

## Summary Report on SUN user workshop

Final version, 2 February 2015

A key objective of EU FP7 Sustainable Nanotechnologies (SUN) project is to build a software Decision Support System (DSS) to facilitate safe and sustainable manufacturing and risk management of nanomaterials. The aims of this workshop<sup>1</sup> were to introduce potential users to the state of the art of the development of SUN Decision Support System (SUNDS), and to collect their feedback to improve the design of the tool. Participants included representatives from SMEs and large industry, policy makers, authorities, insurance companies, risk assessors and tool developers (see annex 2).

Plenary discussions with users was facilitated through presentations on the concept of sustainable nanotechnology, the aims of the SUN project, results of stakeholder interviews, and the initial proposal on the framework and methodology of the SUNDS Decision Support System. SUNDS was proposed to comprise of a two-tiered framework with different complexity of tools and data requirements to cater to different types of users and availability of data. Tier 1 comprises of LICARA NanoSCAN, which is a deterministic tool with low data requirements that was developed for Small and Medium Enterprises (SME) by the LICARA FP7 project. Tier 2 comprises of modules based on more specialized tools developed in SUN whose outputs will be integrated using Multi Criteria Decision Analysis (MCDA) to produce a ranking of technological alternatives based on their cost and efficiency. Modules in Tier 2 include Risk and Environmental Impact Assessment module (which in turn includes sub-modules on Ecological Risk Assessment, Human Health Risk Assessment and Environmental Impact Assessment), Economic Assessment Module and Benefits Assessment module.

Two breakout sessions were conducted to discuss in detail risk assessment aspects and decision analysis aspects. While the former was intended for regulators and the latter for industry, participants were given a choice to attend the session most useful to their interest.

A summary of the issues discussed follows below.

Some participants felt that in moving from screening risk assessment in Tier 1 to detailed risk assessment in Tier 2, the tiers proposed did not show a seamless progress in the complexity of the analysis. Overall, **a three tiered approach** was favoured by attendees: the LICARA approach, followed by an approach that is more data-driven (potentially based on category analysis), and finally a detailed risk assessment tool that is the most quantitative but also requires the most data input. The Tier 1 approach which is user friendly and requires little investment of time and resources would perfectly address SMEs' needs. It is designed as a **modular** tool, allowing the user to select which modules he needs. In the second tier, a category approach, which was not included in the current SUNDS proposal, was favoured by regulators and industry: this approach would use data from categories of similar materials, or read-across, to drive risk assessment outcomes and is intermediate in terms of effort needed. This approach would be more quantitative than Tier 1, and

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<sup>1</sup> See agenda in annex 1.

also useful in a regulatory context of Manufactured Nanomaterials risk prioritization and identification of testing needs; such methods are under development in the FP7 GUIDEnano project. A final tier is the most comprehensive Tier 2 in the SUNDS proposal.

Finally, a **Multi Criteria Decision Analysis (MCDA)** approach could be used to integrate conclusions from across the three tiers. If an MCDA approach is utilized, then regulators at the Workshop recommended that individual data and individual tier analyses remain so that they can be isolated for more quantitative analysis and evaluation of assumptions introduced.

**Lack of data:** The tool should use defaults and be able to produce results even when there is not enough data. Further, as the user gets an estimation on the uncertainty, he or she can decide whether there is a need for more data.

**Flexibility to be applied to range of materials:** In the future it may be desirable to adapt SUNDS for nanohybrid materials, but this could be too challenging according to some participants. It should also be open to other materials including clays, fibres and 150 nm particles. Another participant considered that the tool could already be applied to nanohybrid materials as nanoSCAN already deals with nano-based coatings with hybrid properties, nanoclays, and nanofibres. The 150 nm limit is just an issue of definition according to him.

**User feedback, continuity and openness of information:** Industrial users may require protection of proprietary data costing a lot of money, while insurers and regulators would be interested in a system that reflect the emergence of risks that would call for new regulation or increases in insurance premiums. How to ensure continuity of the tool after the end of the SUN project is an open question.

**Novel exposure models:** Among the novel tools being developed by SUN, in SUNDS both a high tiered occupational and consumer exposure model and a probabilistic environmental exposure model will be included, thus allowing quantitative human health and ecological risk assessment.

**Human health issues & endpoints** will be based on the results of dose-response modelling in existing tools external to the SUNDS tool. As far as the selection of endpoints is concerned, regulator participants advised to use endpoints suggested by regulations as a basis, but expand with endpoints suggested by the scientific community where possible.

**Human health: threshold vs non-threshold.** SUNDS should include algorithms for threshold as well as non-threshold effects assessment (the latter to be able to accommodate genotox data should this become desirable in the future).

**Data quality** can be ensured by offering users guidelines on how to integrate data. Defaults will be used for lacking data. It is suggested to use protocols as well as expert judgement to determine the data quality.

**Weighing:** The inclusion of weights is encouraged. But it needs further development; e.g. in which weights will be suggested/default and which options the user will have.

Opinions differed on the need and feasibility of **incorporating absolute or comparative assessment of technological alternatives**. For regulation and in court cases absolute assessment is the ultimate

requirement, but in the short term the required data may not be available, so comparative assessment could be more feasible. Further, a comparative assessment could be useful as a screening tool to identify commercially viable nanomaterials with better performance than existing alternatives.

**Implementation of precautionary principle in SUNDS:** Different interpretations of the **precautionary principle** play a role in the discussion on risk management of nanomaterials. This ranges from applying protective measures to ensure worker safety via alternative methods such as control banding to identify risk management methods to not handling the materials at all. Currently, the precautionary principle is interpreted as supplying risk management measures before you actually know the risks. Formerly, it meant: if you don't know enough about it, we don't even produce it. With time, the view on what is an acceptable risk has changed. The precautionary principle should not be implemented in the SUNDS tool, but the uncertainties should be made explicit so that the users of the tool can decide to what extent they want to be precautionary. In the USA, certain components of the precautionary principle are not applied: risk assessment is done on as much of a quantitative basis as is possible, followed by application of protective measures such as PPE for workers or limitations on releases to environmental media where uncertainty exists.

**What role could the outcomes of the SUN project play in court cases?** Some participants were concerned that industry might challenge the data provided by the SUNDS tool in court cases, and that this could have legal implications for the companies that deliver input data for the tool. One should distinguish the SUN partners and users inputting their own data. The data produced in SUN by the SUN partners will become available 18 months after the end of the project and the partners are aware of that, but the proprietary data input by users is protected by design of the tool.

Another problem is that the evidence on which one bases claims of harmfulness of substances has to be strong enough as basis for court judgements. Some participants questioned the feasibility of generating such hard data for nanomaterials at this time. The matter merits further discussion.

**'Noise' in decision making arguments** has to be taken into account. High unemployment levels may influence the political debate on occupational health and safety regulation. Therefore it is important that risk management decisions are science based and not influenced by other types of criteria. It should be noted that it conflicts with encouraging the inclusion of weighing in the tool.

A question for some regulators is: **Can a life cycle approach indicate the most significant exposures to environment and the general population?** Although the important role of a life cycle approach (as requested by REACH) was recognized, this question was not addressed.

**The scope of use of SUNDS by regulators** encompasses the following aspects:

- Regulators are mainly interested in risk assessment, driven by quantitative analyses and with clearly stated assumptions. Larger industry favours the same approach, and this type of analysis is required for commercialization in most OECD member countries.
- Environmental impacts resulting from LCA including ecotoxicity and human toxicity should be included in the scope of the tool
- Compare technological alternatives and Implement suitable risk management measures to reduce risk to acceptable levels

**Scope of use of SUNDS by industry:** Industry could use SUNDS for risk management and sustainability evaluation. Combined with cost data the SUNDS could support industrial decisions of whether or not to invest in developing new nanotechnologies.

**Scope of use of SUNDS by insurance:** Insurance companies play an important role in risk management of nanomaterials through providing products that transfer some risks. Insurance companies offer incentives for industry to use non-regulatory risk assessment and implement risk management measures. Insurers could ask companies to acquire the information in return for benefits (lower premium), but cannot insist on it as they have to compete with other insurers. The insurance sector does not currently use many tools to support the evaluation of premiums for nanomanufacturing. One insurance company has used PraediCAT, an analysis of nanomaterials citations in 250 medical journals, and is continuing discussions on how this tool can be used effectively.

**Decision Context in industry:** The lack of reliable data is a bigger problem than the lack of tools. Most SMEs will not use tools if it is not compulsory. The INSCX index<sup>2</sup> has data on nanomaterial, risk management and production volumes in the value chain that could be relevant to SUN. Consultants and tools could support SMEs in implementation of higher tiers of SUNDS. To be able to use tools, SMEs need a library of data as well as guidance and clear interpretation.

**Adapting SUNDS to REACH regulation:** SUNDS should be adapted to REACH and biocides regulation, which comprise comprehensive framework for assessing nanomaterials including risks and socioeconomic aspects. REACH contains advice on specific technical issues discussed in the workshop like absolute vs comparative evaluation, deterministic vs probabilistic tools, threshold vs non-threshold endpoints, etc. By tailoring SUNDS to REACH requirements, the tool could potentially find users to support the next ECHA deadline for registration of nanomaterials in 2018.

**Sustainability Assessment:** is relevant to long term business success and insurance. It is incorporated in the value chain in cooperation between large and small companies. A quantitative evaluation of sustainability is important, and tools can play a role in it.

## Conclusions

The workshop resulted in some practical design recommendations for the SUNDS tool discussed above that will be incorporated in the next step of the project. It is also recommended to coordinate the development of the SUN and GUIDEnano tools to develop a three tiered approach. The first (LICARA) tier could address the needs of SMEs, the second GUIDEnano tier could be used in a regulatory context of Manufactured Nanomaterials risk prioritization and identification of testing needs and the third would be the most data demanding SUNDS tier 2.

Given the current lack of consensus about the precautionary principle at global level, this principle should not be implemented in the SUNDS tool, but the uncertainties should be made explicit in its output. The tool may be used in different regulatory and legal context where conflicting interests

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<sup>2</sup> <http://inscx.com/nanomaterials.html>

play a role. This calls for science based outcomes of the SUNDS tool. In industry, the tool could support decision making on risk management as well as sustainability, but the lack of tools is currently less of a problem than the lack of hard data.

Due to several suggestions by participants to tailor SUNDS to REACH regulation requirements, the SUNDS team will consult the REACH guidelines and revise the framework and tools accordingly.

## **Annex 1: SUN User Workshop Agenda**

10.00-10.10 Welcome and Aim of the Workshop - Dr. Ineke Malsch

10.10-10.40 Presentation of participants

10.40-11.00 What does Sustainable Nanotechnology mean and how it relates to SUN - Dr.Igor Linkov

11.00-11.15 SUN aims to develop a Decision Support System for industries and regulators - Dr.Elena Semenzin

Coffee Served

11:15-11:30 Findings from the User Elicitation Processes - Dr.Ineke Malsch and Dr.Finbarr Murphy

11.30-12:00 Group Discussion

12.00-12:30 SUNDS Framework and Methodology - Vrishali Subramanian and Dr.Elena Semenzin

12.30— 13:00 Group Discussion

13.00-14.00 Lunch

14.00-15.30 Industry and Regulator parallel breakout sessions

15.30-16.00 Coffee break

16.00-17.30 Report to Plenary and Discussion

17.30-18.00 Conclusions and closure of the workshop

## Annex 2: SUN Stakeholder workshop 21-10-2014, participants list

Dr. Avtar Barhey	XL Group London, UK	Insurance company
Dr. Peter Baricic	EC DG Enterprise, EU	Policy officer, REACH
Dr. Jorge Costa-David	EC DG Employment, EU	Policy officer, Occupational H&S
Dr Mujdat Cravets	INSCX™ exchange, Manchester, UK	Engineered Nanomaterials Futures Exchange
Dr Fotini Giannakopoulou	Glonatech, Greece	SME, nanomaterials producer
Dr Leonid Goldenberg	Plasmachem, Germany	SME, R&D, nanomaterials, end products
Dr Sabina Halappanavar	Health Canada, Canada	Research Scientist, occupational and consumer health
Dr Barry Hardy	Douglas Connect, Switzerland	Consultant
Dr Toon van Harmelen	TNO, LICARA, Netherlands	Decision support tool developer
Dr Danail Hristozov	Ca'Foscari University, Italy	SUN consortium
Ms Katja Kruit	TNO, Netherlands	Report
Mr Ben Laidlaw	Catlin (London) UK	Underwriting and general liability
Dr Tom Ligthart	TNO, LICARA, Netherlands	Decision support tool developer
Dr Igor Linkov	Ca'Foscari University, Italy	SUN consortium
Dr Ineke Malsch	Malsch TechnoValuation, Netherlands	SUN consortium
Mr Charles McGovern	INSCX™ exchange, Manchester, UK	Engineered Nanomaterials Futures Exchange
Dr Finbarr Murphy	University of Limerick, Ireland	SUN consortium
Dr Peter Saling	BASF SE, Germany	Large company, materials & chemicals
Dr Phil Sayre	Former EPA, USA, currently independent consultant on nano and biotech risk issues	Authority, environmental protection
Dr Elena Semenzin	Ca'Foscari University, Italy	SUN consortium
Dr Birgit Sokull-Klüttgen	EC DG JRC, EU	Risk assessor
Ms Vrishali Subramanian	Ca'Foscari University, Italy	SUN consortium
Dr Susan Wijnhoven	Guidenano project, RIVM, Netherlands	Risk assessor
Dr Alex Zabeo	Ca'Foscari University, Italy	SUN consortium