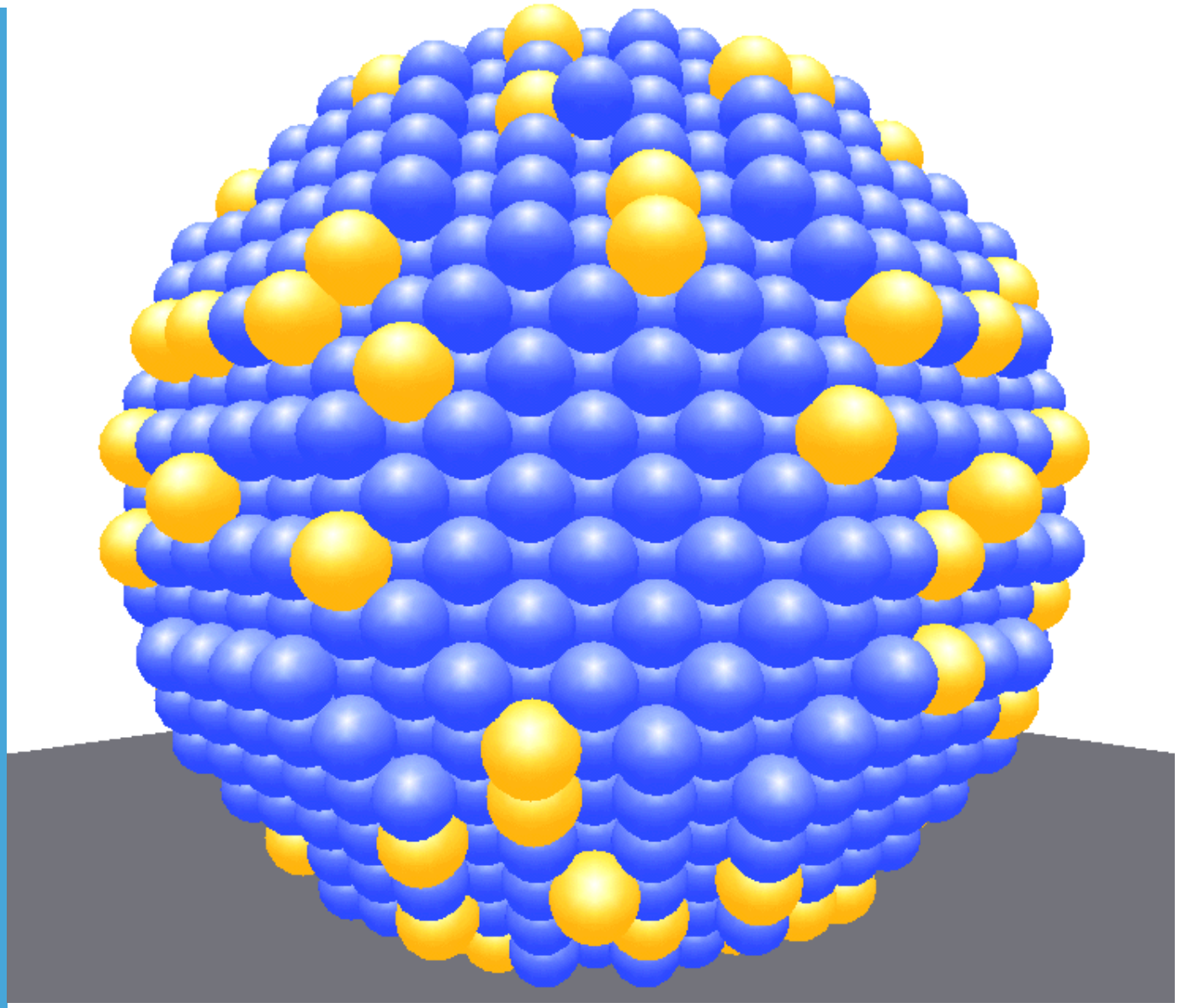
Safe-by-Design

In practice



NanoSafe 2016, 7-10th November
Grenoble

SAFE-BY-DESIGN (SbD IN PRACTICE)

Outline

» SbD concept

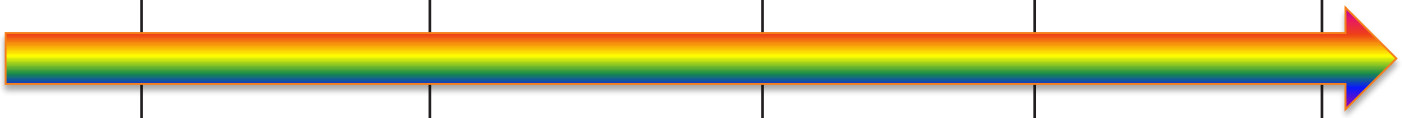
» Strategy for SbD safety assessment

» Illustrative projects

One definition of SbD:
Timely identification of uncertainties and potential risks as well as timely measures to reduce or eliminate these uncertainties and risks during an innovation project

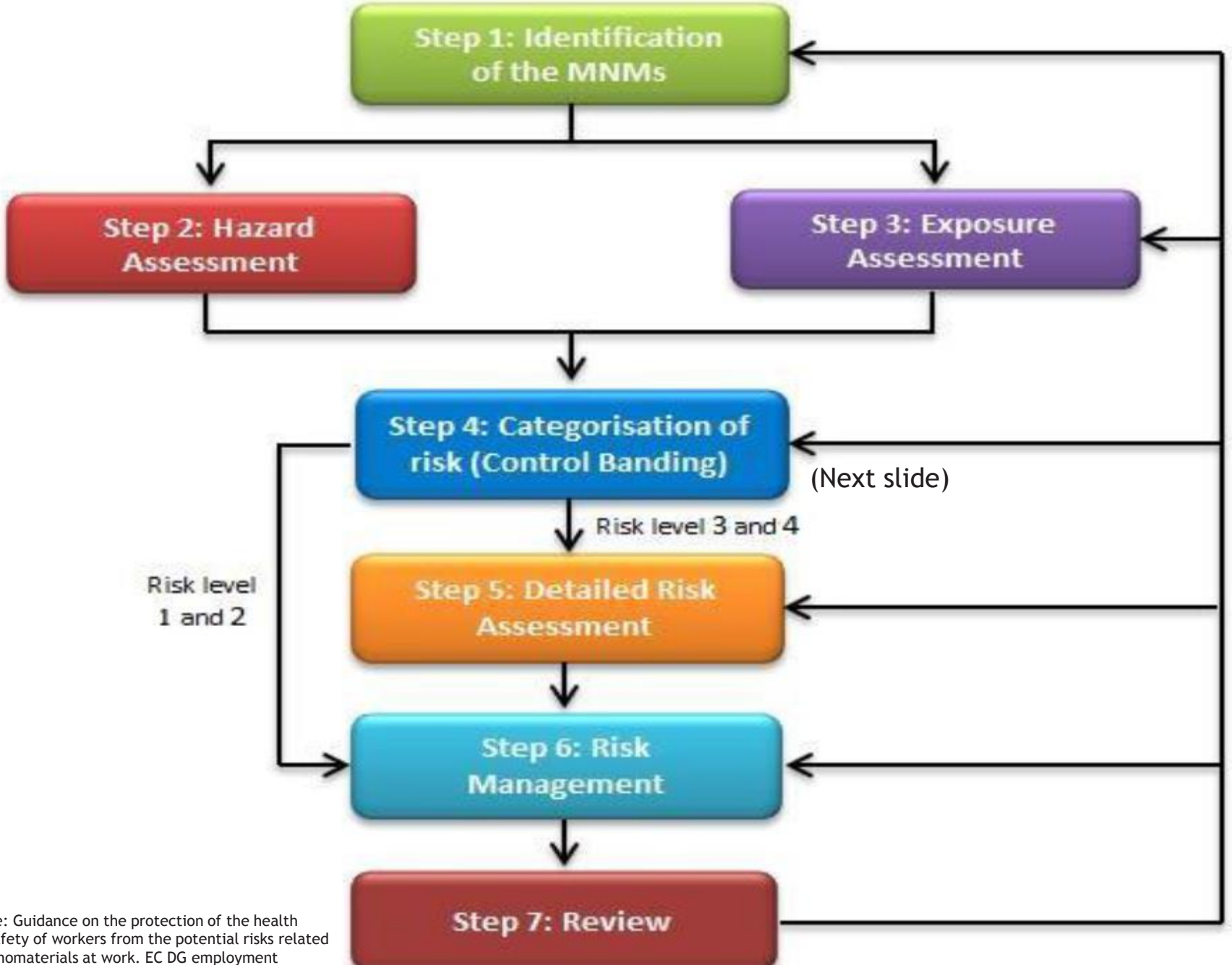
vito

SBD CONCEPT (AFTER NANOREG SAFE-BY-DESIGN (SBD) CONCEPT, WORKING DOCUMENT. RIVM AND TEMAS AG, 2015)



Industries innovation processes	**IDEA**	**Sketch business concept**	**Build business case**	Product **R&D** Prototypes	Market **testing** (volume, price,	**Market launch Full production**
SbD process integration in industries innovation process	**No SbD** activities No risk management	Reduction of nano-related uncertainties **List of potential nano-related risks** Analysis of alternatives Risk reduction	**Theoretical nano-related risk analysis** Nano-related risk mitigation Grouping principles Read-across	**Experimental nano-related risk analysis**	**Nano-related risk assessment before launch**	**Update nano-related risk assessment** after launch **Occupational health management** during production
		Occupational and product safety, consumer safety, environmental safety			Nano-related risk management	
		Comparison with pre-defined safety levels				
		Organized dossier shared by stakeholders (robust nano safety data) (pre-regulatory information)			REACH dossier	

SbD AND 'NORMAL' RISK ASSESSMENT: IDENTICAL RISK ANALYSIS STEPS



Source: Guidance on the protection of the health and safety of workers from the potential risks related to nanomaterials at work. EC DG employment

RISK BANDING

Priority setting in the risk banding system

Hazard band	Exposure band			
	EB1	EB2	EB3	EB4
HB1	Low risk	Low risk	Low risk	Medium risk
HB2	Low risk	Low risk	Medium risk	High risk
HB3	Low risk	Medium risk	Medium risk	High risk
HB4	Medium risk	Medium risk	High risk	High risk
HB5	Medium risk	High risk	High risk	High risk

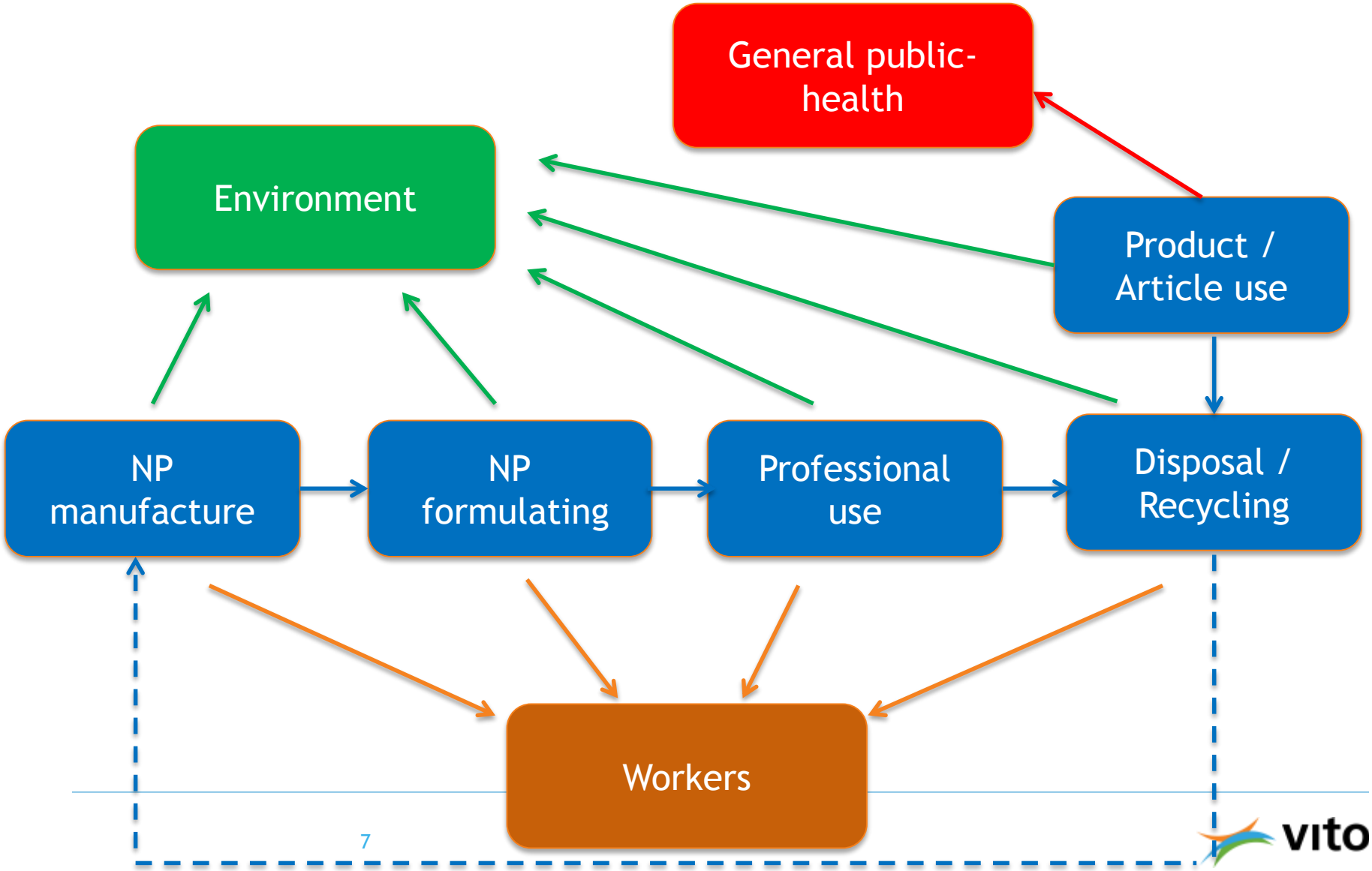
Source: ISO/TS 12901-2

SbD IN PRACTICE

VITO's approach for the safe-by-design assessment

Action	Detail
Plant visit (R&D)	Description of exposure scenarios
Material identification	NM characterisation
Literature review	Toxicity, ecotoxicity Exposure/release (relevant scenarios)
Teststrategy for effects	Ecotoxicity – human toxicity Acute - chronic
Exposure	During all relevant life cycle stages (next slide) Relevant route(s) Measurements (R&D – pilot - simulation) Modelling (industrial scale, environment)
Risk characterisation	Compare exposure values with safe values for effects
Risk management	Recommendations for safe use (general for NP; plant specific)

LIFE CYLCE STAGES FOR EXPOSURE ASSESSMENT



vito

SbD IN PRACTICE: EXPOSURE SCENARIOS

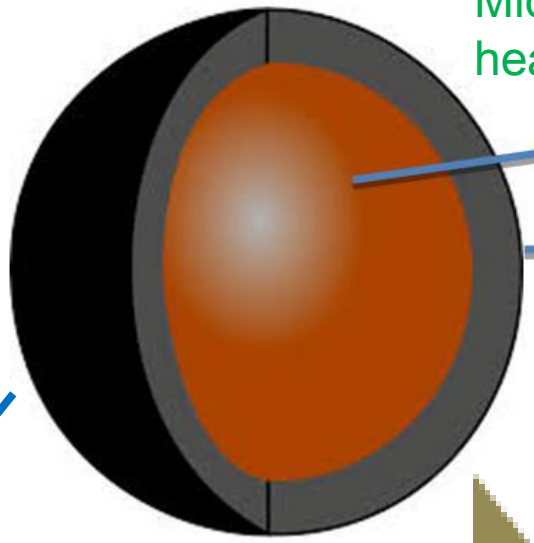
Based on plant visits - description of the actual / future way of working

Focus	Examples
Activities	Weighing, pouring, stirring, transport, pumping, sonication, …
Technical measures & operational conditions	Ventilation, safety cabinet, decontamination unit
Personal protection	Face mask, gloves, lab coat, overall, sleeves
Environment	Release to surface water, air, soil Waste, waste water treatment

NANOTUN3D

Development of nano-based materials for metal additive manufacturing and characterisation of their operative life cycle from nanoparticles and raw metal powder to final parts

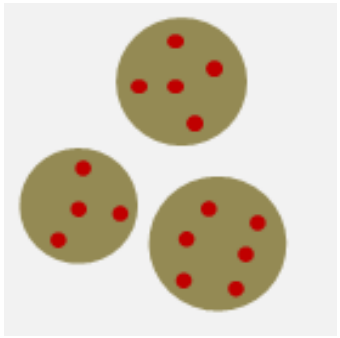
Microwave heating technology



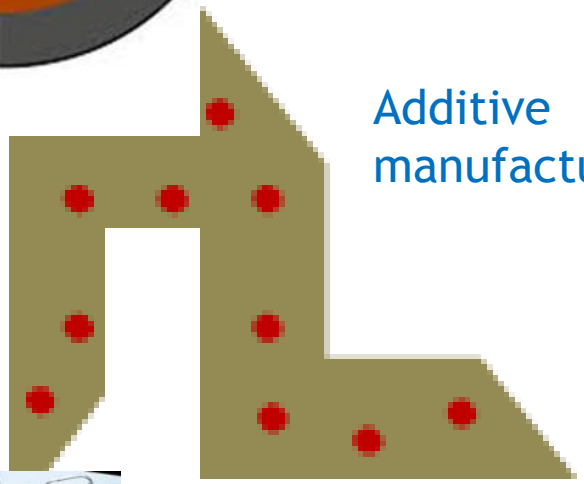
Ti64 POWDER

CORE SHELLS

Gas atomisation technology



Powder



Additive manufacturing

Direct applications e.g. aircraft components

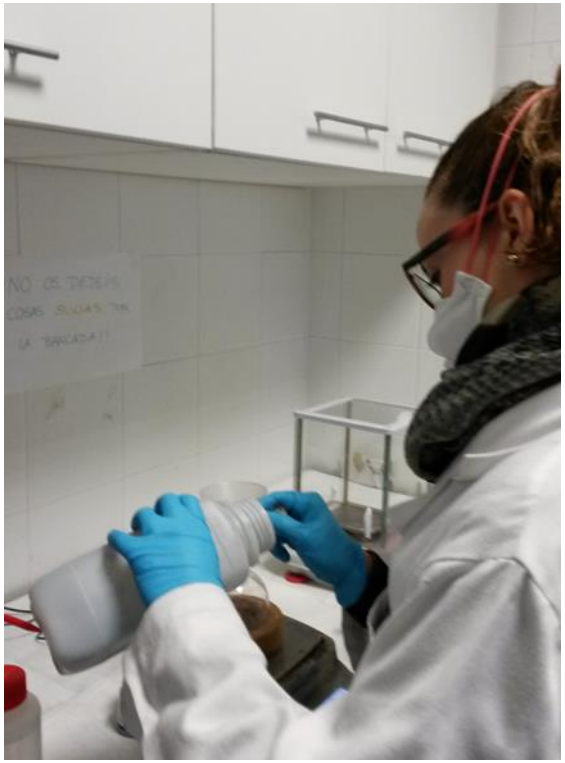
FIRST RESULTS FOR NANOTUN3D

Literature review overview

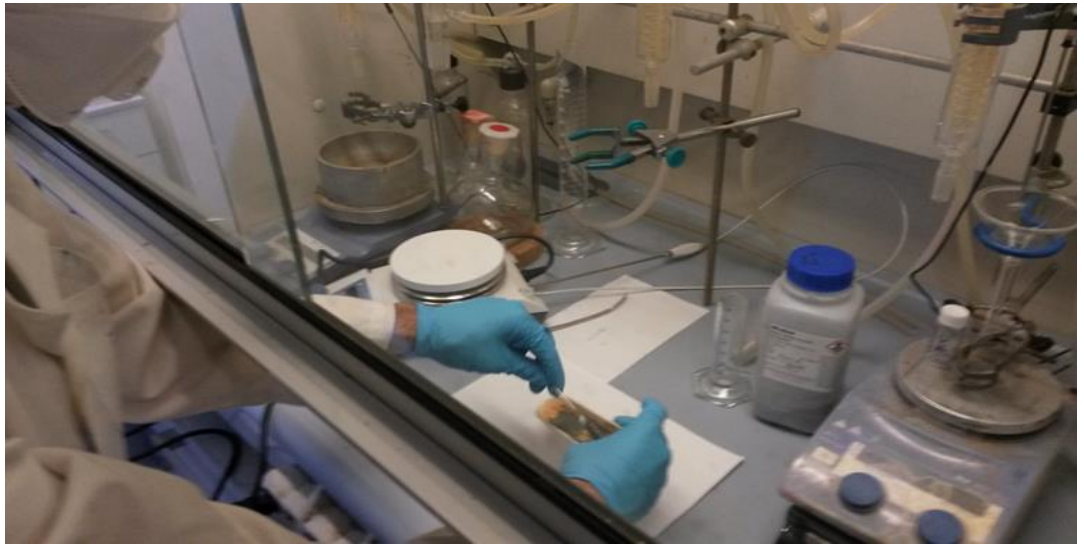
	Endpoint	SiC-NP	TiO2-NP	Fe2O3 and Fe3O4-NP
In vitro	Cytotoxicity (cel viability)	-	-	-/+
	Genotoxicity	- (non-fibrous)	+/- (IARC 2B)	+/-
	Inflammation	+	+/-	+ (Fe_2O_3)
ecotox	Aquatic life	-	+	Fe^{3+} release > NP
	Sediment/soil	-/+ (after sonication of SiC wires)	+	Fe^{3+} release > NP

NANOTU3D: FIRST RESULTS

Occupational measurements (R&D)



Weighing of SiC-NP



Scratching crucible to remove all residues

Pouring calcine SiC-TiO_2 residues on paper, and pour in glass vial using a funnel

FIRST RESULTS FOR NANOTUN3D

Occupational measurements (R&D)

Activity	Background corrected number concentration (10-700 nm) pt/cm^{-3}
Weighing SiC	10343
Adding liquid in fume cupboard (FC)	690
Sonicating in FC	2082
Pouring dry powder in crucible	13537
In/out oven	15044
Pouring calcine powder	43245
Scraping calcine powder	12589
Cleaning with ethanol	3275

Note: TiO_2 preliminary reference value = 20000 pt/cm^3

vito

FIRST RESULTS FOR NANOTUN3D

Work in progress

Item	Action	Outcome
Exposure scenarios	Literature review of relevant scenarios	Possible exposure via inhalation from NP-powders: weighing, transferring, bagging
	Measurements during coreshell manufacture (lab scale and up-scaling)	For some acitivities: number of NPs higher than the background
Risk management	Based on plant visits and on-site NP measurements	Case-by-case recommendations on safe handling in current R&D scenarios General: back in back recommendation for all products with NP

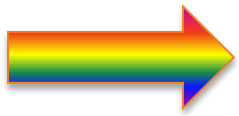
vito

FUTURE ACTIONS ON HAZARD AND EXPOSURE ASSESSMENT IN NANOTUN3D

Some future actions

- ➢ Testing *in vitro* and ecotoxicity
- ✓ raw materials, core-shells, printing powder
- ➢ Exposure measurments in other scenarios & exposure modelling
- ➢ Exposure from use (simulate wearing in test chamber)

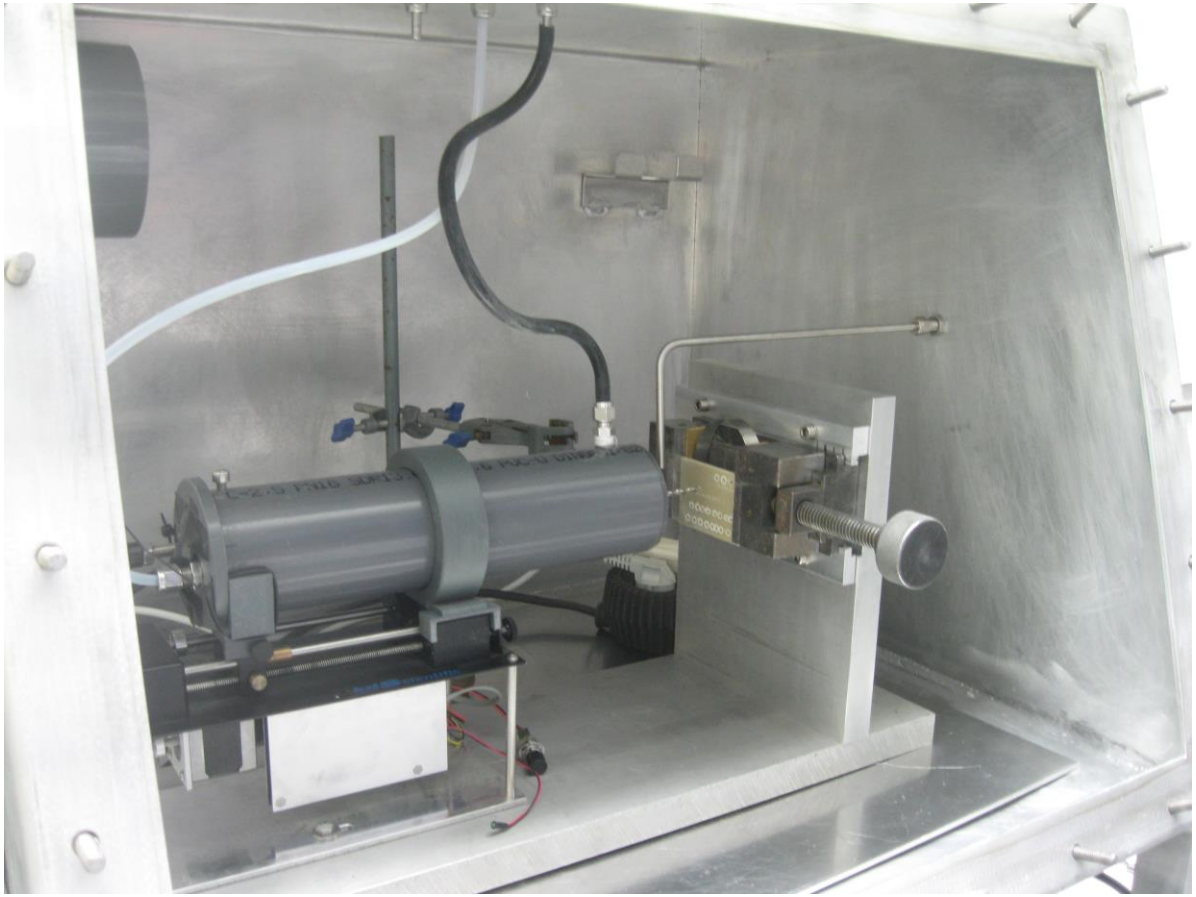
- ➢ …



Safe manufacture and use

SbD IN PRACTICE

Simulation of drilling composite nanomaterial in test chamber

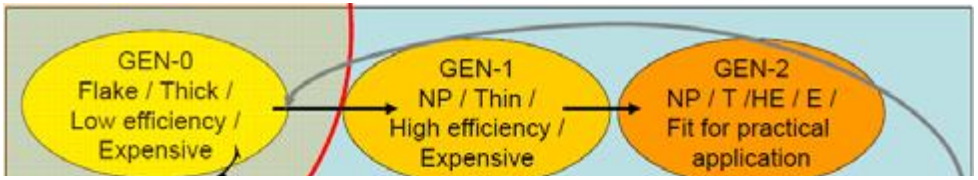


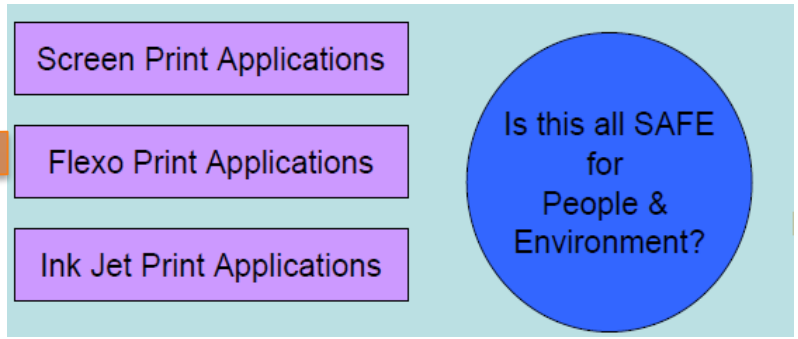
Source: picture taken during the QualityNano project

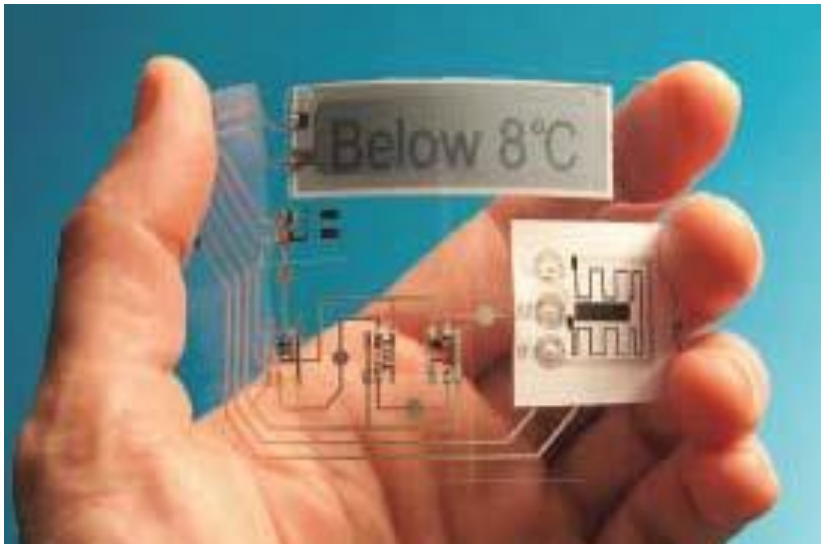
vito

MET@LINK

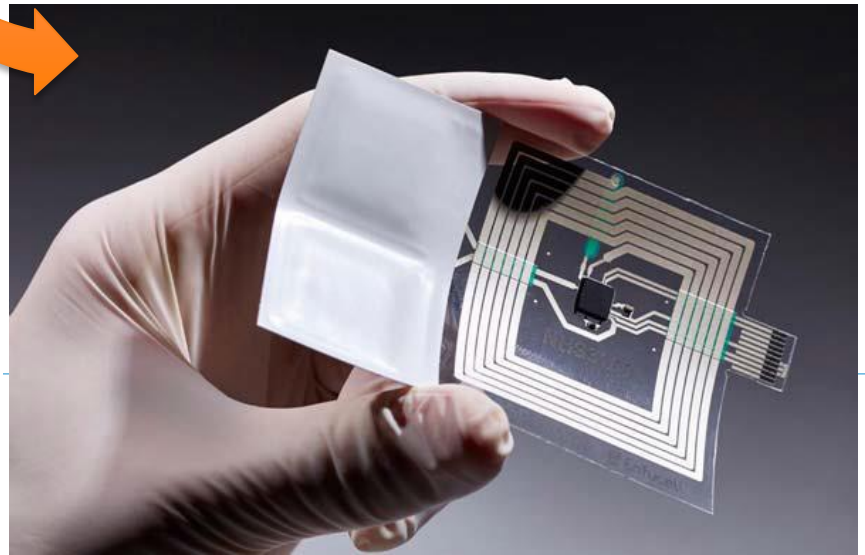
Development of NP (Ag, Cu) inks for printing metallic conductors for electronic circuits (antennas for NFC and RFID tags) used in e.g. sensors, smart packaging, keyboards, internet of things, …







Temperature sensitive tag



Printed antenna on flexible substrate

MET@LINK: FIRST RESULTS FOR AG-NP INK

Work in progress

Item	Action	Outcome
Ag-NP	Literature review	Very toxic to aquatic life Severe eye irritation (category 2)
Ag-NP inks GEN 1 and GEN 2	Acute ecotox testing	Very toxic to algae and Daphnia (WAF*)
	In vitro eye irritation	Severe eye damage (category 1) (WAF: no eye irritation)
Exposure scenarios	Literature review of relevant scenarios	Possible exposure via inhalation from NP-suspensions: sonication, inkjet printing (droplets of nozzle forming a liquid jet), release from dried ink stains & wearing of printed surfaces (eg abrasion/cutting)
	Measurements during inktjet printing	Number of NPs not increased compared to the background
Risk management	Based on plant visits to ink manufacturer and printing companies	Case-by-case recommendations on safe handling in current R&D scenarios

*Water accomodated fraction

FUTURE ACTIONS ON HAZARD AND EXPOSURE ASSESSMENT IN MET@LINK

Some future actions

- Chemical analysis of the WAF
- Other endpoints testing
- Other products: varnish ink (without NP), NP-powder, Cu-NP inks
- Waste water ecotoxicity testing
- Exposure measurments in other scenarios & exposure modelling
- Exposure from use (simulate wearing in test chamber)

- …

Safe manufacture and use

vito

QUESTIONS ? - SUGGESTIONS ?

NanoTun3D is supported by the European Commission through the Horizon 2020 framework program for Research and Innovation. (Grant Agreement nr. 685952)

Met@Link is supported by the Strategic Initiative Materials (SIM) Flanders and the Institute for Innovation through Science and Technology in Flanders (IWT)

www.nanotun3d.eu

AIMME (lead)
UPV
LAURENTIA
CEIT
VITO
APR
TWI
ZOZ
TLS

Industrial partners
AGFA-GEVAERT (lead)
QUAD INDUSTRIES
SEGERS & BALCAEN
AVL METAL POWDERS

Research partners
FLAMAC
IMEC/IMOMEC
UNIVERSITY OF GHENT
UNIVERSITY OF HASSELT
VITO