potentially a source of additional confusion and bureaucracy.

When asked if they ever contacted the worker health and/or environmental authorities about their findings, one OHS-representative answer: "No, no, no, no, we would never communicate anything to the Danish Working Environment Authority or the Danish Environmental Protection Agency; the general notion is that one should be very careful with sharing anything with the authorities and if you do, then you should be prepare on that it can turn out to be a disadvantage for

you in the end. They will turn up and investigate you, if you provide them with too much information". "Nobody is interested in the knowledge that you have unless there are problem and the problem is that either the Danish Working Environment Authority or the Danish Environmental Protection Agency can match our insight when it comes to research, if you have really investigated the matter in depth."

They had not contact authorities and really did not see the point with doing so: "Why should we contact the authorities when we make the dish with milk instead of cream"? Instead, the company OHS-representatives had focussed on initiating and sponsoring toxicological studies with the aim of publishing it in the scientific journals. The work was going through peer-review at the time of the interview, but the company doctor has presented results to internal expert forum and part of the results of this work had already been published via poster presentations around the world. This was found to be the best way to share results and policies in order to "...be rid of "suspicion" about hiding nasty stuff" and the OHS-representatives assumed that it would be "case closed" once the articles have been published – "we have done our homework".

Despite of quite some effort being done in order to communicate the results externally, internal in house communication had been limited, but it had been presented for health and safety officers at semi-annual meetings noting that "The safety department knows and determines what is specifically relevant for the different health and safety officers at the specific units..." of the company. Sales department had been informed about the safety of the final products as customers had and/or could potentially ask about the safety about nanomaterials e.g. German news articles about concern about "nano" triggered request from German, French and Swiss sales department even before the material came into the marked.

During the design and commissioning of toxicological studies, no communication had been attempted internally and externally and no effort is made to make contact to authorities as "where is no reason to cause concern". Interestingly, one OHS-representative told us that they did not see any need to have new information sources. Scanning the news in the media, along with receiving news letters from different scientific sources, etc. seemed to be good enough a catch emerging risks, but underline that "we are in coherent with existing legislation and if there is no legislation, we develop our own guidelines but it is hard without Occupational Exposure Limits but when it is low values, low values, etc.". An University OHS-representatives mention sometime along the same lines noting that they had a series of standard OHS-sentences and remarks that they insert to the safety guidance on a materials if it is on the nanoforms along with recommendations about "If the material is available in the bulk form, then buy that if it does not have to be on the nanoform" but noting that: "It is hard for us to prepare guidelines as the materials differ so much from each other and hence we do not quite how to take that into consideration". One OHS-representatives from the worker union that represent worker exposed to incidental nanomaterials from combustion processes mentioned that they deliberately had decided to go via the media in order to get some attention draw to the emerging risks.

3.5 Analysis and implementation of management options

The analysis, selection and implementation of management options often involved a pro et con analysis of various options considering various technical and operational barriers whereas implementations often followed a process of: 1) Double-checking that company is in compliance with existing legislation and guidelines - often non-NM specific; 2) Initial mapping of NM R & D within the company; 3) Initiation of a capacity building process; 4) Mapping of NM exposure (sometimes very extensive); 5) Mapping of health effects among employees (again sometimes very extensive) and 6) Mapping and implementation of possible management options.

Summarizing this 6-step process that eventually led to the implementation of risk reducing measures, the worker union OHS-representative explains: "An operation committee started to discuss various issues and they establish a steering group to investigate the problem with exposure to incidental nanomaterials and this group initiated the beginning of a smaller research project to establish the levels of exposure". The outcome of the small consultancy project, subsequently lead to a bigger independent research project to establish the exposure-level of incidental nanoparticles. After the publication of the research report from the larger research project, the focus moved from studying the pollution levels to studying the adverse effects of the exposure of incidental nanoparticles as well as to what one can reasonably expect in regard to options and demands in regard to air pollution. No one wants to set a safe level of ultrafine particles and we still want to keep jobs, growth, etc. We have picked the low hanging fruits such as initiating behavioural changing campaigns that would reduce levels of ultrafine particles".

One of the global manufacturers similarly stated that no specific measures taken in regard to nanomaterials noting that they "measure dust levels in all our factories and they are in compliance with all worker safety directives, but we do not measure different parameters such a particle number, surface area, etc.". Still, they had taken an "a number of measures have been taken to limit dustiness of their product".

Only a few companies had been through the whole 6-step process. One OHS-representative noted that they often stranded on the first step noting: "We constantly create different working groups about safety, but it is hard to get people to participate because research is more interesting". Another noted that they use different mechanisms to build capacity within the organization: "We arrange theme days about the newest knowledge in the field so that we can all be inspired".

Finally, some go through step 1-5, but fail to complete step 6 on mapping and implementing management options: "We took people that worked with nanomaterials with us to workshop on health and safety of nanoparticles and that really make people think but as far as I know no health and safety guidance initiatives have been implemented and we long for clear guidance on which lab condition are sufficient to protect our workers".

Overall, very few options had been implemented about mostly "easy", "low-hanging fruit" - PPE-options and administrative controls. Limited or no implementation of more thorough process-related options or engineering controls was identified. Interestingly, we find that if the first alert about an emerging risks comes via "bottom-up" requests from students, lab people and workers, it seems to led to action being taken by the OHS-personal whereas if the first awareness came via a "top-down" approach, it often led to a three-step process of clearly defining of the problem ("e.g. our materials is not a nanomaterial"); focus on obtaining more knowledge to confirm safety, and finally, close the case.

Implications of action taken within the companies have had little impacts, but in generally company representatives noted that they had gotten an improved knowledge about nanomaterial risks; that there was a general alertness regarding risks related to airborne NPs and – in some companies - that there was an increased dialogue between workers and leadership. One company had the OHS-personnel integrated into the R & D department of the company and argued that this had major advantages: "We save them money – e.g. we are 10.000 employees. Assuming that we use 60.000 pairs of gloves per 24 hours and someone chooses a chemical which has half the penetration time compared to the chemical that we used today, - how many time would that be able to pay our wages?" Furthermore, "The work that we do save our regional and local OHS-representatives time and money. They do not have to be alert to new products all the time because they know where they can find information and they know that it has been through a screening process. We constantly have to be the link between the production and the R & D department. The OHS-

department needs to be an integrated part of R & D because if it is not, we would constantly be behind the curve".

4. Discussion and Recommendations

The companies that we interviewed varied greatly in regard to number of employees and overall R & D capacity and health and safety personnel, but also in regard to level of which, they already used/produce products that contain nanomaterials. They also varied greatly in regard to how much knowledge they had about nanomaterial risks and it cannot be ruled out that some companies might have been willingness to participate in the interviews because they have realized that they do not have sufficient knowledge about these risks and that they have used us to discuss what their challenges might be and get new knowledge on the subject.

That said, we find that blue-color employee noting that, "something might not be right" as well as the media coverage turned out to be the two main sources of identification of emerging risks, whereas ad hoc personal and non-formal networks and meetings with academics and health care professionals also played a role. In regard to the initial identification of emerging risks, general and continued alertness seems to be the one determining factor. The general alertness does not mean that lots of resources have to be set aside, but it does mean that resources have to be available to do this as part of the daily established organizational routines. Besides general alertness among OHS-staff, ad hoc networks and attendance in meetings with academic and health officials has proven to be an effective manner in which to identify emerging risks continually as the reoccurring nature of such meetings enables OHS-staff to hear and learn about emerging issues that might be relevant for them business. Therefore, we recommend that resources be set aside for OHS-staff to nurture ad hoc networks and attend OHS-network meetings.

In most cases, various sources were used in obtain more factual information for risk assessment including: Google; Newsletters from the National Research Centre for the Working Environment; chemistry databases and scientific articles, but the information gathering process itself is most often somewhat unsystematic and seems to be completed ad hoc over time. Overall, the results of our interviews shows that OHS-staffers use a number of different sources to identify additional information about an emerging risk once it has been identified. Regulators and others that wishes to provide information about emerging risks need to be aware of the fact that Google and web-based research is predominate in most companies. Secondary efforts should into reaching people through the newsletters that they normally get e.g. in DK we found that the newsletter from the National Research Centre for the Working Environment and branch guidance documents.

We found that OHS-personnel on a consistent basis did the data analysis internally with due consideration of resources available, priorities, possible management options, etc. e.g. "when I feel like it". Hence, it is important to ensure that internal resources are available among OHS personnel to explore and go into new and emerging risks as overworked OHS-personnel will be less likely to explore new areas of responsibility.

Results of the data and information collection were mostly communicated internally via intranets or internal workshops with OHS- representatives. Externally communications included publication of scientific papers, posting of information on company websites, but surprisingly involve no or very limited dialogue with authorities as this was considered irrelevant at best and potentially a source of additional confusion and bureaucracy. This, we find it a major problem not only for the authorities, but also for the companies that work with innovative and emerging technologies and in end also for researchers and workers involved in the R &D and manufacturing of innovative technologies. Addressing this problem would require that regulatory agencies become

a lot more involved in field and that they reach out to companies in order to build trust. From our interviews, is it clear that regulators do not have the luxury of not having an opinion on an emerging issue such as nanomaterials. As companies do turn to them and often express disappointment about their capabilities to assist, they cannot anymore chose not to communicate about what is known and not known, what should be done and what initiatives that have been taken as this lack of communication creates a innovation deadlock.

The selection of management options often involved a pro et con analysis of various options considering various technical and operational barriers whereas implementations often followed a process of: 1) Double-checking that company is in compliance with existing legislation and guidelines - often non-NM specific; 2) Initial mapping of NM R & D within the company; 3) Initiation of a capacity building process; 4) Mapping of NM exposure (sometimes very extensive); 5) Mapping of health effects among employees (again sometimes very extensive) and 6) Mapping and implementation of possible management options. The clear-cut focus on compliance could cause problems on the longer term, in an area where much new regulation is under way, and stresses the importance of national regulatory authorities to communicate about future regulation.

Overall, implications of action taken within the companies have had little impacts, but in generally company representatives noted that they had gotten an improved knowledge about NM risks; that there was a general alertness regarding risks related to airborne NPs and – in some companies - that there was an increased dialogue between workers and leadership. This might be explained by the fact that very few options had been implemented about mostly "easy", "low-hanging fruit" - PPE-options and administrative controls. Limited or no implementation of more thorough process-related options or engineering controls was identified. The backbone response to double-check that the company is in compliance with existing legislation and guidelines is unfortunate as most OHS-representatives know very well that the legislation often is non-nanomaterial specific. But we recommend the authorities use this behavioural tendency to their advantage and implement revisions of the statutory order on 'work with substances and materials' as well as the codes for Measuring Technical Occupational Air Requirement (called MAL-codes in Danish) more periodically in the future. Although, the six-step approach seems reasonable, we recommend that more focus is put on limiting exposure from the outset and go through the process faster – more screening - and commit to implementing management options. Hence, that would mean less focus on mapping and more focus on implementing low-hanging fruits as well as more focus on exposure limitation and on technical fixes, and finally, the implementation of more thorough process-related options/ engineering controls.

In figure 1 we have summarized the major sources of information and factors that influence decision-making and action in relation to handling newly identified nanomaterial risks.

Figure 1

Illustration of the major sources of information and factors that influence decision-making and action in relation to handling newly identified nanomaterial risks
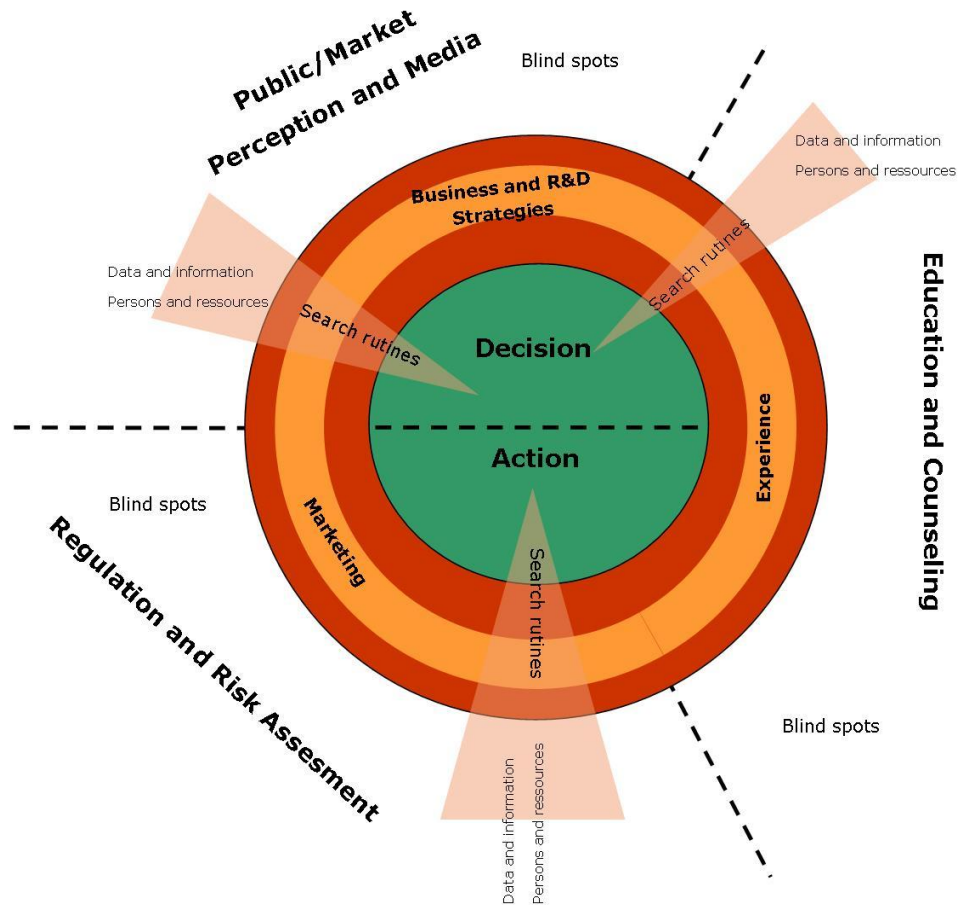
As illustrated in figure 1 both internal and external organizational sources and factors influence decision-making and the action making. In general, these fall into three overall categories: 1) Regulation and risk assessment; 2) Education and counseling; and 3) Public/marked perception and media. When and how these sources and factors have a varying influence and role in the process from first alert about an emerging technological risk until any action – if any - is eventually taken to address this risks. Different search routines provide access to various data and information, key persons to contact and resources, which again is affected by OHS-resources available as well as the overall business-, R&D- and marketing strategy of the company. It is important to stress that most companies are aware of that their current level of knowledge is inadequate, and that there might be many blind spots in regard tot the state of the science, best practices and regulation.

It is almost self-evident that research is needed into the scientific gaps of knowledge, but we find that capacity building and education of workers and OHS-personnel is almost equally important. Most importantly, however, seems to be that regulators and OHS-authorities provide clear communications on 1) the adequacy of existing experiences with handling with volatile

organic compounds, fine dust and carcinogenic substances and 2) the adequacy of existing engineered controls, PPE and control strategies (like the control hierarchy).

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