Nanoreg: Towards a harmonized approach to NM regulation

Blanca Suarez-Merino DPhil

Barcelona 15-16 March

Nanoreg: Towards a harmonized approach to NM regulation

Nano products

VS

Some Australians Prefer Skin Cancer to Sunscreens with Nanoparticles

By Dexter Johnson

Posted 10 Feb 2012 | 18:09 GMT

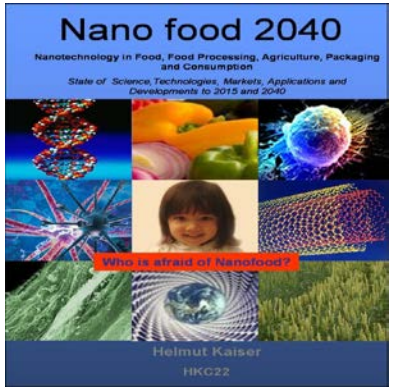
EU votes for labels on nano, cloned and GM food

Ecologist

5th May, 2010

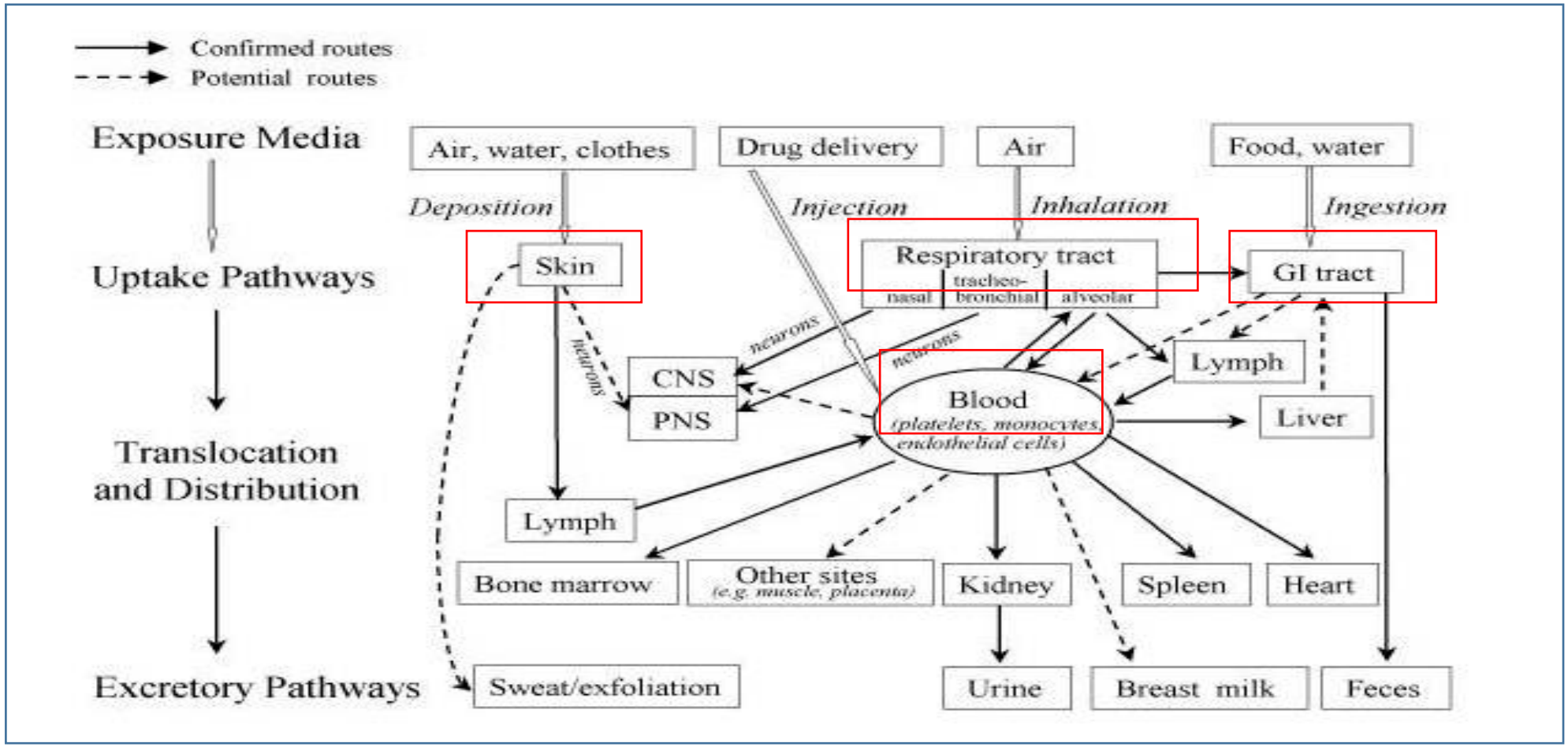
UK and other member states expected to fight proposals to bring in compulsory labelling for consumers on novel foods

MEPs have voted almost unanimously in



Regulation needs to keep pace with innovation!

What we know…



Biokinetics of nanoparticles. Diseased or compromised organisms where not considered.

Oberdorster *et al* 2005.

European Comunity Regulation on Chemicals (REACH)

Is the European Community Regulation on chemicals and their safe use (EC 1907/2006). It deals with the **R**egistration,**E**valuation, **A**uthorisation and Restriction of **Ch**emical substances. The law entered into force on 1 June 2007.

a. Improve the protection of human health and the environment
b. Enhance innovation and competitiveness of the EU chemicals industry
c. Transparency
d. Avoid unnecessary animal experimentation

Toxicity studies with nanoparticles according to the REACH regulations have not been validated for nanoparticles. These are being looked at by European authorities so nanoparticles could be evaluated for safety as any ordinary chemical product. Major problem is adapting dosage.

- RIPoN reports

REACH Implementation Project on Nanomaterials (RIPoN), which it intended to provide advice on key aspects of the implementation of REACH with regard to nanomaterials. They are REACH annexes.

- RIPoN 1: Substance identification
- RIPoN 2: Information requirements
- RIPoN 3: Chemical Safety Assessment

Nanoreg: Towards a harmonized approach to NM regulation

Harmonization:

To obtain good quality, reproducible data

To avoid unnecessary/duplicative data

Save testing resources

Experimental results may be accepted by all OECD countries

To achieve harmonization of manufactured nanomaterials:

Working party on manufactured nanomaterials (WPMN) was created in 2007 (OECD)

- To address whether existing Guidances´ (TG) are adequate to nanomaterials
- 115 test guidelines have been reviewed

Results:

•Amendments to the Inhalation Test Guidelines and Guidance to Accommodate Nanomaterials

• Guidance Document on Aquatic Toxicology Testing of Nanomaterials

• Test Guideline for the Dissolution Rate of Nanomaterials in the Aquatic Environment

• Guidance Document for Dispersion and Dissolution of Nanomaterials in Aquatic Media – Decision Tree

•Guidance Document on Assessing the Apparent Accumulation Potential of Nanomaterials

• Test Guideline for Dispersibility and Dispersion Behaviour of Nanomaterials in Aquatic Media

• Development of a Draft Test Guideline for Nanomaterial Removal from Wastewater

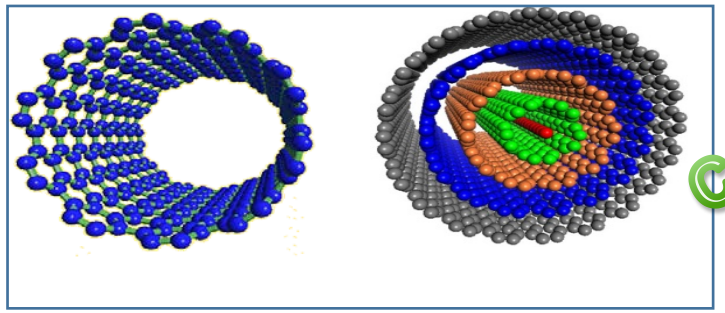
•Physical-Chemical Parameters: Measurements and Methods

•Categorization of nanomaterials

•Interlaboratory study on colony forming efficacy test

EXAMPLE: CARBON NANOTUBES

Dimensions 0.5-2µm x 1-2 nm



CANDIDATES

NEW DISCIPLINE: NANOTOXICOLOGY

Costs in EEUU:
>249 millions of $
34-53 years

Toxicology evaluation

Size?
Length?
Catalyst?
Pristine nanomaterials
Functionalized nanomaterials?

Identify characteristics and

Tests to predict toxicity

Safe by design

Nanotechnology– Time for decision-making

Shape

Biodegradability

Surface modification

Cause

Purification

Formulation

Inflammation

Biodisponibility

Effects

Oxidative stress

Disease

Which characteristics provoke which biological responses?

NANoREG is …

‘common’ and ‘regulatory’ relevant

1. Regulatory relevant scientific questions formulated in collaboration with regulators and regulatory agencies (under consideration of non-European aspects and developments)

[WP1]

2. Coordinated scientific research targeted to answer the regulatory relevant questions

[WP2 – WP5]

3. Acknowledgement of and in-built **degree-of-freedom** for **nanotechnology innovation**

[WP6]

Links to regulatory questions

- Link to regulatory questions:
  - Q2 & Q3 Measurement, characterization & transformation
  - Q4 & Q5 Metrology, dose metrics, extrapolation & grouping
  - Q6 & Q7 Fate, kinetics, persistence and long-term effects
  - Q9 & Q10 Hazard & mode of action

Potential impact:

  - Strategic use of solubility, predictive in vitro toxicity assessment and high throughput screening methodology within the risk assessment of nanomaterials

Possible implementation:

  - Within the NANoREG toolkit for risk assessment and decision making instruments for the regulators
  - Within REACH guidance for testing requirements
  - Within OECD test guidelines
- International cooperation: OECD WPMN, other research projects such as MARINA, NanoMILE, CEFIC-LRI project on grouping etc.

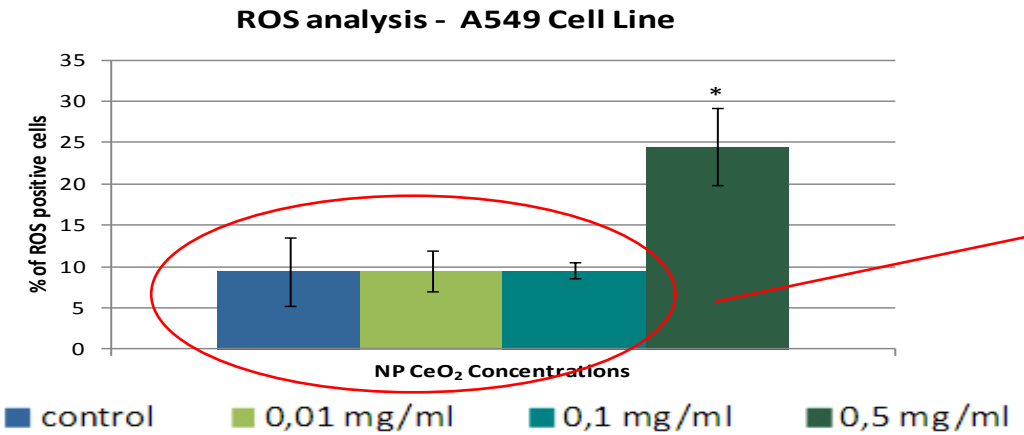
OUTCOMES OF PREVIOUS ACTIVITIES

- Similarities and Extrapolation
  - ✓ Development of a proposal for grouping of nanomaterials in categories with similar biological, ecological and/or toxicological effects
- Stability and Elimination
  - ✓ Development of a strategy for solubility testing
- Alternative Testing and Predictive Screening
  - ✓ Development of an alternative predictive screening methodology
- Decision Tree for Risk Assessment
  - ✓ Development of a decision tree for risk assessment based on results from experimental workpackages and points mentioned above

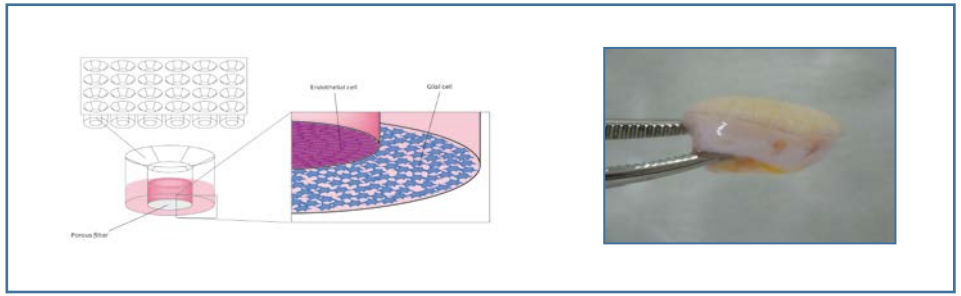
Nanoreg: Towards a harmonized approach to NM regulation

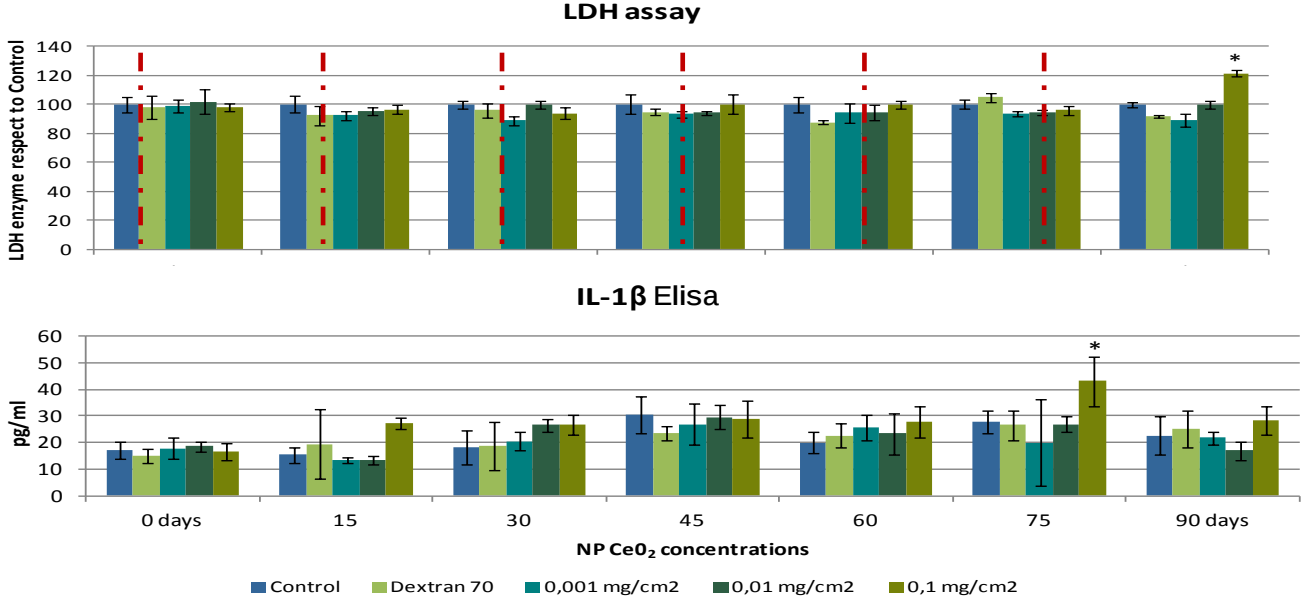
Acute vs subchronic (multidose) exposure of airway epithelia to CeO2 NM

Traditional MTT assay (72 hours)



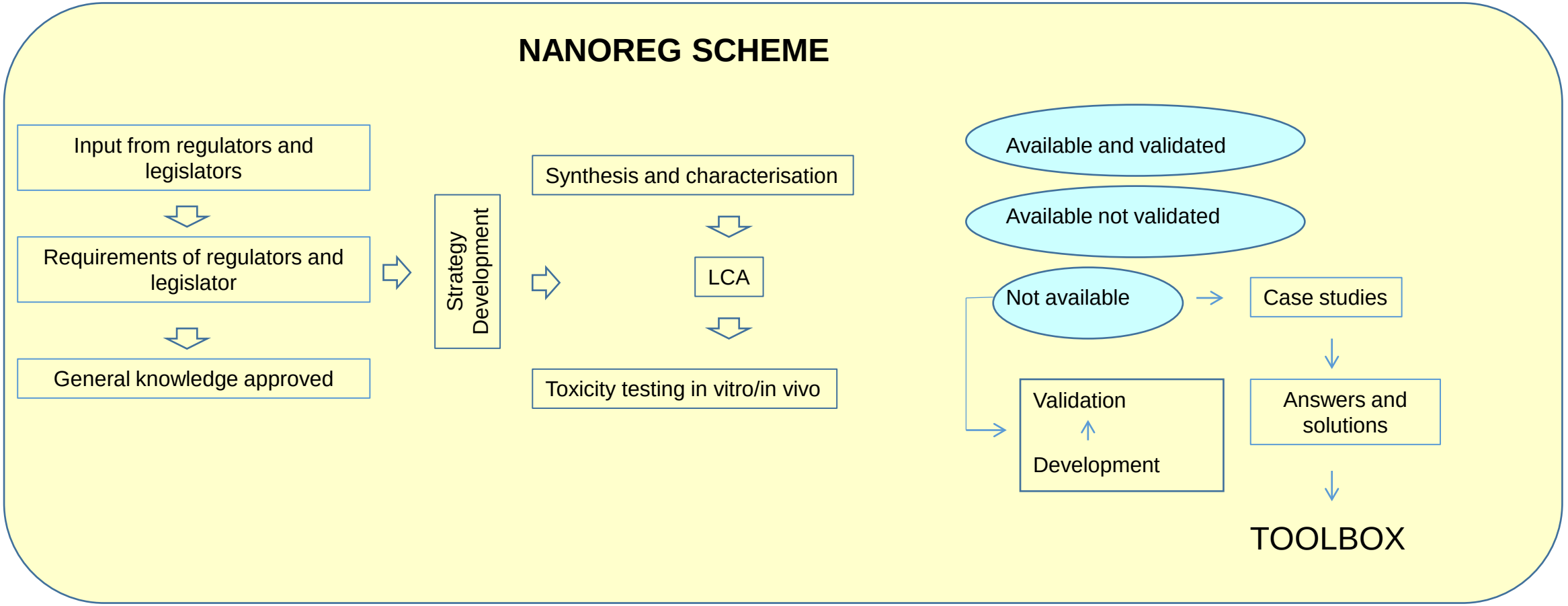
ex-vivo exposure (90 days)





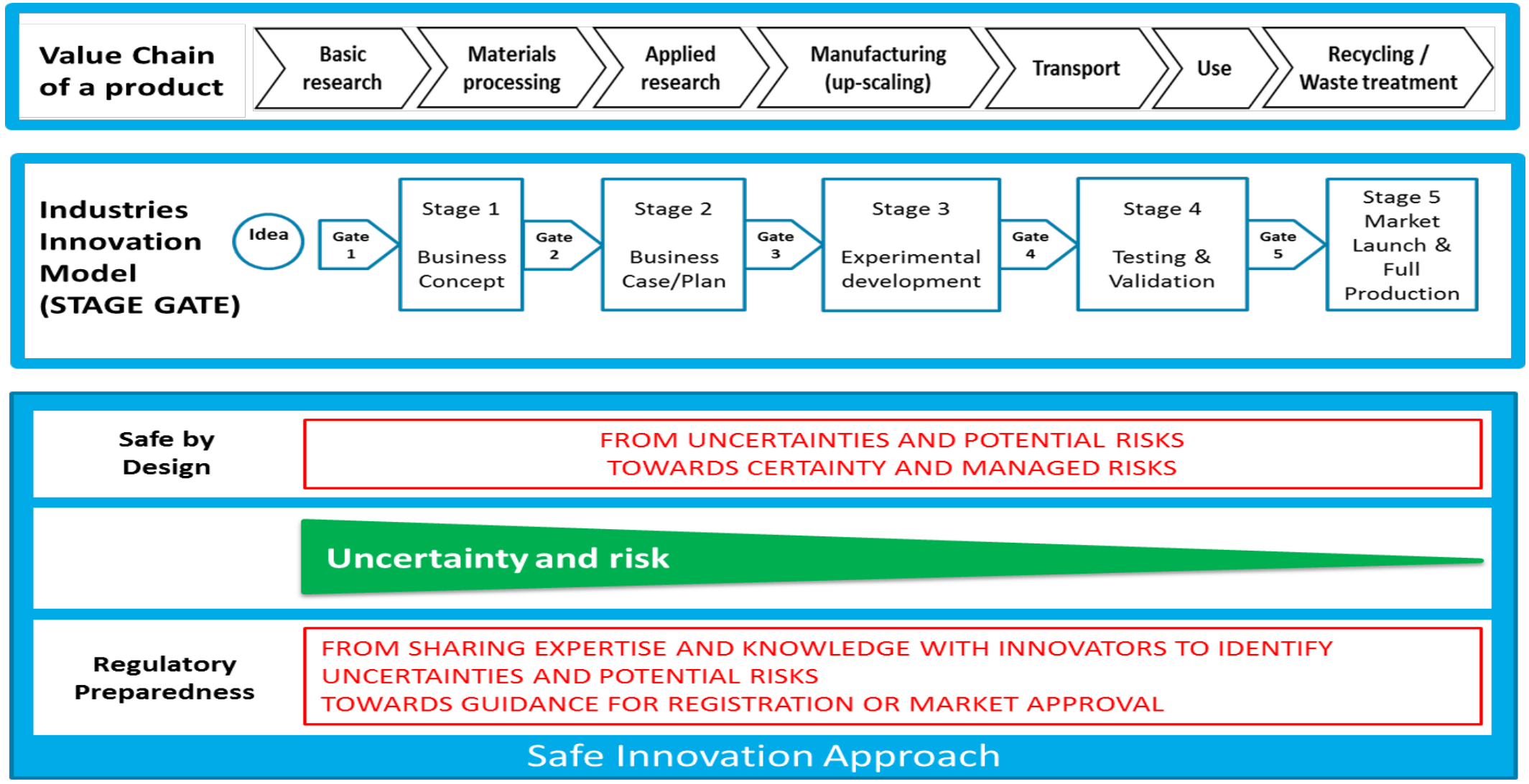
Nanoreg: Towards a harmonized approach to NM regulation

NANoREG – A common European approach to the regulatory testing of nanomaterials



Development and implementation of grouping and safe by design approaches within regulatory frameworks

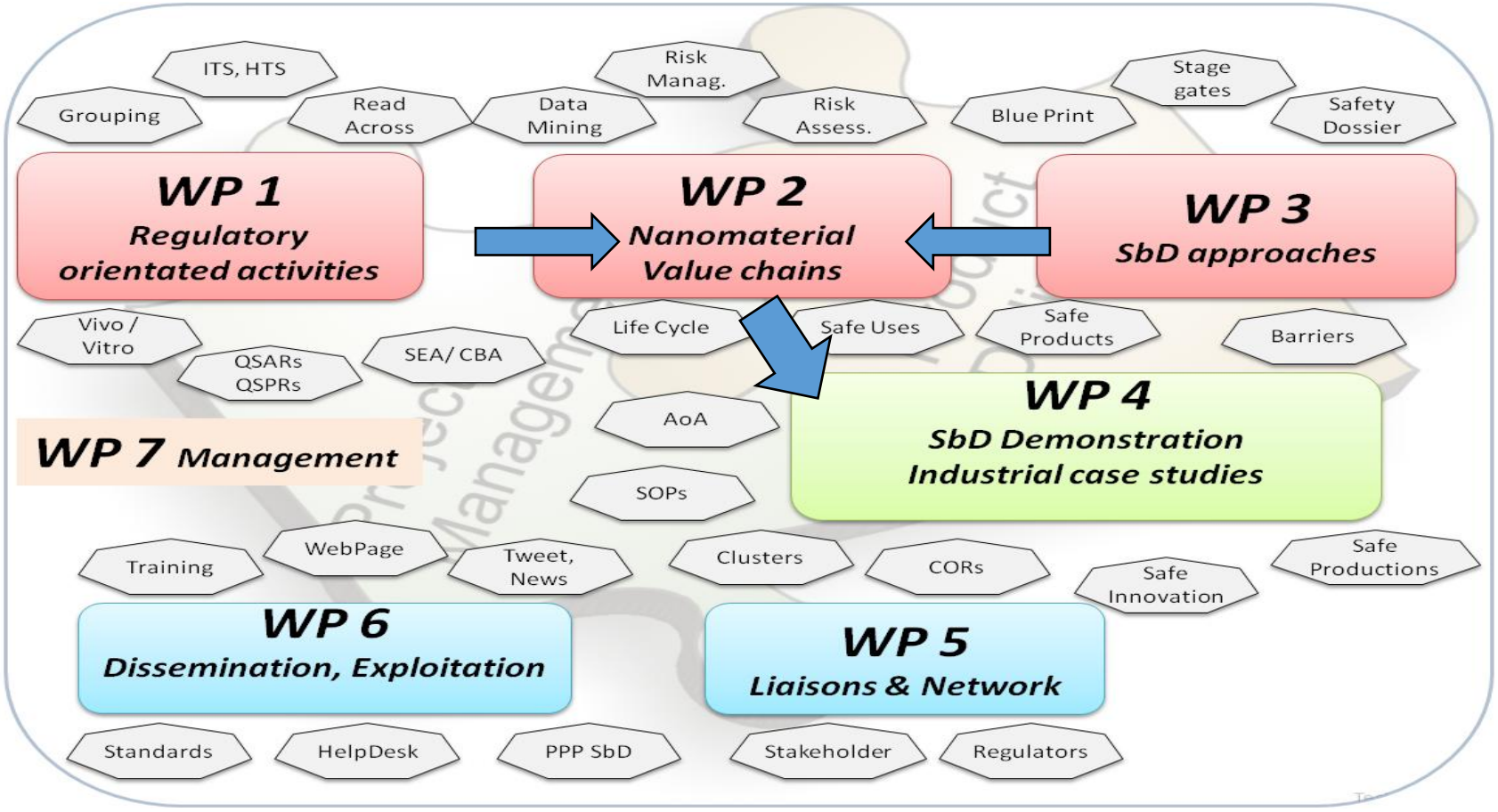
Safe innovation approach



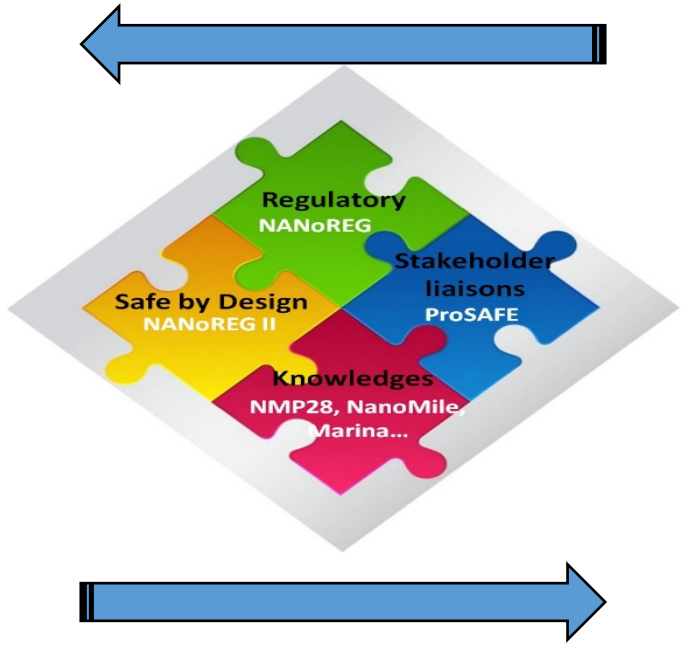
Development and implementation of grouping and safe by design approaches within regulatory frameworks

NANoREG II

Work plan

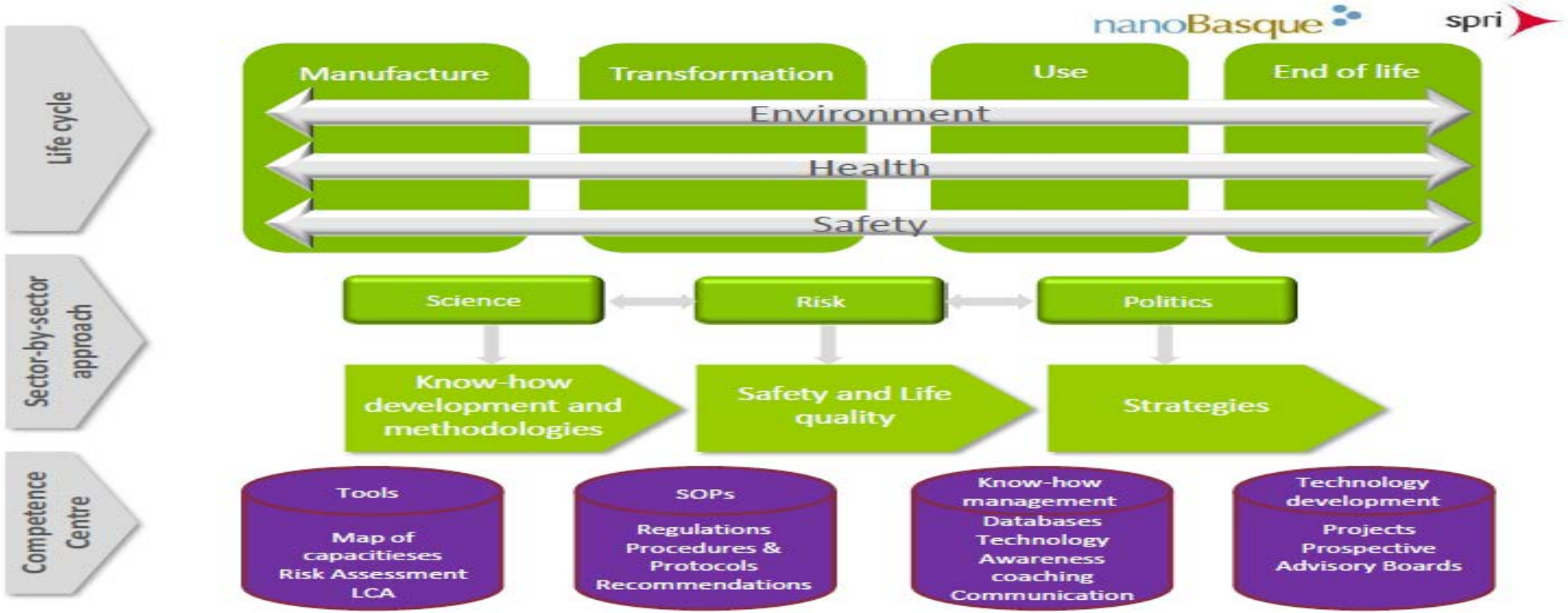


Inputs from on-going Research & regulatory oriented projects



Outputs to regulatory and standardization activities
To be implemented in industry

Centro de Competencias en nanotecnologias




thank you
bedankt
cám òn qúi vi rhât
谢谢
eskerrik asko
eskerrik asko
grazie
go raibh maith agaibh
شكرا
evgaristó
Shokrán
arigato
gracias
matu suksama
gracias
spaisíva
danke
moltes gràcies
merci
khrap
gracias
ありがとうございます
Xié Xie
thank you
eskerrik asko