NanoSafety Cluster

Combining key lessons learned from H2020 and FP7 projects to underpin the next generation of nanosafety research

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A few things from past projects…

- Generated a wealth of data, especially on the hazards of engineered nanomaterials (NMs)
- We improved our understanding of the need for physicochemical characterisation, and how to do it
- We improved understanding of which physicochemical characteristics influence hazard
- We advanced methodologies for assessment of exposure
- We initiated templates for collection of data in a common format
- We initiated templates for method sharing

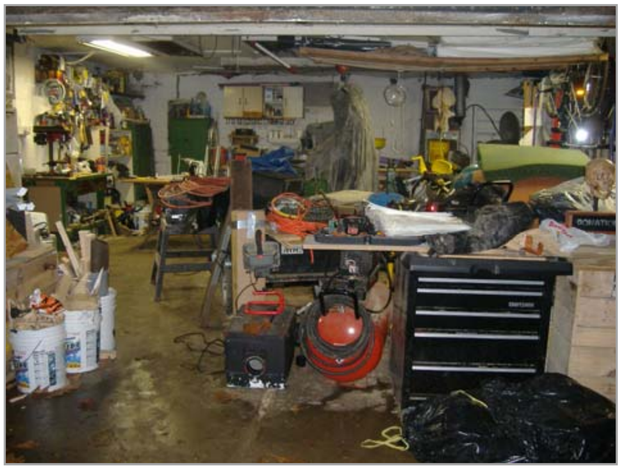
What are we doing now?

- We need to deliver ‘tools’ for stakeholders that are useful.
  - Useful for regulators and industry
  - Useful for regulatory purposes
  - Useful for innovation and safe(r) by design

- We need to make sure that the ‘tools’ generated by individual projects are sustainable and are utilised after each project is complete.

NanoSafety Cluster

The evolution of nanosafety



- We have tools
- But they were not well organised or linked
- The quality is variable

- Our data is now well organised
- Our tool quality is being improved
- We have a great toolbox

- The toolbox needs to be accessible
- The tools need to be fit for different users and purposes
- Guidance needed
- Streamlined processes needed

What are we doing now?

- An accessible data repository.....

- The European NanoSafety database
- A computational infrastructure for toxicological data management of NMs
- Improved the utilisation of data through the implementation of data storage, searching and sharing
- Accelerating knowledge exchange and reuse
- Enabling the meta analysis of nano-bio interactions
- Instances generated for individual projects such as caLIBRAte, PATROLS and GRACIOUS – allow project partners to more readily access the most relevant data

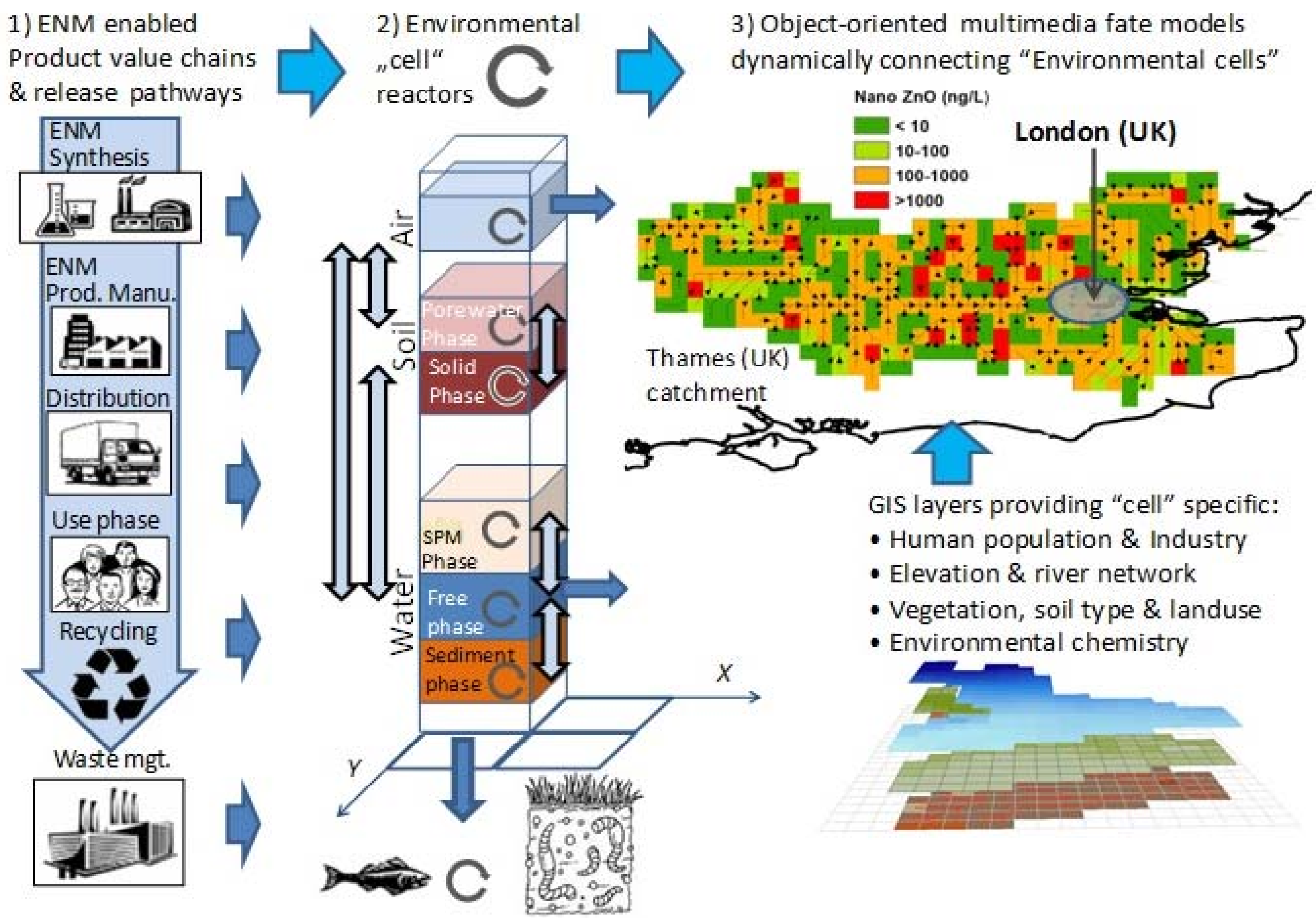
http://www.enanomapper.net/enm

What are we doing now?

- Exploitation of data repositories to develop models of NM behaviour…..

Nanomaterial Fate and Speciation in the Environment (2015-2019)

Fate and Exposure models and tools for you – www.NanoFASE.EU

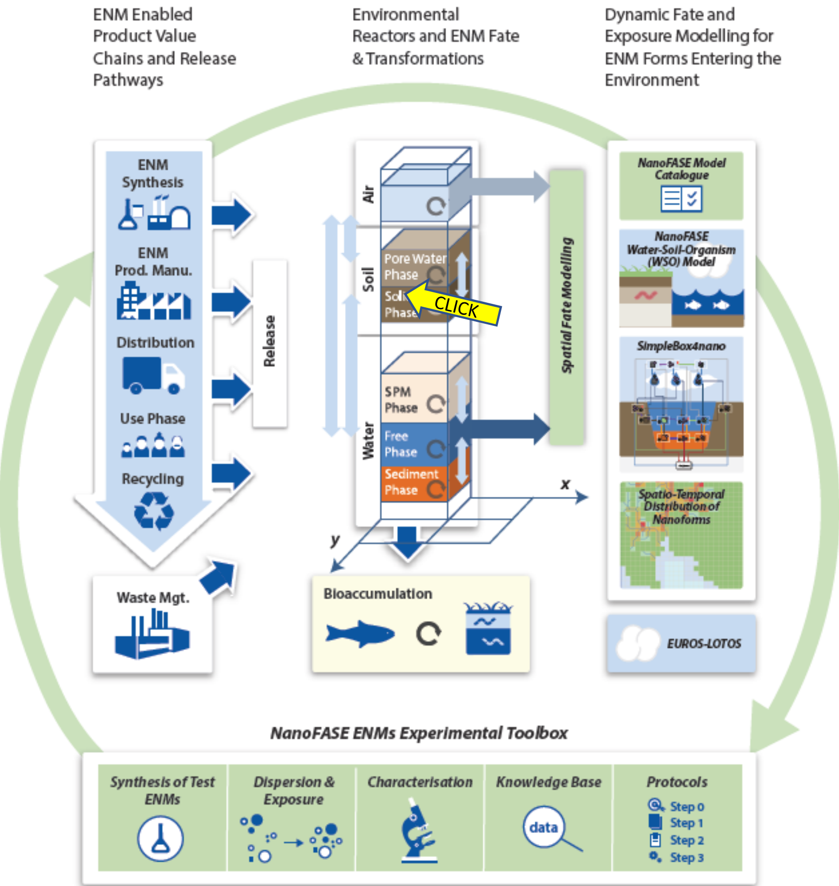


Nanomaterial Fate and Speciation in the Environment (2015-2019)

NanoSafety Cluster

Fate and Exposure models and tools for you – www.NanoFASE.EU

Delivered in a transparent online “Clickable Framework”



“Clickable” links for all elements:

- Product lifecycle release processes
- Environmental compartments
- Models for all Different complexity levels
- Protocols and Data

These links allow progressive access to deeper levels of details and protocols

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LEVEL 1 - CONCEPTS

Nanomaterial Fate and Speciation in the Environment (2015-2019)

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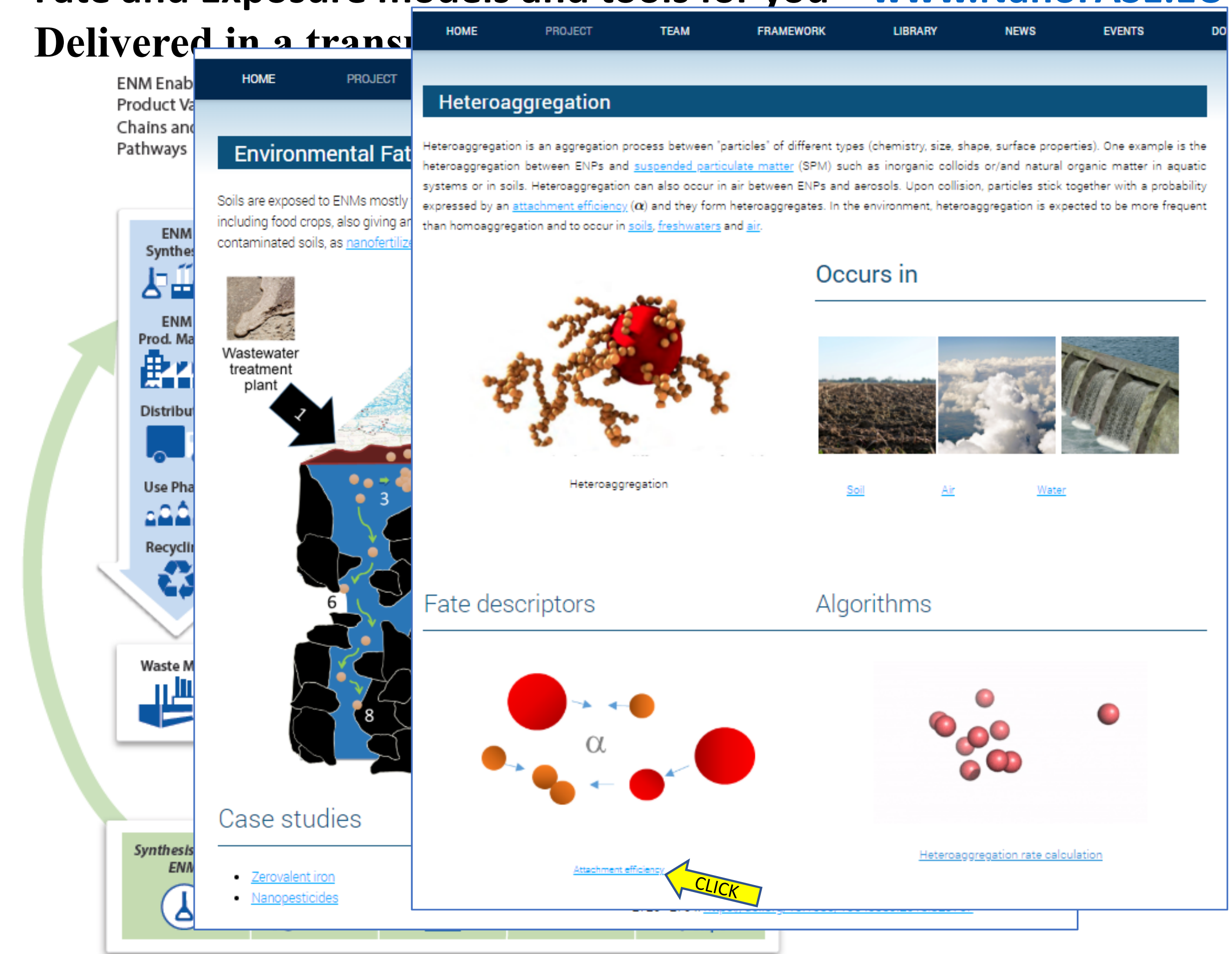
Fate and Exposure models and tools for you – www.NanoFASE.EU

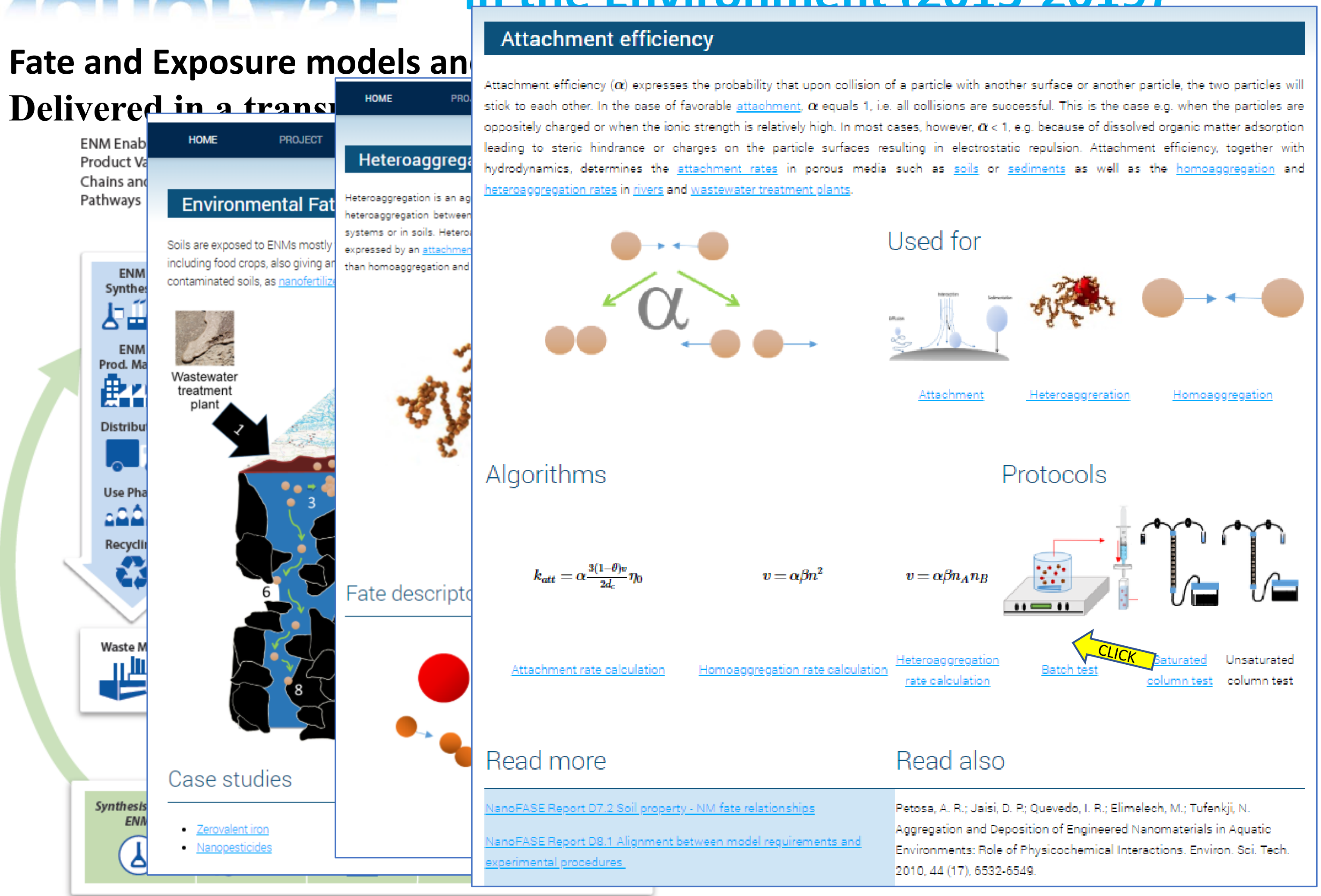


LEVEL 2 – DETAILED PARAMETERS & ALGORITHMS

Nanomaterial Fate and Speciation in the Environment (2015-2019)

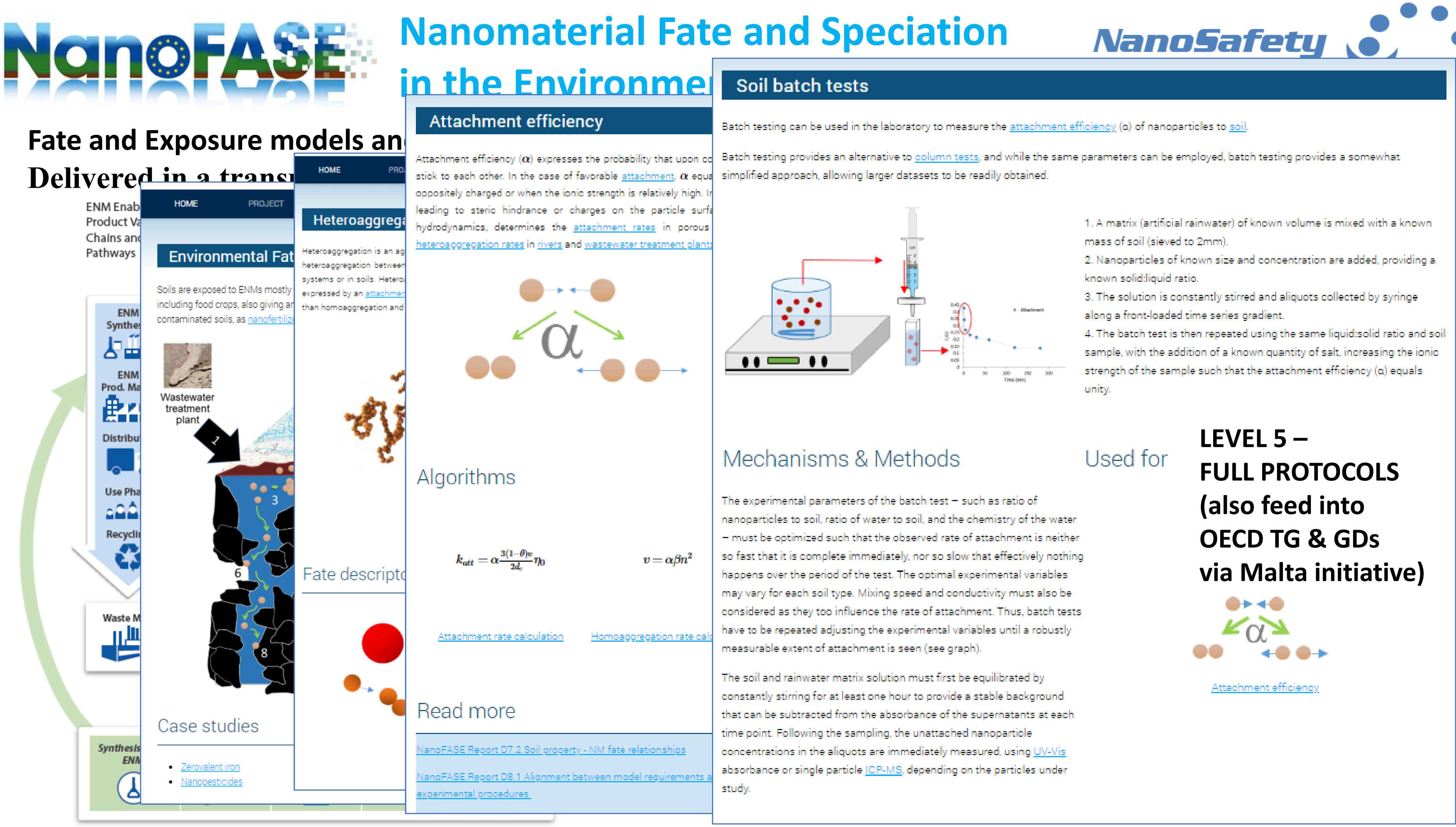
Fate and Exposure models an

Delivered in a transp



LEVEL 4 – EXPERIMENTAL & ALGORITHM OPTIONS for PARAMETERS DETERMINATION

Nanomaterial Fate and Speciation in the Environment



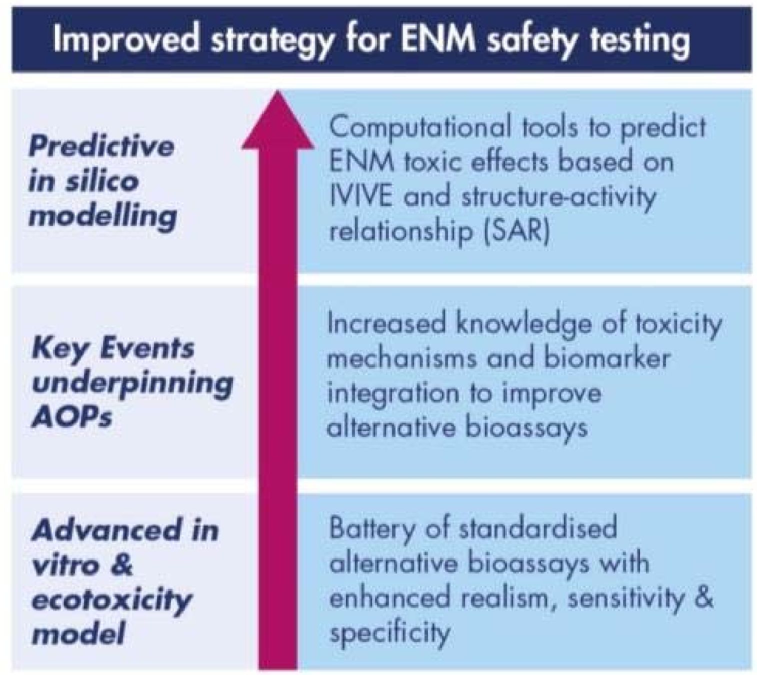
LEVEL 5 – FULL PROTOCOLS (also feed into OECD TG & GDs via Malta initiative)

What are we doing now?

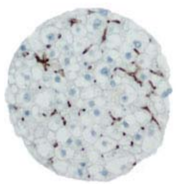
- Making the hazard tools more realistic, relevant and longer term …..

PATROLS Vision

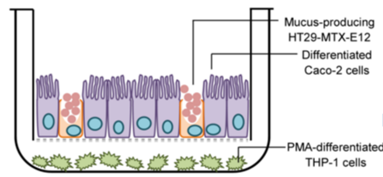
Establish and standardise a battery of next generation hazard assessment tools to predict adverse effects caused by long-term, low dose ENM exposure to humans & the environment, supporting regulatory risk decision making



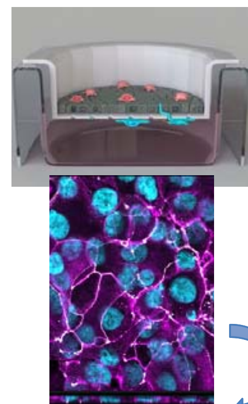
Developing advanced hazard testing systems



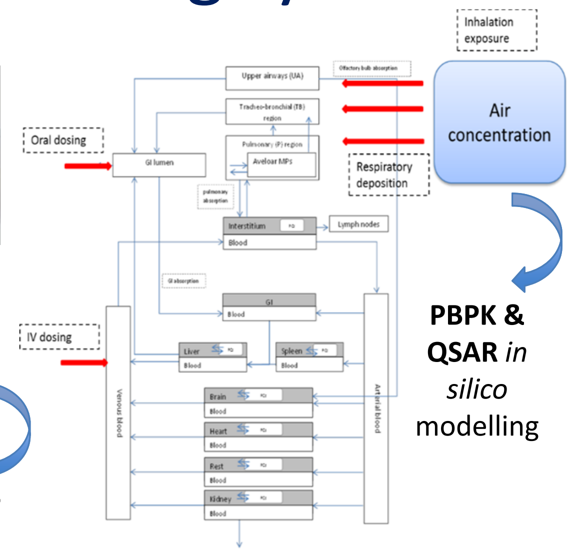
3D liver microtissues; primary cells & cell line based models



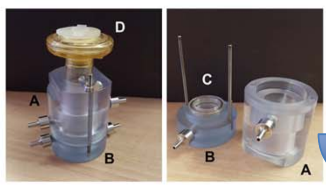
Advanced **triple culture gastro-intestinal tract** models



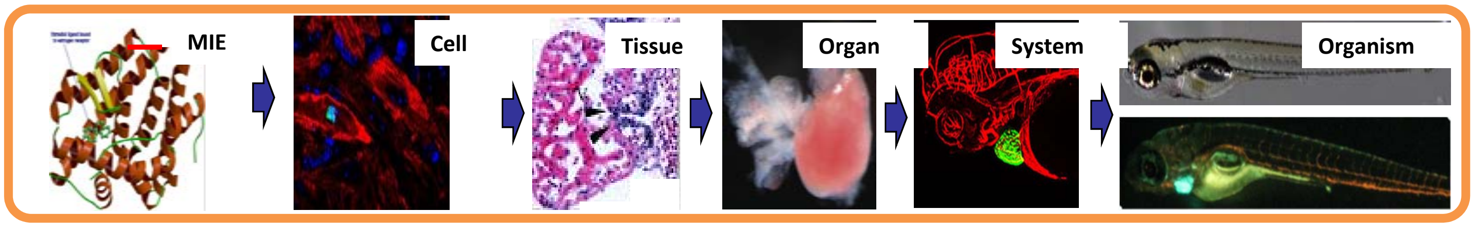
Advanced **alveolar 3D** models



PBPK & QSAR *in silico* modelling



Bioreactor for **dynamic culture** of the epithelial cells



Transgenic fish models enable molecular initiating events in AOPs to be identified and quantified by fluorescent protein reporters linked to specific receptors or enzymes

PATROLS
Advanced Tools for NanoSafety Testing

https://www.patrols-h2020.eu/

What are we doing now?

- Combining different sources of information for risk assessment and decision making .....

SUN Developed Innovative Tools

Hazard

- *In vitro* screening tools
- Rapid high-throughput and content tools for predicting long-term environmental consequences and impacts on ecosystem services
- Short-term inhalation and oral studies

Exposure

- A stochastic fate and exposure tool to calculate predicted environmental concentrations (PECs)
- 3-tier qualitative to quantitative inhalation, dermal and dermal-to-oral occupational and consumer exposure assessment tool

Release

- Validated tools to collect manufactured nanomaterials (MN) released from products
- Tools to analyse and characterize the released MN
- Modelling tools to predict the release and transformation of MN over the whole lifecycle

Risk assessment

- A tool for quantitative human health Risk Assessment of MN based on REACH
- A tool for stochastic ecological Risk Assessment based on Species Sensitivity Distributions

Decision support

- A user-friendly, software-based Decision Support System for informing industrial and regulatory decisions about the safe production, handling and disposal of MN

Lifecycle impact

- A comparative LCA model for nanoproducts and MN

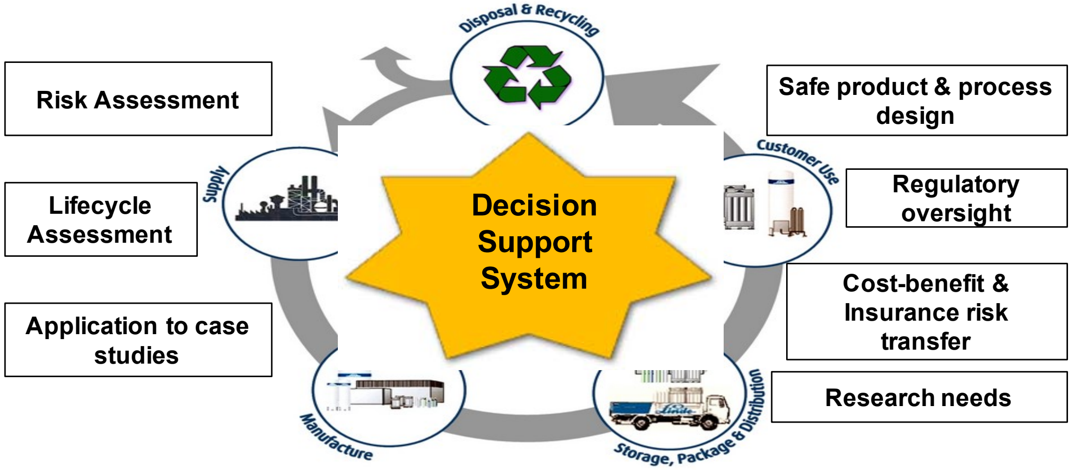
Safe product and process design

- Safety by design ($S_{by}D$) elimination/substitution and waste isolation practices to reduce the release of nanomaterials from products/composites/waste or to induce their accelerated alteration/degradation in order to reduce their environmental persistence and bioaccumulation
- Tools to analyse the evolution of the product quality parameters, process conditions and interactions, in real-time, to subsequently exercise control over them, increasing both product safety and quality

SUN Concept

Bottom-up generation of environmental, health and safety (EHS) data and tools

Top-down design of a Decision Support System for use by industries and regulators



GUIDEnano Tool

Quantitative risk assessment, allowing a justified assessment for each scenario

The tool is not for screening of risks or prioritization, but it **supports decision-making**

It is a complete (hazard & exposure assessment, different exposure routes and scenarios along the life cycle) **and flexible Tool** (allowing future updates)

The tool **matches with existing regulatory accepted risk assessment methods, e.g. REACH, OECD**

OVERALL: GUIDEnano enables science–based risk assessment of nanomaterials and nano-enabled products in a more transparent and reproducible way compared to current practice

GUIDEnano

The Tool Inside

Activities | (Nano)materials | Compartments | Exposure | Hazard Assessment | Risk Assessment | Report

Complete **description of exposure scenarios**, including amounts and form of released materials

Users can **define their materials** (nanoparticles, nano-enabled products, articles) **and their properties along the life cycle**

The user can enter different environmental compartments and different system compartments **Kinetic world fate model** has been implemented

Quantification of the Hazard (incorporation of both human and environmental endpoints) **Implementation of the similarity algorithms for grouping and read-across purposes**

The **user can use external tools** for human exposure assessment, provide the measured data **or** use values from **GUIDEnano exposure scenario library or release activity card library**

Output report for users with details

Quantitative human and environmental risk assessment with uncertainty factors assigned

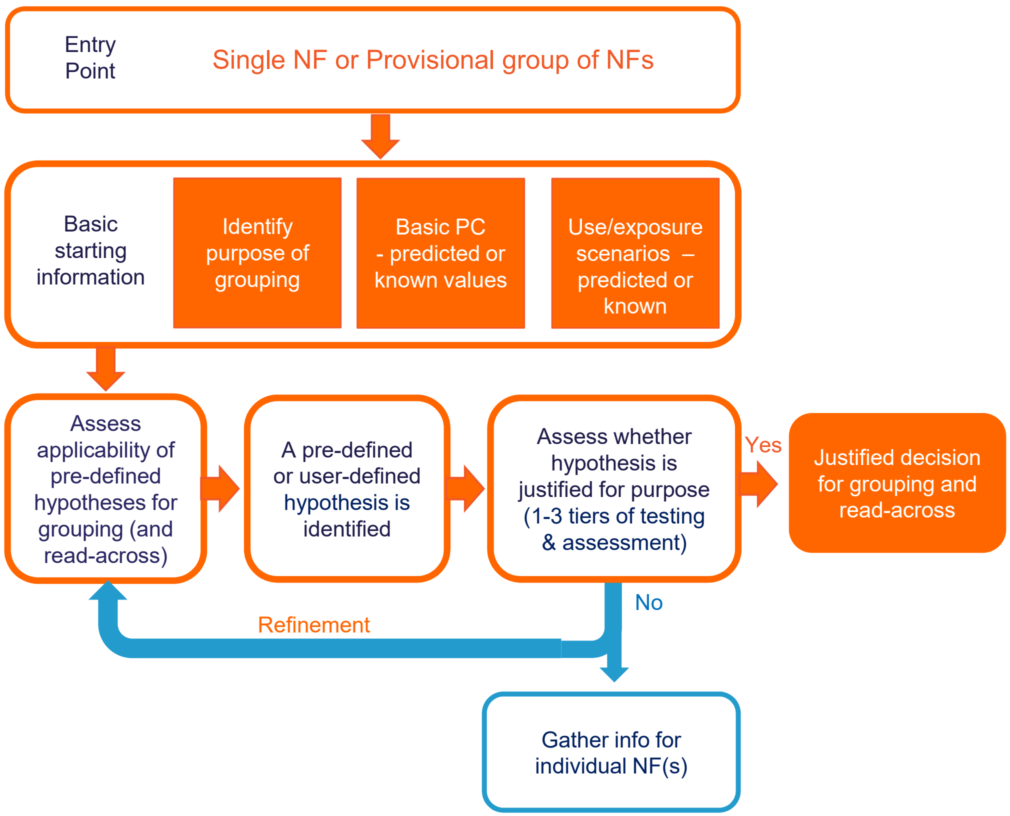
LEITAT managing technologies

What are we doing now?

- Streamlining physicochemical, exposure, hazard and risk assessment .....

GRACIOUS FRAMEWORK

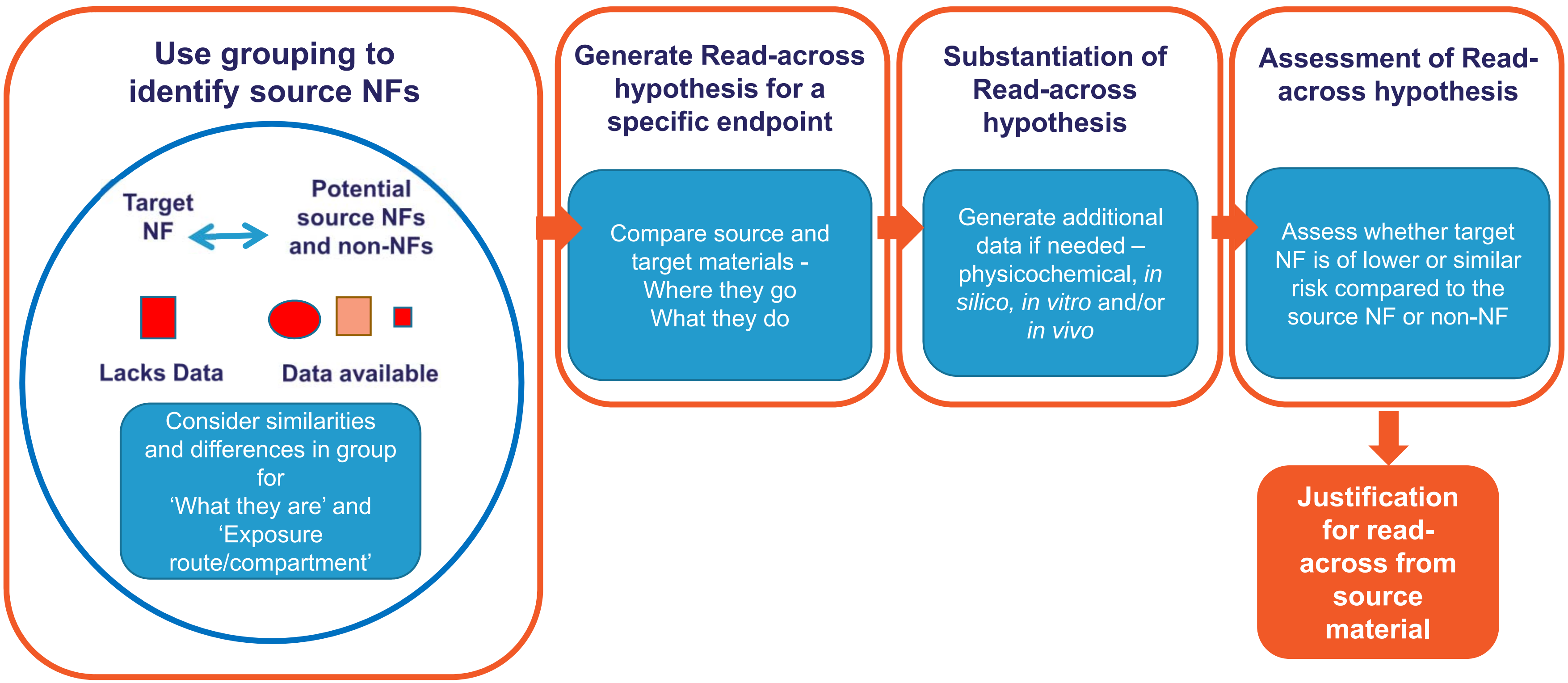
Grouping Nanoforms to streamline risk management



https://www.h2020gracious.eu/

GRACIOUS FRAMEWORK

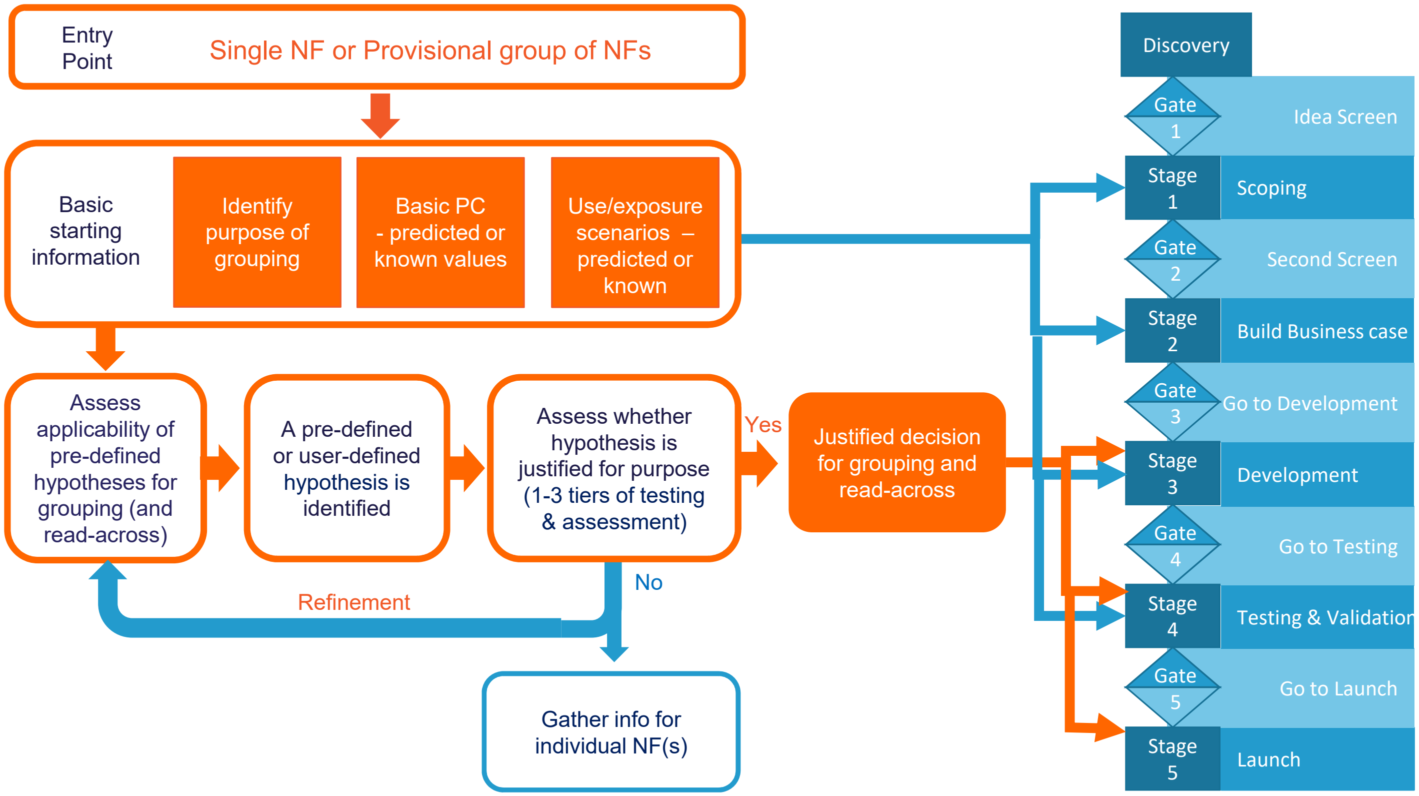
Grouping for regulatory Read-Across



GRACIOUS FRAMEWORK

Grouping for innovation / Safe(r) by Design

gracious



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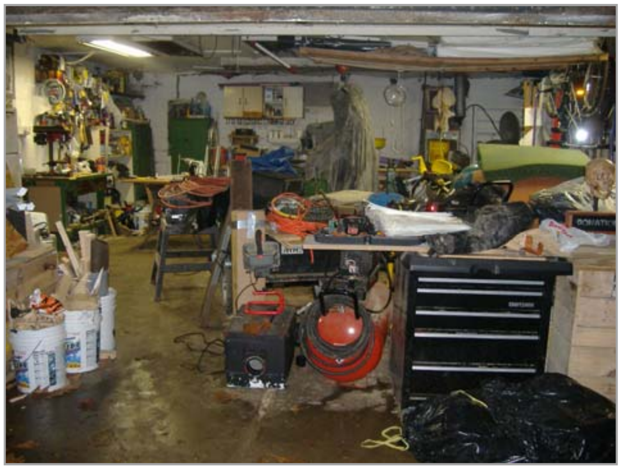
NanoSafety Cluster

What are we doing now?



SEVENTH FRAMEWORK PROGRAMME

ENM eNanoMapper

caLIBRAte nano risk governance

PATROLS Advanced Tools for NanoSafety Testing

gracious

SUN Sustainable Nanotechnologies Project

GUIDEnano

What I have shown you……

Exposure & Hazard assessment

Contributing projects

NanoSafety Cluster

ProSafe eNanoMapper gracious FUTURE NANO NEEDS PATROLS Advanced Tools for NanoSafety Testing NanoFASE ACEnano caLIBRAte nano risk governance BIORIMA NANOINDEX NanoTEST nanoMONITOR NanoReg2 NANOSOLUTIONS SUN Sustainable Nanotechnologies Project ec4SafeNano CERASAFE nanoMICEX NANORISK GUIDEnano NANOSTREEM SmartNanoTox HISENTS NanoCommons Nano-Knowledge Community NanoMILE SEVENTH FRAMEWORK PROGRAMME NANoREG

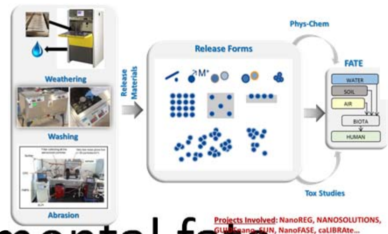
More information can be found at the NanoSafety Cluster website

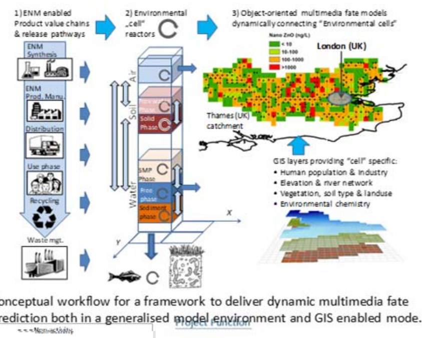
- https://www.nanosafetycluster.eu/

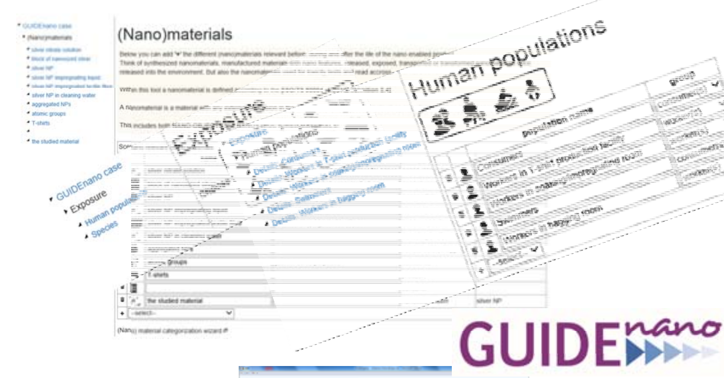
Exposure & Hazard assessment

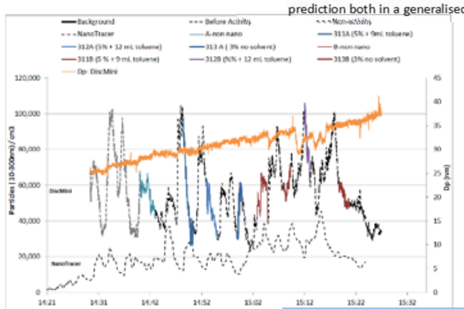
Progress made 2014-2017

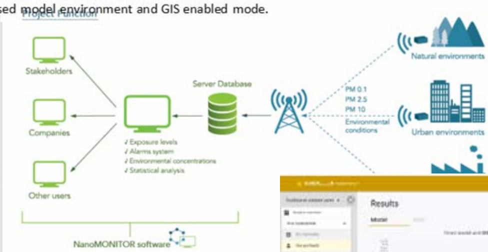
- Release
- Environmental fate
- Human Exposure
- Human Hazard
- Ecotoxicology

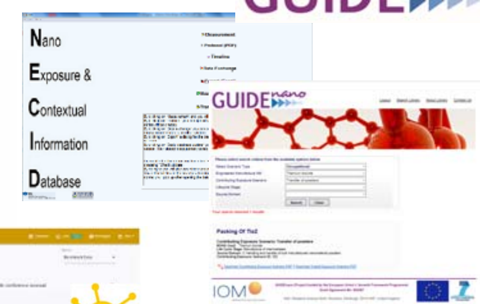


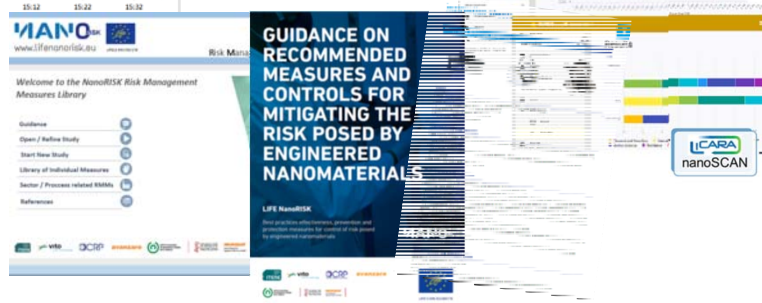


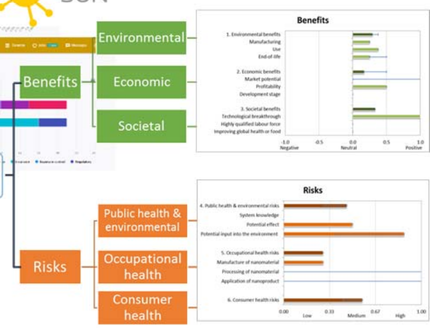










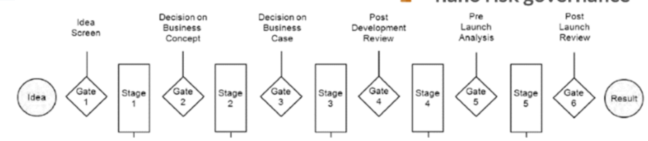


Exposure & Hazard assessment

Remaining H2020 aims

	Exposure assessment				Hazard assessment
	Manufacturing processes	NOAA in solid matrix	NOAA in liquid	NOAA powder	
Tier 1	ISO standard proactive approach				ISO hazard bands
Tier 1a	Stoffenmanager-nano (retroactive approach)				
Tier 2	NanoSafer	ART	Consexpo	NanoSafer/ART	NRV
Tier 2a					Bulk OELs
Tier 3	Use exposure data/measure				Toxicity data

Refinement assessment



- Match with stakeholder needs
  - Workshops/webinars with / for industry
- Networking & Harmonisation
  - Joint project workshops

- Databases and data management
  - Harmonised collection and storage
  - Open access
- Innovative methods for exposure & hazard testing