

SUN Stakeholder Workshop 3 – Summary Report

Location and date: Heriot Watt University, Edinburgh, 6 October 2016, 9.00-13.30.

Summary

The aim of the workshop was to generate ideas for potential future uses of the SUNDS Decision Support System. The first version of this tool has been developed in the SUN project, and it will be further developed in the subsequent project CALIBRATE. The following issues were discussed:

- **There is a risk of misinterpretation and bias in case of public use of output.** The SUNDS tool consists of a screening level self-assessment tool and a more data-rich Tier 2. The quality of the output depends on the quality of the data, which the company or other user inserts. The output cannot be taken at face value by non-experts such as SME owners or politicians, but needs expert interpretation. This introduces a risk that the output of the tool could be biased and misinterpreted by decision makers.
- **The lack of good quality data and common definitions are more pressing needs than the lack of decision support tools.** Several initiatives are underway to develop ontologies, uniform descriptions, nomenclature and definitions in EU funded projects, at the OECD, ISO and other platforms.
- **SUNDS may support in-company teams of experts compiling a REACH dossier.** The current design of the tool can be installed by companies in their intranet. Different users can be created who can insert risk assessment experimental results and other data. Similarly, use in an industrial consortium collaborating in data generation may also be possible. Confidentiality and proprietary data issues are barriers preventing more open access applications.
- **Primary insurance companies might be interested to use such a tool, but only to facilitate data collection, not as an expert system.** Reinsurance companies would not be interested, as their market is based on differences in risk appetite. Standardisation would eliminate this market. Companies applying for insurance policies could perhaps be offered a discount if they use the tool in generating their risk assessment.
- **In CALIBRATE, a viable business model for exploitation of the tool should be developed, through embedding in appropriate partnerships.** On a practical level, services and consultancy fees could be charged to make the tool self-sustainable. On a more strategic level, the tool should be embedded in the right partnerships. Cooperation with ECHA is needed to make the tool useful for SMEs interested in compliance with REACH. For policy makers, a tool could be useful that supports Sustainability Impact Assessments for international trade agreements.
- **The use of SUNDS could create uncertain judgments in court.** For some judges, evidence that a company had used the tool and toggled its risk appetite could be taken as an indicator that the company was aware of the risk. For others, it might be considered an indicator that the company was taking a precautionary approach.
- **How could the design of the SUNDS tool be adapted to accommodate differences in regulatory systems?**
- **An additional module could be envisaged that includes a taxonomy of regulatory regimes.** This could be useful for supporting joint regulatory risk assessment. E.g.:
 - High and low cost legal systems
 - Open and closed legal systems
 - Strict and low liability system

- **A common 'nano-constitution' could be envisaged**, offering a framework for more specific rules that can be applied to specific nanotechnologies. This could go beyond traditional risk assessment. Such a framework has been developed in the EU funded FramingNano project.
- **A business ethics tool could be useful.** It could incorporate a function warning if you are breaking current regulations in any country. Regulatory geography along the supply chain of a product could also be included to warn for non-tariff trade barriers.
- **Could the tool support traceability-by-design of nanoproducts?** This might be more easy for end products such as pharmaceuticals and food, than for nanomaterials and chemicals.

- **Viability of a wiki-tool supporting public dialogue on nanorisk governance**

- **Confidentiality of data generated by companies is a key bottleneck preventing an open access version of the decision support tool for nano.** This data is needed for risk governance and regulation, but companies have valid reasons not to make this data public. However, there are ways to disclose at least some data that are already used.

- **However, an open wiki-like tool could support trust-building in nanotechnology among citizens.** This could be primarily in the interest of industry. Current barriers preventing participation of CSOs in risk governance are primarily economic, not legal. Differences in business cultures also influence their willingness to take responsibility for risk governance.

- **Politicians will not use tools, but they may listen to experts who could use the tools.**

- **Participants with different backgrounds revealed different evaluations of risks and benefits and different tolerance to uncertainty.**

Discussion notes

Ineke Malsch welcomed the participants and briefly introduced the SUN project and the purpose of the workshop: to generate ideas for potential future uses of the SUNDS Decision Support System. The first version of this tool has been developed in the SUN project, and it will be further developed in the subsequent project CALIBRATE. (Slides attached).

Elena Semenzin explained the design of the SUNDS tool (slides attached), which generated some questions and discussion.

Tier 1 of the SUNDS tool is the LICARA Nanoscan, a screening-level self-assessment tool into which the company using it should insert its own data. A considered the balance between the modules to be arbitrary, comparing apples and pears. B was concerned about potential conflicts of interest as the data input could be biased by the person's opinion. Some kind of external review was deemed necessary. C responded that the LICARA Nanoscan was designed as a self-assessment tool, not for external use outside the company. B remarked that the output of the tool was a document that can be disseminated widely, and give rise to interpretations that are not in accordance with the original data. People will not delve into the data, but take the output at face value. D explained that the tool output consists of real data and interpretations. In Tier 1 (LICARA Nanoscan) it is mostly interpretations, in Tier 2, it includes both data input and predictions based on data.

Elena Semenzin continued: The data input in Tier 2 follows a decision tree. The risk assessment is in accordance with REACH guidelines. From distributions of exposure and hazard, it is possible to derive a probabilistic assessment. In the SUN project, we have done some case studies, where we collected data to allow for probabilistic risk assessment. This forms the basis for selecting appropriate risk management measures.

What is acceptable risk? If the ratio exposure/effect > 1 , it is not acceptable. If it is < 1 , it is acceptable.

E remarked: we are not in a position to be quantitative. We should be more cautious in making judgements. F asked: can we do risk assessment for nanomaterials as we do for chemicals? This tool is an attempt to move in that direction. It is an academic exercise. Nobody in the US authorities would accept it. Would it be acceptable to European regulators? How would European courts interpret risk and duty of care? It would not be accepted in court. Human Health Risk Assessment targets effects of pristine nanoSiO₂. The human body is a system, uptake of nanoSiO₂ may open the door to new vulnerabilities. Risk assessment in silos may not be sufficient. Toxicity assessment is mostly restricted to pristine nanomaterials. People could be exposed to released fragments from products. What happens to the form of a nanomaterial along the life cycle?

One issue is data availability. Do we have enough data? This determines which method we can use.

G asked: is it a qualitative ratio benefit/risk? No, it is quantitative.

The effects may also be determined by the shape of the particle. If it is very long and thin, or very short, it may have no effect, while materials with an intermediary shape may have an effect. Do you diversify the shape of the nanomaterial it may have in real product?

The user will have to input data on the individual product. You can't do Risk Assessment for a nanomaterial with an average shape. If the model is to be issued and used by many people, you should include a disclaimer that you have to diversify according to size and shape of the nanomaterial.

The European Commission asked for a traditional Risk Assessment, they are not interested in more innovative approaches.

The tool combines Human Health and Ecological Risk Assessment data in one risk control module, recommending personal protective equipment and other risk management measures. The tool selects the cost effective risk management measure that reduces risk.

Are you assessing alternative (nano)materials which cause the risk, or alternative technologies such as personal and institutional protective measures for occupational health and safety?

We extract information from previous projects and build a database for the measures. The tool does not include new software for conducting LCA, but we import data from external models and translate these data into shadow prices.

The current version of the SUNDS tool combines Risk Assessment with Risk Control, LCA and Socio-Economic Assessment.

B: It is an interesting frame to integrate many things. The problem is the availability of data, that is a challenge. REACH has no uniform description of a nano-form. The guidelines of the OECD and EUCLID have no nomenclature for nanoproducts. The CASG will never evolve into describing the nanoform. How do you inform this properly? Partnerships are important. SUNDS cannot inform decisions, it depends on the partnerships. The uniform description system of a nanoform supported by the EU-US and China will be presented at a meeting later this year. ISO TC 229 is at the beginning of a description – name - ontology development. Partnerships with CODATA (a uniform description system) and maybe REACH are essential.

A: Yes, it will be nice to have a uniform description. However, for an individual company, you don't need such a uniform description. For this model (SUNDS) I am not sure if all of it will be required. In the eNanoMapper project, they have a task to develop an ontology. The tool will be exactly applicable to conventional products; you will make the comparison. Is there enough data for conventional products to make the comparison?

H: The tool is a collection of models; it is not specific for nano. Only the exposure models are specific for nano. If you want to use it for conventional products, you should link it to conventional models. However, you can also input your own data on any product.

If you are the director of an SME with 50 staff members, the tool could be cool. How much time and resources do you need?

For Tier 1 – 2 hours; for Tier 2, the time needed could be modest if you already have the data on experiments. It is not an expert system. It uses a decision tree to input data. If you have to collect the data, that takes a lot of time. For an SME, Tier 1 is most relevant: the LICARA NanoScan.

Why should an SME bother to use the tool? REACH mentions a probabilistic approach. However, we have not certified this tool.

F: Will the tool be useful for insurance companies? If it can be used to demonstrate compliance with regulations? We don't know how to do nano-risk assessment. We don't know what nano is.

Maybe in 10 years, the US will adapt its regulations. SUN did a great job. No data – no regulatory push.

B: The EU decided last spring not to go for a European register for nanomaterials, but to install a European Nanomaterials Observatory at ECHA. Will they be able to develop its mission? Partnering with ECHA is essential for the SUNDS tool. SMEs will contact the ECHA observatory. They received a small budget to set it up. They are planning to launch the observatory this Autumn (of 2016). A collection of various tools is envisaged. We need to ask our contact persons at the EC.

F: In the future, you will want to know the risk. From an insurance perspective, it is: one strike, you're out.

G: In Germany, you must have basic coverages. If you can't prove to the authorities that you have an insurance policy covering it, you won't get a permit. The minimum requirement is to comply with regulations. The primary insurer will want to insure nanocompanies. Reinsurance companies have no data. In that case, they use their own internal system, based on a Likert scale. They follow a wait and see approach: close monitoring to see if similar effects occur as those of asbestos. We have a very small share in this product now.

B: To be allowed to produce nanomaterials is one thing; to be allowed to trade is another. Sustainability Impact Assessment (SIA) is mandatory for the EU.¹ The EU is not allowed to sign a trade agreement without an SIA. The methodology for SIA has been outsourced by the EU. It is available online. If we have a proposal for an SIA, we can make partnerships.

Round 2: Introduction by Alex Zabeo

Alex Zabeo introduced the weighting. This is currently not included in the SUNDS tool, but could be inserted in a future system. Today, we would like to see how you prefer to weigh the different risks and benefit categories in the LICARA nanoscan Tier 1. You can put in weights for the three risk and three benefit categories, and also for total risk and total benefits.

A: will the weights not be similar, as everyone wants social and environmental benefits?

E: If you left a paper trail indicating that you have a particular attitude to risk, that could be damaging your position in court.

F: Yes, but if it will guide investment decisions, you will put more emphasis on economic benefits, and less on social and environmental. This may be different if you show it to an insurance company.

G: I don't care about benefits, only about risks. Insurance companies will need Tier 2.

B: Is it ok that SUN is limited to nanomaterials and disregards other nanotechnologies?

F: This is a traditional risk assessment tool, what regulators wanted.

B: Then you should change the title of the project to Sustainable Nanomaterials instead of Nanotechnologies. Nanotechnologies require different ways of producing them.

A: Occupational H&S is not the issue to me. We have it in place, so the weight can be zero. But then it will seem like you don't care about the issue. What do you care most about? The consumer should be supplied with a safe product. Occupational H&S is not an issue if you take appropriate measures.

The system is comparative and relative. It consists of conventional risk assessment to some extent. You are just comparing what you did yesterday for a traditional product, to the future handling of a nanoproduct. The risk can be high / average / low compared to the conventional product, for all risks.

D: Is nanotechnology riskier, compared to a conventional product? It must be assessed case by case. Some nanoproducts may be safer than the conventional alternative.

¹ <http://ec.europa.eu/trade/policy/policy-making/analysis/sustainability-impact-assessments/>

B: The implicit assumption we will make on the probability of the risk, is that the short term risk has a low probability. Can we make this tacit assumption? Comparing short / medium and long term estimates, the assumptions and weights may be different.

Round 4: accommodating different legal frameworks

Martin Mullins: Is the SUNDS system updateable? Can it be a live or an organic system? Next year, the SUN project will end, but the SUNDS system and two or three other systems will be updated and combined in a system of systems, in the CALIBRATE project. We will now discuss the future of the tools, and how flexible they could be. How to envision SUNDS in a future context? Can it be targeted to new regulations and legislations?

A: We are also involved in CALIBRATE. It is good that SUNDS will be updated, and not die at the end of this project. Eventually, we will need a business plan. The tool will need to be self-sufficient, and self-funding.

H: We want it to be useful to industry. A possible business model would be based on services or monthly subscriptions, or on consultancy. The tool itself will be free.

F: It will not work for other new technologies, such as cyber or 3D manufacturing. Those technologies are not easily captured in traditional toxicity studies. If REACH adopts traditional risk assessment for emerging risks, we will be rich. So far, no regulators have accepted the concept of probabilistic Risk Assessment. The output will be limited to academic papers, unless regulators adopt probabilistic risk assessment. The EC decision is their call.

Martin Mullins: question 3: Is there a regulatory geography? Can we prepare a taxonomy of regulatory regimes? What are lessons to be learned from the experience with SUNDS? Regulatory systems exist. It is important to go into joint regulatory risk assessment. The EC should enter into a dialogue with the rest of the world to accomplish that. The Sustainability Impact Assessment (SIA) offers a good framework for this. SUNDS may be used by businesses. It shines a light on regulatory systems. There is a value to engage into a multicriteria impact assessment early in the decision-making process. Early engagement in a deliberative regulatory process is important.

B: There is a current 'responsible industry process' in the pharmaceutical industry. This does not cover nano. It is important to get industry to engage into a deliberative process as early as possible. We need a constitution, the rule of law. Sheila Jasanoff has argued for a bioconstitution governing synthetic biology, which sets the rules for all. A nano-constitution should be a framework to set rules which can be applied. The European Union adheres to the UN Sustainable Development Goals². At least 60% of H2020 funding will have to be spent according to these goals.³ If the SUNDS tool can help show to which extent projects fulfil the goals, that could be useful. This goes beyond a traditional risk framework.

F: How do EU regulators look at trade-offs?

B: I participated in the FramingNano project⁴, where we discussed a governance continuum of nano-issues. This was bi-directional. We developed a set of criteria, evaluated them and modified the criteria and weights. We considered a deliberative process. Which stakeholders should be included and which criteria should be applied? We used a Delphi-methodology.

² <https://sustainabledevelopment.un.org/>

³ See also: http://ec.europa.eu/research/iscp/pdf/policy/progress_report_oct-2016.pdf

⁴ http://cordis.europa.eu/project/rcn/89673_en.html

Martin Mullins: Is SUNDS a normative system? The EU regulatory philosophy is embedded, including economics and ethics. Do we need more data on legal systems? We could distinguish:

- High and low cost legal systems
- Open and closed legal systems
- Strict and low liability systems

Having such a classification is important for decisions on nanomaterials. The legal risk to the company is important to take into account. If something goes wrong, the company may end up in court. Currently, this issue is not being discussed. There is currently no case law. We need transparency about the considerations taken into account. A higher risk may be acceptable if there is a higher expected benefit.

F: In the USA, the independent Government Accountability Office⁵ reports to the Congress. It assesses the performance of administrations. Such an independent government accountability system is not in place in Europe. This is a condition for success. How is accountability being developed in Europe? It is important to install the right institutions to do this.

A: this is not a nano-specific issue. In Europe we have very few independent assessment institutions. Maybe the European Medicines Agency for Pharma, and the EFSA, they do work with independent experts. The existing scientific committees of the EC (e.g. SCENIHR) consist of very few people, and are not specific for nano.

F: In the USA, EPA committee members will follow EPA rules. This may be the same for European expert committees.

The SUNDS tool is normative. It is a decision support tool. If you insert all this information, the tool will tell you that A is better than B. Decision support tools can have a direction too.

G: In the insurance sector, we don't care about the benefits. The range of losses can be wide in cases of uncertain risks. This topic is cold for us.

Nanotechnology as a disruptive technology could disrupt the business of insurance companies. What if nanotechnology introduces less risk? The benefits may give rise to less need for insurance policies.

B: In synthetic biology, CRISPR-Cas9 claims to reduce genetic risks.

H: SUNDS is a transparent system. If you produce cigarettes, this is allowed, but it kills people. In our tool you will have to prove that you don't intend to harm people. You can prove that you did everything possible to prevent harm. The results are indicative.

Martin Mullins: A business ethics tool could be interesting too. Should there be a function in the tool that warns that you are breaking regulations? Is it possible to design that into the tool? If the acceptability thresholds are different per country, you can set these thresholds independently.

H: Currently, we have not included data on existing laws.

F: Regulators want a bright line. SUNDS offers options to toggle with the risk appetite and level of uncertainty you want to allow. Regulators should give input to determine this. Now SUNDS gives a bright line, you can move it up and down.

⁵ <http://www.gao.gov/>

Martin Mullins: What are the positions of insurance coverage in law? Are there any legal implications of the use of a decision support system? The problem is that deliberations about the risk appetite may be considered as a sign of willingness to take responsibility, but it may also be penalised in court, because it is seen as an indicator that you are aware of the risk.

Will the SUNDS be evaluated? The problem is that you have no external measure to validate the system against. It is a model; you can present data in different ways.

Why would an SME use this tool, rather than hiring an expert for half a day?

G: For the sake of transparency. Once you put numbers in, you can show the output to insurance companies. Experts can be challenged by other experts in court. An insurance company could give a discount to the company if it uses the tool. If insurance companies would use the tool, all would have the same opinion. If we use it in the insurance sector, we have no market. Everyone would herd behind the model.

Martin Mullins: If there is a regulatory geography and divergence along the supply chain, should that be incorporated into the model? Is it likely that non-tariff trade barriers will emerge for nanoproducts? What is missing before we can insert this information?

B: There is no uniform data. Traceability is important. The model should prescribe traceability to allow international trade, based on safe-by-design. Trade is based on trust, and on traceability in the value chain from business to business. Regulators have to rely on that.

Martin Mullins: Did SUNDS miss an opportunity to offer a platform for exchange of information, and for learning and growing together?

H: Industrial confidentiality makes this difficult. You can register to the system as a company, and create different users inside a company. The system allows for communication in a team inside a company, but not with external stakeholders. Industry requires confidentiality, and wants to download and install the system on its own intranet.

There is a trade-off: if a product could be traceable-by-design, this might be relevant to industry. In that case, there would be no need to disclose everything. In addition, Intellectual Property also discloses a lot. For comparison: over 70,000 proteins are available online in databank. There is no problem with a similar databank of uniform descriptions of nanoforms.

A: Traceability-by-design is feasible for pharmaceuticals, but it is hard to imagine this for chemicals. Regulators should initiate regulations. Industry may say we can trace our device, but why should they if regulators don't ask for it? People coming from different industries work in different cultures. Some cultures are confrontational. Food regulations require traceability at product level. Regulators must see how shocks of cultures of domains will impact regulations. Dialogue is key.

The EC is setting up a risk governance observatory. Disruptive innovation is not possible. Citizens are free to think about disruption. Resilience is important.

Round 5: Ineke Malsch: empowering citizens in risk governance

This round will address the question: "How can citizens be empowered in international governance of nanomaterials (input legitimacy, output legitimacy and governance during international norm creation) through decision support?"

F: If we have in mind a risk governance-tool, in EU risk governance is done through risk management and the tool is risk assessment. In US you have something different, you have alternative assessment

where Decision Analysis, LCA, RA, etc are the tools. EPA is going to alternative assessment and also REACH is including it. In alternative assessment citizens are involved to represent their values.

B: In risk governance we have a conservative approach. It does not have the possibility to have disruption. A useful approach should include the resilience concept.

F: Resilience is included in alternative assessment through decision analysis.

B: In the paper “empowering citizens...” you write that ISO is working behind closed doors, but this is not correct. At the OECD, industry is represented by BIAC⁶ and Trade Unions by TUAC.⁷ Currently, non-governmental organisations are not engaged, maybe we could add them. The OECD WPMN invited environmental groups as well. The barriers to participation are not legal, but perhaps economic.

Business confidentiality is an issue. Trust is an issue: citizens will not trust non-transparent decision making. Another issue is the lack of knowledge. GMOs are a success anywhere in the world, but not in Europe. Currently, people are not scared of nanotechnology. Developing an open, online collaborative decision support tool for nanotechnology could function as a trust-building tool. This could be more useful for industry than for citizens. It should then not be called a ‘trust-building tool’, as this might raise suspicions about the underlying intentions.

Would such a collaborative tool be used by primary insurers? If it is open access, the market advantage may be lost. This is an argument in favour of closure.

Reinsurance companies use a scoring system, but only for risks which cannot be assessed. For GMO’s, NOx, and antibiotics confidential information is being used. We use control banding type tools. The new tool could inform the tools used already by the reinsurance companies. Each would have the same risk appetite. RMS models (?) are already used by all reinsurers. The action in the insurance companies is in the top right quadrant of the risk matrix. (?) This fits together with their risk appetite. That is where exclusions will take place.

How would primary insurers use the tool?

Currently, there are 6/7 reinsurers. In each sector, one leader decides which risks are acceptable or not. Nano is already listed. The primary insurer has to ask the reinsurer if the risk is acceptable or not. The people involved are risk engineers, chemical specialists and underwriters. The company Zurich / US North America has already developed a tool for such assessment. Risk engineers don’t use models. Nobody trusts the tools. They read literature based on their own experience. Tools can be used to collect data, but do not substitute expert interpretation. In the future, expert systems may evolve. The WATSON supercomputer can give an indication of the type of options you have, but not evaluate these options. In artificial intelligence, it takes 6 months to train WATSON on a specific field. Then the outcome is the same as what a risk assessor does today. Artificial Intelligence will not be able to learn the risk appetite of an individual company. You have to show your workings to an insurance company, not put a finger in the air. You need to argue how you took your decision. In insurance companies, despite all the evidence, a decision is based on a rule of thumb. Artificial Intelligence can’t replace intuition. Tools are useful, but you need to triangulate your opinion, in the insurance sector.

A: that is the value of the tool, that it is transparent and helps me to put in values and compare it with others. An expert can use the tool to build up his expertise.

⁶ <http://biac.org/>

⁷ www.tuac.org

Democratic: the level of uncertainty brought to any decision with a lack of criteria. Industry tries to avoid uncertainty. How will uncertainty be taken into account in long term decisions? Citizens have input, but less direct than other stakeholders.

Ineke Malsch: Could the tool help parliamentarians take more science based decisions?

Politicians will never use a tool, but they may call an expert who can use the tool and inform the politician in the decision-making process. Regulation is an effect of a perceived risk. For decision makers, balancing is needed, if we can support this with science, that is valuable. Other considerations also play a role, such as keeping voters happy. If we could have a tool that is useful for politicians, that might be interesting. The output would have to be black and white. You need knowledge on a particular thing.

Does the SUNDS tool give an explanation why a weight results in an outcome?

The politician would put in his weights, and get the output red / yellow / green. The underlying data would not be understandable to him. He would need an expert to interpret it. In SUNDS you don't have all underlying original sources of information. A wiki-like tool could give access to those underlying papers and other sources of information. The question is: if you can use the tool and get output, can you then delve into it and identify the underlying data and sources?

Now, the SUNDS is a tool with numbers. It does not give access to the underlying data and papers. You need the interpretation by an expert to determine if it is relevant to your product.

Confidentiality and proprietary data are bottlenecks preventing open access. Companies have paid for tests and don't want to offer the results to their competitors for free. Substance information exchange forms are currently required by REACH. It is difficult to find information on nano, but also on conventional chemicals. The data is not there yet. It takes time to generate specific information on nanomaterials. It is a huge amount of work for lawyers, how to cooperate in industry. For the generation of toxicity data, collaboration is important, to avoid duplication of effort. Collaboration tools could be possible for use inside consortia of industrial companies. You could let users share data and discuss input for common reports. This concerns information in the form of research. The expert should do the experiment and keep track of the evaluation of the result he wants to communicate.

Who would be allowed to input data? You need to justify who is an expert. The means exist, but time and resources are difficult to allocate. Currently, ECHA is acting as a clearing house. However, users of ECHA reports may not see the raw data, but only see the results. Many people would have wanted data on nanomaterials 5 years ago. The definition of a nanomaterial is key. That adds a complication. The project eNanoMapper has developed an open database, and collected a lot of information. Their nanomaterials are clearly defined; they have identified data related to specific size and material. The first step is defining an ontology. Another issue is to get the data in their database. The EC should be forced to use this database. The data is generated, but there is no overview. This is a nanospecific issue. The assessment of the end product is not really an issue.

Return to round 2: Alex Zabeo: playing with the weights

An insurance perspective is biased towards risks, and wants to be very certain. For industry, economic benefits rank high, and social and environmental benefits rank less.

Discussion: What is a societal benefit? Why are public health and environment separated from consumer risk? The public health effect is caused by exposure to nanomaterials released in the environment, while consumer risks are caused by direct exposure to nanomaterials in the product. If

you rank the benefits higher, does that indicate that you care more about them? No, it means that you give more value to results on benefits than on risks. An SME manufacturing nanomaterials would be focused on worker health, and need to consider environmental impacts. Consumers would not be exposed to his products. It also depends on the position of the company in the value chain. The tool gives indicators of all the information you must supply to be sure that the product will be safe along the life cycle of the product.

An academic perspective does not assign different weights to each risk or benefit.

Why would you want to assess economic benefits?

I would need to have an overall picture of the sustainability of the product, including economic benefits. This view stems from my recent experience in this field. The three indicators of benefits should be balanced in the final assessment. I attach equal weight; I know what is important. The same goes for risks, because I think along the lifecycle of the product. Uncertainty of the output can be reduced.

A consumer perspective would interpret 'economic benefit' as an indicator of a good price for the product, not as an indicator of the profit for the company. If you want to let consumers use the tool, you need to explain that economic benefits are for the companies and societal benefits for consumers. Will consumers care about the environment? Yes, more and more consumers are aware of sustainability. Do you consider how the product was produced? This is more common for food than for non-food products. You have already done the case study (nanoTiO₂ in wall paint). The output is undecided, with average risks and benefits. As a consumer, it is not logical to put my weights on these aspects. The criteria are not important to me. The uncertainty tolerance is less than the standard setting.

Recommendations to SUNDS and CALIBRATE

The SUNDS tool as it is offers a good starting point. It would have been interesting to see quantitative assessments. Cancer risks cause 40,000 casualties per year. You need an estimate of the chance, and assess exposure. Rely on existing data for worst case cancer morbidity rates. This can be based on existing data. What is the public liability? E.g. plastic surgery used industrial material silicone under the skin (?) Assume average risks and endpoints.

A: In CALIBRATE, you should move away from the academic 'nice to know' towards practical tools. Make them user friendly for industry, and communicate them to industry. Industry needs to know what to do for regulation. Make things practical for SMEs, try to test different things in industry. If the outcome is good, put it in a tool. Don't create just another opinion. Does it work for industry? Make it user friendly.

H: The interface is not the problem. The absence of default values is what makes it difficult to use. There are no data for nano. From the industrial point of view, we are far from data. We have an excel sheet of the output. This is a framework to make the assessments. It would be dangerous to create a big tool, where you can just push a button, and get results. Avoid the illusion that we can generate data, by letting industry push buttons to get results. For REACH, we hoped to generate data. For industry, we can give you tools, that will result in less costs for paying experts, but you still need the experts to fill the tool. LICARA nanoscan is too simplistic. However, it was addressing SME needs, by being simple enough to be used by them. TNO originally advised more complex tools, which were rejected by the participating SMEs.

Sun Stakeholder Workshop 3 Agenda

Date: Thursday 6 October 2016

Location: Heriot Watt University, Edinburgh Conference Centre, James Watt Centre 2, Edinburgh, Scotland, UK

NB: The discussions will be recorded to facilitate reporting, after asking permission of the participants. The recording will not be made public, and the report will be published in anonymised form after circulation among the participants, inviting comments and corrections.

9.00-9.20 Ineke Malsch: Welcome and introduction to Engaging Civil Society in Risk Governance of Nanomaterials

9.20-9.40: Elena Semenzin: presenting the SUNDS design

9.40-9.50: Introductions of the participants

9.50-10.30: Round 2: Introduction by Alex Zabeo, followed by practical exercise inserting weights in Tier 1

10.30-11.00: Break

11.00-11.40: Round 3: separating data and values in an online Decision Support System

This round will address the question: "How can we ensure good data quality and the protection of proprietary data while allowing anyone to toggle with the weights in an online tool?"

11.40-12.20: Round 4: accommodating different legal frameworks

This round will address the question: "Could the design be flexible enough to accommodate different emerging legislative frameworks (including a new 'Lex Specialis' for nanomaterials as well as distinct legal frameworks for each of the four phases in the legislative cycle and for each type of consumer product)?"

12.20-13.00: Round 5: empowering citizens in risk governance

This round will address the question: "How can citizens be empowered in international governance of nanomaterials (input legitimacy, output legitimacy and governance during international norm creation) through decision support?"

13.00-13.30: Wrap up

13.30-14.30 Light lunch

Background reading:

Ineke Malsch, Vrishali Subramanian, Elena Semenzin, Danail Hristozov, Antonio Marcomini, Martin Mullins, Karena Hester, Eamonn McAlea, Finbarr Murphy, Syed A. M. Tofail. Empowering Citizens in International Governance of Nanotechnologies. In: Journal of Nanoparticle Research, May 2015, 17:215 (12 May 2015) <http://link.springer.com/article/10.1007/s11051-015-3019-0>

Ineke MALSCH, Vrishali SUBRAMANIAN, Elena SEMENZIN, Danail HRISTOZOV and Antonio MARCOMINI, Supporting Decision Making for Sustainable Nanotechnology, in Environment, Systems and Decisions, online first, 17-02-2015, March 2015, Volume 35, Issue 1, pp 54-75, <http://link.springer.com/article/10.1007/s10669-015-9539-4>

Ineke MALSCH, Vrishali SUBRAMANIAN, Elena SEMENZIN, Danail HRISTOZOV and Antonio MARCOMINI “Collective decision making on risk management and sustainable manufacturing of nanomaterials and the role of decision support tools”. In Proceedings 5th STS Italia Conference; A Matter of Design: Making Society through Science and Technology Milan, 12–14 June 2014, <http://www.stsitalia.org/?p=1548&lang=en>

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