



Link Research outputs to Standardization bodies for innovation objectives

Case of FP7 CSA nanoSTAIR

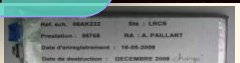
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US-EU nanoEHS CORs, 3rd December 2013

INERIS activities related to Nanotechnology Risk Assessment

PROCESS SAFETY

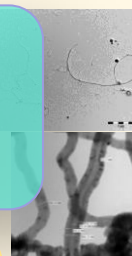
- Fire, explosion hazards
- Electrical charging hazard
- Loss of containment



Fire test for ENM battery

METROLOGY

- On-line monitoring, sampling
- Characterization (decret ...)
- Nanosafety bench



Online CNT detection unit

LIFE CYCLE STUDIES

- Dustiness of nano powders
- Use and aging (emissivity...)
- End of life & recycling capabilities



Calorimeter Tewarson
ASTM E 2058 – NFPA 287

Nano-Safety Lab

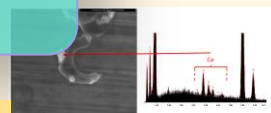
TOXICOLOGY

- Vitro models (cells, barriers models)
- Inhalation exposure (Vivo)



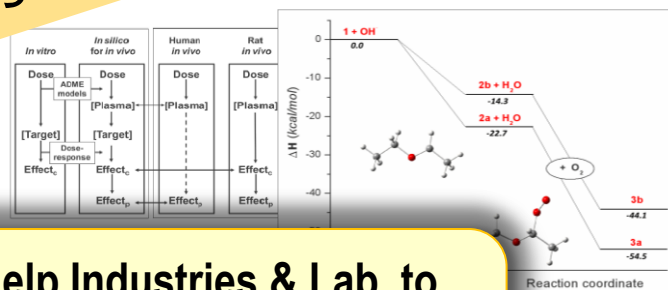
ECOTOXICOLOGY

- Experimental (Ageing, OECD)
- Large scale (mesocosm)



GLP facilities

Help Industries & Lab. to develop safer nanotech. Processes & products



MODELISATION

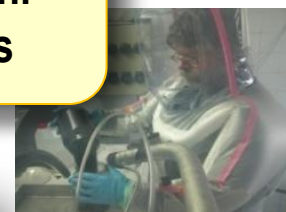
- nucleation, agglomeration
- Reactivity-Transport
- QSARS, QSPRs, Q. Meca.

RSIK ANALYSIS

- "Control banding" tools
- Safety barriers management

EXPOSURE ASSESSMENT

- Occupational exposure
- Environmental exposure



STANDARDIZATION

- nanoREACH, Decret
- ISO, CEN & AFNOR
- OECD

LIFE CYCLE ASSESSMENT

- Integration of LCA and LCC results
- Cost/benefit /efficiency (CBA, CEA)
- Multi-criteria analysis (MCA)

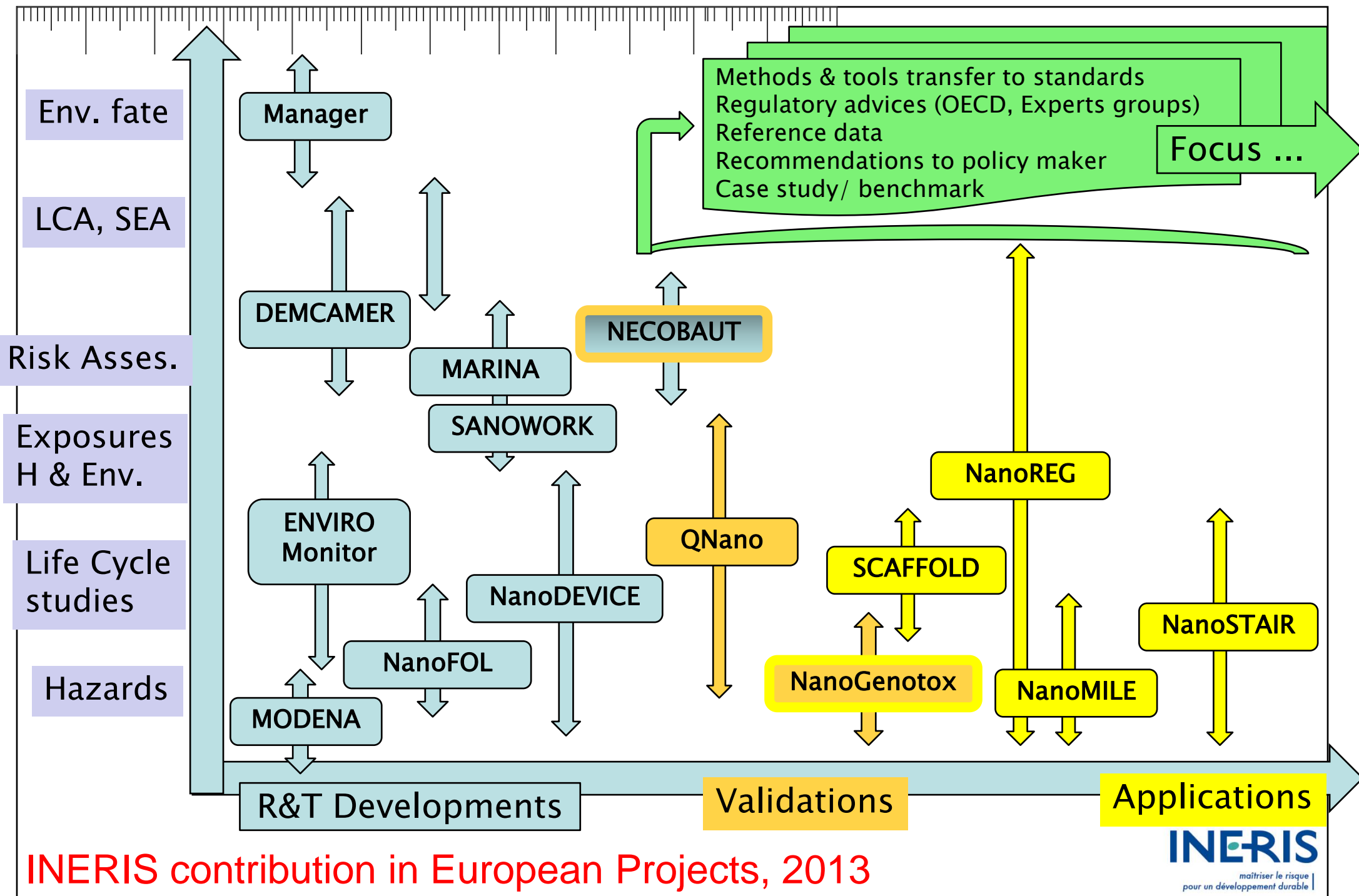
TRAINING

- Workers, H&S dept.
- nanosafety /workplace
- risk assessment

CERTIFICATION → NANOCERT

- Workers, H&S dept.
- Collective protection







Creating link with standardization, why ?

World Economic Forum in Davos 2007 :

- The importance of technical standards was reported
- Standardization : also a tool for promoting innovation
- Research and innovation are to be more closely interlinked with standardization

Standardization related to the safety of NM

→ **Support** the spreading of **good practices** and **rationalize the communication** between the authorities, the industry and other stakeholders

Promoting innovation

Research capabilities

Intensive R&D on Toxicology
Poor research on Exposure & enviro fate
Nothing done on end of life/recycling

Innovation needs → KET, Market

New materials, safer by design
Knowledge of all life cycle of ENM
Substitution or new market strategies

Standardization objectives

Identify candidate/new standard
Support validation actions
Supporting Technical Groups

nanoEHS CORs actions

Hazard knowledge: Tox, ecoTox, safety parameters
→ Data, methods and tools → inputs for prediction
Exposure knowledge on main routes
→ Both worker and consumer point of view

Innovation is
challenged with
cost/effective
studies → risk ?

? Focus on Hazard (intensive research) or Exposure (a regulatory concern)?
→ Both as barriers mean costs → need to be adjusted to be competitive
→ As effect on an existing market of a common new UN GHS nano code based on most hazardous ENM would be huge.



Standards activities can address US-EU nanoEHS in :

ENM measurement infrastructure CORs

- Define and validate metrics, methods, instruments & share best practice or ref data infrastructures (inhalation facility, metrology lab, mesocosm...)

ENM Toxicology, eco toxicology tests

- Develop or adapt & validate reference methods for main exposure routes

Exposure during all life cycle (production, use, end of life, recycling)

- Share & validate methods (emissivity, transfer, including aging if needed)

Risk assessment and management

- adapt, share and validate methods on case studies → inputs for ISO
- Up to risk assessment models (develop or adapt existing methods)

Database, informatics and modeling :

- Define descriptors for grouping, prediction, built ref. data for benchmarking

We can find ideas (results) but the main problem is to link communities (Tox/ ecotox/ metrology, or research–industry–standardization, ...) and moreover to know if expression of needs can be understood and if it can fit research capabilities.



nanoSTAIR

From Sept. 2012 to March 2014



Establishing a process and a platform to support standardization for nanotechnologies

Bringing research results to standardization

*...a **sustainable process and platform** in the field of nanotechnologies to support the **transfer of knowledge** gained through research **to documentary standards** in the context of the **STAIR approach***



Finnish Institute of
Occupational Health

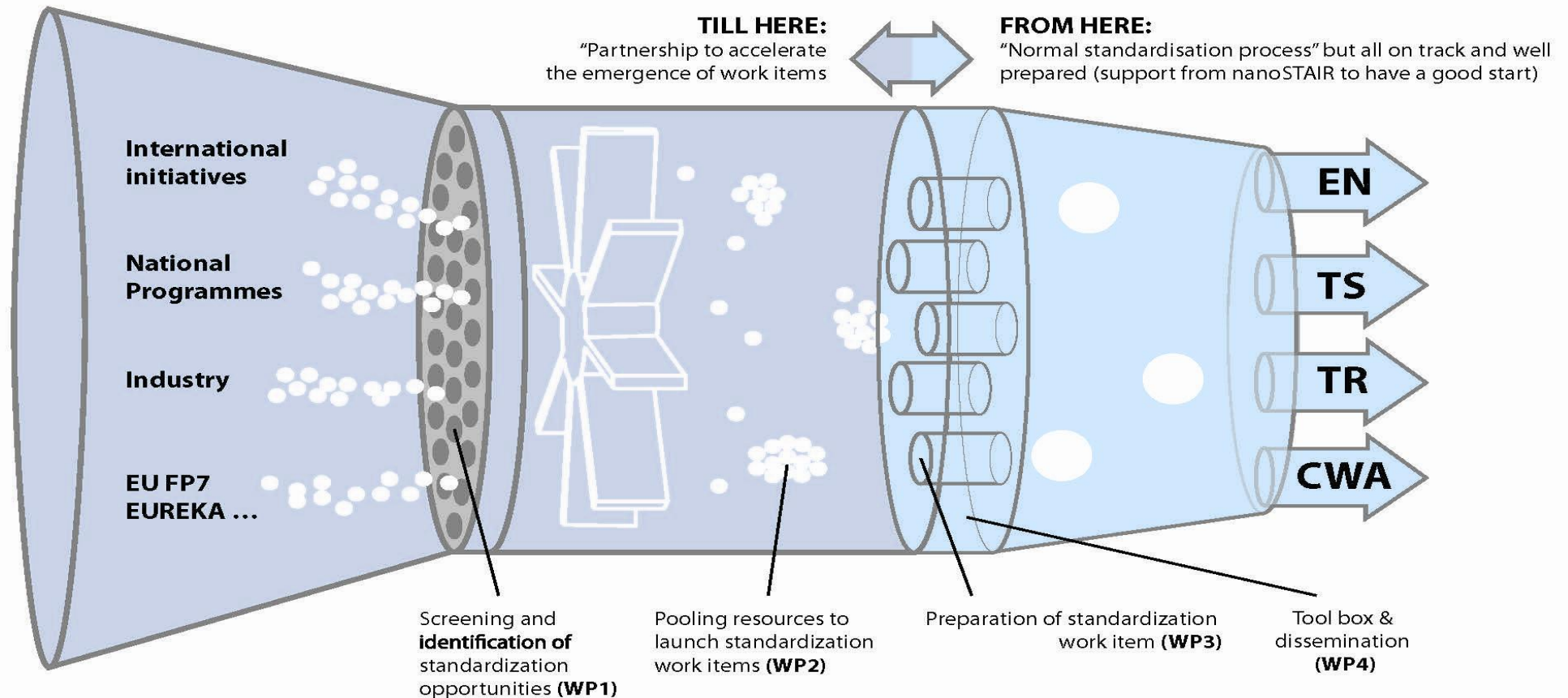


EUROPEAN COMMITTEE
FOR STANDARDIZATION

nanoSTAIR, the Turbine concept !!!

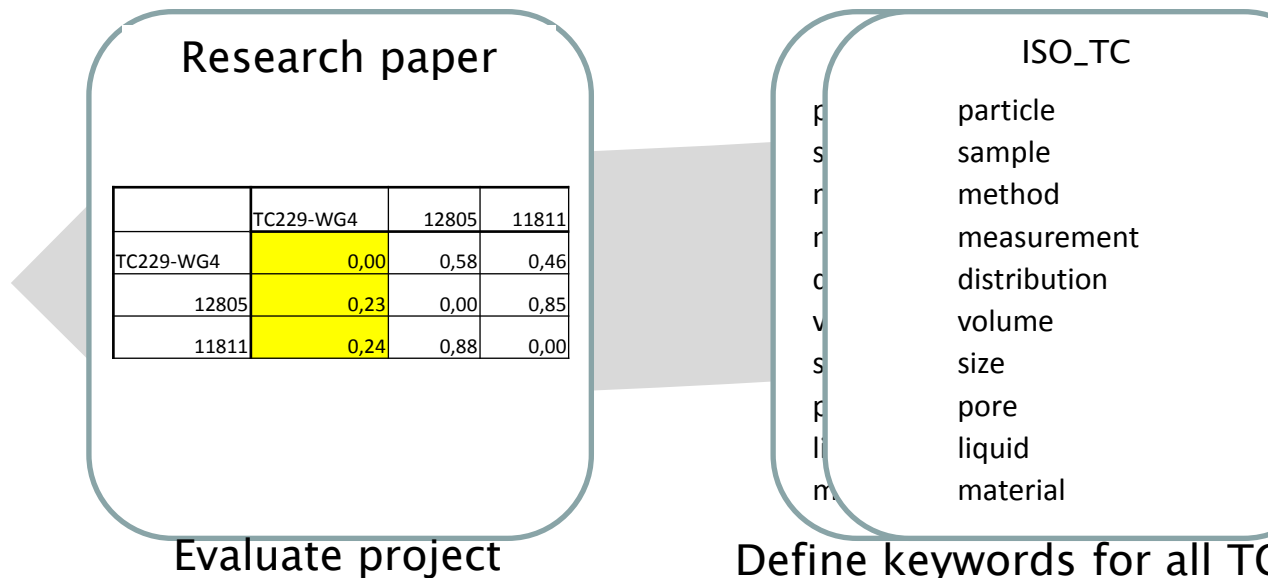
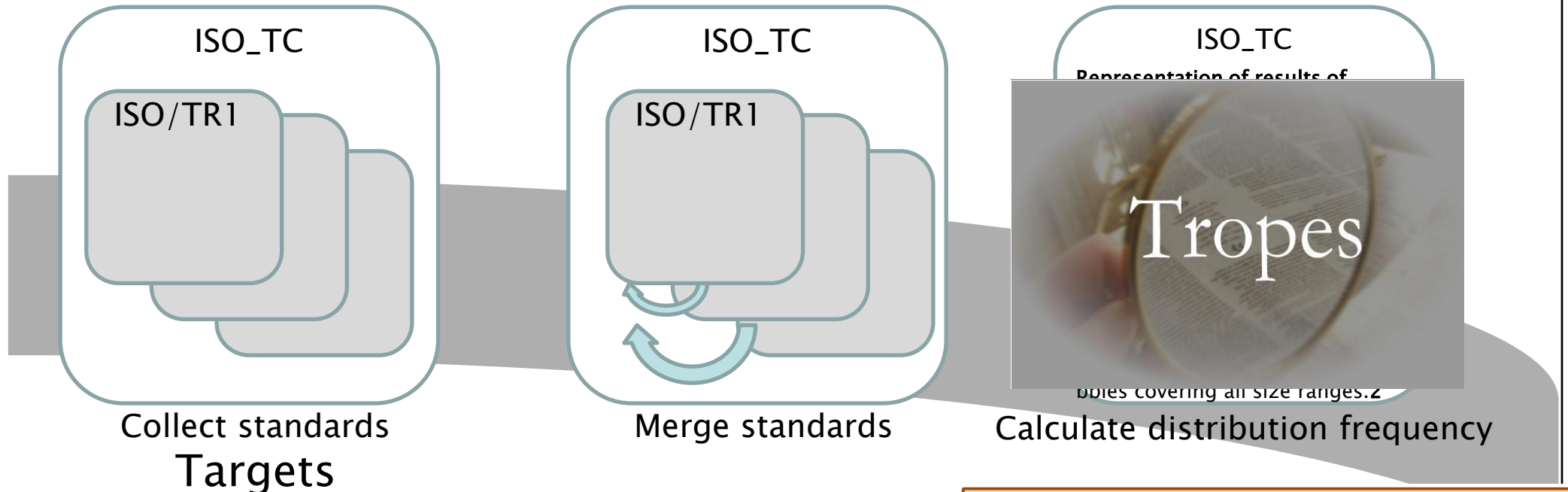
Bridges between stakeholders

TOPICS FOR STANDARD COMING FROM R&D PROJECTS



All nanotechnologies & especially :
"Characterization of and exposure from MNMs" and "Health, Safety & Environment"

How the nanoSTAIR tool works?



nanoSTAIR candidate evaluation

Welcome to the pre-screening tool for allocating scientific paper to Technical Committee!

Before running the two modules, first you have to use the Tropes software (<http://www.semantic-knowledge.com/download.htm>)

- 1 Transform your scientific document (description of research method) into .doc file
- 2 Run Tropes analysis and copy the "substantives" frequency table into Excel sheet following other data sheet presentation
- 3 Name the corresponding Excel sheet

This module allows for selecting the most relevant keywords beyond the most frequent ones given by the Tropes software. They are copied in the "Keywords list" Sheet.

Calculate the most relevant keywords of the research candidate

This module allows for calculating the distances of the research candidate to the TCs (in line) and of the TCs to the research candidates in column) and other TCs.

Calculate the distances between the research candidate and the TCs



List of targets : TCs - case of the mandate M/461

CEN/TC 137	Assessment of workplace exposure to chemical & biological agents
CEN/TC 138	Non-destructive testing
CEN/TC 162	Protective clothing including hand and arm protection....
CEN/TC 195	Air filters for general air cleaning
CEN/TC 230	Water analysis
CEN/TC 352	Nanotechnologies
ISO/TC 24/SC4	Particle characterization
ISO/TC 142	Cleaning equipment for air and other gases
ISO/TC 194	Biological evaluation of medical devices
ISO/TC 201	Surface chemical analysis
ISO/TC 202	Microbeam analysis
ISO/TC 209	Clean room and safe environment
ISO/TC 229	Nanotechnologies
IEC/TC113	Nanotechnology std for electrical and electronic products and systems

nanoSTAIR official links with research & standardization activities :

Official liaison with CEN T 352

In charge of NSC WG 7, Subgroup on Standardization

Link with QNANO expert group on standardization

Link with SIINN ERANET, national funding agencies

Already working → Check made on candidates

Doc. #	Topic of research candidate	Type of candidate
ACOSTA	Atomic Force Microscopy Based Micro/Nanomanipulation	PhD Thesis ^[10]
BLEEKER	Considerations on the EU definition of a nanomaterial: Science to support policy making.	Paper of Scientific journal ^[11]
MOTZKUS	Size characterization of airborne SiO₂ nanoparticles with on-line and off-line measurement techniques: an interlaboratory comparison study	Paper in JNR - Springer (source: VAMAS : J.M. Aublant)
DENG	Study on RAFT Polymerization and Nano-structured Hybrid System of POSS macromers	PhD Thesis ^[13]
UKNSPG	Working Safely with Nanomaterials in Research & Development	NanoSafety Cluster document ^[14]
SCOPE OF GUIDANCE	Facilitating the safety evaluation of manufactured nanomaterials by characterising their potential genotoxic hazard	NANOGENOTOX Scientific Report ^[15] .
RIEDEKER	Experimental protocol validation to design a standard using 2'-dichlorodihydrofluorescein (DCFH) for nanoparticle oxidative reactivity detection	Paper in grey literature (source: M. Riedeker) ^[16] .
KOIVISTO	SOURCE SPECIFIC RISK ASSESSMENT OF INDOOR AEROSOL PARTICLES	PhD Thesis - KOIVISTO
LYNCH	Labelling nanoparticles with non-radioactive isotopes	Paper of scientific journal - Lynch
NANODEVICE	Hydrochemical reactivity and biodurability of nanoparticles used for toxicity studies in NANODEVICE	Project report-NANODEVICE
NANOGENOTOX	Hydrochemical reactivity, solubility, and biodurability of NANOGENOTOX nanomaterials	Project Report-NANOGENOTOX
HINAMOX	Data on metal leaching and dissolution rates of NPs under different physiological conditions	Project Report-HINAMOX
ENPRA	Physical-chemical Data for QSAR-like modelling -In vitro sedimentation rates, dissolution and hydrochemical reactivity of the ENPRA nanomaterials	Project report- ENPRA

Examples of evaluation of distances to target

	TC24-SC4	TC201	TC202	TC209	TC229-WG1	TC229-WG2	TC229-WG3	TC229-WG4	
Acosta	0,76	0,73	0,85	0,94	0,88	0,91	0,82	0,82	New Topic
Bleeker	0,56	0,75	0,75	0,81	0,63	0,69	0,31	0,75	Close
Motzkus	0,52	0,65	0,70	0,78	0,96	0,65	0,74	0,78	Quite new
Deng	0,82	0,76	0,88	0,91	0,85	0,82	0,76	0,85	New topic
UKNSPG	0,83	0,78	0,91	0,83	0,87	0,87	0,22	0,87	Close
NanoGenotox	0,65	0,70	0,70	0,75	0,95	0,80	0,60	0,75	Quite new
Riedeker	0,59	0,53	0,71	0,71	0,88	0,71	0,53	0,71	Quite new
Lynch	0,80	0,60	0,85	0,95	0,95	0,75	0,75	0,85	Quite new
Koivisto	0,68	0,74	0,84	0,79	0,95	0,89	0,42	0,89	Close
NANODEVICE	0,67	0,57	0,71	0,81	0,81	0,62	0,62	0,76	Quite new
Nanogenotox	0,76	0,76	0,94	0,82	0,94	0,82	0,76	0,82	New topic
HINAMOX	0,47	0,53	0,71	0,65	0,82	0,71	0,53	0,65	Quite new
ENPRA	0,58	0,63	0,74	0,68	0,84	0,79	0,58	0,68	Quite new

Distance between a candidate and targets → matching is fine when distance is short to one TC but still need the expert judgment

→ Can help but not replace the expert evaluation



nanoSTAIR outputs and perspectives in US-EU nanoEHS

Web applet Giving closest TC(s) to the candidate (document analyzed)

Give information about the person to contact to interact with the TC

Prepare inputs to standardization: recommendation to submit a New Work Item Proposal in the right TC SC or WG

Support for the organisation of the contributions and linkage with other teams able to contribute by a NSB (DIN during the project)

Support for the secretariat for NWIP (DIN during the project)

nanoSTAIR can be Extend to other TCs (eg. 292 waste) or ASTM

Ontology can be adjusted, weight can be affected to keywords

It can be adapted to analyze distance of a project or a result (document) with expressions of needs or requests defined by CORs (eg. Keywords)

→ This action can be proposed through joined action or a joined agenda and it can be made in partnership with a dedicated CORs group



Conclusions

nanoSTAIR → an example of a living procedure and a set of tools to support **transfer of research results to standardization**

Perspectives within the US-EU CORs :

❑ **nanoSTAIR** : extend targets & check periodically for some projects & to have standardization seminar to support exploitation of results. Include in next call the need to define a standardization strategy if the TRL is above 5 & that the nanoSTAIR can help to prepare standardization strategies

❑ nanoEHS standardization activities : specific seminars in each CORs group but if some actions are requested (eg validate a method), who will pay ?

→ Through a joined Research agenda between EU and US

→ Extend Mandates to new work items in both CEN (eg M461) and ASTM

→ Make existing standards available to research community to increase confidence on results → Standards access policies

❑ Promote pre-standardization activities eg. voluntary certification scheme (eg. NanoCERT MTD include a validated method to certify protection efficiency of collective protective system → download the method at www.ineris.fr)

INERIS:

Public Body having industrial activities, delivering an assessment based on the experimental approach, the modeling and the knowledge of the industry

- Long-time experience of the industrial world (> 60 years)
- under the trusteeship of the Ministry in charge of Ecology
- Annual budget ~70 M€, staff of 600 (350 engineers & researchers)
- 50 PhD students & 15 post-doctoral fellowships
- Full scale tests facilities (animal facilities, mesocosm, labs ...)
- Headquarters extend to 50 ha , 25 000 m² of laboratories

Synergy between services for private customers, research activities and technical support for regulators

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