5th STS Italia Conference
A Matter of Design: Making Society through Science and Technology
Milan, 12–14 June 2014

Collective decision making on risk management and sustainable manufacturing of nanomaterials and the role of decision support tools

Ineke MALSCH[*a], Vrishali SUBRAMANIAN[b], Elena SEMENZIN[b], Danail HRISTOZOV[b] and Antonio MARCOMINI[b]

[a] Malsch TechnoValuation, Utrecht, The Netherlands; [b] Ca'Foscari University, Venezia, Italia

The paper presents the methodology and preliminary results of a study aiming to contribute to understanding mental models on management of uncertain risks and sustainable manufacturing, and to understanding the existing tools used within this context as a source of capabilities and potential adaptation. Central research questions are: What criteria are determining factors in collective decision making on risk management and sustainable manufacturing of nanomaterials? And what role can a decision support tool play in distributed cognition regarding such collective decision making? The paper analyses a survey among 13 participants in the SUN project and describes how a respondent population was chosen for a series of semi-structured telephone interviews conducted from January until March 2014 with decision makers from mainly European industry and regulators involved in risk management and sustainable manufacturing of nanomaterials.

***Keywords**: nanomaterials; decision support; risk management; sustainable manufacturing*

Introduction

Nanotechnology has the potential to address pressing societal problems through its applications in information technology, energy production, environmental protection, biomedical applications, food and agriculture (Koehler and Som, 2008). However, nano-Environmental Health and Safety

[*] Corresponding author: **Ineke Malsch**| e-mail: postbus@malsch.demon.nl

(EHS) implications are difficult to predict and regulate since our understanding is constrained by substantial knowledge and data gaps.

While research to understand the environmental and human health impacts proceed slowly, industry and regulators need to make near-term decisions about nano-EHS. The project on Sustainable Nanotechnologies (SUN, www.sun-fp7.eu) aims to develop a software Decision Support tool (SUNDS). SUNDS should support decision makers in industry, regulators and insurance companies in

(i) Estimating Nano Objects, their Agglomerates and Aggregates (NOAA) risk for workers, consumers and ecosystems in each life cycle stage

(ii) Estimating the environmental impact of NOAA-enabled products along their lifecycles

(iii) Evaluating to which extent the available technologies could reduce the risk (including cost-effectiveness evaluation).

SUNDS will be based on a Multi Criteria Decision Analysis (MCDA) computer programme. SUNDS will be based on a conceptual framework for measuring and monitoring sustainable nanotechnology, including empirical indicators, and stakeholder values. The development of SUNDS is underpinned by a comprehensive user engagement methodology that aims to understand mental models of decision making on management of uncertain risks and sustainable manufacturing, and the existing tools used within this context for potential adaptation. In the second stage, user engagement will also be used to seek feedback on the MCDA framework criteria, as well as other capabilities and features of the DSS user interface. Finally, user values will be elicited to analyse chosen ENM case studies using SUNDS.

This paper discusses the methodology used in a survey among 13 partners in the SUN project and a series of 27 semi-structured telephone interviews held in the first instance to identify the needs of industry and regulators regarding SUNDS design.

Central research questions of the study are: What criteria are determining factors in collective decision making on risk management and sustainable manufacturing of nanomaterials? And what role can a decision support tool play in distributed cognition regarding such collective decision making?

Study Design

The overall study design is based on mental modelling theory. This is a psychological theory according to which individuals observe and act in the world based on more or less correct "mental models" they have formed of reality. Different concepts of mental models have been proposed, as well as different methods for investigating them (e.g. Morgan *et al*, 2002). The International Risk Governance Council (IRGC) has convened a meeting on the application of the mental modelling approach to nanomaterials. IRGC references the mental models approach implicitly in a white paper on nanotechnology risk assessment (IRGC, 2006, p 57).

For the aim of the present study, a decision analysis based mental models approach appears most suitable (c.f. Wood, Bostrom, Bridges and Linkov, 2012). In this method, a (multidisciplinary) expert model or influence diagram is compiled that focuses on the influence of factor X on factor Y, investigates the probability or magnitude of this influence, and compares expert with lay person knowledge. The original expert model can be compiled through a group modelling session, literature / peer review or other methods. Lay beliefs are solicited through semi-structured interviews that are mapped by the analyst onto the expert model followed by analysis of the mapping. In a third round, the frequency of occurrence of the lay beliefs in the target population are assessed through a survey with closed questions. The metrics to analyse lay beliefs are completeness, similarity and specificity. The outcomes are an expert influence diagram, characterisation of lay mental models, and comparison between the two.

For the present study of desired capabilities of SUNDS and relative weights of SUNDS criteria, this method will be adapted somewhat. The study will not compare expert and lay mental models, but the mental models of different groups of experts in particular domains of risk management: risk assessment specialists developing the contents and criteria for the SUNDS tool and decision makers in industry, regulators and insurance companies that attribute different weights to different types of criteria. None of them is a lay person, but each has different (overlapping and complementary) expertise relevant to decisions on risk assessment and management. The expert model in question is the SUNDS decision framework rather than a drawn influence diagram.

Methodology

This paper reports results of two rounds of the study consisting of a survey among 13 participants in the SUN project and of 27 semi-structured telephone interviews with industrialists and regulators responsible for nanomaterials that were held in the period January-April 2014.

Survey

During the kick-off meeting of the SUN project, 29-30 October 2013, the participants were asked to fill in a short qualitative scoping questionnaire exploring the potential need for decision support tools. The questionnaire was handed out to 58 participants in total, including organisers and support staff. Thirteen responses were received either on paper, through an online questionnaire or by e-mail. This constitutes a response rate of 22%. The survey questionnaire is included in Annex 1.

Semi-structured Interview Questionnaire

For the questionnaire, relevant decision makers were selected from the larger population that had been identified in earlier projects as discussed below. Persons whose e-mail addresses could be retrieved were asked for their cooperation in a semi-structured telephone interview of 30-45 minutes. The indicative questions were sent before the interview and the transcript was sent to the interviewee allowing him or her to make corrections or add information. The corrected transcripts were then analysed as background information to identify elements of mental models of decision making regarding risk management and sustainable manufacturing of nanomaterials. The questionnaire is included in Annex 2 below.

Survey results

Of the thirteen respondents, two worked in SME's, four in large industries, and seven in higher education institutes or public research organizations. Two respondents had a senior management position, five were group leaders /middle management, and four were researchers. Two

did not answer this question. The number of respondents is too small to make any statistical inferences.

Decisions taken regarding producing or using nanomaterials

Respondents report four types of decisions they have taken on producing or using nanomaterials: on marketing or production of a particular nanomaterial, on laboratory safety and on selecting a particular nanomaterial in risk assessment studies. One large industry has taken a decision on marketing. Three large industries and an SME have decided on production processes. Three public research organisations and an SME have taken decisions on priorities in risk assessment. Four public research organisations have decided on laboratory / occupational safety.

Required information

The industrial marketing decision was based on qualitative risk assessment parameters. Industrial production decisions were based on toxicity & risk information and quantification of sustainability, or in two cases advice from external partners. Academic decisions on laboratory safety were based on physical-chemical properties and Materials Safety Data Sheets (MSDS) from suppliers (in two cases), in house characterisation (in two cases), procedural and technical information on the planned experiment and equipment, regulatory guidelines in place, the precautionary principle and external expert advice. Academic and SME decisions on priorities in risk assessment studies were based on how much of the nanomaterial was used in products (two cases), exposure potential, environmental impacts, personal preferences and state of the art. Information used came from literature and the internet, or included qualitative data.

Decision criteria

Three decisions were based on the precautionary principle (marketing and production in industry, laboratory safety in academia). Health and safety at work guided other decisions on laboratory safety. Available information, technical options and costs also influenced decisions. Academic and SME decisions on priorities in risk assessment studies were based on the availability of the material (two cases), scientific aspects and exploitation potential. In one case a multi-stakeholder team decided on risk assessment priorities.

Self-assessment of decision

The industry that decided not to market a CNT-nanocomposite would - given the current state of the art - have allowed marketing under specific safety conditions. Two other industrial companies deciding on production, two academic institutions deciding on laboratory safety and one on priorities in risk assessment were positive about their decision and its outcomes. One academic institute preferred improving MSDS or risk phrases for nanotech raw materials, and the other intended to review after the research protocol has been conducted. One academic group working in risk assessment would prefer more knowledge about production and tools, and one SME on the use of the nanomaterial in products. One risk assessment specialist preferred hypothesis driven research to screening a random set of nanomaterials, as sometimes happened.

Decision making process

One large and one small company based decisions about technology selection or optimization in producing nanomaterials on safety, simplicity and costs. One large company used established chemicals risk assessment methods with adapted methods to quantify nano-end points. Another company used holistic analysis, market research and stakeholder discussion. One academic laboratory deciding on lab safety would inform everyone about safety issues before consent, another resorted to empirical decision making on risks. A research group setting priorities in risk research based this on experience, knowhow and process scalability. Three academic groups and an SME did not consider this question relevant to them.

Use of software tools

Most respondents don't use any software tools for technology selection or optimization. The three who use such tools made the following comments. One large industry respondent commented: "Yes, the risk-vs-benefit is assessed on levels of economic, ecological, societal indicators. However, very detailed inputs are required and only comparative assessments are possible." Another large industry respondent wrote: "LCA software and database. Using open LCA software with specific data and ecoinvent data. Support can be better for ecoinvent." A participant from a HEI/ Public Research Organisation remarked: We are going to support experimental activity with computational tools, but they are not available at the moment"."

Interest in decision support tools

Seven respondents were interested in using a decision support tool, five were not and one did not answer this question. Positive respondents were interested in the characteristics of a decision support tool listed in the table in Annex 2.

Discussion

The aim of this scoping exercise was contributing to targeting the SUNDS decision support tool to the professional needs of the companies, research institutes and government bodies represented during the SUN kick-off meeting. This aim was specified in two sub-goals:

(i) Defining the scope of the literature review enabling us to identify a preliminary list of desired SUNDS capabilities, and

(ii) Expanding the list of interview candidates through snowballing (the qualitative social science research method).

From the responses, it appears that there may be more interest in a decision support tool in industry and perhaps government bodies such as authorities, notified bodies and inspectorates who have to verify compliance with regulations, and / or policy making bodies (ministries, European Commission). The latter were not represented among the respondents, only suggested as other organisations that could be interested in a decision support tool. Whether or not such organisations would be interested in a decision support tool should be investigated further. A decision support tool appears to be less relevant to academic institutions, even though some academic respondents expressed interest. Some suggestions for literature and existing relevant decision support tools were made, as well as some suggestions for organisations that could be approached for interviews.

Semi structured interviews

The selection of target populations and the design of the semi-structured interview questionnaire were based on the outcome of the survey among SUN partners. The methodology for determining the target populations is presented below, but the interview material is currently being analysed.

Determining the target populations for the interviews

Internet and literature searches indicate that companies in all phases of the value chain exist that are explicitly handling nanomaterials. ObservatoryNano (2011) identified 1540 different nanocompanies in Europe. Nanowerk's online database includes 2106 commercial companies active in business to business activities in nanotechnology worldwide. This includes 307 nanomaterials suppliers, 305 in biomedicine and life sciences, and 1297 in products, applications, instruments and technologies. The Nanosafety Cluster compendium 2013 includes details of all partners in current and finished EU funded projects on nanosafety. This includes at least 26 large industries and SMEs manufacturing or working with nanomaterials. For the purpose of our study, we can take the industrial population to consist of those companies presented in at least one of these databases with activities related to manufacturing, processing or marketing nanomaterials and products containing nanomaterials in Europe. It is safe to assume that this would amount to around 800 companies. A proposed categorisation of relevant companies is: R&D&I, nanomaterials producer, chemistry & (other) materials, intermediary products, end products, marketing and waste processing. Large companies as well as some SMEs may cover more than one category in the value chain of nanomaterials. This value chain is accompanied by services and instrumentation providers and interest associations.

In addition, University College Dublin (NUID-UCD) has compiled a database of participants in nanotechnology related events including contact persons for around 200 government organisations active in regulation of nanotechnology in Europe. This includes ministries, the European commission, notified bodies / inspectors / authorities, and international organisations (c.f. Malsch, 2013). Other contact persons include the SUN Advisory board, the contacts list of NANoREG and contacts of earlier projects. Within the general category "Regulators", three subcategories of organisations may be distinguished: national policy makers (ministries), bodies that implement policies (notified bodies, inspectors, authorities etc) and trans- and international bodies where regulations are coordinated (e.g. EC, OECD). Another categorisation is by policy area (Chemicals safety, occupational health and safety, health / consumer protection and environmental protection).

For the present study, fourteen decision makers in two associations and eleven companies producing nanomaterials, chemicals & materials, intermediary products and end products have been interviewed, in SMEs as

well as large companies. These kinds of companies are most likely to be interested in decision support for risk management and safe manufacturing of nanomaterials. For reference, a decision maker in a nano-instrument business was also interviewed. The companies were headquartered in Belgium, Germany, Greece, Italy, UK and USA. Most companies were involved in SUN or other EU funded projects in the Nanosafety Cluster.

Thirteen regulatory decision makers including seven national and international policy makers, and six authorities and risk assessors have also been interviewed. Chemicals safety, Health/consumer protection and environmental protection have been covered. The interviewed persons came from Canada, Malta, the Netherlands, Switzerland, the UK, the USA, European Union bodies and an international organisation.

Conclusions

Despite "sustainable nanotechnology" being a buzzword, there are no understanding of how nanotechnology stakeholders manage the risks associated with ENM (Subramanian *et al*, 2014). This paper reports on the methodology used to determine how collective decisions are taken on safe and sustainable manufacturing of nanomaterials, and what role software decision support tools could play in this process. This research is expected to shed insight on the appropriate technical tools and social means of risk management in the decision making community that faces high degree of uncertainty.

In the first two rounds of this investigation, 13 survey responses and 27 interviews were held to collect insights on how decision makers in large and small companies, industry associations, regulatory policy makers, authorities and risk assessors take their decisions. The survey among 13 partners in the SUN projects resulted in a list of features to include in a software decision support tool including risk assessment, ecological, economic, societal and technical specifications.

Analysis of databases of companies and regulators involved in nanomaterials developed in other projects suggests that there may be around 800 European companies that manufacture or apply nanomaterials in the value chain, and around 200 regulatory bodies that are involved in regulation of nanomaterials. These are taken as an estimate of the target

populations for our continuing study on mental models in collective decision making on safe and sustainable nanomaterials.

Acknowledgement

The research leading to these results has received funding from the European Union Seventh Framework Programme [FP7/2007-2013] under EC-GA No. 604305 'SUN'. This publication reflects the views only of the authors, and the European Commission cannot be held responsible for any use, which may be made of the information contained therein.

Annex 1: Survey

Dear participants,

Please fill in the attached questionnaire and contribute to a key aim of the SUN project: to develop a Decision Support System for practical guidance towards sustainable nanomanufacturing (SUNDS) (see Pert diagram below, SUN DOW part B, p 19). We - the partners engaged in WP 8, T8.1: Malsch TechnoValuation, University of Venice and University of Limerick - need your ideas and suggestions to help us target this tool to your professional needs and the needs of the companies, research institutes and government bodies you work for. This preliminary questionnaire will help us plan our work in WP 8. In particular it will contribute to (i) defining the scope of the literature review enabling us to identify a preliminary list of desired SUNDS capabilities, and (ii) expanding the list of interview candidates through snowballing (the qualitative social science research method). This preliminary questionnaire is distributed to each participant in the kick-off meeting of the SUN project, 29-30 October 2013 and explained during the presentation on WP 8. You can fill in the questionnaire anonymously and the results will only be used within the framework of the SUN project. It is available on paper and online via this link: www.ethicschool.nl/test. Please hand it in by 7 November 2013.

In the coming months, we will furthermore contact you and/or your colleagues for further semi- structured telephone interviews assessing your needs in regard to SUNDS design as input in MS14: a report to be presented

and evaluated by the consortium and Advisory Board of the SUN project by March 2014.The study will be conducted in accordance with relevant EU legislation and ethical guidelines including The Charter of Fundamental Rights and Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data. If you have any questions regarding this questionnaire, please contact XXX

Questions

1) What kind of organization do you work for?

SME < 250 employees

Large industry > 250 employees

HEI/public research organization

Government policy making body (e.g. ministry, European Commission, OECD etc)

Authority / notified body / inspectorate etc

Other (please specify):

2) What is your position?

Senior management

Group leader/ middle management

Researcher

Other (please specify):

3) Could you briefly describe a decision you have taken regarding producing or using nanomaterials?

4) What information did you need to be able to take this decision? How did you obtain this information? Was the level of information satisfactory for your decision making needs?

5) What criteria did you use to make this decision?

6) How do you assess this decision in retrospect? Could you comment about how your decision making process could be improved?

7) How do you make decisions about technology selection or optimization in producing nanomaterials?

8) Do you use any software tools for technology selection or optimization? If so, what do you use? What kinds of parameters does the software optimize? Are you happy with the support provided by the software?

9) Would you be interested in using a decision support tool? What would you want to use it for? What characteristics should such a tool have in order to be useful for you?

10) Could you suggest companies / research organizations / government bodies that might be interested in using a decision support tool for decisions in manufacturing/using nanomaterials? If possible suggest contact persons for interviews.

11) Please list any references to literature on capabilities for risk assessment decision support tools that you are aware of.

12) Do you have any other comments or suggestions?

Thank you for your cooperation. If you have filled in this questionnaire on paper, please hand it in to Danail Hristozov / Elena Semenzin during the SUN kick off meeting or send it by post / a scanned copy by e-mail by Friday 7 November 2013 to: XXX

Annex 2: Questionnaire

Dear XXX

Thank you for agreeing to a semi-structured telephone interview assessing your needs in regard to the design of the SUNDS Decision Support System. Please find attached the indicative list of questions. During the interview I may ask follow-up questions to explore interesting issues that come up. With your permission I will record the interview. This recording will only be used for transcribing the interview and then deleted. I will send you the transcript enabling you to correct errors and/or add clarification after the interview. The transcript will be used as background information for our study and not published as such. Anonymised quotes from the interview may be used in publications. Your responses will be used as input in a report to be presented and evaluated by the consortium and Advisory Board of the SUN project by March 2014. If you are interested, I can send you a pdf of the final report.

The study will be conducted in accordance with relevant EU legislation and ethical guidelines including The Charter of Fundamental Rights and Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing

of personal data and on the free movement of such data. If you have any questions regarding this study, please feel free to ask me.

Kind regards,

Ineke Malsch

General open questions:

1) I have collected some information about your organisation and your function from open sources (see below). Is this correct?

2) What type of decisions regarding nanomaterials and products containing nanomaterials are you involved in?

3) Do you use any software decision support tools? What do you consider the advantages and disadvantages of the tools you use or have heard of?

4) Would you be interested in a new Decision Support System for decisions regarding nanomaterials? If so, what capabilities should this system have? If not, why not?

Specific question industry

3a) Does your company use decision support tools to guide manufacturing? If so, which tools and how do you use these tools? If not, why not?

3b) [If the user mentions one of the tools the SUN project partners reviewed] Which capabilities/features do you like more?

Insurance-related questions: is there a need for specific risk coverage products?

Specific questions regulators

3b) Does your organisation use decision support tools in risk governance? If so, which tools and how do you use these tools? If not, why not?

5) Please rate from 1 to 10 the value of having the following features in the SUN Decision Support Tool:

Feature	**Value (1=low, 10=high)**
Output of risk assessment	
Read across approaches to quantitative data on alternatives for research materials with uncertainties and data gaps before investments in scale up	
banding approaches to quantitative data on alternatives for research materials with uncertainties and data gaps before	

investments in scale up	
grouping approaches to quantitative data on alternatives for research materials with uncertainties and data gaps before investments in scale up	
Quantitative consideration of toxic effects	
Quantitative consideration of release rates to human space	
Quantitative consideration of release rates to environment	
Ecological indicators	
Environmental risk management	
Open LCA software with specific data and ecoinvent data	
Economic indicators	
Quantitative consideration of use amounts	
Large overview of patents and scientific literature	
Societal indicators	
Social perceptions of risk	
Factors influencing political decisions	
Large overview of normative frames	
Technical features	
Support experimental activity with computational tools	
How hazard data can feed into this process and influence output	
Easy to use	
Online	
Sharable with others	

References

ECETOC report TR93 (2005) *Tiered approach to risk assessment in chemical processes*. [Online] Brussels: ECETOC. Available from: http://www.ecetoc.org/ [Accessed: 13th October 2014].

Hollan, J. Hutchins, E. and Kirsh, D. (2000) Distributed Cognition: Toward a New Foundation for Human-Computer Interaction Research. *ACM Transactions on Computer-Human Interaction*, 7 (2), 174–196.

Hristozov D and Malsch I. (2009) Hazards and risks of engineered nanoparticles for the environment and human health. *Sustainability*, 1, 1161–1194.

Hutchins, E. (1995) How a cockpit remembers its speed. *COGNITIVE SCIENCE* 19, 265-288.

IRGC (2006) *White Paper on Nanotechnology Risk Governance.* [Online] Geneva: International Risk Governance Council. http://www.irgc.org/IMG/pdf/IRGC_white_paper_2_PDF_final_version-2.pdf, page 57 [Accessed 13th October 2014].

Koehler A.R. and Som C. (2008) Environmental and health implications of nanotechnology - Have innovators learned the lessons from past experiences? *Human and Ecological Risk Assessment*, 14, 512-531.

Malsch, I. (2013) Nano-education from a European perspective: nano-training for non-R&D jobs. *Nanotechnology Reviews*, 3(2) 211–221.

Morgan, M.G., Fischhoff, B., Bostrom, A. and Atman, C.J. (2002) *Risk Communication: A Mental Models Approach*, Boston and New York: Cambridge University Press.

Nersessian, N.J. Newstetter, W.C. Kurz-Milcke, E. Davies, J. A (2003) *Mixed-method Approach to Studying Distributed Cognition in Evolving Environments*. Paper presented at the Proceedings of the International Conference on Learning Sciences. 307 - 314.

ObservatoryNano (2011) *European Nanotechnology Landscape Report*. [Online] ObservatoryNano. http://bwcv.es/assets/2011/11/22/European_Nanotechnology_Landscape_Report.pdf [Accessed 13th October 2014].

Porter, M. E. (1985) *Competitive Advantage: Creating and Sustaining Superior Performance.* New York: Free Press.

REACH Regulation Annex XI. {Online] ECHA. http://echa.europa.eu/web/guest/regulations/reach [Accessed 13th October 2014].

Som, C. Nowack, B. Krug, H. and Wick, P. (2013) Towards the development of decision supporting tools that can be used for safe production and use of nanomaterials. *Accounts in Chemical Research* 46: 863–872.

Subramanian V, Semenzin E, Hristozov D, Marcomini A, Linkov I. (2014) Sustainable nanotechnology: Defining, measuring and teaching. *Nano Today* 9: 6-9.

Wood, M.D. Bostrom, A. Bridges, T. Linkov, I. (2012) Cognitive Mapping Tools: Review and Risk Management Need. *Risk Analysis*. 32 (8).