Ecam Ricert
Innovation in research

ecsin
european center
for the sustainable impact
of nanotechnology

Regulatory preparedness workshop Ispra, 5-6 October 2017

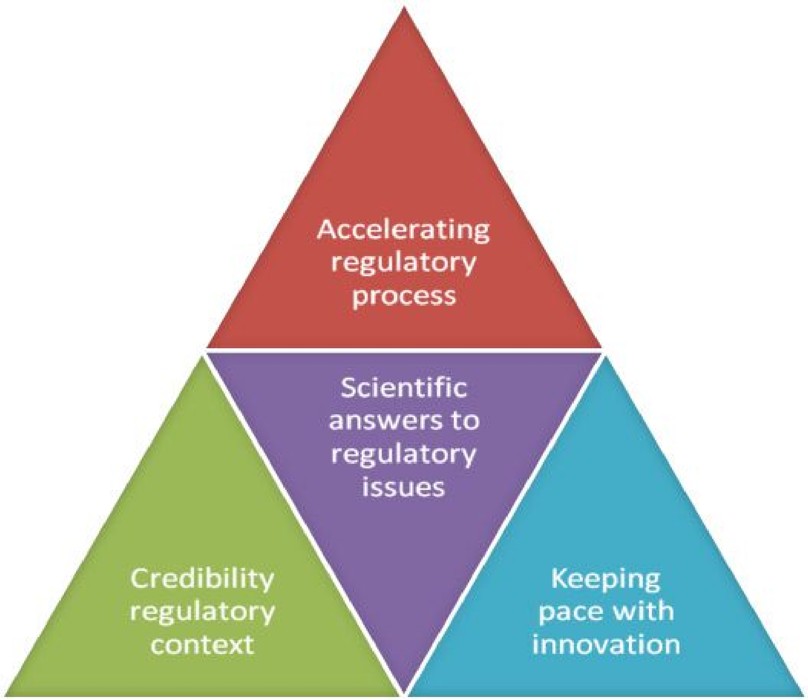
NANoREG Foresight (System) Platform

Christian Micheletti

Context: NANoREG project

NANoREG

A common European approach to the regulatory testing of Manufactured Nanomaterials

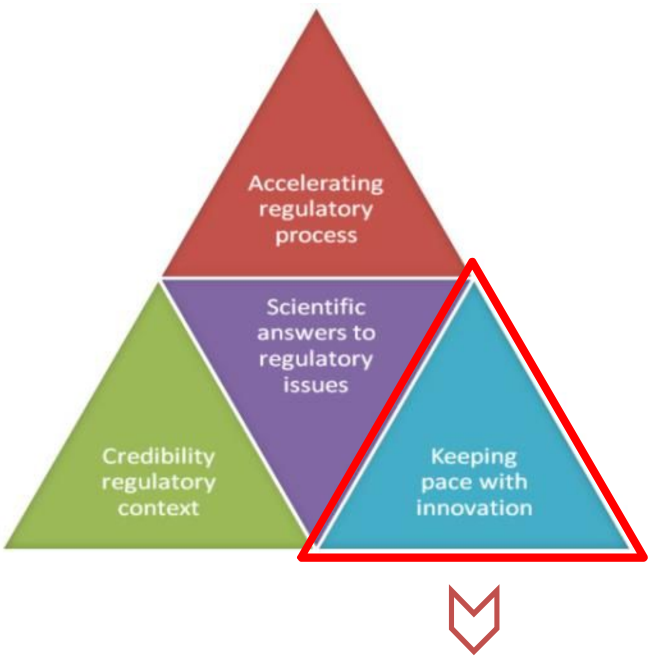


Project objectives

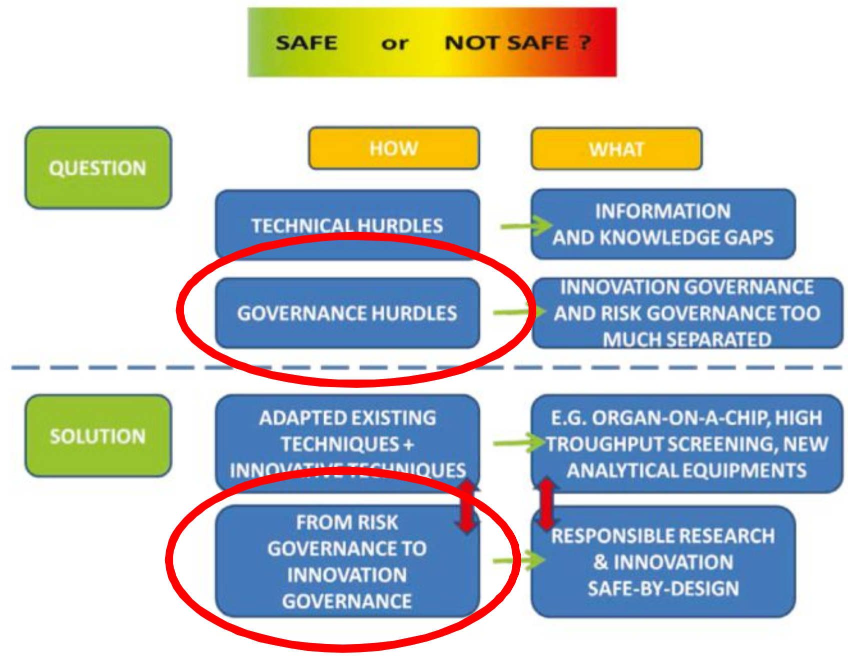
1. Risk assessment and decision making tools for legislators
2. Developing new testing strategies
3. Establishing close collaboration among authorities and industry

Context: NANoREG project

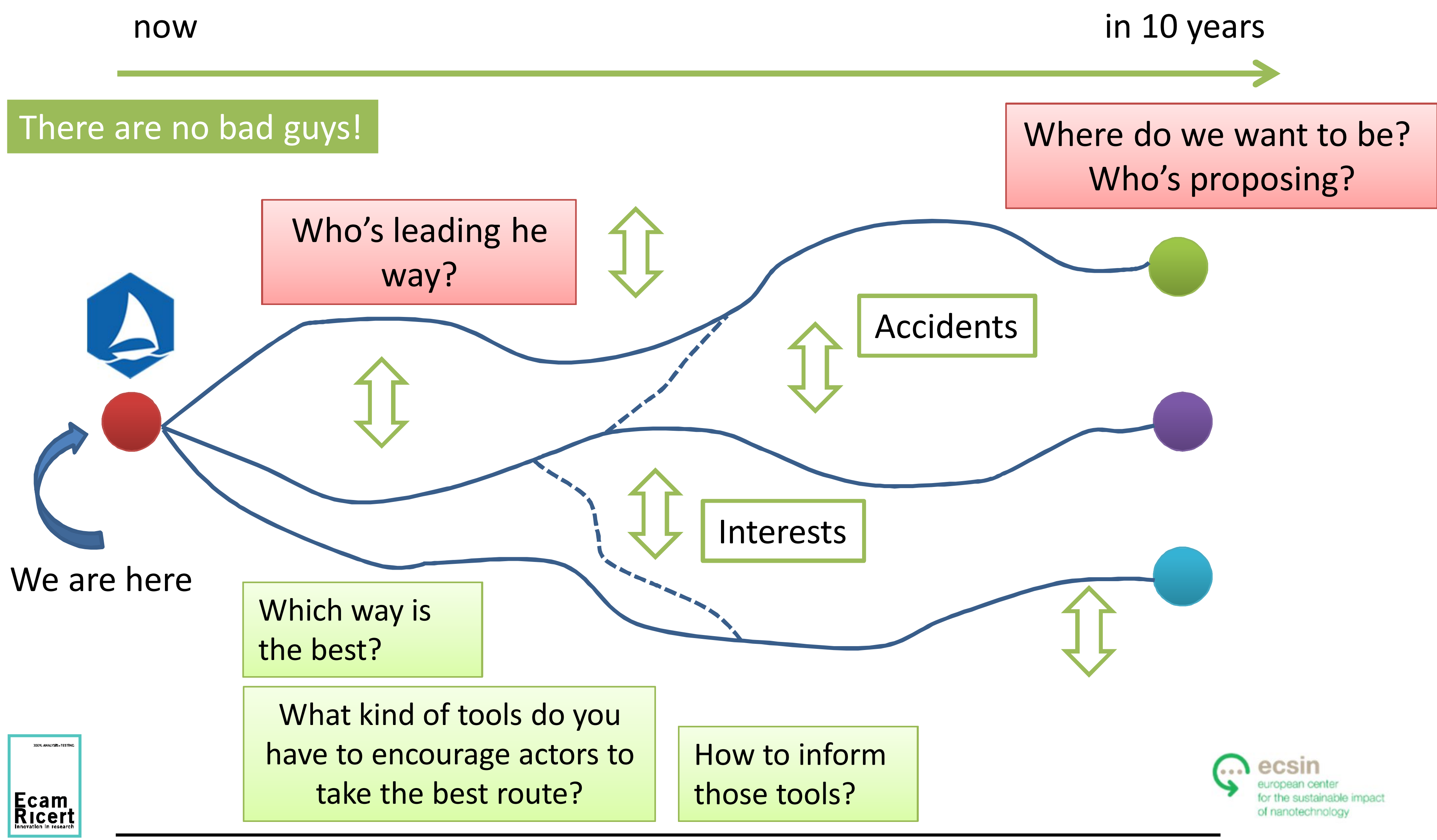
A common European approach to the regulatory testing of Manufactured Nanomaterials



Linking risk analysis into innovation



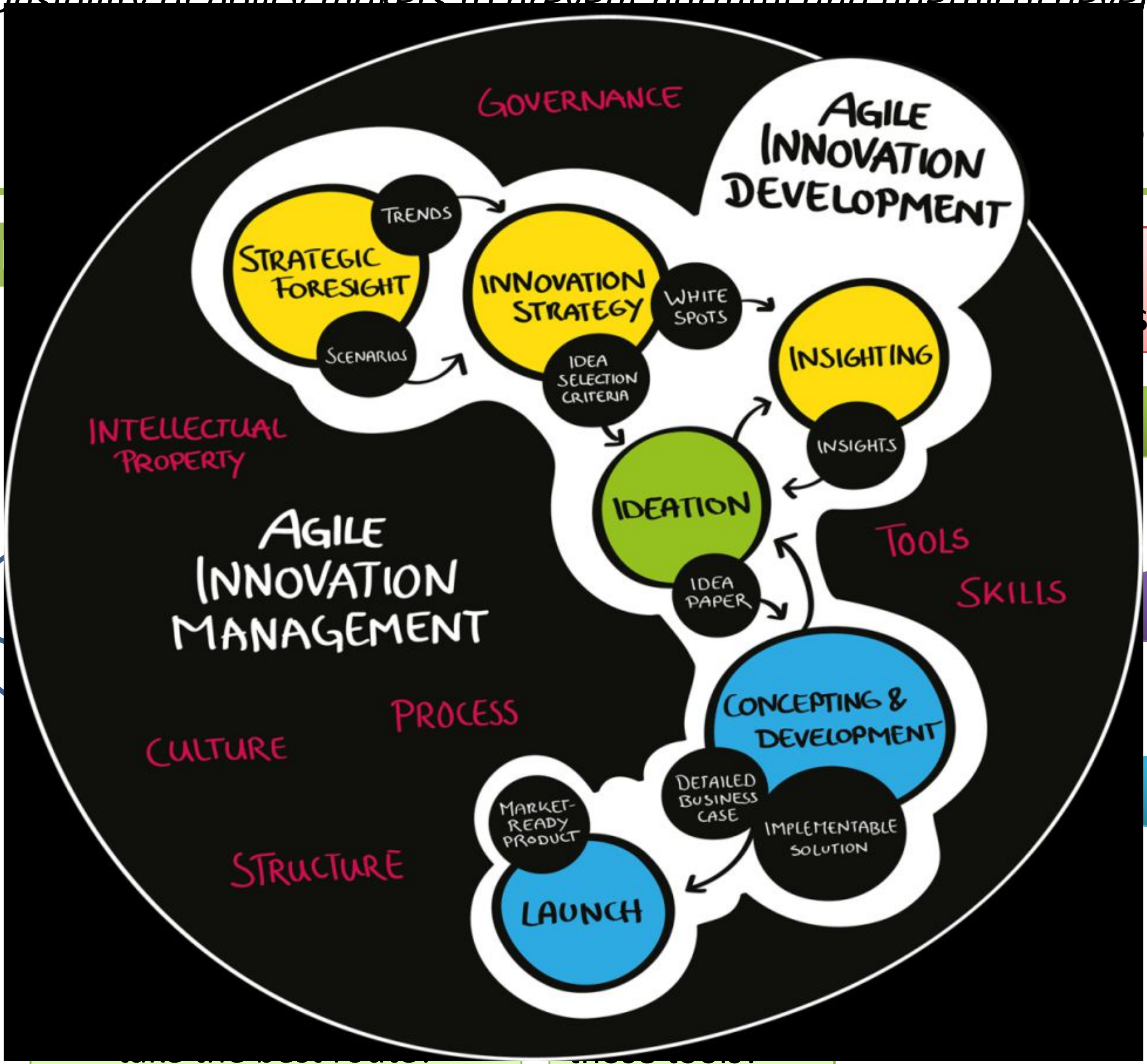
... the responsibility of policy makers to prevent harmful and unethical developments in <u>research</u> and <u>innovation</u> (EC, 2012)



… the responsibility of policy makers to prevent harmful and unethical developments in

now years

There are no we want to be?
proposing?



We are here

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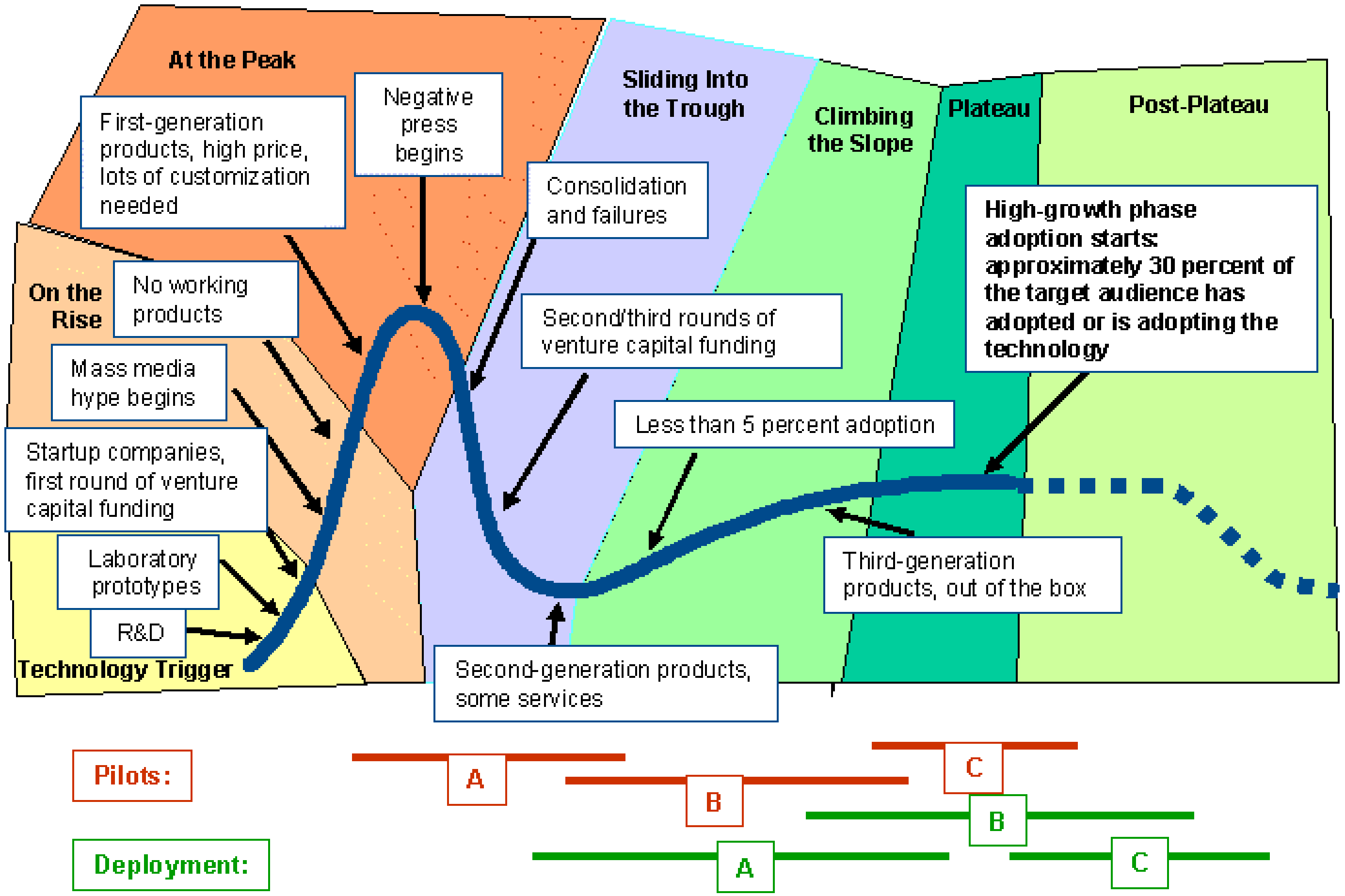
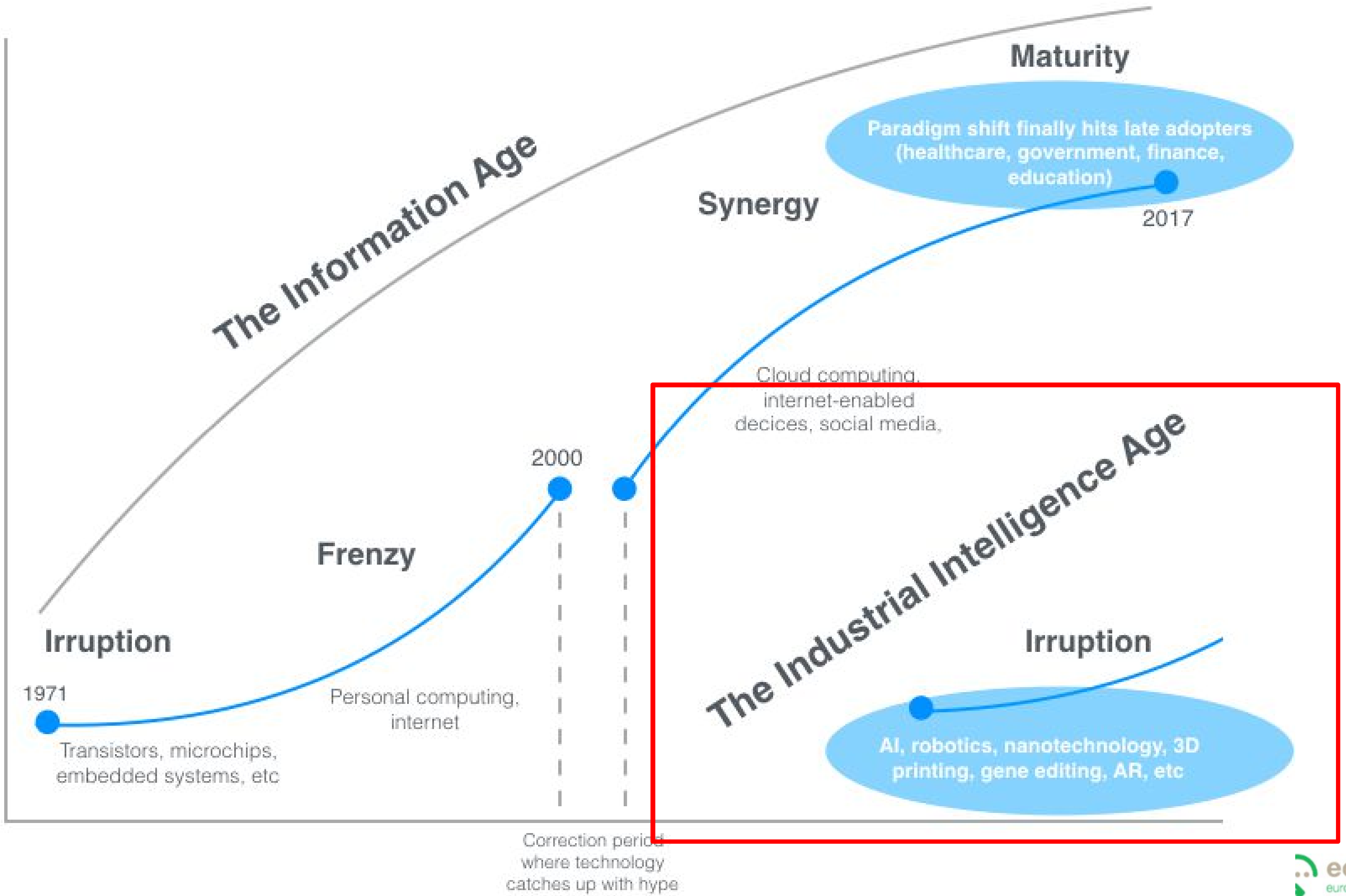
Timing of emerging technologies



Gartner

https://ekp.is/welcome-to-the-industrial-intelligence-age-17562501ac34



Late lessons from early warning (EEA, 2001)

Lessons 1 and 3: heed the «warnings»

- Blind spots: are we asking the right questions? Is nanomaterials novelty an additional factor?

Lessons 4 and 11: reduce obstacles to action

- Change of perspective: interdisciplinary approach, contamination between specialties, as the only way to act. Are we doing enough?

Lessons 5 and 8: stay in the real world

- Do not restrict the field: non specialists may have clear ideas about what is important

Lessons 6 and 9: consider wider issues

- Balancing benefits and risks: to determine more likely scenarios for a sustainable nanotechnology development, to build and conserve public trust

Foss-Hansen et al., 2013. Late lessons from early warnings, Vol. II. EEA

Lesson 7: evaluate alternative solutions

- Nanotechnology solution for everything: should nanotechnology (or the newest technology) be used to solve all problems?

Lesson 10: maintain regulatory independence

- Regulators responsibility to …: is EHS always considered by regulators? How is the need of economic growth, societal benefits, and safety balanced?

Lesson 12: avoid paralysis by analysis

- "We need more research …": we cannot wait for all the information to be there, but we need robust information, ways to reasonably deal with remaining uncertainty and start acting

→ Lack of a responsive strategy for nanotechnology innovation governance

Foss-Hansen et al., 2013. Late lessons from early warnings, Vol. II. EEA

Since 2013: we know what to do, but are we doing it right?

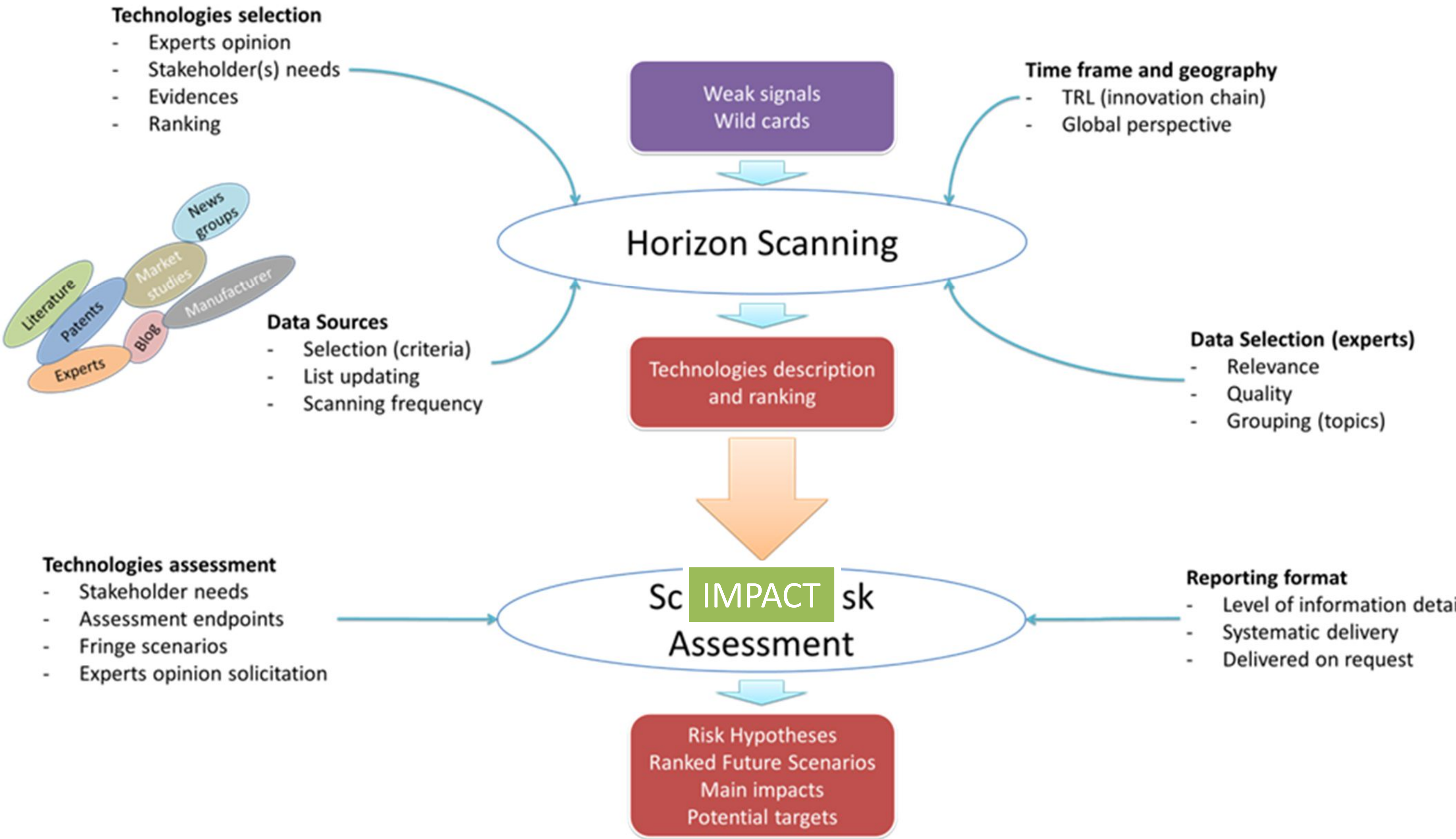
1. Decision support tools (working with qualitative or low amount of information)
2. Risk assessment models (but mostly control-banding type)
3. Research for regulators (NANoREG, ProSafe, NANOREG^2)
4. Increased international collaboration/coordination (OECD, EU-USA)
5. Working toward a nanotechnology risk governance framework

but …

1. Applied **after** a technology is adopted/developed by industry
2. Still limited cooperation between regulatory agencies
3. Little involvement of the public (and non specialists) in the decision making process

NANoREG Foresight Platform

The Conceptual Framework



Objectives and Scoping

- To assess the potential impacts of future nanotech innovation on Environment, Health, and Safety
- Practical applications (group of applications) based on use profile for a specific nanomaterial
- Taking into account the whole life cycle of the product/application
- Normative foresight (*to change the socio-economic conditions through policy actions*) based on explorative foresight
- Could be applied to industrial sectors
- Does not include SEA

Users, Beneficiaries, Expected Results

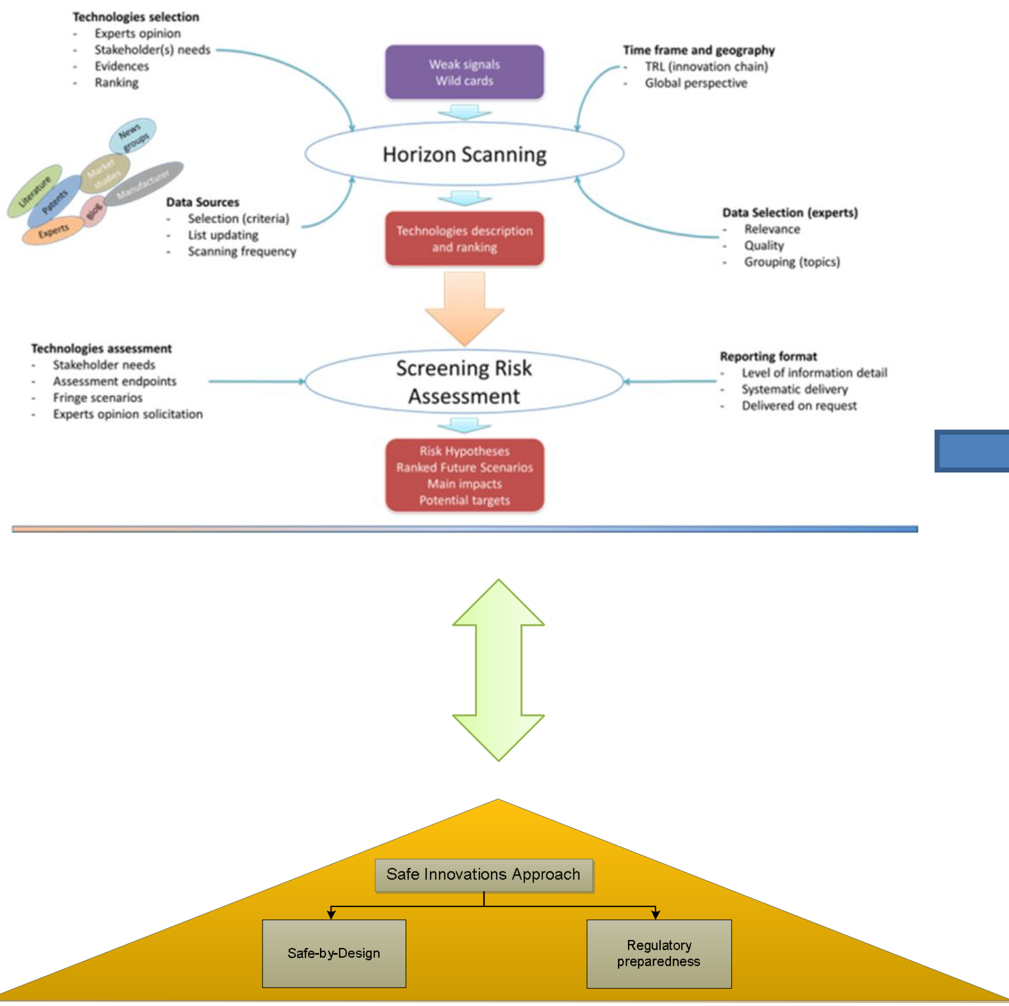
- Users: regulators (supported by experts)

- Beneficiaries:
  - regulators
  - financial institutions
  - industry

✓ Negative impacts of relevant (for the specific stakeholder) applications

✓ Comparison of the available data for SRA and the data gaps in terms of safety assessment

✓ Regulatory implications in terms of current regulation and needed regulation/guidelines

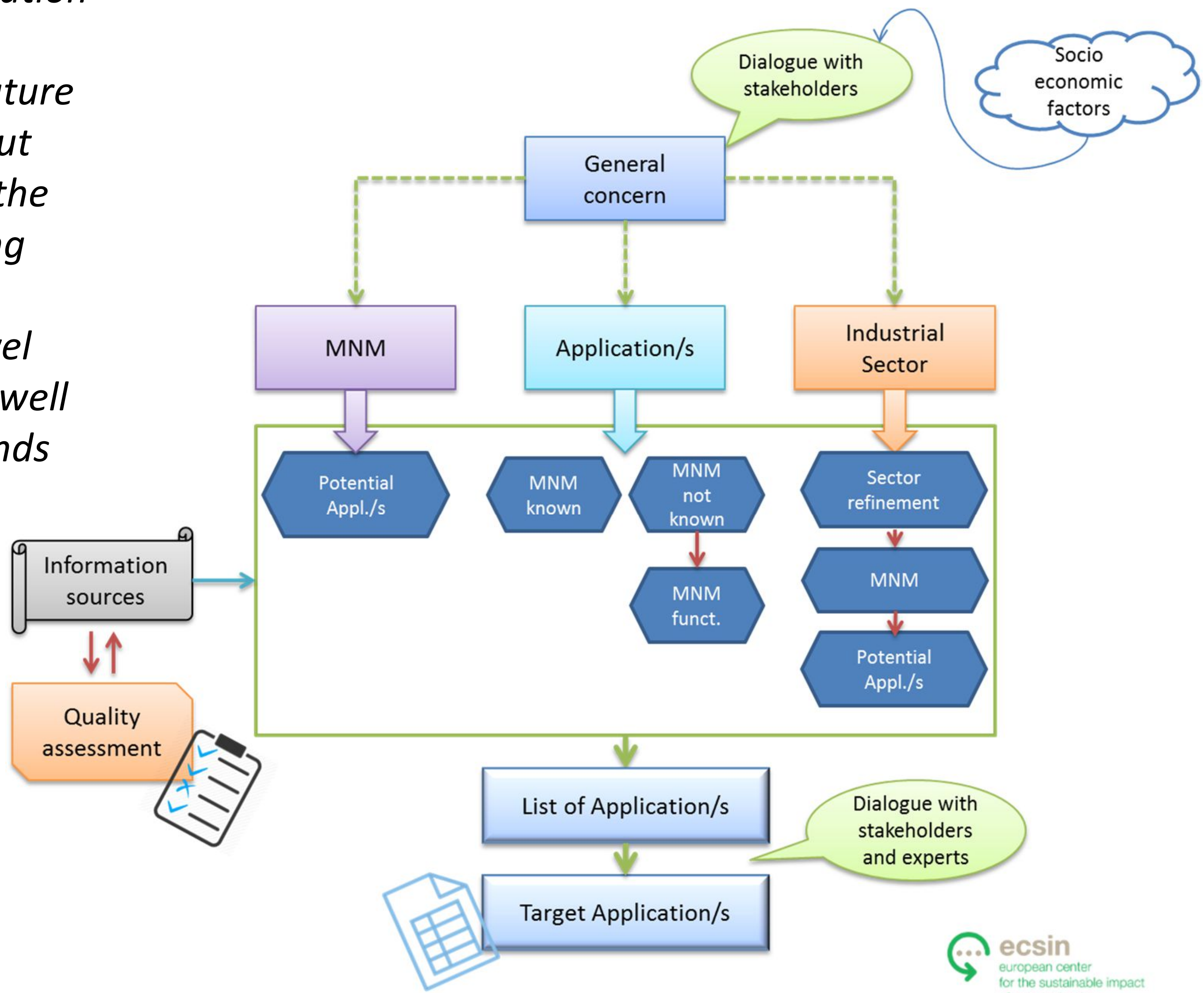


To industry

1. «Testing» innovation at the idea stage
2. Providing signals of «what not to do»
3. Sieving the “good” research (open innovation)

. . . the systematic examination of potential threats, opportunities and likely future developments including but not restricted to those at the margins of current thinking and planning. Horizon scanning may explore novel and unexpected issues as well as persistent issues or trends

Miles and Saritas (2012)



- General Concern: based on policy considerations, is the socio-economic input of the System

European Parliament

Horizon scanning and analysis of techno-scientific trends

Scientific Foresight Study

07/2017

- high presence in social media and news
- strong controversy
- high potential of societal impact

big data, gene technology, electric vehicles, autonomous cars, impact of algorithms, screen addiction, fake news and bioterrorism

Mandate

MNM	e.g. graphene	1. Identification of (all) possible (likely, interesting) uses based on functionality 2. Comparison to existing products
Application/s	e.g. energy saving material	1. MNM known or unknown 2. Substitution scenario 3. Use profile mostly known
Industrial sector	e.g. agrifood sector, energy	1. Specific sub-sectors 2. Identification of MNM and/or functionality

Information Sources

Web based

Search engines
Blogs, newsletters, discussion groups
Active actions (ask for feedback)
Snowball sampling
Peer reviewed journals
RSS feeds

Experts

Delphi (Real Time Delphi)
Expert panels
Meetings/conventions
R&D, Companies

Table 2. Comparison of tools used in scanning process (rate of appropriateness and usefulness: low, medium, high)

Amanatidou et al., 2012	Phase 1: Identification of weak signals	Phase 2: Processing of weak signals	Phase 3: Analysis and interpretation
Focused expert review	High	High	High
Wiki	Low	Low	Low
Twitter	High	Low	Low
Surveys	Low	High	High
Conferences	Low	Medium	High
Text-mining	Low	Medium	Medium

Table 2. Evaluation Criteria, Scores, and Recording System

Smith et al., 2010

Factors and description	Usefulness t	
	Very low 0 points	Low 10 points
Accessibility of information: level of effort required	Limited access	Resource intensive: manual scanning of literature
Contact point for the source: contact details for further information	No	–
Cost: level of annual subscription or registration cost	>£1,000	£500–1,000
Coverage: approximate percentage of relevant information in source	<10%	10–50%
Efficiency of search: estimated time to identify one potentially significant health technology or other relevant information	>1 hour	30–60 minutes
Frequency of scanning: how often the source information is updated	Yearly or less	Quarterly
Memory: news archive	None	<3 months
Quality of information: should be reliable, accurate, objective	No quality	Questionable quality, elements of bias

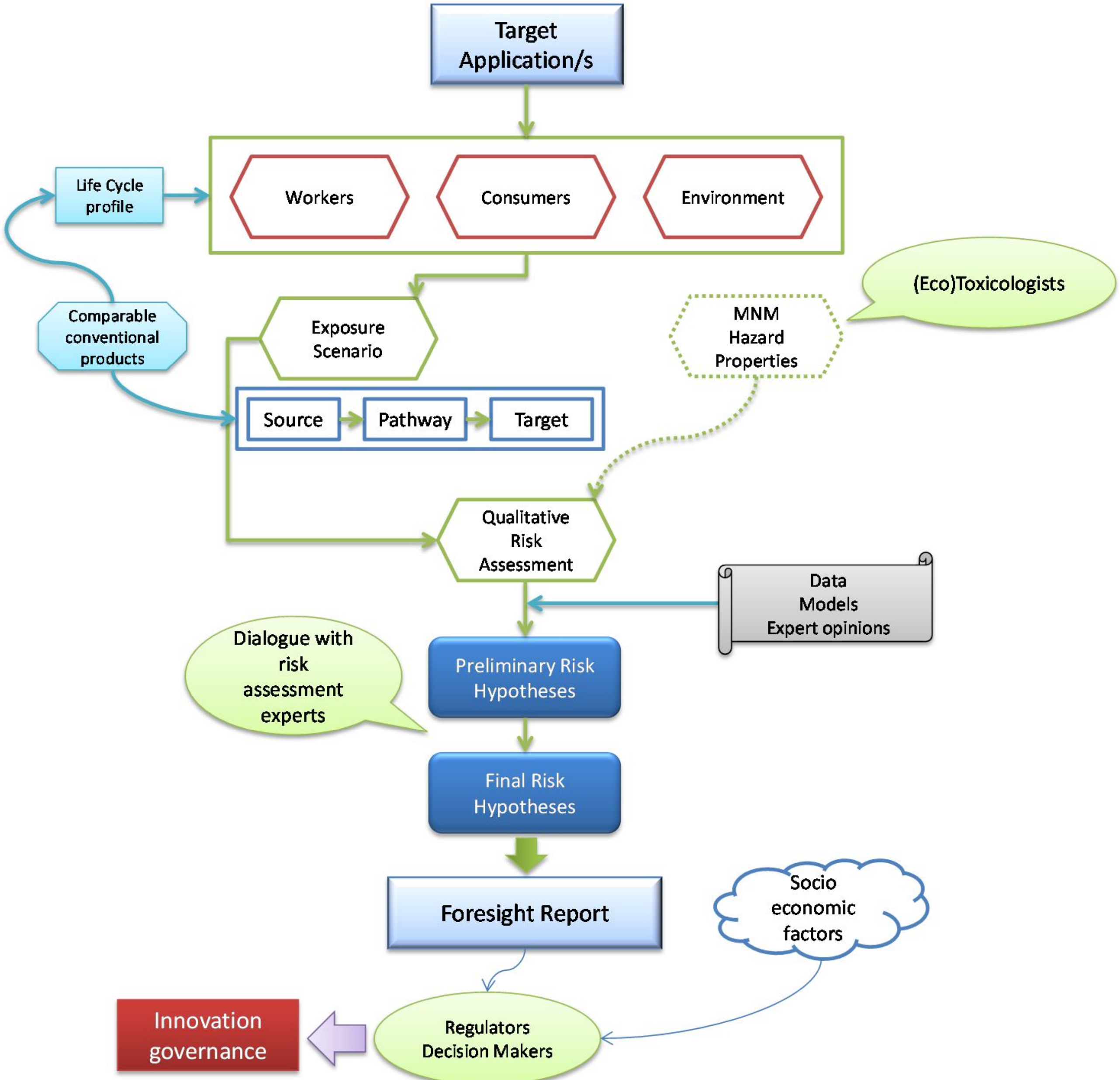
List of Applications

↓

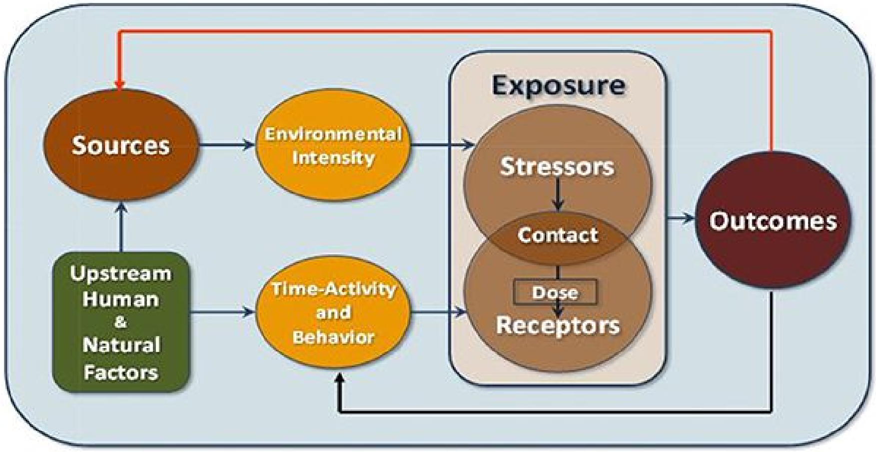
Target Applications

- Estimated level of use (is it going to be widespread?)
- Type of use (what is the target? Is there the possibility of misuse of the application?)
- Sensitive population (is there a sensitive population?)
- Included in EU and/or national economic strategies (is there an economic relevance?)
- Public perception (how is the application seen by the public?)
- Potential benefits (how important are the expected benefits? For which target?)

Screening Risk Assessment



- Qualitative assessment
- Based on Problem Formulation of ERA
  - Conceptual model



- «Simple» tools: grouping and read across, exposure models, control banding, CLP, expert judgment
- Risk Hypotheses

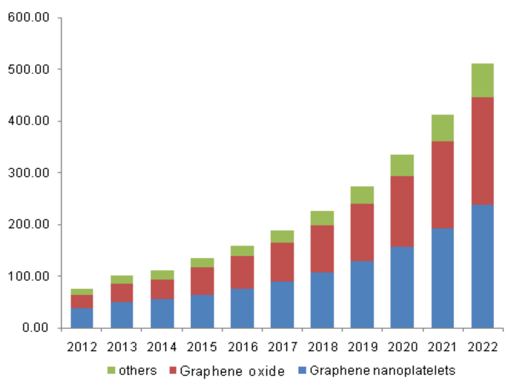
Case Study

GRAPHENE FLAGSHIP

The European roadmap for graphene science and technology (Ferrari et al., 2015)

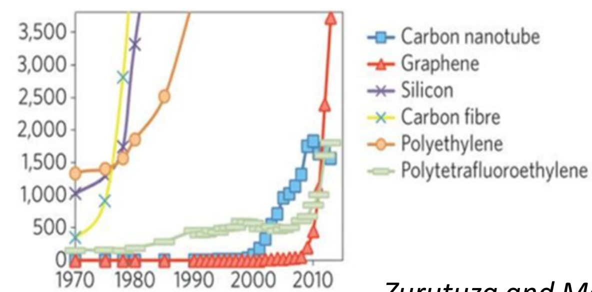
Case Study: relevance for regulators

- Market forecasts (CAGR increase)
  - Graphene: around 40-45 % (2014-2022)
  - Graphene in electronics: around 60% (2014-2025)

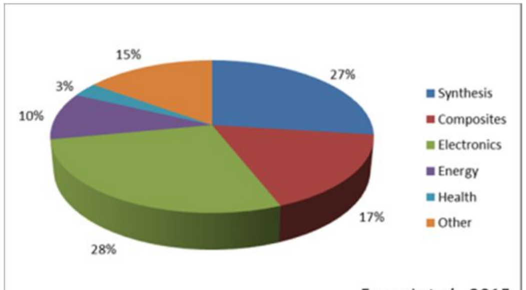


http://www.grandviewresearch.com/industry-analysis/graphene-industry, graphene value;

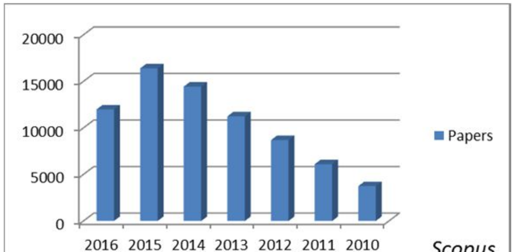
- Patenting and Research



Zurutuza and Marinelli, 2014



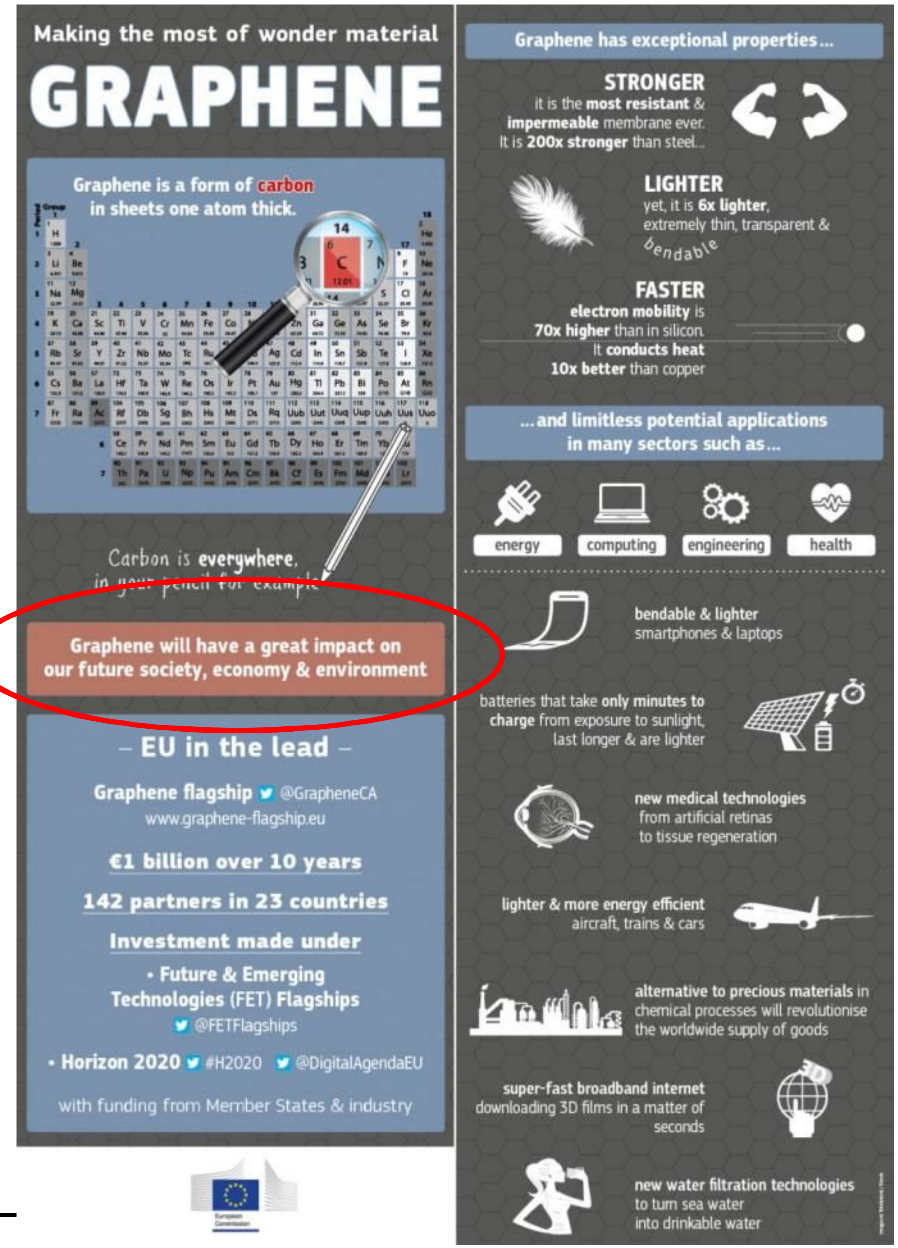
Ferrari et al., 2015



Scopus

- Prospective applications and investments

graphene has the potential to become a disruptive technology, i.e. to be able to create its own <u>not incremental</u> applications (Ferrari et al., 2015)



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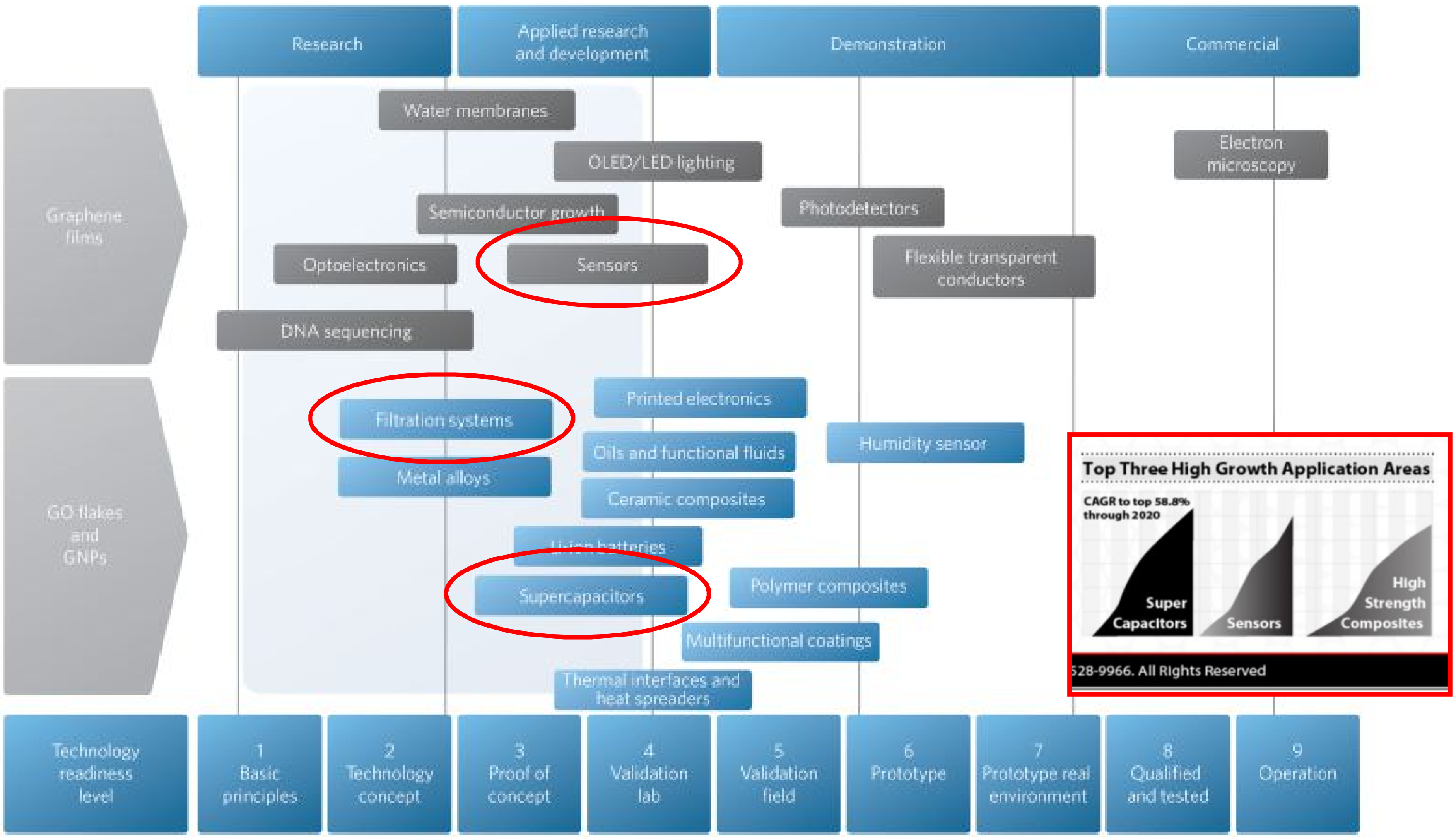
Case Study: Horizon Scanning (Target Applications)



Zurutuza and Marinelli, 2014

Case Study: Horizon Scanning (Target Applications)

Industry sector	Novel materials, Water treatment
Generic application name	Nanocomposites
Products already or close to the market	e.g. G2O water membranes (coating existing membranes with graphene oxide) (http://g2o.co/); it is a start-up.
Nanocomposite production method	Starting from graphene, different approaches are used to link graphene to polymer, and in case, to functionalize the graphene layer. An example is The "graft to" method uses the functional groups of polymers to attach graphene to the polymer matrix, via regular chemical reactions or thermal treatment. The "graft from" methods include polymerization, chemical oxidation, and electrochemical polymerization
Nanocomposite production scale	Currently mostly lab scale. No scale up hypothesis available at this point.
Foreseen use	Mainly Industrial and Professional, less for Consumers at this stage
MNM	Graphene, Graphene Oxide
MNM function	Act as sorbent for chemicals (heavy metals) from water increasing the adsorption properties and the reusability of the composite
MNM production method	Graphene can be produced in many different ways. A detailed list of methods is reported in Ferrari et al. (2015)
Sources of information	Peer Reviewed literature; News services (see Nanowerk).
Source Quality	Papers are very recent, and more than one paper was selected to cover different aspects of the specific application. Impact factors of the journals varied a lot, from 6.18 of the journal Carbon to 1.025 of the Journal of water and health, to 0 for Nano LIFE.
Information type and quality	There are several publications on this topic, but more technical in nature, without much information on potential impacts (e.g. release from polymers). The technical information (production process, performances) is usually very detailed.
Regulatory context	There is no nano-specific environmental legislation. In case of release in water, there are no environmental concentration limits for graphene. Graphene is not in REACH yet, while CLP is available on ECHA website.

Case Study: Screening Risk Assessment

- Production of graphene or graphene oxide

- Production of the membrane:
  - Incorporation of graphene oxide into polymers
  - Generation of filter

- Use (scale)
  - Desalinization (industrial)
  - Water purification (industrial, household)
  - Decontamination (industrial, household)

12 kT globally (2015)

Release of GO into environment?

- End of life

Life span? (5 years conventional)

Reuse is possible, recycling is unlikely

Risk Hypotheses

1. Worker exposure
    1. **Exposure is possible, but high uncertainty. Need to collect more data**
2. Environmental exposure (decontamination)
    1. Limited amount used
    2. No data about release from polymers (but possible)
    3. Graphene oxide toxic for the environment
3. Environmental exposure after disposal
    1. Easily reactivated and reused
    2. Incineration as best option for disposal
4. Direct consumer exposure
    1. Not enough kownledge about release of graphene
    2. Chronic exposure to low concentrations a potential issue
    3. Potential sensitive populations

Case Study: preliminary conclusions

- Potentially high benefit for clean and safe water resources
- Simple systems could be used in portable apparels

- Emission of graphene from nanocomposites to be better studied
- Workplace emissions have to be measured
- Toxicity studies on graphene family materials are still lacking, in number and quality

How to implement?

- Independent organization
  - European Foresight Agency
- Stakeholder engagement
  - Scientific/Industrial Panels
  - Trusted environment
- Recursive analysis
- Adaptive regulatory approach (CE label)
  - Nanotech complexity
  - Adaptability to novel products
  - Define principles, let someone else deal with the particulars

Thank you for your attention