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## *Seeking User Feedback on SUN Decision Support System*

7<sup>th</sup> OCTOBER 2015

Sala Conferenze, [Scientific Campus](#) of the University Ca' Foscari of  
Venice, Via Torino 155, Mestre, Venice (IT)

### **Workshop Agenda**

9.20-9.30 Welcome and Aim of the Workshop

9.30-10.00 Round-table presentation of participants

10.00-10.50 Introduction to SUNDS: from the conceptual decision framework to the software system

10.50-11.10 Coffee break

11.10-13.00 SUNDS Hands-on Demo – part 1

13.00-14.00 Lunch

14.00-15.30 SUNDS Hands-on Demo – part 2

15.30-16.00 Coffee break

16.00-17.30 Companies in a value chain need to decide on sustainable manufacturing

17.30-18.00 Conclusions and closure of the workshop

### **Summary of Discussion**

#### ***Introduction to SUNDS: from the conceptual decision framework to the software system***

Dr. Elena Semenzin presented the SUNDS conceptual decision framework and methodology to the workshop participants.

With regard to the SUNDS Risk Control (RC) module, the discussion focussed on data gaps in efficiency of Technological Alternatives and Risk Management Measures (TARMM). While data on efficiency of traditional chemicals was available, there was limited data available on engineered nanomaterials. Specific data and knowledge gaps discussed include:

a) Data on dermal and oral exposure routes for ENM are sparse. SUNDS would compile data generated in the project within the database, but it is expected that data on these exposure routes to engineered nanomaterials (ENM) are not currently available (particularly for dermal exposure).

b) With regard to inhalation exposure, it was discussed whether accidental exposure due to spray applications (i.e. overspray) could be different in the context of ENM as compared to traditional chemicals. An exposure assessment expert stated his professional opinion that ENM were similar to traditional chemicals with regard to exposure rate per functional unit. A regulator said that different spray guns and spraying techniques could make a difference in exposure due to overspray, and should be investigated further in a RC context.

c) One regulator mentioned the difficulty in quantifying the efficiency of engineering controls, which led to fallback on personnel protective equipment whose efficiency was better characterized like respirators, clothing and nitrile gloves.

d) It was discussed how Safety by molecular Design (S-by-D) alternatives to ENM were too context-specific, and only the efficiency and cost of modified S-by-D alternatives developed within the SUN project would be included in the TARMM inventory.

e) The assessment of uncertainty in risk assessment was discussed. Uncertainty was explicitly addressed using probabilistic risk assessment using a methodology in which the Derived No Effect Level distribution would be considered. In case of deterministic risk assessment, conservative assessment factors address uncertainty. Additional measures to represent uncertainty in output graphs will also be considered (e.g. uncertainty in TARMM efficiency).

f) One participant asked if SUNDS exposure assessment modules would consider aggregation of ENM, given the evidence of CNT aggregation being different from that of Carbon Black powder. The human health exposure sub-module in SUNDS would address agglomeration in space and time, but not aggregation.

One measure used in the RC module- Technology Readiness Level (TRL)- was considered as inadequate to describe the evolution of nano-enabled products. One participant suggested that many measures could be considered relevant including risk readiness level, environment readiness level, socioeconomic elements and other TRL. These measures are complex to operationalize in the context of evolving technologies, and may be evolving at different pace(s). While important, it is challenging to account for all these factors within SUNDS.

Discussion on the SEA module centred on the use of user preference profiles. Most participants agreed with the idea of using thresholds and weights instead of fully integrated output (which may be nearly impossible to interpret). To start with, a framework of thresholds based on general view should be defined and users should be given the flexibility to vary few parameters (the example of advanced search on a

website was given as an example). However, the framework should not be completely open in order to secure the reliability of the results. This framework could be updated as new information becomes available on ENM. Lastly, it was discussed that SUNDS would not be a normative tool, but allow different users to define their preference for sustainability criteria.

### ***SUNDS Hands-on Demo – part 1***

Dr. Wouter Fransman and Dr. Tom Ligthart presented a hands-on demo of the LICARA nanoSCAN tool. The following points can be summarised from the discussion following this presentation:

- a) For a more intuitive understanding of the LICARA nanoSCAN decision matrix, participants suggested that they would like to see the “green” part in the upper right corner (“Further research needed”) rather than in the bottom right (“Go ahead”).
- b) It was noted that recently (after the launch of the LICARA NanoSCAN), the ConsExpo model has been made nano-specific, and could be considered to be used for consumer exposure assessment within SUNDS Tier 1.
- c) As environmental criteria were more numerous than economic criteria, a “not known” response for the later would have a much greater impact than the former. A better balance between these two modules in terms of number of criteria was deemed as desirable.
- d) There was a valuable discussion on the economic risks that could be reduced if risk transfer through insurance was possible. This had not been explicitly expressed in the LICARA project (but is included in SUNDS Tier 2).
- e) More detailed guidance is needed in the LICARA NanoSCAN tool (or documentation thereof) to clarify how the framework is grounded, the meaning of various criteria and the assumptions which are not currently explicit in the tool. It was suggested that this information should be provided next to the relevant output graphs.
- f) Some people had doubts on the scoring system of LICARA NanoSCAN, and asked for more guidance on that. It was suggested that a scaling factor could be used in comparison (e.g almost twice better than/worse than).
- g) The “unknown” choices should be made more explicit in the reporting to convince people to retrieve more info on these.
- h) There was confusion on the fact the the Life Cycle Assessment was comparative, but the Risk Assessment was not, and how they were combined in the LICARA NanoSCAN.

### ***SUNDS Hands-on Demo – part 2***

Dr. Alex Zabeo presented a prototype of interfaces (not actual working sub-modules) for SUNDS Tier 2. The following points can be summarised from the discussion following this presentation:

- a) The participants wanted support in addition to the SUNDS database to guide user input, given the high information requirements for Tier 2. A regulator suggested using default REACH exposure scenarios provided for some industries to be used as default values in case better information was not available.
- b) One participant wanted to know if SUNDS addressed both uncertainty and variability. This distinction was present in the human health exposure assessment sub-module.
- c) A participant suggested that normalized outputs be presented for all SEA sub-modules. The other option was to present all outputs in their native units along with thresholds. In the second option, definition of threshold should carefully consider the functional unit and reference materials being compared.
- d) In real industrial context of RC, the manufacturer may be interested in comparing the efficiency and cost of TARMM that he already has available within his manufacturing context, and hence, users must be allowed to apply the RC module to these relevant TARMMs.
- e) One user wanted to know the geographical scale at which the environmental exposure sub-module was based. Currently, geographical scale was dependent on user input.

Tobias Widler presented the stand alone module based on the CENARIOS standard to be used in SUNDS. The following points can be summarised from the discussion following this presentation:

- a) Participants wanted to know more about what were the nano-specific aspects of the module, which mainly included the risk assessment matrix to be derived for nano-enabled products.
- b) Participants suggested that the CENARIOS module could be directly linked to the output of the risk assessment sub-modules. This was not considered feasible as the CENARIOS standard lays down guidelines for organisational risk management, which was not affected by outputs of risk assessment.
- c) One insurance sector participant recognized the value of the CENARIOS stand-alone module in pointing interested industry clients to assess their organizational risk management system. At the present moment, insurance forms have about three questions with yes/no options, and no nano-specific questions. The insurance sector could offer discounts in premium for companies that had comprehensive organisational risk management, but could not mandate the use of CENARIOS stand-alone module.

Dr. Eamonn McAlea and Dr. Martin Mullins presented the underlying principles and research upon which the SUNDS economic assessment sub-module was based. The following points can be summarised from the discussion following this presentation:

- a) Participants from the insurance sector noted the utility of cost analysis and its link to ENM risk, but noted that actuarial models were based on precedent of actual claims that were missing for ENM. Insurance claims and tort litigation could also affect the ability of nanotechnology SMEs to get insurance in the future, thus directly impacting their viability.
- b) It was noted that the SUNDS tool was a proxy for appetite for risk and uncertainty of the stakeholders, which could be implicating in a legal context. Thus, the main intended use of SUNDS would be in a single stakeholder context (mainly industry).

### ***Companies in a value chain need to decide on sustainable manufacturing***

Dr. Ineke Malsch moderated this session that considered the current role of each stakeholder within the nanotechnology value chain and how SUNDS tool could support decision making therein. The following points can be summarised from this discussion:

- a) The nanotechnology value chain is larger and more complex than usually considered. The real world value chain is fragmented and incoherent, and often players have conflicting interests (e.g producer and insurer). Information in this value chain can also be broken as in the case of a house with nano coating that goes through change of ownership during the lifetime of the coating and the new owner not being aware of this.
- b) Civil Society Organization and consumer acceptance are the most critical forces within the value chain that can facilitate coherent action toward product stewardship.
- c) Two key challenges to sharing information in the value chain were noted: Confidential Business Information (mainly on use, hazard and exposure) and potential ramification of exposing stakeholder risk appetite in a litigation context.
- d) Use of decision support in nanotechnology value chain was discussed at two levels or “working environments”: 1) for internal use by companies for risk and sustainability assessment of their nano-enabled products, and 2) on a multi-stakeholder platform where outputs were presented at an aggregated level and stakeholders could exchange information at an appropriate level to coordinate actions in a way that sustainability of value chain would be enhanced. In the context of 2), grouping approaches may provide classes for which aggregated outputs can be produced.
- e) A key step in linking the two levels mentioned in point d) from an industry perspective is to have the following types of validation: 1) validation of SUNDS algorithm, 2) validation of analytic methodology followed by a third party. Once these validations are conducted, aggregated data can be presented on a multi-stakeholder platform at industry level or using aggregate classification of outputs.

- f) Information Technology based solutions such as linking SUNDS to a system of access rights can also help facilitate the right level of stakeholder information sharing.
- g) Regulators mentioned the following issues to be addressed in SUNDS use: 1) Regulatory decision-making occurs in tight timeframes (even two weeks), and SUNDS has significant data requirements. A well-illustrated case study providing detailed justification for data input and gaps will help regulatory decision-making on ENM. 2) Data quality is a key issue for regulators, and they warned against the dangers of adopting a “big data” approach in SUNDS. Data should be generated in accordance to well established protocols (e.g. OECD protocols) and explicit data quality standards should be applied to data used in risk assessment sub-modules. 3) Industry validation of methodology (described in e)) alone may not be enough for regulatory decision-making as regulators need to see the actual data used in the risk assessment and ask further questions.
- h) The association of sustainability with product stewardship and market acceptance is increasing, and as a result both industry and regulators are paying attention to sustainability analysis. SUNDS offers a tool for analytical and communication purposes in the context of sustainability analysis.

### List of Participants

Name		Affiliation
Thomas	Zadrozny	Nanofutures
Peter	Saling	BASF
Phil	Sayre	ex EPA, USA
Robert	Caroll	Agpyme
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## 2<sup>nd</sup> SUN STAKEHOLDERS' WORKSHOP REPORT

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