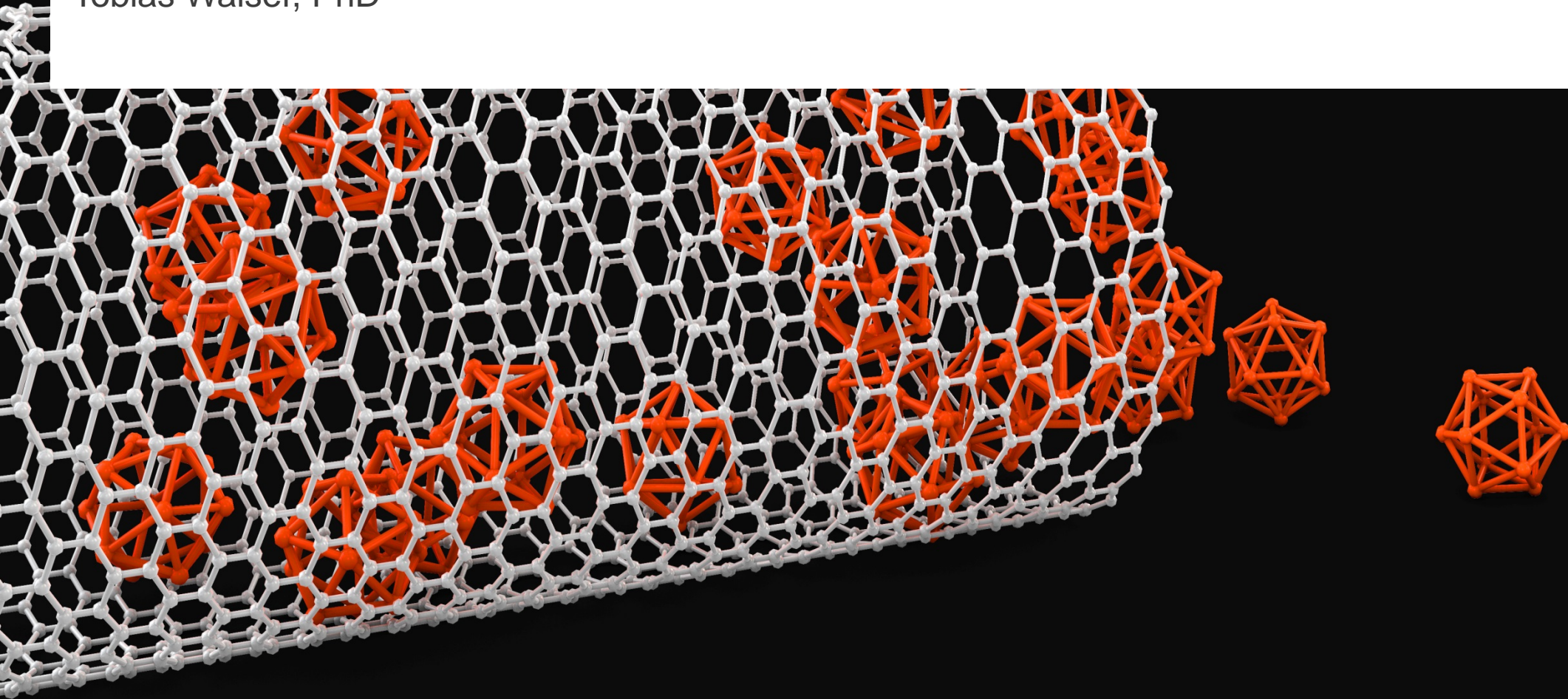


LCA Discussion Forum 65 / May 24, 2017

# Regulation of Nanomaterials – the relevance of LCA and RA

Tobias Walser, PhD



# A look back into the outlook of DF38, 2009


**ETH**  
Eidgenössische Technische Hochschule Zürich  
Swiss Federal Institute of Technology Zürich

**IfU**  
Institute of  
Environmental Engineering

## Prospective Assessment of Nanotechnology: Case Study on Nanosilver in Textiles

**Tobias Walser**<sup>1</sup>, Evangelia Demou<sup>1</sup>, Daniel J. Lang<sup>2</sup>, Stefanie Hellweg<sup>1</sup>

*Master Thesis, Presentation for DF38, June 19 2009*



<sup>1</sup>Institute for Environmental Systems Design, ETH Zurich <sup>2</sup>Institute for Environmental Decisions, ETH Zurich

» Introduction    » Methods    » Results    » Summary    » Outlook

## Outlook

- Consideration of nanoparticle-related effects in LCA
- Measurement of release rates and effectiveness of nanosilver applications
- Performance based indicators for nanoenabled products – what are net environmental benefits or impacts?

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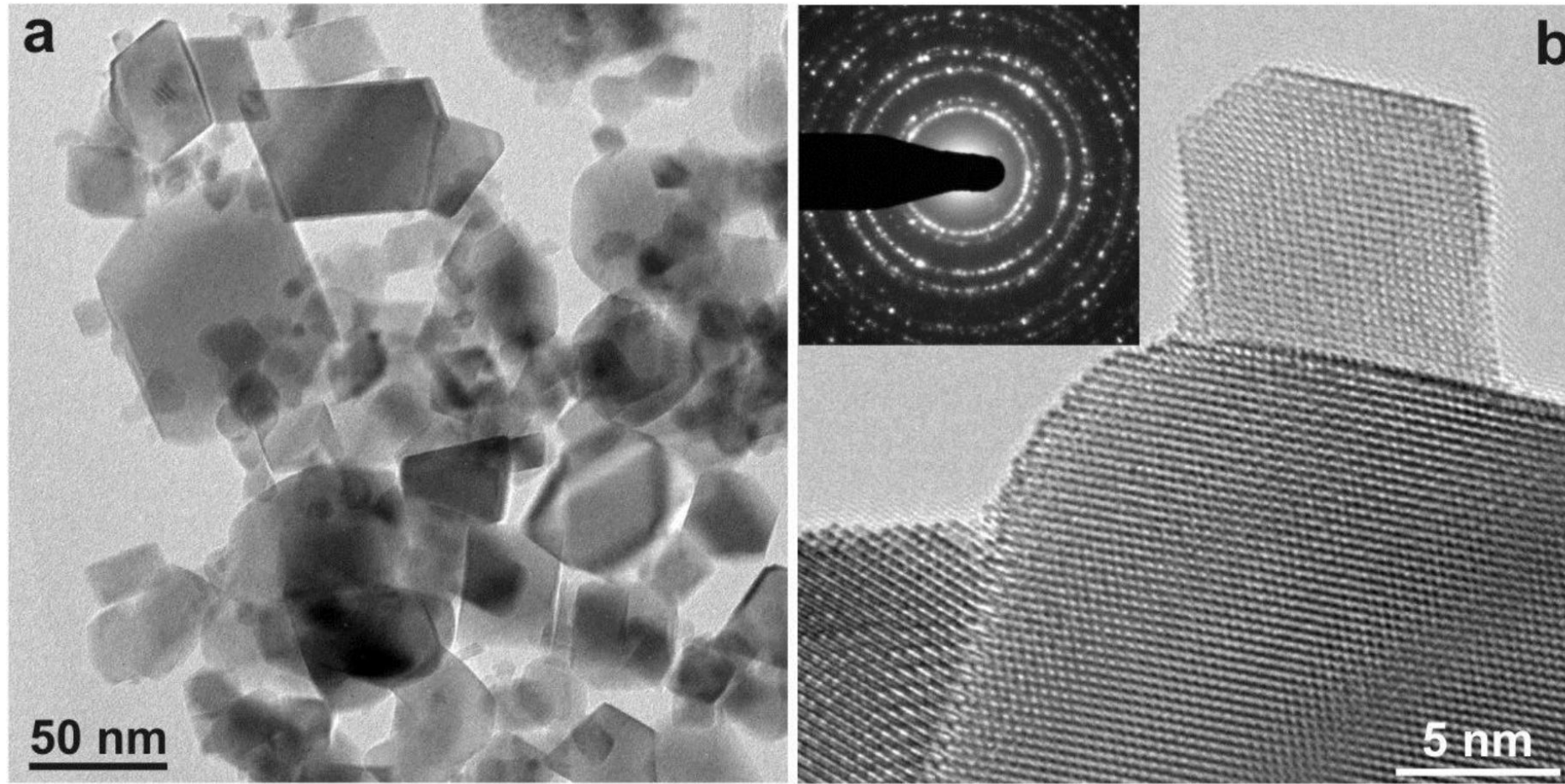
Ecological Systems Design  
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# Designed Nanomaterials



# Disposal of Nanomaterials



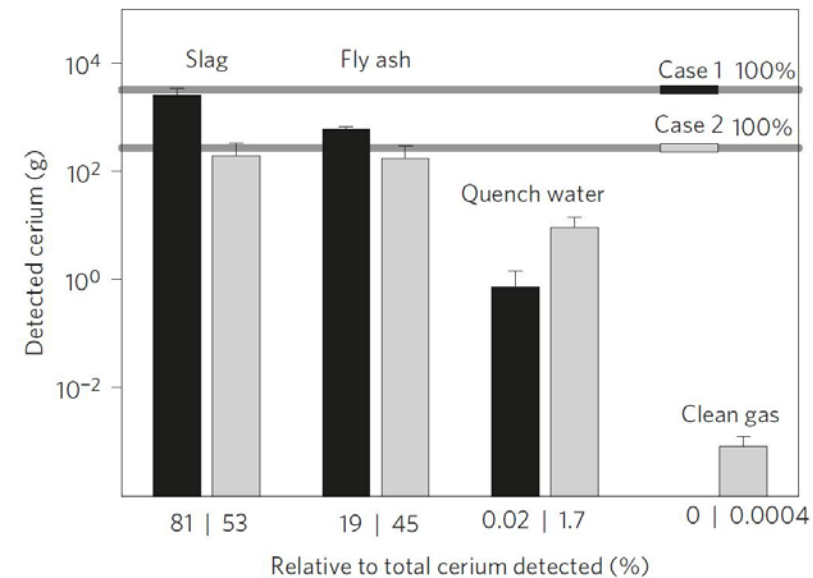
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nature  
nanotechnology

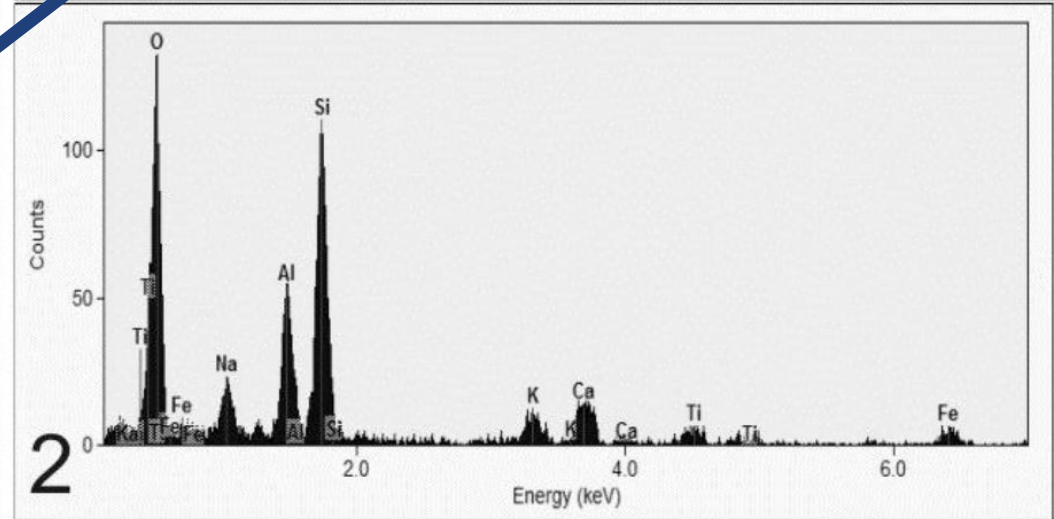
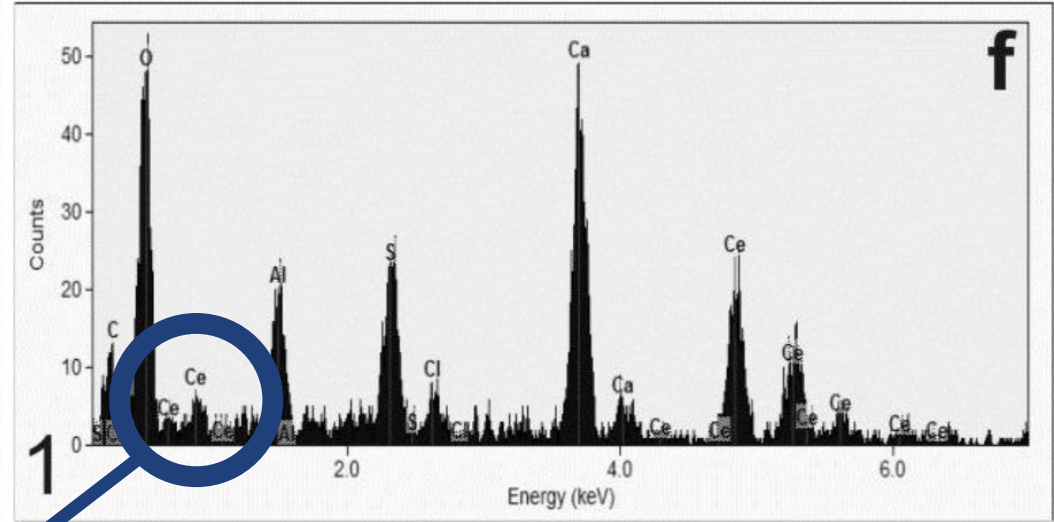
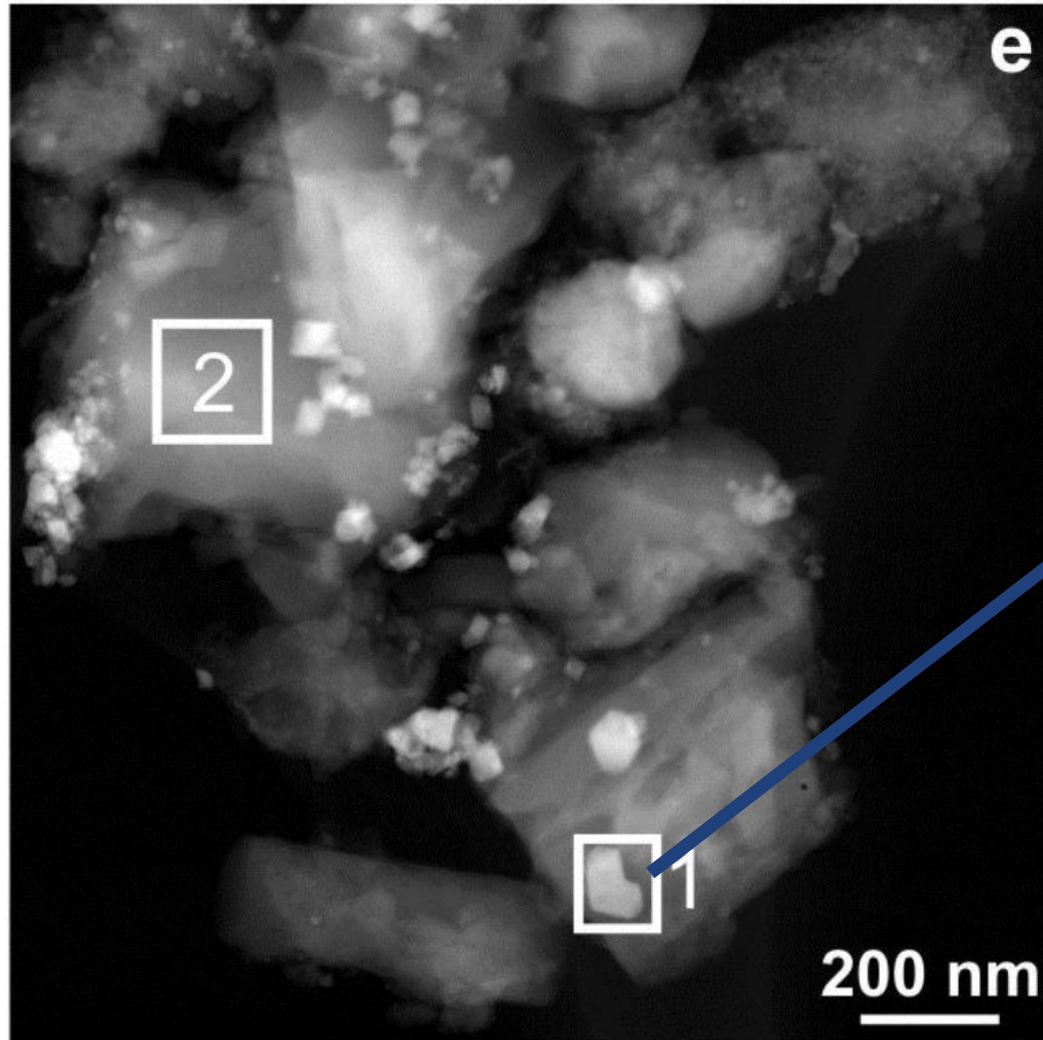
## Persistence of engineered nanoparticles in a municipal solid-waste incineration plant

Tobias Walser<sup>1</sup>, Ludwig K. Limbach<sup>2</sup>, Robert Brogioli<sup>3</sup>, Esther Erismann<sup>4</sup>, Luca Flamigni<sup>3</sup>, Bodo Hattendorf<sup>3</sup>, Markus Juchli<sup>5</sup>, Frank Krumeich<sup>3</sup>, Christian Ludwig<sup>6</sup>, Karol Prikopsky<sup>4</sup>, Michael Rossier<sup>2</sup>, Dominik Saner<sup>1</sup>, Alfred Sigg<sup>4</sup>, Stefanie Hellweg<sup>1</sup>, Detlef Günther<sup>3</sup> and Wendelin J. Stark<sup>2\*</sup>





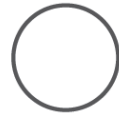
# Disposal of Nanomaterials



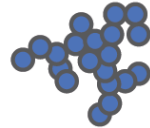
# Too many regulatory definitions lead to confusion

<b>Why a definition?</b>	Reporting and assessment of nanospecific properties of new chemicals
<b>Definitions</b>	Vary between countries and regulations
<b>Consensus</b>	None, maybe 100 nm in one dimension
<b>Example Switzerland</b>	Nanomaterial: Material, welches Partikel in ungebundenem Zustand, als Aggregat oder als Agglomerat enthält, bei welchen <b>ein oder mehrere Aussenmasse im Bereich von 1 bis 100 nm</b> liegen oder ein Material, das ein spezifisches Oberflächen-Volumen-Verhältnis von über 60 m <sup>2</sup> /cm <sup>3</sup> aufweist. Ein Material gilt nur dann als Nanomaterial, wenn es gezielt zur Nutzung der Eigenschaften hergestellt wird, die sich aus den genannten Aussenmassen der enthaltenen Partikel oder dem genannten Oberflächen-Volumen-Verhältnis des Materials ergeben. Fullerene, Graphenflocken und einwandige Kohlenstoff-Nanoröhren mit einem oder mehreren Aussenmassen unter 1 nm gelten als Nanomaterialien.
<b>Chemicals</b>	
<b>Pharmaceuticals</b>	Nanopartikel: <b>mindestens eine Dimension im Grössenbereich 1-1000 nm</b> sowie eine auf nanotechnologische Eigenschaften basierende Funktion/Wirkungsweise

# Nanomaterial Definitions: Beyond size and composition



Spherical homogeneous



Agglomerate homogeneous



Agglomerate heterogeneous



Fibrous homogeneous



Heterogeneous concentric



Active particle



Non-spherical homogeneous



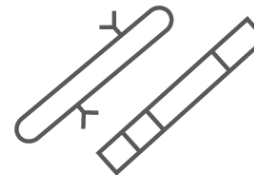
Heterogeneous distributed



Multifunctional particle



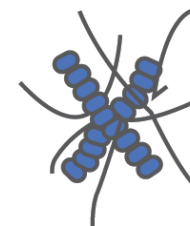
Non-spherical heterogeneous



Fibrous heterogeneous



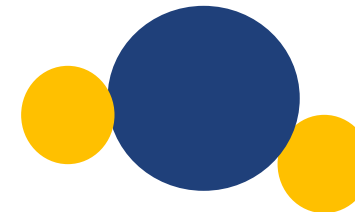
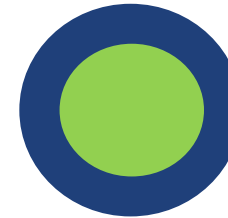
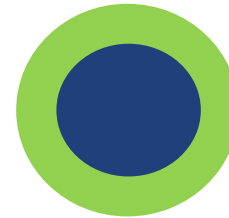
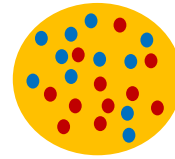
Agglomerate fibrous homogeneous



Agglomerate fibrous heterogeneous

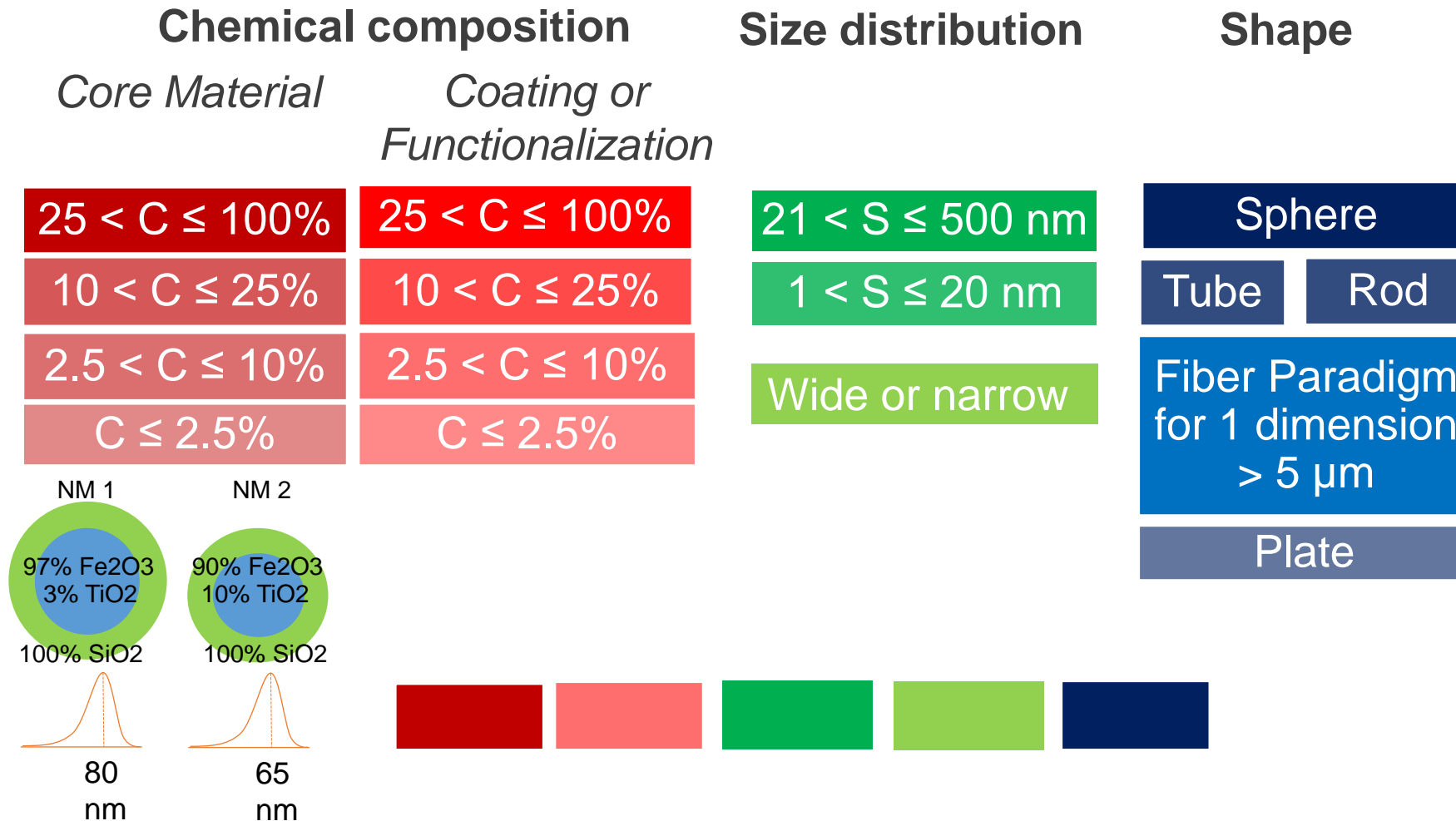
# Nanomaterial Definitions: Beyond size and composition

- Uncoated nanomaterials consisting of different substances
- Coated nanomaterials with sealed or permeable surface
- Aggregates or agglomerates of different nanomaterials





# Not definition, but characterization matters!



# Robust Study Summaries: Requested (additional) parameters

- **Chemical composition (incl. crystalline structure)**
- Impurities
- **Surface chemistry**
- **Size**
- **Shape**
- **Surface area**
- Solubility (rate)
- Dispersibility
- Dustiness
- Biological reactivity (e.g. ROS formation)
- Photoreactivity
- Stability in storage
- **Rigidity for fibers**

# Risk Assessment is used for Regulatory Assessments of Chemicals

Hazard identification

Hazard assessment, incorporating the dose-response relationships

Exposure assessment

**Risk characterisation, integration of hazard and exposure assessments**

$$R = f ( D , H )$$



# Risk Assessment is used for Regulatory Assessments of Chemicals

A **variety of tools are available** to guide industry through the **registration process** (Europe: European Chemicals Agency ECHA)

**Data provider is industry (Safety Dossier)**. At the same time they are responsible for classification, labelling and packaging (**CLP**) of the chemical.

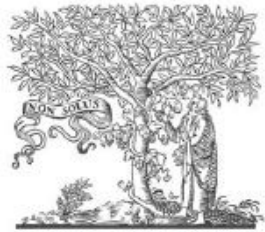
Nanomaterials: **The same aspects as conventional chemicals plus nanospecific properties, plus:**

- Exposure pathways
- Altered behaviour in the environment and the human body
- Mode of actions
- ...



# Combined use of LCA, RA, and HBM for Chemicals, CS Nanomaterials

Environmental Impact Assessment Review 65 (2017) 156–163



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Contents lists available at [ScienceDirect](#)

Environmental Impact Assessment Review

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Combination of life cycle assessment, risk assessment and human biomonitoring to improve regulatory decisions and policy making for chemicals

Tobias Walser<sup>\*,1</sup>, Réjane Morand Bourqui, Christoph Studer

*Risk Assessment of Chemicals, Federal Office of Public Health (FOPH), Schwarzenburgstrasse 157, 3003 Bern, Switzerland*

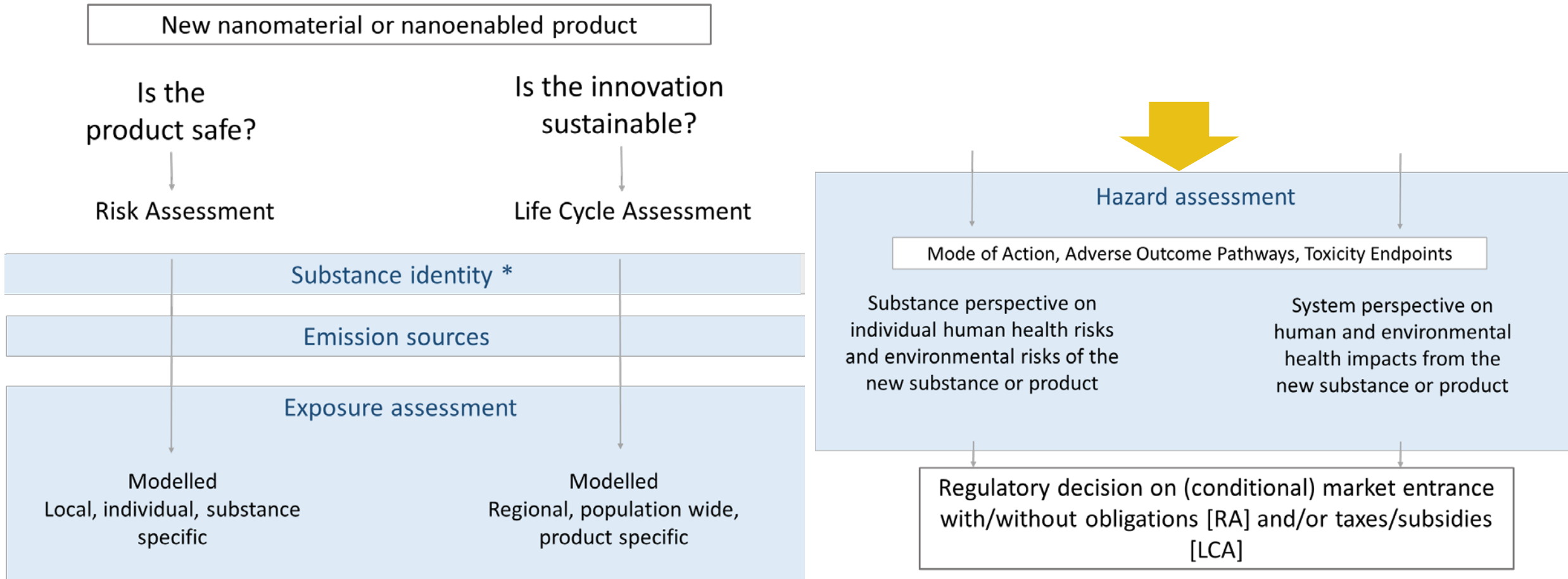


# Complementary information from LCA

	Time span	Geographic specificity	Population or individual impact?	Data demand	Granularity of data	Informative value for regulators	Regulatory use
LCA	Integrated	Rather generic	(sub-) population impact	Low to high, LCA practitioner decides	Coarse but comprehensive	Low, expert knowledge needed	Low, but slowly developing
RA	Specific point in time	Rather specific	Individual health risk	Rather high, tonnage and hazard triggered	Fine, case specific	High, tiered testing	Fully implemented

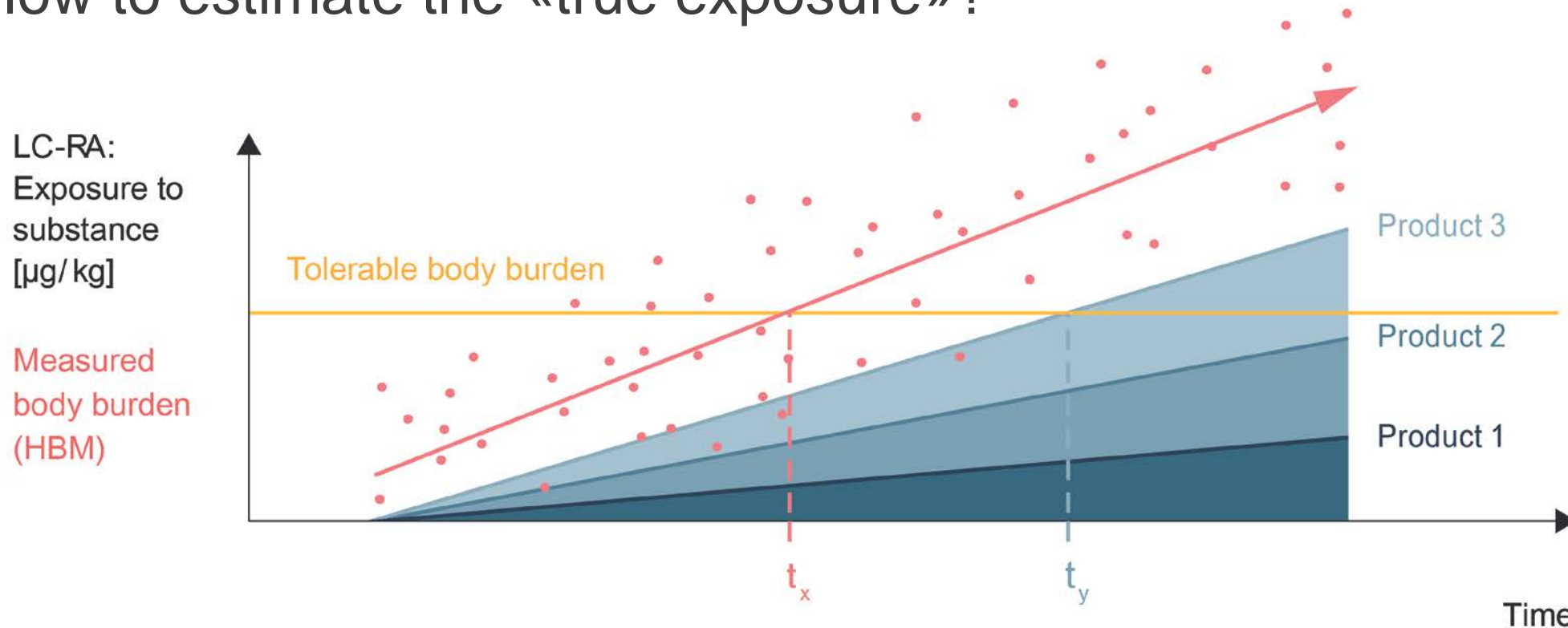


# Combined use of LCA and RA for Nanomaterials



# Cumulative Exposure in Regulatory Risk Assessment

- 3 products, each releasing the same nanomaterials. Industry perspective vs. perspective of regulators
- How to estimate the «true exposure»?



## Policy decisions based on LCA studies of an entire sector

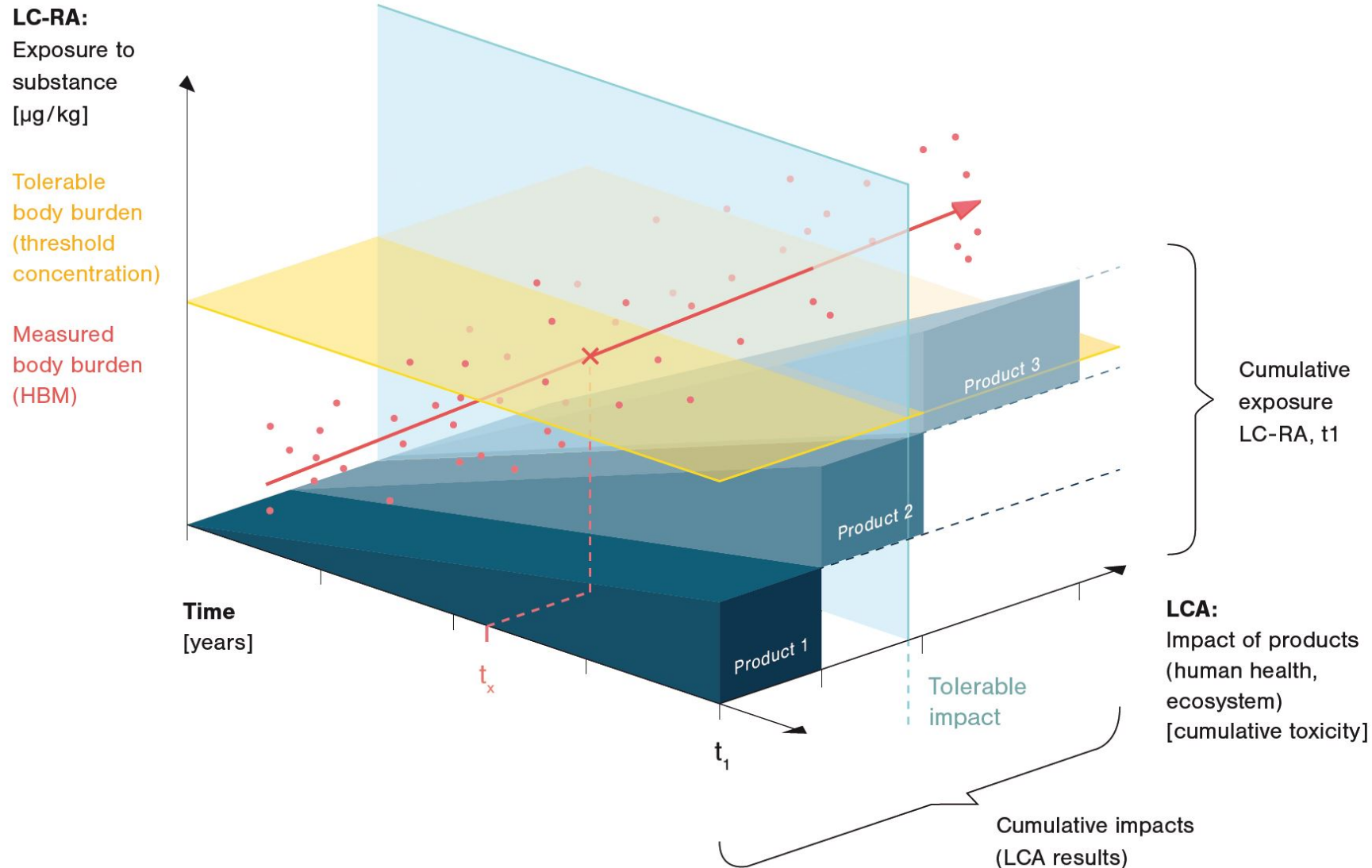
- 3 products, each releasing nanomaterials. Industry perspective vs. perspective of policy makers
- Product sector: Lowering the impact of all products equally? Or focusing on the «worst»?



**LCA:** Cumulative impact of products (human health, ecosystem)



# Using the Strengths of LCA and RA for Chemical Assessment



## Keep in mind

- **LCA & RA practitioners:** Be transparent, report assumptions and uncertainties
- **LCA developers:** standardization, transparency of industrial data, comprehensive and valid data for product sectors
- **Industry:** Be agile, and adapt to regulatory changes and new knowledge

# verreala

Complex chemicals or materials? - We build bridges between  
Science, Regulation, and Industry.

Kickoff: July 2017

**Thank you for your attention!**

**tobias.walser@verreala.com**

# Backup: It is worth looking into regulation

**A promising new  
nanomaterial or  
nanoproduct**

Country and Quantity  
Regulatory Area  
«Soft and hard»  
regulation

