International Industry Perspectives – Expected outcomes

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Things that I will talk about

1. **Risk from an industry perspective**

2. **Industry perspective of NANoREG outcomes**

Nanotechnology Industries Association – NIA

…the sector-independent, responsible voice for the industrial nanotechnologies supply chains…

…the only global industry-focused trade association for the nanotechnology sector…

…proactively supports the on-going innovation and commercialisation of the next generation of technologies and promotes their safe and reliable advancement…

…cooperates with regulators and stakeholders on national, European and international levels so as to secure a publically and regulatory supportive environment for the continuing advancement and establishment of nanotechnologies…

NIA Membership

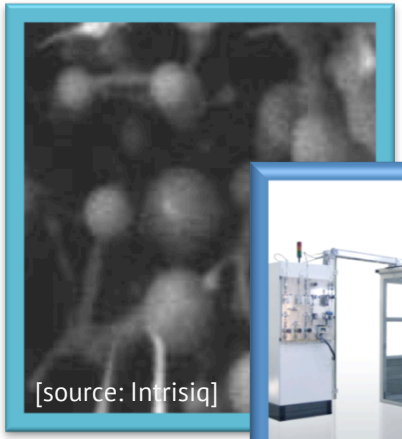
Spanning the production chain

Manufacture of (Nanomaterials &) nanoenabled Products

Trade & Manufacture of intermediate nanoenabled Products

Retail of nanoenabled Products

Instrumentation & Services: Characterisation , Analysis, Detection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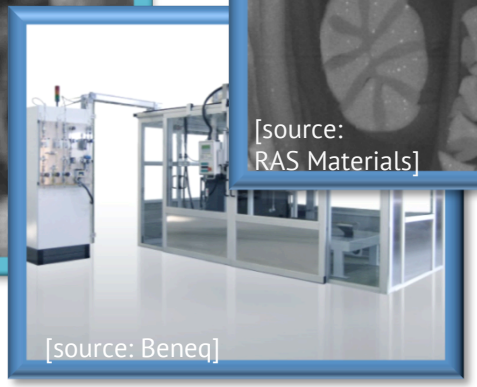

[source: Beneq]


[source: RAS Materials]

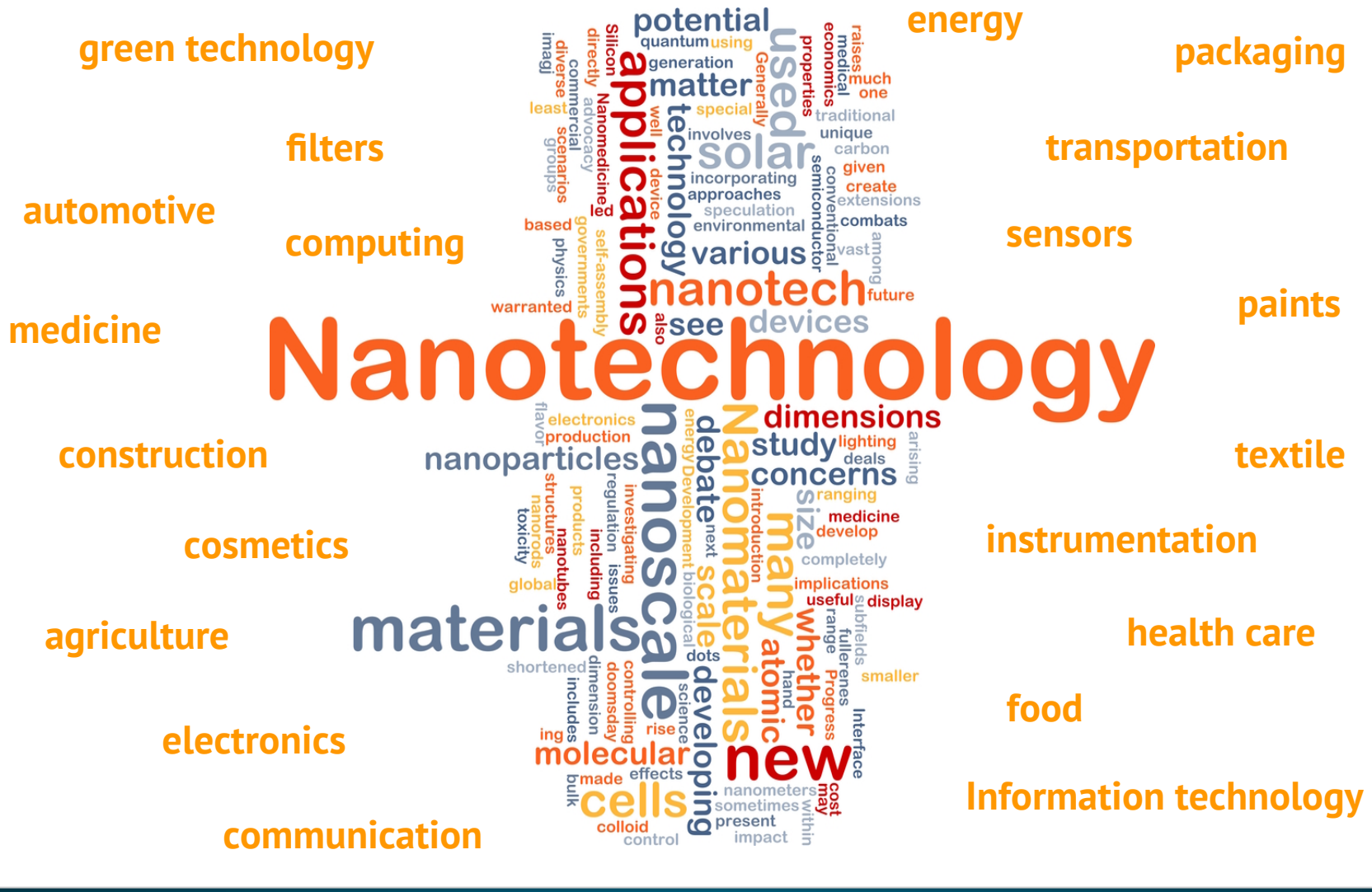

[source: Naneum]


[source: Oxonica]

[source: BASF]

Associated Support Services (Insurance, Legal Representation, etc.)

Nanotechnology is a key enabling technology



Nanotechnology is a key enabling technology

- Provide **employment and societal solutions**
- Major driver to **improve existing products** by creating smaller components and better (functional and environmental) performance materials and creating **new products and applications**
- Nanotechnology companies are likely to have a **rapid growth** (especially building on Europe's strength of SME's in conjunction with large industry)
- **High employment** in areas where EU industries are traditionally world leaders (i.e. materials, consumer, automotive and ICT)

Nanotechnology is a key enabling technology

'…the **benefits** of nanomaterials range from **saving lives**, breakthroughs enabling **new applications** or **reducing the environmental impacts** to **improving the function of everyday commodity products**…'

'…**nanomaterials are similar to normal chemicals/substances** in that **some may be toxic and some may not**…'

[European Commission 2nd Regulatory Review on Nanomaterials Published 3 October 2012
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2012:0572:FIN:en:PDF]

Managing risks of substances – the basics (...not nanospecific)

Human and environmental health is paramount for society *including industry*

- There is no such thing as no risk!
- We live in a risk based society!
- Uncertainty is part of science!
  - No such thing as full scientific certainty!
- Politics frames policy and the regulatory landscape
  - Policy should be driven by science and knowledge
  - Regulations are focused on risks

Reasons for testing chemicals (...including nanomaterials)

SAFE HANDLING – SAFE PRODUCTS

- Human and environmental safety
  - Workers/consumers
  - Effect of flora and fauna

- Testing to
  - Stay competitive!
  - Understand and develop product properties
  - Inform downstream users (customers, formulators, consumers...)
  - Comply with regulatory requirements
    - EU and national regulations (e.g. REACH, Biocides, Cosmetics, Food regulations etc...)

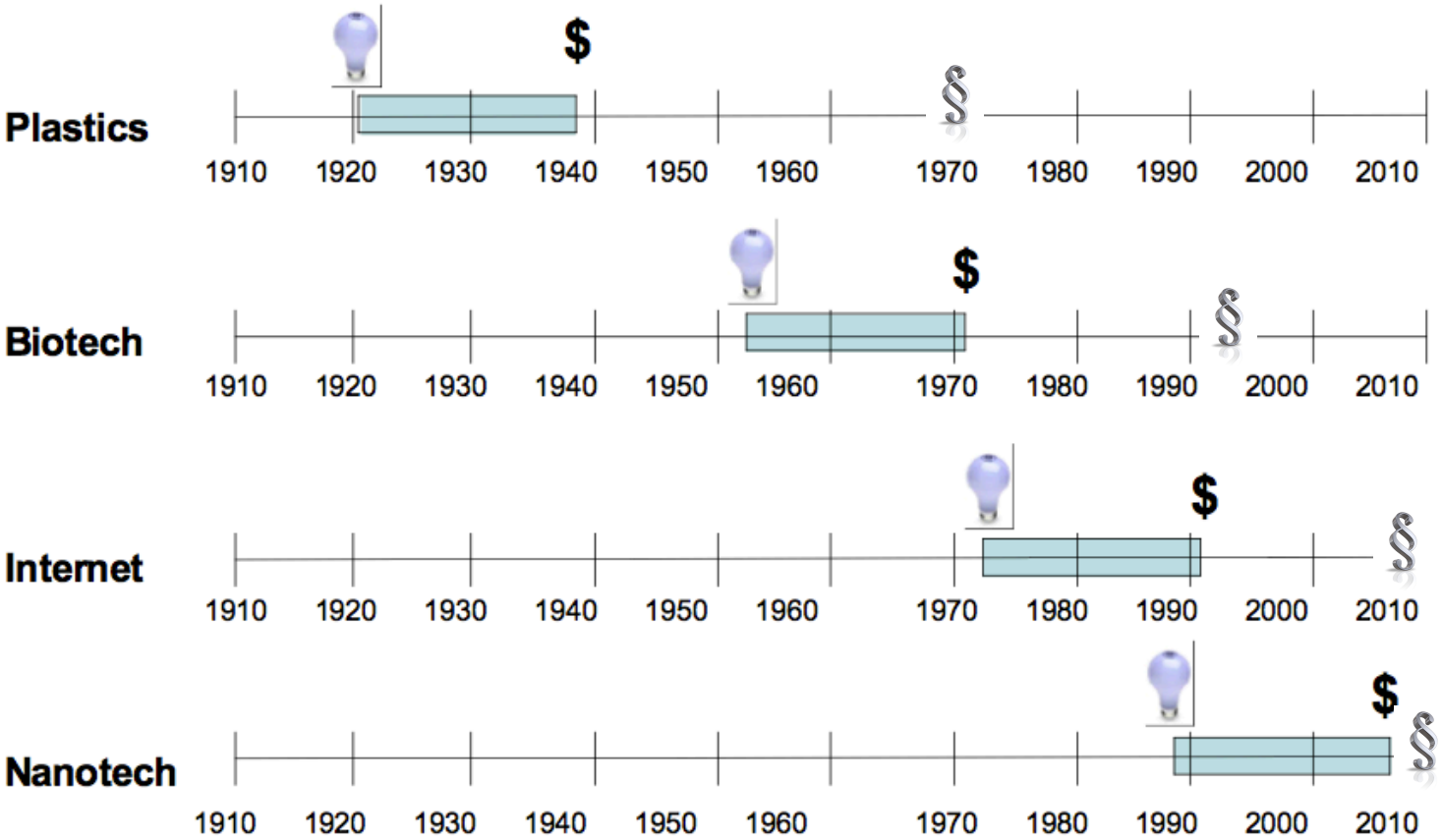
Nanomaterial specific toxicity?

- To date, **no new type of toxic effect has been described for NM**
  - i.e., no effects which have not been observed with any other substance or particle before

- However, uptake, tissue distribution and clearance of NM may be different from dissolved molecules or larger particles

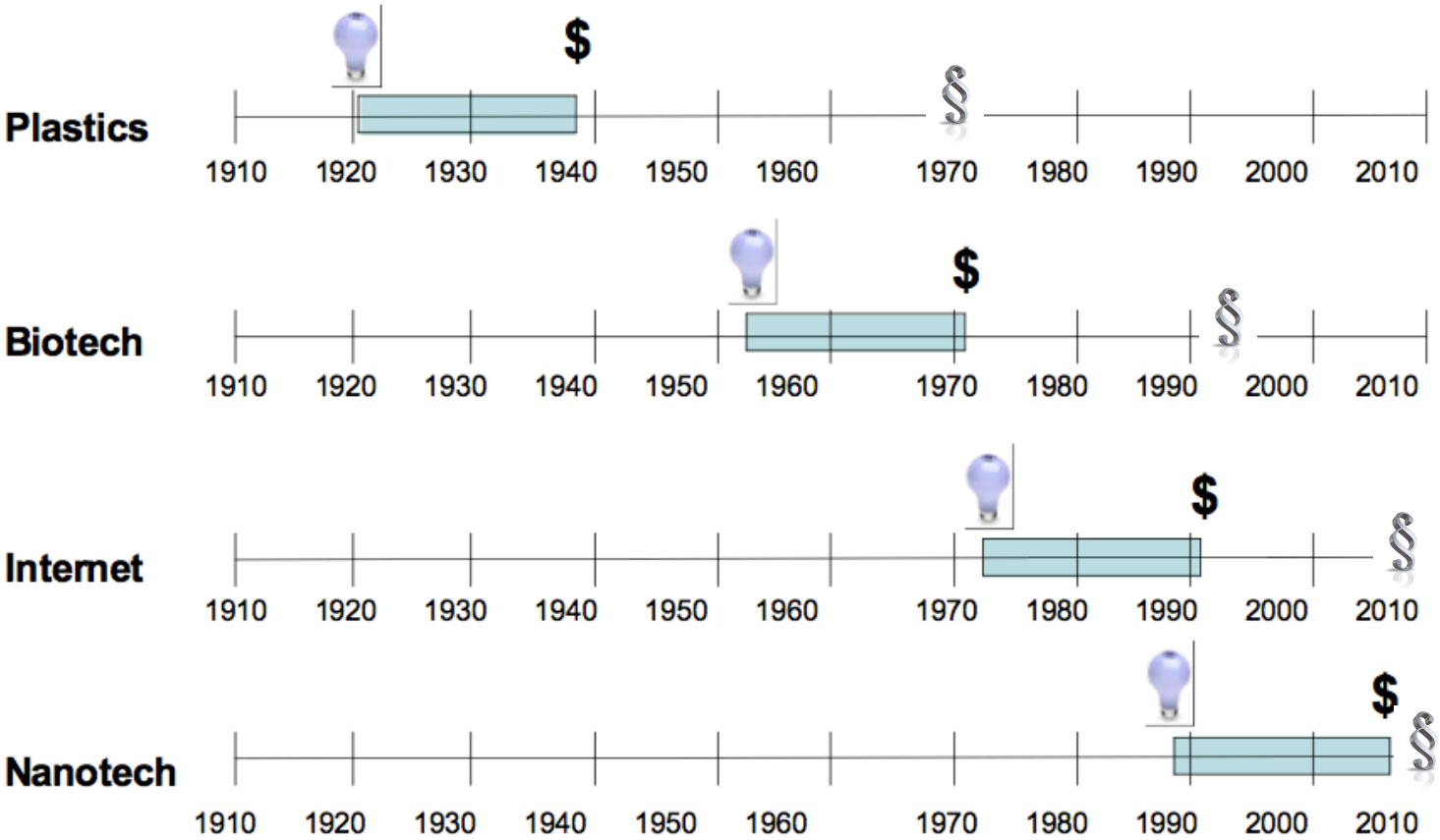
[Oomen et al., 2013, Nanotoxicology]

Commercialisation patterns and regulations



[Modified from Lux Research Inc., Murday et al Nanomedicine NBM, 2009, Vol.5(3),251-273]

Commercialisation patterns and regulations



Regulators are closing the gap!

[Modified from Lux Research Inc., Murday et al Nanomedicine NBM, 2009, Vol.5(3),251-273]

A common European approach to the regulatory testing of nanomaterials

www.nanoreg.eu

What is NANoREG

Providing legislators with a **set of tools for risk assessment and decision making instruments for the short to medium term**, by gathering data and performing pilot risk assessment, including exposure monitoring and control, for a selected number of nanomaterials used in products

Developing, for the long term, **new testing strategies** adapted to a high number of nanomaterials where many factors can affect their environmental and health impact

Establishing a **close collaboration among authorities and industry** with regard to the knowledge required for appropriate risk management, and create the basis for common approaches, mutually acceptable datasets and risk management practices

Industrial and societal benefits from NANoREG

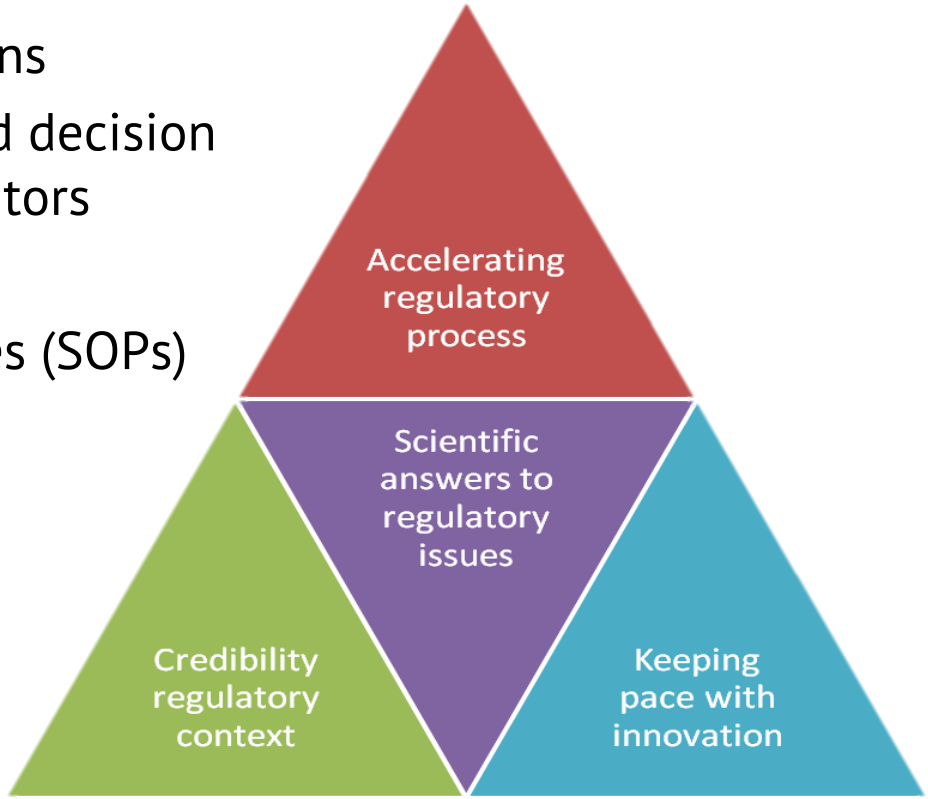
- Reduce time to market for nanomaterials

- Measures that promotes and focuses the use of limited resources both for industry and regulators

Create a win-win situation

Expected outcomes from NANoREG

- Safe Products and Processes
- Safe by Design Processes
- Answers to regulatory questions
- Toolkit for risk assessment and decision making instruments for regulators
- Test guidelines
- Standard Operation Procedures (SOPs)
- Reference materials



Industrial relevance – Continued knowledge generation

- Generate new insights and possibilities for innovators and industries
  - Foster solutions with with more beneficial materials
- Safe(r) by design measures
  - Early risk estimation and reduction
  - Product design phase
- Final product with mitigated risks for human and environmental safety
  - Competitive advantages

International harmonisation

- Support the use of OECD Harmonized Templates
- OECD Mutual Acceptance of Data (MAD)
- Support ISO and CEN standard development
- Support the use of IUCLID format for data submission

Harmonised risk assessment practices to optimise resources of industries present on the international market

Regulatory testing of nanomaterials

- Prioritization criteria for phys-chem properties and minimal set of testing
- Standardized sample preparation, dosimetry, grouping, extrapolation and repeated dose toxicity
- Focus on *in vitro* testing and extrapolation of *in vitro* results
  - Validation with *in vivo* testing
- Use of *in silico* methods and computational modelling for supporting toxicology assessments

Exposure control

- Develop exposure scenarios with industrial relevance
  - Operational conditions
  - Mitigation measures
  - Exposure estimation modelling
- Industry input to the Value Chain Case Studies
- Outcomes will provide input to REACH Exposure Scenarios

Input do develop and update test guidelines

- Input to OECD test guidelines and guidance document revisions and modifications
- Input to REACH Guidance for nanomaterials, grouping, read-across and extrapolation…

NANoREG Industry Consultation Committee (NICC)

- Gateway for industry to bring in their needs
- Evaluate answers, solutions and tools of NANoREG with respect to the applicability by enterprises (large and SMEs)

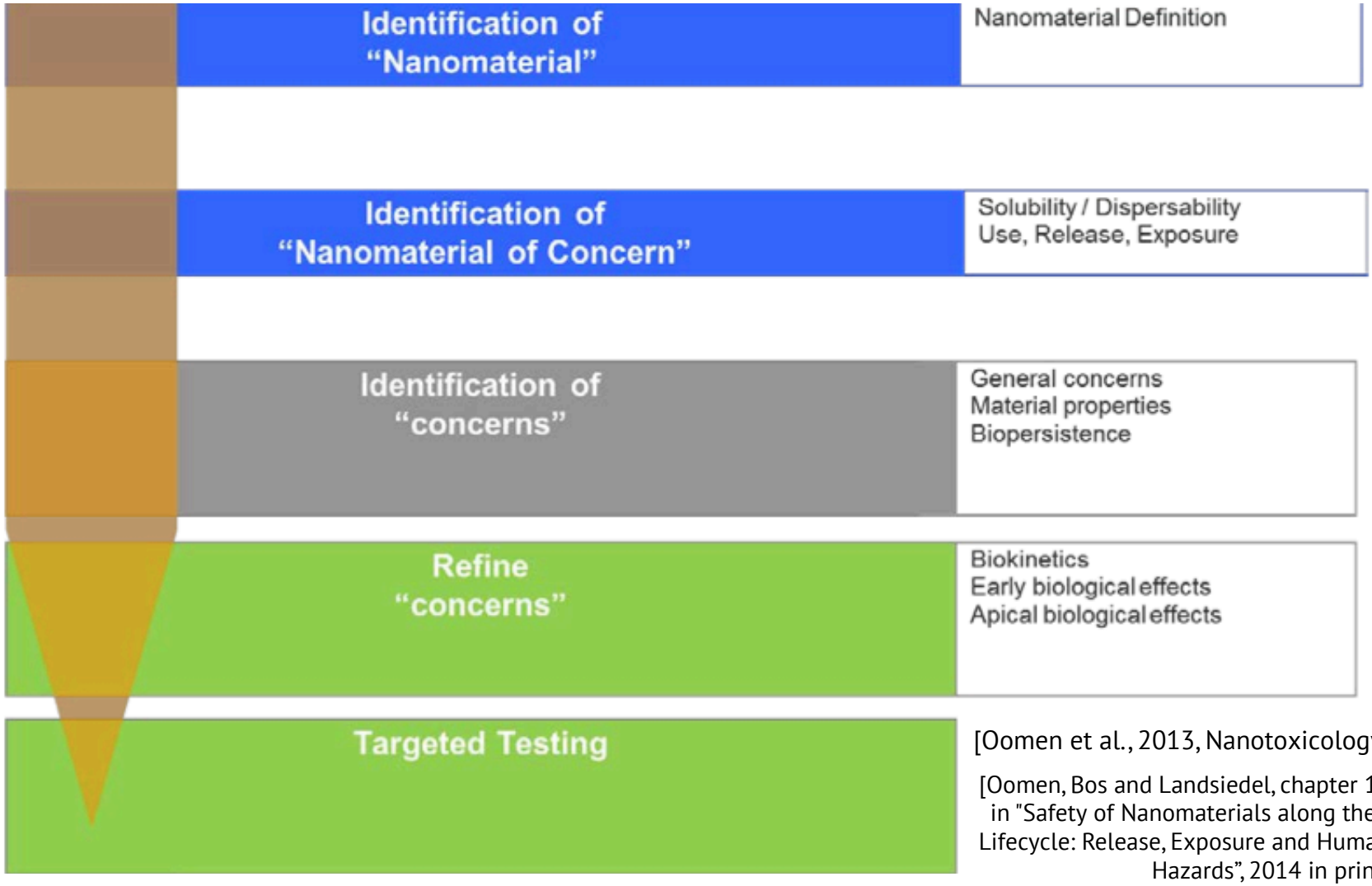
WP5 – Advancement of Regulatory Risk Assessment and Testing

WP5 is lead by NIA together with RIVM and GAIKER

Main objectives:

1. **Similarities and extrapolation**
   - Development of a proposal for grouping of nanomaterial in categories with similar biological, ecological and/or toxicological effects
2. **Stability and elimination**
   - Development of a strategy for solubility testing
3. **Alternative testing and predictive screening**
   - Development of an alternative predictive screening methodology
4. **Decision tree for risk assessment**
   - Development of a decision tree for risk assessment

Concern driven approach for nanomaterial testing



[Oomen et al., 2013, Nanotoxicology]

[Oomen, Bos and Landsiedel, chapter 16 in "Safety of Nanomaterials along their Lifecycle: Release, Exposure and Human Hazards", 2014 in print]

Industry research activities – Public-private partnerships

Industry is actively performing safety research and participating in public-private partnerships (PPP) and in EU funded research projects

Research: Good intentions

Journal of Oleo Science
Copyright ©2013 by Japan Oil Chemists' Society
J. Oleo Sci. **62**, (11) 961-971 (2013)

JOURNAL OF OLEO SCIENCE
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Potential Impact of Quercetin and Idebenone against Immuno- inflammatory and Oxidative Renal Damage Induced in Rats by Titanium Dioxide Nanoparticles Toxicity

Nouf M. Al-Rasheed[1], L. M. Faddah[1], Azza M. Mohamed[2, 3*], Nayira A. Abdel Baky[1], Nawal M. Al-Rasheed[1] and Raeesa A. Mohammad[4]

TiO_2 administered orally to rats for five consecutive days, **600 or 1000 mg/day/kg bw**

[bw=body weight]

Research: Good intentions – bad results?

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2 EXPERIMENTAL

2.1 Chemicals

The TiO_2-NPs (<100 nm) powders were purchased from Sigma Co. (USA). All other chemicals used in the study

TiO_2 administered orally to rats for five consecutive days, **600 or 1000 mg/day/kg bw**

- No material characterisation
- Considering the **very high administration** it is not surprising that toxicity was observed…
  - Perspective: NaCl (table salt); acute human toxicity is observed at 500-1000 mg/day/kg bw (higher dose can be fatal)

[bw=body weight]

Research: Good intentions – bad results?

Unbalanced media coverage – Stigmatization

FOODCONSUMER

Nutrition | Avoiding Illness | Safety | Environment | Food Chemicals | Cooking & Dining | Shopping | Sci-T

Home | Safety | Chemical | Titanium dioxide nanoparticles cause damage to kidneys

Titanium dioxide nanoparticles cause damage to kidneys

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Tuesday Nov 26, 2013 (foodconsumer.org) -- Titanium dioxide nanomaterial is commonly used in cosmetic products and food products although it has not been proved to be safe to use and quercetin or idebenone supplements can help ameliorate the reno-toxicity of the artificial nanoparticles. A new study in Journal of Oleo Science suggests that the artificial nanoparticles can cause damage to the kidneys.

[http://www.foodconsumer.org/newsite/Safety/chemical/titanium_dioxide_nanoparticles_toxicity_1126131100.html]

Better instrumentation for analysis and monitoring

- Nanotechnologies drives development of more sensitive instruments with lower detection limits
  - Miniaturisation of sensors: e.g. moisture, UV, temperature etc…

- Impacts
  - Improved instrumentation availability for monitoring purposes both during production and for market monitoring
  - Increased detection of incidental contaminants can result in increased media attention and increased pressure to act on levels that are of no risk

Presence does not indicate a hazard

Industry risk assessment follow regulations

Guest Column – David Carlander

ChemicalWatch

CW52, October 2012

The legal framework is there

The Commission's nanomaterials regulatory review has struck the right note

Guest column | David Carlander

Nanotechnology Industries Association's view on nanomaterials under REACH

Since the beginning of REACH, which coincided more or less with the increasing political interest in nanomaterials, discussions have been ongoing as to how nanomaterials ought to be managed under REACH.

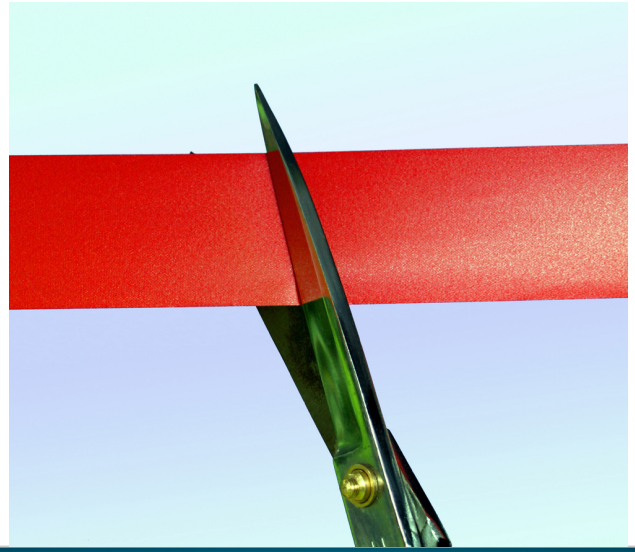
ECHA has already embarked upon this and in 2012 published specific requirements for nanomaterials in a number of their guidance documents.

© NIA

ECHA Newsletter No 5, October 2013

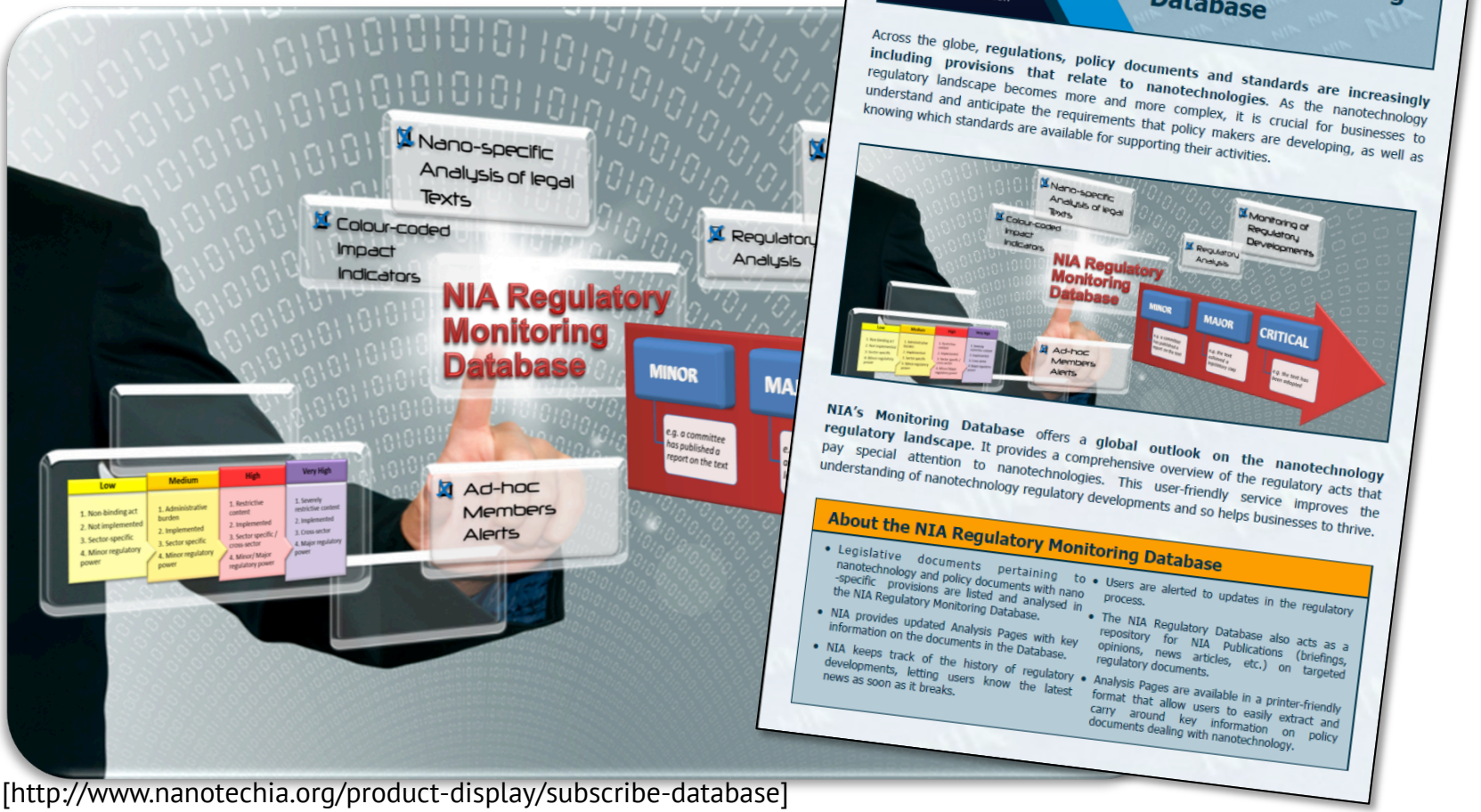
Regulating nanomaterials

- The current EU regulatory landscape is applicable to nanomaterials
- There is no need for specific regulations for nanotechnologies or nanomaterials
- Avoid overly cautious policy and regulations
- Find balance for EU competitiveness



NIA Regulatory Monitoring Database – A dedicated service

Worldwide regulatory coverage



NIA Nanotechnology Industries Association

Regulatory Monitoring Database

Across the globe, **regulations, policy documents and standards are increasingly including provisions that relate to nanotechnologies.** As the nanotechnology regulatory landscape becomes more and more complex, it is crucial for businesses to understand and anticipate the requirements that policy makers are developing, as well as knowing which standards are available for supporting their activities.

NIA's Monitoring Database offers a global outlook on the nanotechnology regulatory landscape. It provides a comprehensive overview of the regulatory acts that pay special attention to nanotechnologies. This user-friendly service improves the understanding of nanotechnology regulatory developments and so helps businesses to thrive.

About the NIA Regulatory Monitoring Database

- Legislative documents pertaining to nanotechnology and policy documents with nano -specific provisions are listed and analysed in the NIA Regulatory Monitoring Database.
- NIA provides updated Analysis Pages with key information on the documents in the Database.
- NIA keeps track of the history of regulatory developments, letting users know the latest news as soon as it breaks.
- Users are alerted to updates in the regulatory process.
- The NIA Regulatory Database also acts as a repository for NIA Publications (briefings, opinions, news articles, etc.) on targeted regulatory documents.
- Analysis Pages are available in a printer-friendly format that allow users to easily extract and carry around key information on policy documents dealing with nanotechnology.

[http://www.nanotechia.org/product-display/subscribe-database]

...so in short...

- The EU regulatory framework is fit to manage potential risks of nanomaterials
- Risk assessment follow standard procedures with nanomaterial specific modifications
  - Guidance available

- Awareness of issues to consider when assessing nanomaterials:
  - Focus on sample preparation and dosimetry
  - Follow research projects: NANoREG!!!
  - Pay attention to regulatory developments: Modifications of REACH Annexes...

Nanotechnology Industries Association

Thank you!

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