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October 16, Dubendorf (Zurich), Switzerland

AGRO4AGRI

Responsible Innovation and Nanomaterials - A European Perspective

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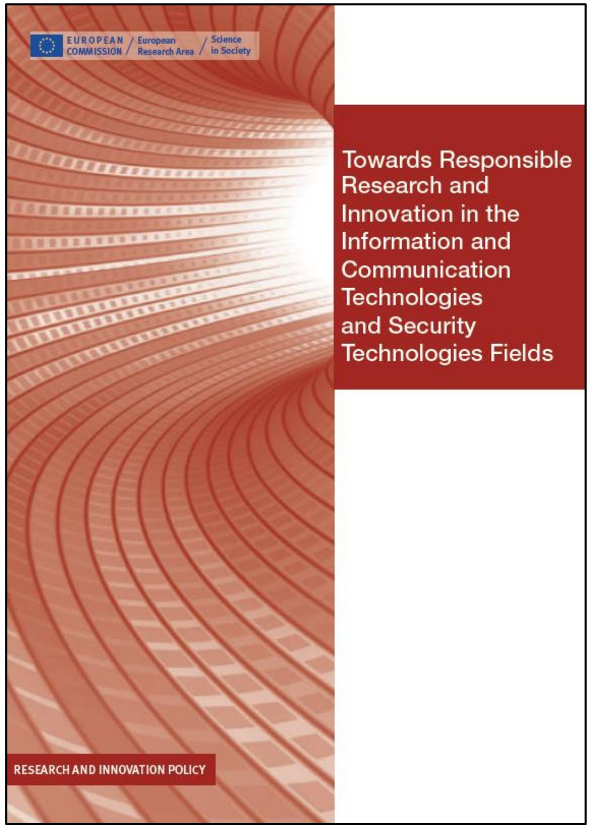
What is Responsible Innovation?

- "Responsible Research and Innovation is a transparent, interactive process by which societal actors and innovators become mutually responsive to each other with a view on the (ethical) acceptability, sustainability and societal desirability of the innovation process and its marketable products(in order to allow a proper embedding of scientific and technological advances in our society)"

- von Schomberg (2011)



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Normative anchors of RRI

Figure 1: Overview on features of responsible research and innovation

Features of responsible research and innovation	
Product dimension: addressing normative anchor points	Process dimension: deliberative democracy
Institutionalisation of Technology Assessment and Foresight	Use of Code of Conducts
Application of the precautionary principle; ongoing risk assessment; ongoing monitoring	Ensuring market accountability: Use of Standards, Certification schemes, Labels
Use of demonstration projects: from risk to innovation governance	Ethics as a design principle for technology
	Normative models for governance
	Ongoing Public debate: Moderating «Policy Pull and Technology Push»

https://op.europa.eu/en/publication-detail/-/publication/60153e8a-0fe9-4911-a7f4-1b530967ef10/language-en

Academic definition of RRI

"Responsible innovation means taking care of the future through collective stewardship of science and innovation in the present." Stilgoe et al. (2013)

Table 1
Lines of questioning on responsible innovation.

Product questions	Process questions	Purpose questions
How will the risks and benefits be distributed?	How should standards be drawn up and applied?	Why are researchers doing it?
What other impacts can we anticipate?	How should risks and benefits be defined and measured?	Are these motivations transparent and in the public interest?
How might these change in the future?	Who is in control?	Who will benefit?
What don't we know about?	Who is taking part?	What are they going to gain?
What might we never know about?	Who will take responsibility if things go wrong?	What are the alternatives?
	How do we know we are right?	

Stilgoe et al. Research Policy 42 (2013) 1568–158

4 dimensions of RRI

Anticipation	Foresight Technology assessment Horizon scanning Scenarios Vision assessment Socio-literary techniques
Reflexivity	Multidisciplinary collaboration and training Embedded social scientists and ethicists in laboratories Ethical technology assessment Codes of conduct Moratoriums

Stilgoe et al. Research Policy 42 (2013) 1568-158

4 dimensions of RRI

Inclusion	Consensus conferences Citizens' juries and panels Focus groups Science shops Deliberative mapping Deliberative polling Lay membership of expert bodies User-centred design Open innovation
Responsiveness	Constitution of grand challenges and thematic research programmes Regulation Standards Open access and other mechanisms of transparency Niche management[a] Value-sensitive design Moratoriums Stage-gates[b] Alternative intellectual property regimes

Stilgoe et al. Research Policy 42 (2013) 1568-158

4 dimensions of RRI vs. Development of NT and NM in Europe

Anticipation	Foresight Technology assessment Horizon scanning Scenarios Vision assessment Socio-literary techniques
Reflexivity	Multidisciplinary collaboration and training Embedded social scientists and ethicists in laboratories Ethical technology assessment Codes of conduct Moratoriums

Stilgoe et al. Research Policy 42 (2013) 1568-158

Early Foresight and Technology Assessment from 2003 and 2004

THE ROYAL SOCIETY

Fellows Events Journals Current topics Grants Medals and prizes

News from the Royal Society

Nanotechnology offers benefits but risks must be assessed

10 November 2003

Scientists and engineers believe nanotechnology can be used to benefit human health now and in the future through applications such as better filters for improving water purification, more effective methods of delivering drugs in medicine and new ways of repairing damaged tissues and organs, according to a report published today (10 November 2003) of a workshop held by the Royal Society and the Royal Academy of Engineering.

However, some nanotechnology experts at the workshop, organise
Engineering study on nanotechnology, believed that more assessm
posed by nanotubes and other nanoparticles, which may have the
studies should be carried out of the behaviour of nanoparticles in t

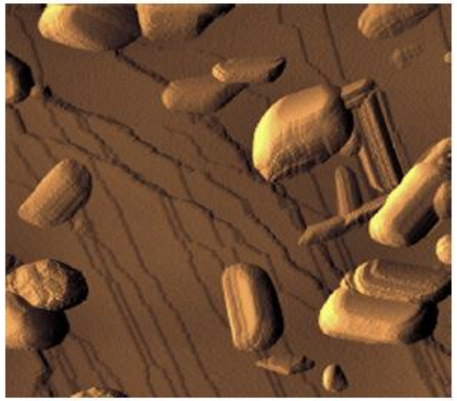
Many participants at the workshop also thought that the constructi
science fiction accounts of nanotechnology, is likely to be physical

The report also warns that participants felt "hyped up reports from
public's perception of nanotechnology". They wanted a public deb
both positive and negative, of nanotechnology."

EUROPEAN COMMISSION

Community Health and Consumer Protection

NANOTECHNOLOGIES: A PRELIMINARY RISK ANALYSIS ON THE BASIS OF A WORKSHOP ORGANIZED IN BRUSSELS ON 1–2 MARCH 2004 BY THE HEALTH AND CONSUMER PROTECTION DIRECTORATE GENERAL OF THE EUROPEAN COMMISSION



Lack of funding of anticipatory research

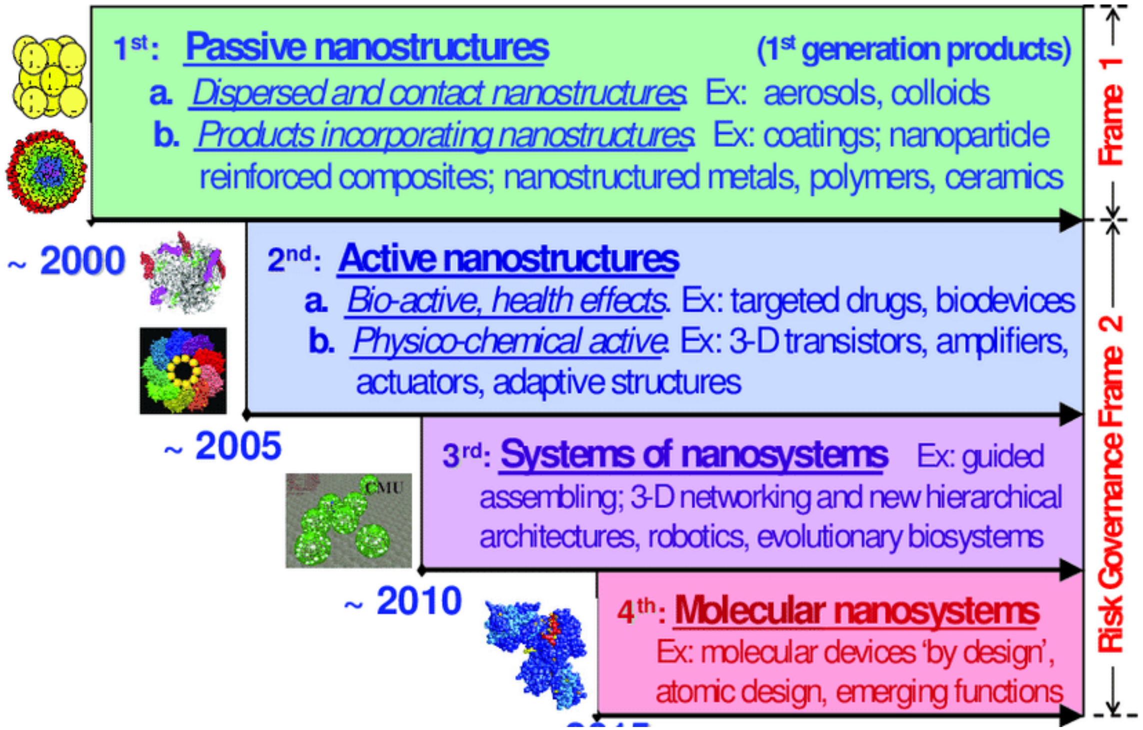
Table 1 EU funding of RTD and EHS-research in NBIC technologies and overall under the FP1–7

Research programme	Overall RTD funding (billion €)	Overall EHS funding (million €)	RTD/EHS-research (%)
(A) Research and Technology Development			
FP4	13 215[9]	n.a.	n.a.
FP5	14 960[10]	160[7]	1
FP6	17 500[11]	≈200[7]	1
FP7	50.5[8]	265[7]*	0.5*
Total	96 175	625	0.6

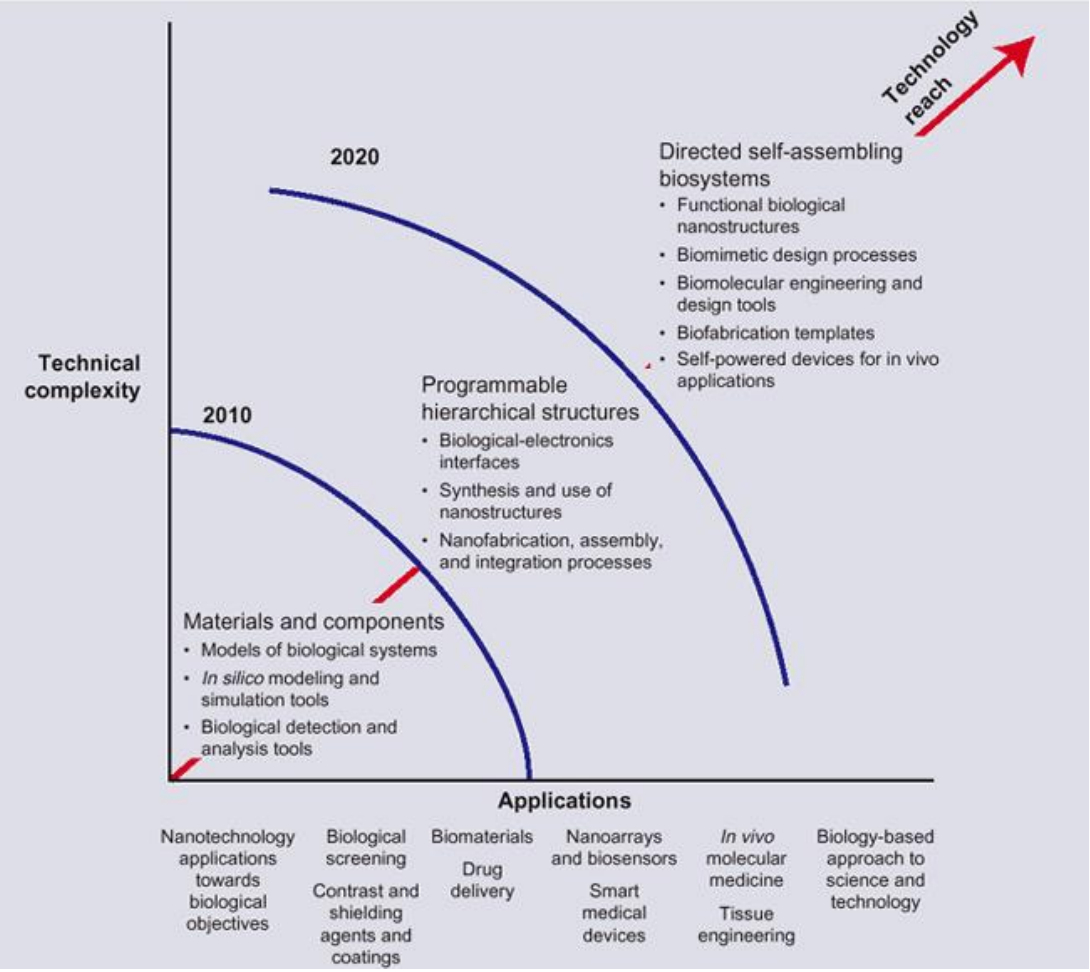
- FP1-7: 2.3, 4 and **0.09%** for Nanotech, Biotech and ICT, respectively
- Holland: A parliamentary debate concluded with **15%** of the total nano government budget being allocated to EHS

Hansen and Gee. J Epidemiol Community Health 2014;68:890-895

Are we do at foresight?



Roco, Mihail & Renn, Ortwin & Jäger, Alexander. (2008). International Risk Governance Council Bookseries. 10.1007/978-1-4020-6799-0_13.



SRI Consulting Business Intelligence (SRIC-BC; Menlo Park, CA, USA) from Mazzola, Commercializing nanotechnology. *Nat Biotechnol* **21**, 1137-1143 (2003).

Reflexivity

- Multidisciplinary collaboration and training
- Embedded social scientists and ethicists in laboratories
- Ethical technology assessment
- Codes of conduct
- Moratoriums

NATURE NANOTECHNOLOGY

correspondence

Balancing scientific tensions

Wickson et al. 2014 Nature Nanotech. 9:870

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Available languages: English

PRESS RELEASE | Feb 8, 2008

European Commission adopts Code of Conduct for Responsible Nanosciences and Nanotechnologies Research

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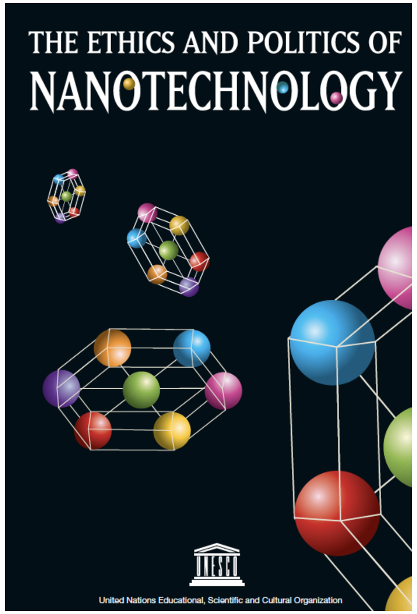
Brussels, 8 February 2008

European Commission adopts Code of Conduct for Responsible Nanosciences and Nanotechnologies Research

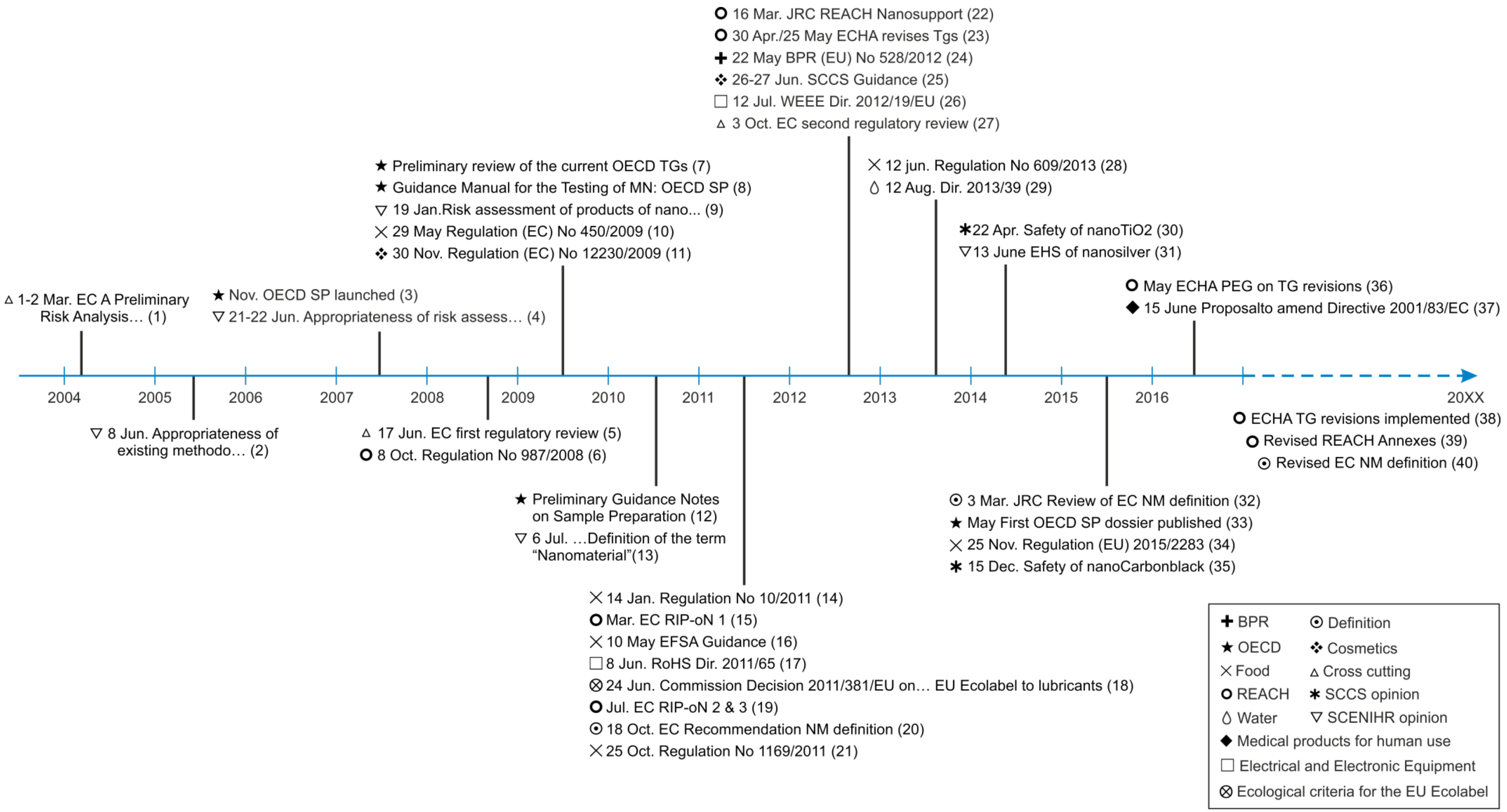


Inclusion and Nanotechnology

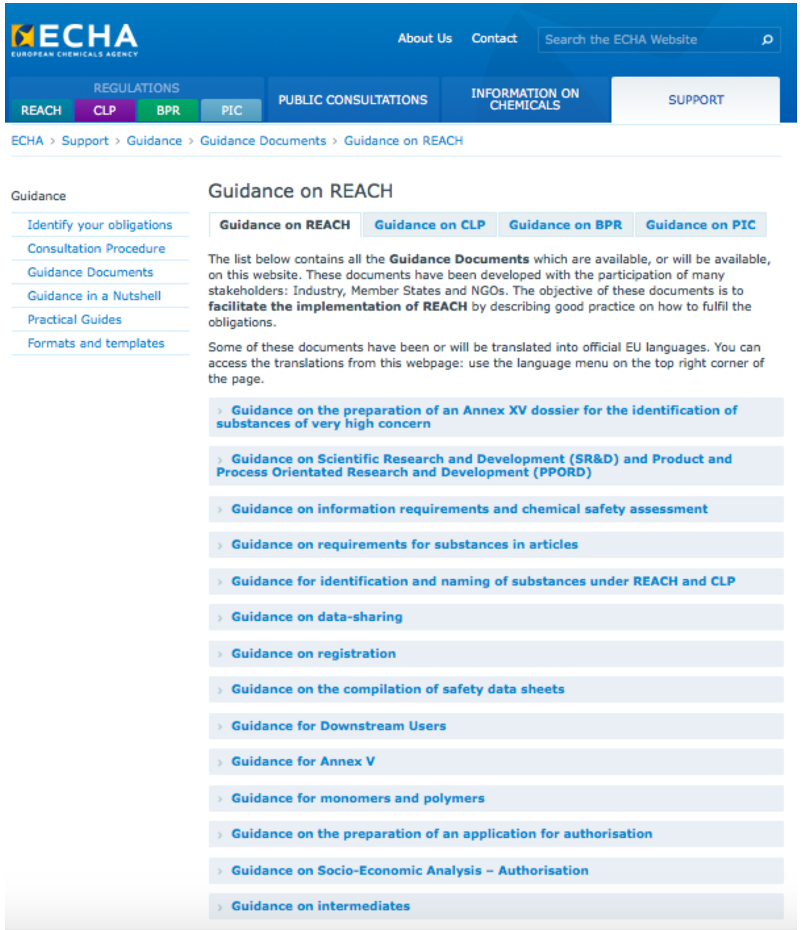
- Inclusion = Consensus conf., Citizen's juries, Focus groups, etc.
- Many initiatives in the 2000s – Not so much anymore (?)
- 2003: Royal Society workshop (50 pers.)
- 2004: Danish Board of Technology (40 pers.)
  - The purpose of NT and controllability
  - Adequate return of investments
  - Health and environmental considerations
  - Social security and control
  - Against using NT to extent the human lifespan and consumer goods
  - Generally more concerned about societal risks than personal risks
  - Whether lessons from the past had been learned

Responsiveness and Nanotechnology

- Responsiveness = Thematic research programmes, Regulation, Standards, Open access, etc.



ECHA Guidance



NanoImpact 32 (2023) 100487

Contents lists available at ScienceDirect

NanoImpact

journal homepage: www.elsevier.com/locate/nanoimpact

Review article

European nanomaterial legislation in the past 20 years – Closing the final gaps

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REACH
Regulation
Risks

ABSTRACT

In 2004, the potential societal implications related to nanotechnology were highlighted in an influential report by the Royal Society and the Royal Academy of Engineering (RS & RAE). It was made clear that legislation is an important tool to tackle the challenges related to nanomaterials and a list of recommendations were put forward. Shortly after, the European Commission also proposed a list of recommendations on how to handle nanomaterial challenges and adopted the so-called "incremental approach", describing that current legislations should be adapted, where relevant, to handle nanomaterials. Now almost 20 years have passed and it seems relevant to take stock and investigate how legislations have been adapted to tackle nano-specific challenges. In this review, we analyze key pieces of European legislations relevant to nanomaterials and assess to what extent these legislations compare with the original recommendations from 2004 by the RS & RAE and the European Commission. We uncover the cross-cutting challenges that remain and provide recommendations on next steps that should be taken to address the risks of nanomaterials. For each recommendation, we assessed whether it was met to a high, medium or low degree by conducting targeted literature searches at Web of Science, screening legislations, guidance documents, databases etc., and applying expert judgement. We found that >90% of the recommendations put forward in 2004 by the RS & RAE and the European Commission have been either met to a high degree (13 out of 29) or met to a medium degree (14 out of 29). This suggests important advancements in the field of nanosafety. At the same time, it is important to address the concerns still left partly or fully unsolved. Such efforts entail e.g. further development of measuring instruments and standardised characterization and risk assessment methods for nanomaterials, application of a uniform nanomaterial definition, maximization of containment of free nanomaterials until hazards assessed/handled and elimination/minimisation of unintentional nanomaterial emission. Furthermore, we recommend prioritising future efforts to ensure enforcement and implementation of existing nano-specific provisions, as well as revision, where needed, of legislations that currently do not account for nanomaterials, such as the Waste Framework Directive.

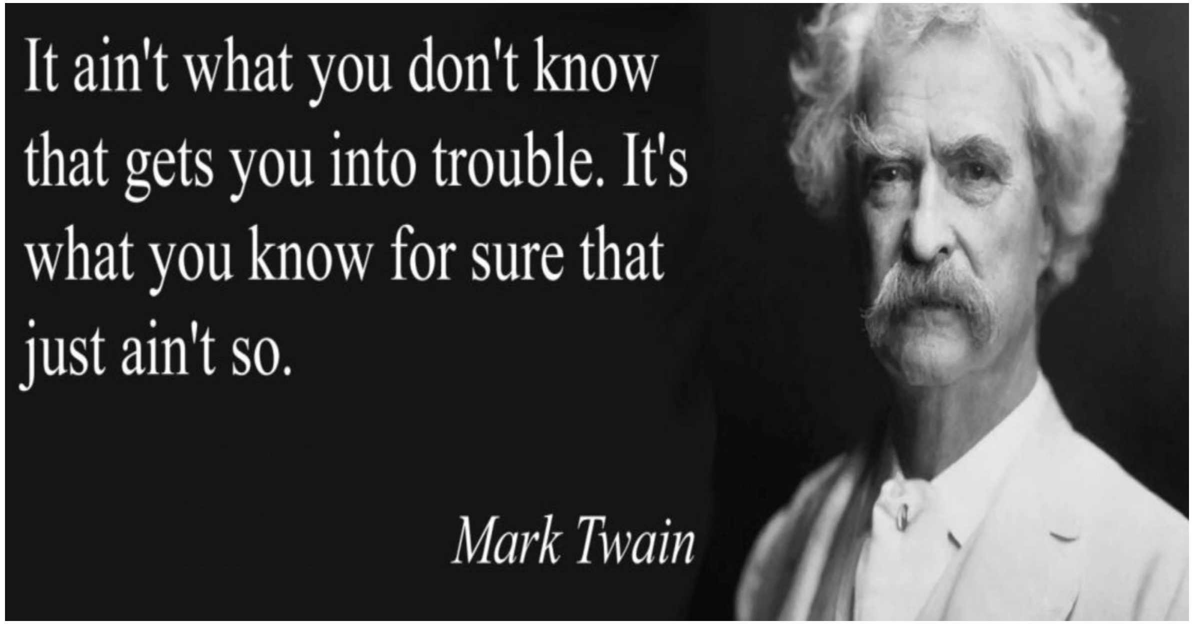
Nielsen et al. NanoImpact 32 (2023) 100487

Having 29 recommendations from RS & RAE been implemented?

- High degree: 13
- Medium degree: 14
- Not meet: Separate CAS registry numbers and extended producer responsibility regimes

Need for further development of measuring instruments and standardised characterization and risk assessment methods for nanomaterials

Did we overlook something?



From RRI to SSbD

Computational and Structural Biotechnology Journal 25 (2024) 105–126

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Computational and Structural Biotechnology Journal

journal homepage: www.elsevier.com/locate/csbj

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Perspectives

Roadmap towards safe and sustainable advanced and innovative materials. (Outlook for 2024-2030)

Flemming R. Cassee [a,*], Eric A.J. Bleeker [b], Cyrille Durand [c], Thomas Exner [d], Andreas Falk [e], Steffi Friedrichs [f], Elisabeth Heunisch [g], Martin Himly [h], Sabine Hofer [h], Norbert Hofstätter [h], Danail Hristozov [i], Penny Nymark [j], Anna Pohl [k], Lya G. Soeteman-Hernández [b], Blanca Suarez-Merino [c], Eugenia Valsami-Jones [l], Monique Groenewold [b]

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Innovative materials
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Harmonization
Standardization
Regulatory preparedness
Sustainability
Nanomaterials
FAIR data management

ABSTRACT

The adoption of innovative advanced materials holds vast potential, contingent upon addressing safety and sustainability concerns. The European Commission advocates the integration of Safe and Sustainable by Design (SSbD) principles early in the innovation process to streamline market introduction and mitigate costs. Within this framework, encompassing ecological, social, and economic factors is paramount. The NanoSafety Cluster (NSC) delineates key safety and sustainability areas, pinpointing unresolved issues and research gaps to steer the development of safe(r) materials. Leveraging FAIR data management and integration, alongside the alignment of regulatory aspects, fosters informed decision-making and innovation. Integrating circularity and sustainability mandates clear guidance, ensuring responsible innovation at every stage. Collaboration among stakeholders, anticipation of regulatory demands, and a commitment to sustainability are pivotal for translating SSbD into tangible advancements. Harmonizing standards and test guidelines, along with regulatory preparedness through an exchange platform, is imperative for governance and market readiness. By adhering to these principles, the effective and sustainable deployment of innovative materials can be realized, propelling positive transformation and societal acceptance.

Cassee et al. 2024 Computational and Structural Biotechnology Journal 25 (2024) 105–126

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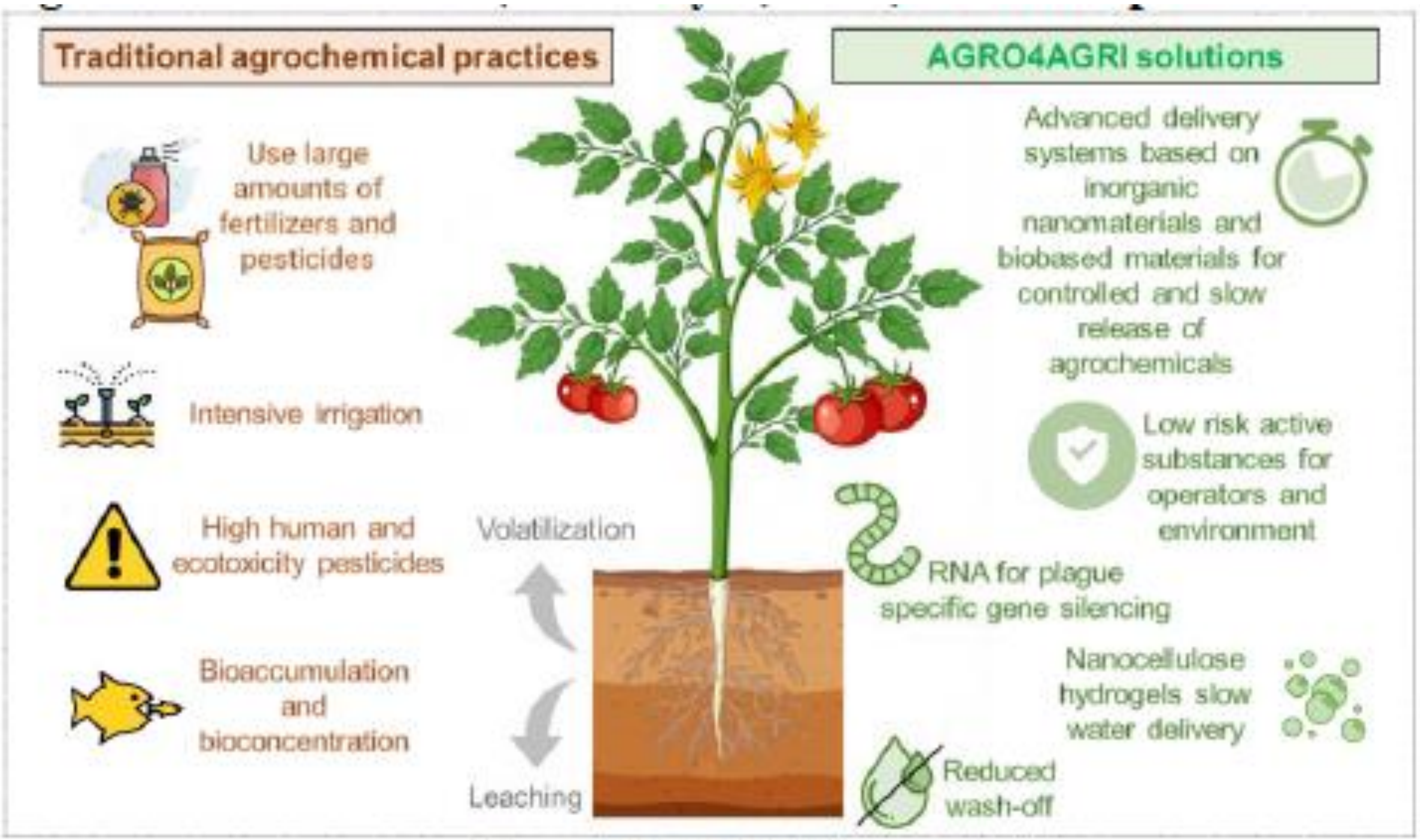
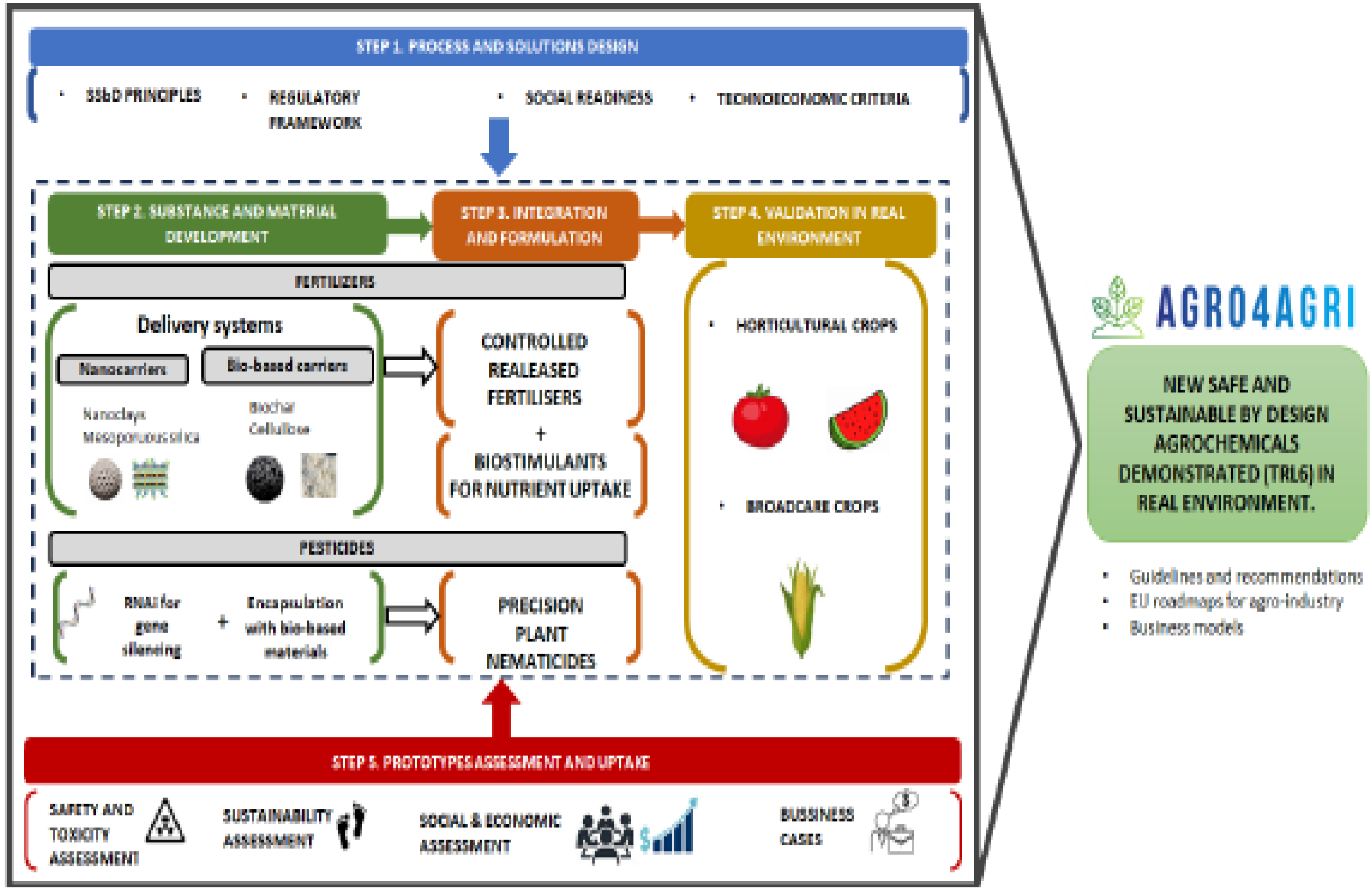


Figure 1 AGRO4AGRI concept



Key SSbD principles

1. Avoid CLP classified substances e.g., CMRs, reproductive toxicants
2. Avoid unintended exposure to humans and environment
3. Avoid substances that fulfill the criteria for being Persistent (P), Bioaccumalte (B), Toxic (T) or Mobile

AGRO4AGRI

Thank you for your attention!

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