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2024 EU-U.S. NanoEHS Communities of Research (CORs
Workshop)

October 16, Dubendorf (Zurich), Switzerland



AGRO4AGRI

Responsible Innovation and Nanomaterials - A European Perspective



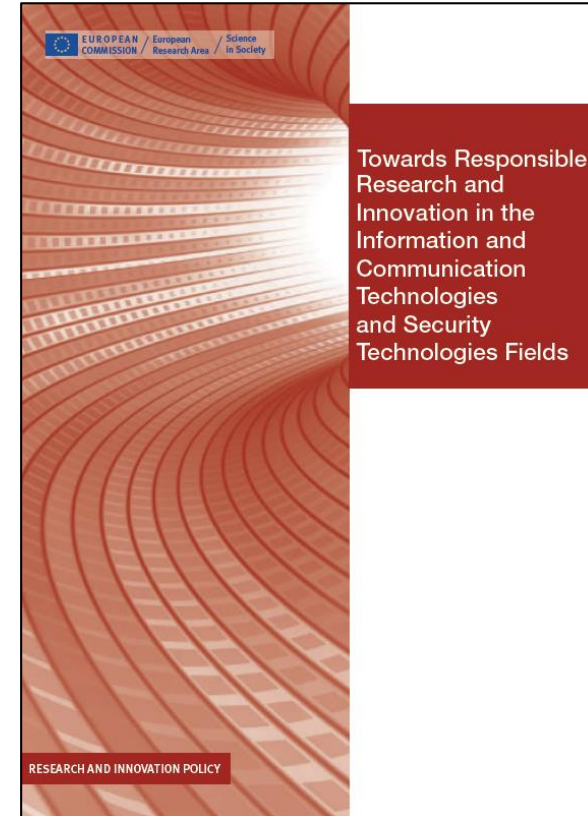
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What is Responsible Innovation?

- “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)



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

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

4 dimensions of RRI

Anticipation	<ul style="list-style-type: none">ForesightTechnology assessmentHorizon scanningScenariosVision assessmentSocio-literary techniques
Reflexivity	<ul style="list-style-type: none">Multidisciplinary collaboration and trainingEmbedded social scientists and ethicists in laboratoriesEthical technology assessmentCodes of conductMoratoriums

4 dimensions of RRI

Inclusion	Consensus conferences
	Citizens' juries and panels
	Focus groups
	Science shops
	Deliberative mapping
Responsiveness	Deliberative polling
	Lay membership of expert bodies
	User-centred design
	Open innovation
	Constitution of grand challenges and thematic research programmes
Responsiveness	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	<ul style="list-style-type: none">ForesightTechnology assessmentHorizon scanningScenariosVision assessmentSocio-literary techniques
Reflexivity	<ul style="list-style-type: none">Multidisciplinary collaboration and trainingEmbedded social scientists and ethicists in laboratoriesEthical technology assessmentCodes of conductMoratoriums

Early Foresight and Technology Assessment from 2003 and 2004



Fellows Events Journals Current topics Grants Medals and prizes

Home / 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, organised by the Royal Society and the Royal Academy of Engineering study on nanotechnology, believed that more assessment should be carried out on the risks posed by nanotubes and other nanoparticles, which may have the potential to cause damage to cells. Further studies should be carried out of the behaviour of nanoparticles in the body.

Many participants at the workshop also thought that the construction of nanotechnology, as depicted in science fiction accounts of nanotechnology, is likely to be physical rather than molecular.

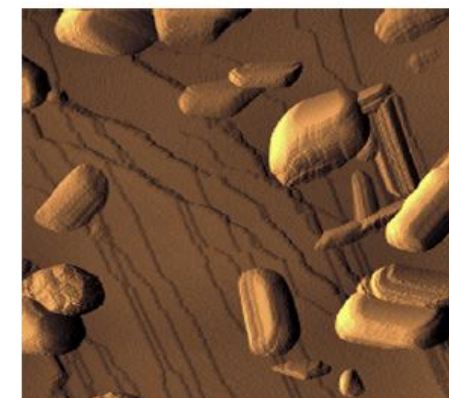
The report also warns that participants felt "hyped up reports from the media have distorted the public's perception of nanotechnology". They wanted a public debate that was balanced, covering both positive and negative, of nanotechnology."



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

Essay

OPEN ACCESS

Adequate and anticipatory research on the potential hazards of emerging technologies: a case of myopia and inertia?

Steffen Foss Hansen,¹ David Gee²

ABSTRACT
History confirms that while technological innovations can bring many benefits, they can also cause much human suffering, environmental degradation and economic costs. But are we repeating history with new and emerging chemical and technological products? In preparation for volume 2 of Late Lessons From Early Warnings (European Environment Agency, 2013), two analyses were carried out to help answer this question. A bibliometric analysis of research articles in 78 environmental, health and safety (EHS) journals revealed that most focused on well-known rather than on newly emerging chemicals. We suggest that this 'scientific inertia' is due to the scientific requirement for high levels of proof in well-replicated studies; the need to publish quickly; the use of existing intellectual and technological resources; and the conservative approach of many reviewers and research funders. The second analysis found that since 1986 the funding of EHS research represented just 0.6% of the overall funding of research and technological development (RTD). Compared with RTD funding, EHS research funding for information and communication technologies, nanotechnology and biotechnology was 0.09%, 2.26% and 4% of total research, respectively. The low EHS research ratio seems to be an unintended consequence of disparate funding options, technological optimism, a prior awareness of safety, collective habit, and myopia. In light of the history of past technological risks, where EHS research was too little and too late, we suggest that it would be prudent to double (one 50–15% of RTD on EHS research to anticipate and minimise potential hazards while maintaining the commercial longevity of emerging technologies.

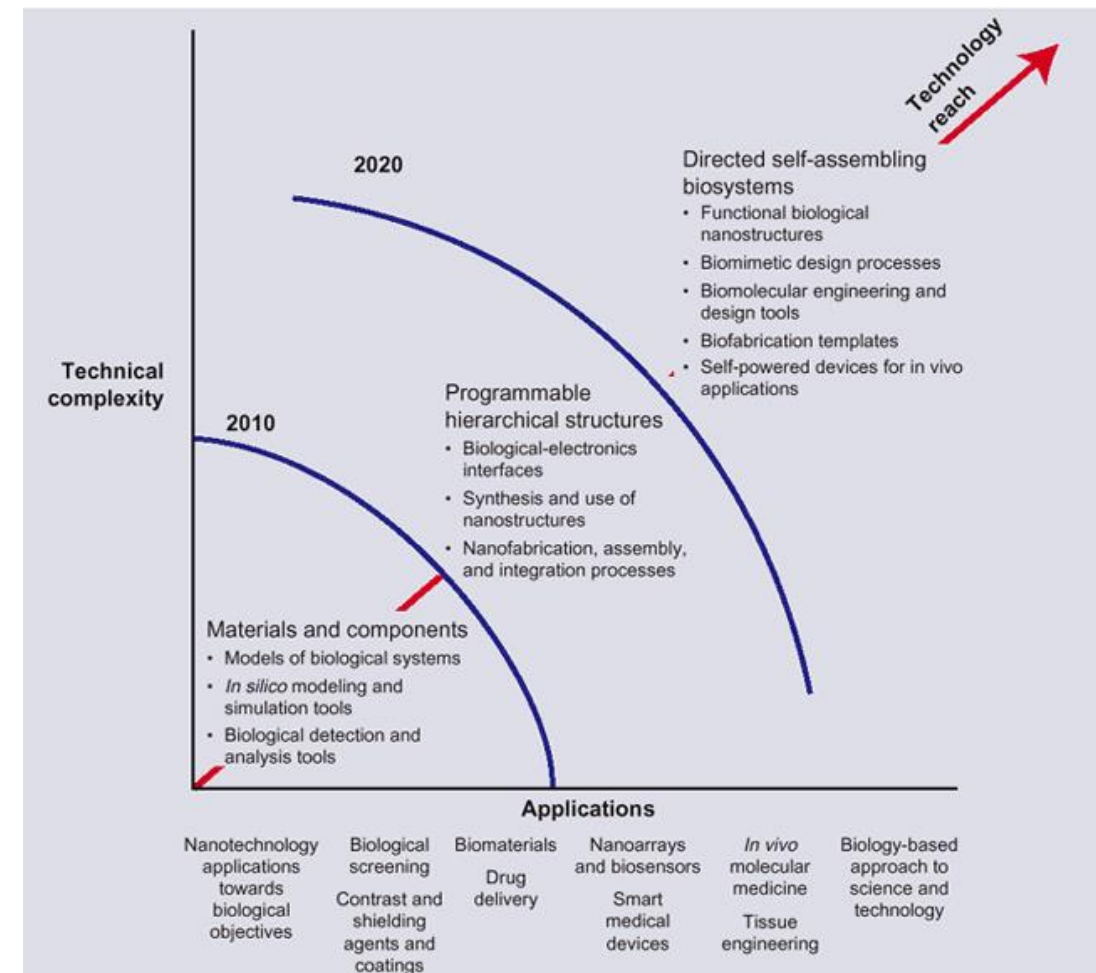
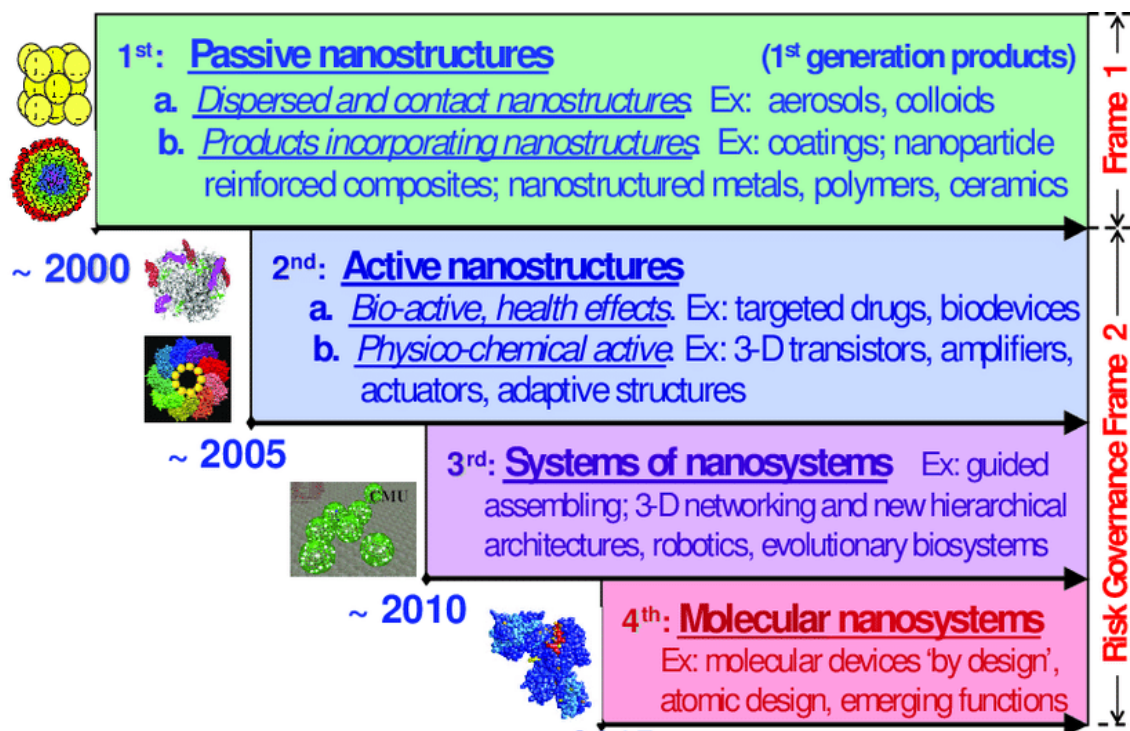
INTRODUCTION
Investment in technological innovation is a public policy priority in Europe and in many other regions of the world. Large amounts of public money are spent on new and emerging technologies and on their product applications in order to create jobs, prosperity and wealth. For instance, since 1984 more than €18 billion of the EU Framework Research budget has been spent on developing information and communication technologies (ICTs). And the European Commission announced in 2013 that the two science project pillars of the EU's Future and Emerging Technologies competition, on mapping the frontiers of the human brain, and on exploring the carbon-based material frontiers, will each receive up to €1 billion over the next decade.¹

There are already thousands of promising and rapidly spreading yet novel commercialised products that are based on the emerging chemical and Nano, Bio, and Information and Communication (NBIC) technologies. However, while technological innovations can bring many benefits, they can also cause much human suffering, environmental degradation and economic costs. In 2001, the European Environment Agency (EEA) published their first of two reports on Late Lessons from Early Warnings: the Precautionary Principle 1986–2000² documenting numerous case studies such as PCBs, sulfur dioxide, benzene, asbestos, trihalomethanes (THMs) and the pharmaceutical agent dieldrin/heptachlor (DHS) where failure to apply the precautionary principle resulted in much harm and delayed innovation.³ In 2013, the European Environment Agency (EEA) published a second report 'Late Lessons from Early Warnings: Precaution, Science, Precaution, Innovation'⁴ which analysed a further 20 case studies focusing, as in volume 1, on the growth of knowledge about their hazards and related actions or inactions by decision makers. The cases studied included lead in petrol, BSE/mad cow disease and polychlorinated biphenyls (PCBs), dioxin and furan, and polychlorinated biphenyls (PCBs) contamination, as well as some emerging technologies including genetically modified crops, nanotechnology and mobile phones. The second report also covered cross-cutting issues such as the economic consequences of inaction; why businesses ignored robust early warnings; the precautionary principle; false positives; and science for precautionary decision making. The report showed that precautionary environmental health regulation does not hamper innovation and concluded that there is a need to reduce delays between early warnings and actions, to rethink and enrich environment and health research, to improve the quality of risk assessments, and to foster greater public participation in choosing innovation pathways.

The history of the now well-known technologies and chemicals in the 'Late Lessons' reports showed that a lack of anticipatory research into the early warning signs of their hazards contributed to the failure to take timely actions to prevent or minimise the serious, widespread and continuing harm to the public and environments caused by these technologies and products. Two of the Twelve Late Lessons from volume 1 of 'Late Lessons' specifically addressed the issue of anticipatory research by calling for 'adequate' research into knowledge gaps and early warnings for more long-term monitoring, and for the promotion of robust, diverse and adaptable technologies that would help to 'mitigate the costs of surprises' and maximise the benefits of innovation.⁵ It is therefore evident that these lessons

Footnote:
¹ To cite: Hansen SF, Gee D. J Epidemiol Community Health 2014;68:890-895. doi:10.1136/jech-2014-206193

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
- Monitors  ums

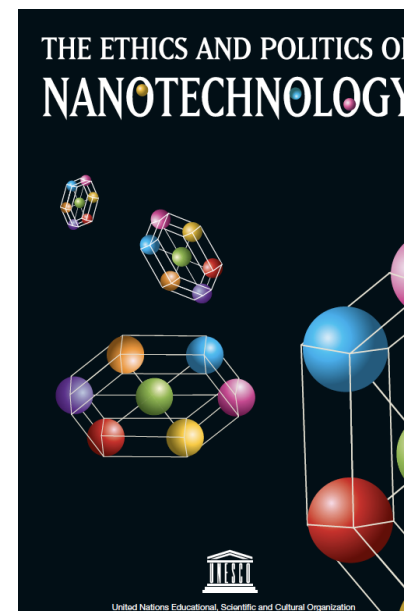


NATURE NANOTECHNOLOGY



Balancing scientific tensions

Wickson et al. 2014 Nature Nanotech. 9:870



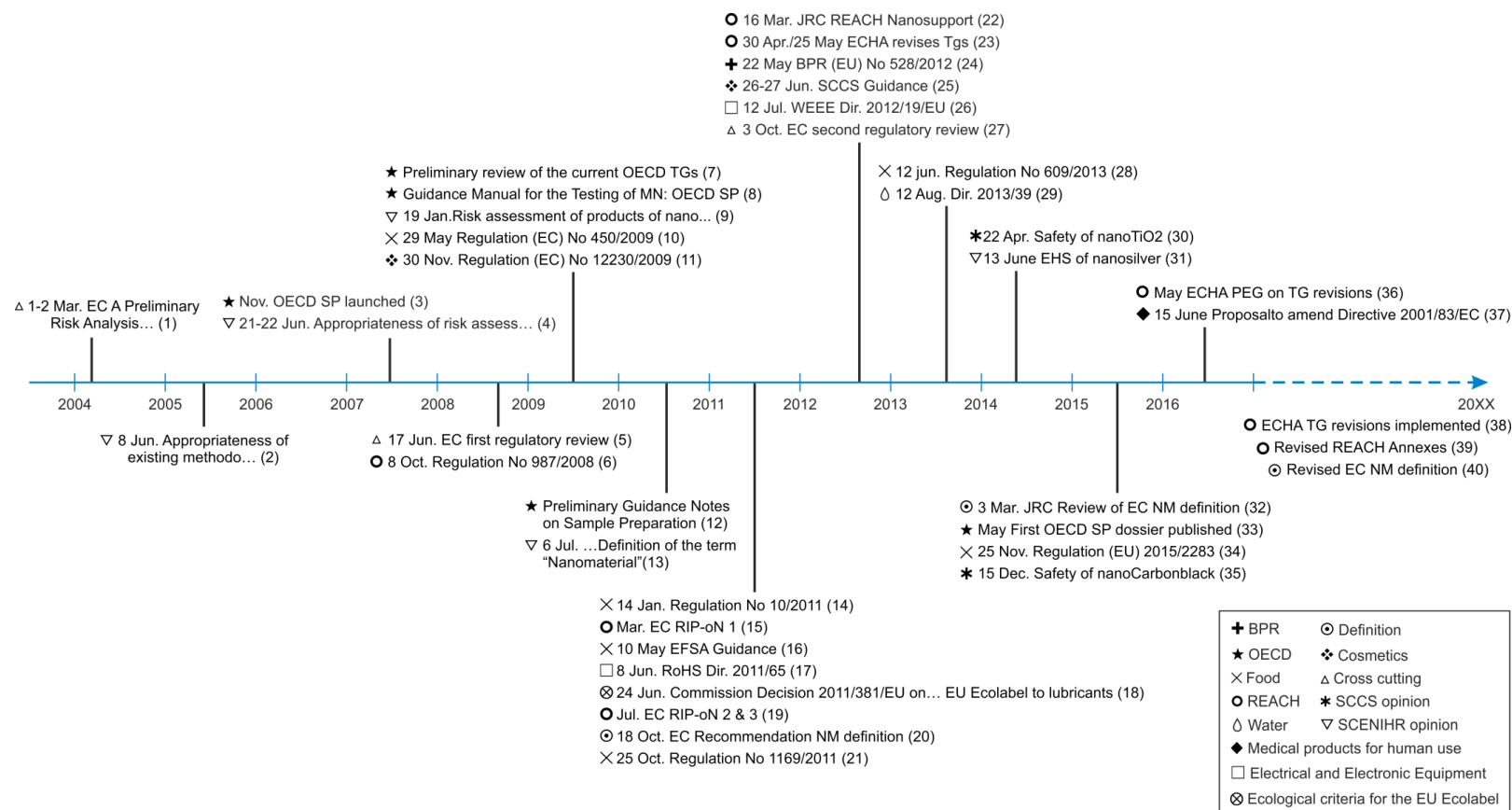
Inclusion and Nanotechnology

- 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

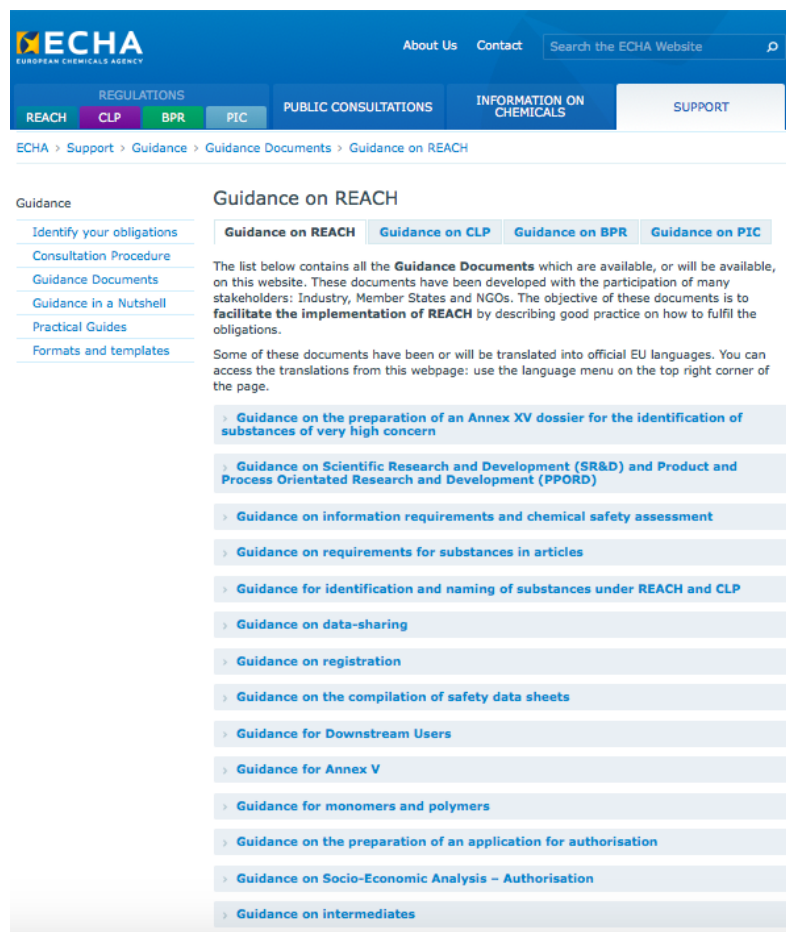


Responsiveness and Nanotechnology

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



ECHA Guidance



ECHA
EUROPEAN CHEMICALS AGENCY

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REGULATIONS
REACH CLP BPR PIC PUBLIC CONSULTATIONS INFORMATION ON CHEMICALS SUPPORT

ECHA > Support > Guidance > Guidance Documents > Guidance on REACH

Guidance

- Identify your obligations
- Consultation Procedure
- Guidance Documents
- Guidance in a Nutshell
- Practical Guides
- Formats and templates

Guidance on REACH

Guidance on REACH Guidance on CLP Guidance on BPR Guidance on PIC

The list below contains all the **Guidance Documents** which are available, or will be available, on this website. These documents have been developed with the participation of many stakeholders: Industry, Member States and NGOs. The objective of these documents is to **facilitate the implementation of REACH** by describing good practice on how to fulfil the obligations.

Some of these documents have been or will be translated into official EU languages. You can access the translations from this webpage: use the language menu on the top right corner of the page.

- Guidance on the preparation of an Annex XV dossier for the identification of substances of very high concern
- Guidance on Scientific Research and Development (SR&D) and Product and Process Orientated Research and Development (PPORD)
- Guidance on information requirements and chemical safety assessment
- Guidance on requirements for substances in articles
- Guidance for identification and naming of substances under REACH and CLP
- Guidance on data-sharing
- Guidance on registration
- Guidance on the compilation of safety data sheets
- Guidance for Downstream Users
- Guidance for Annex V
- Guidance for monomers and polymers
- Guidance on the preparation of an application for authorisation
- Guidance on Socio-Economic Analysis – Authorisation
- Guidance on intermediates





Review article

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

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Editor: Dr. Bernd Nowack

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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.

Having 29 recommendations from RS & RAE been implemented?

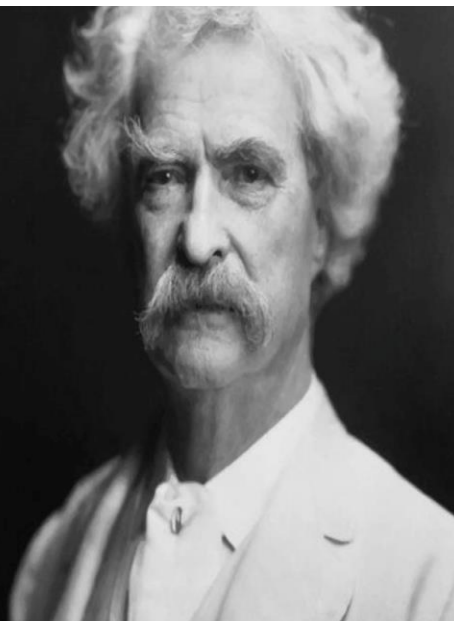
- High degree: 13
- Medium degree: 14
- Not meet: Separate CAS registry numbers and extended producer responsibility regimes

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

Did we overlook something?

It ain't what you don't know
that gets you into trouble. It's
what you know for sure that
just ain't so.

Mark Twain



From RRI to SSbD

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

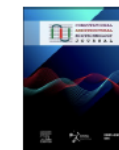


ELSEVIER

Contents lists available at ScienceDirect

Computational and Structural Biotechnology Journal

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



Perspectives

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



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Steffi Friedrichs^f, Elisabeth Heunisch^g, Martin Himly^h, Sabine Hofer^h, Norbert Hofstätter^h,
Danail Hristozovⁱ, Penny Nymark^j, Anna Pohl^k, Lya G. Soeteman-Hernández^b,
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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.

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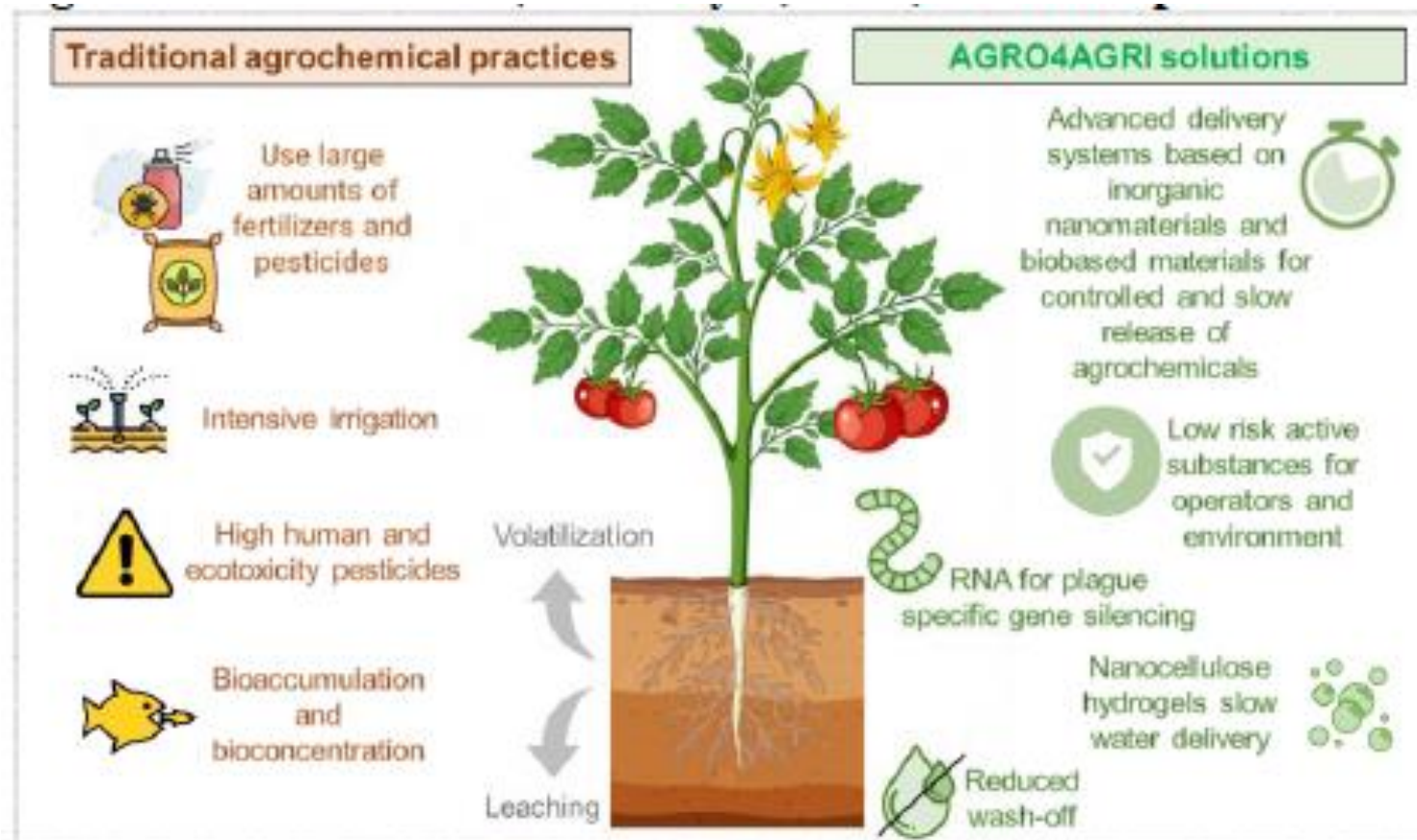
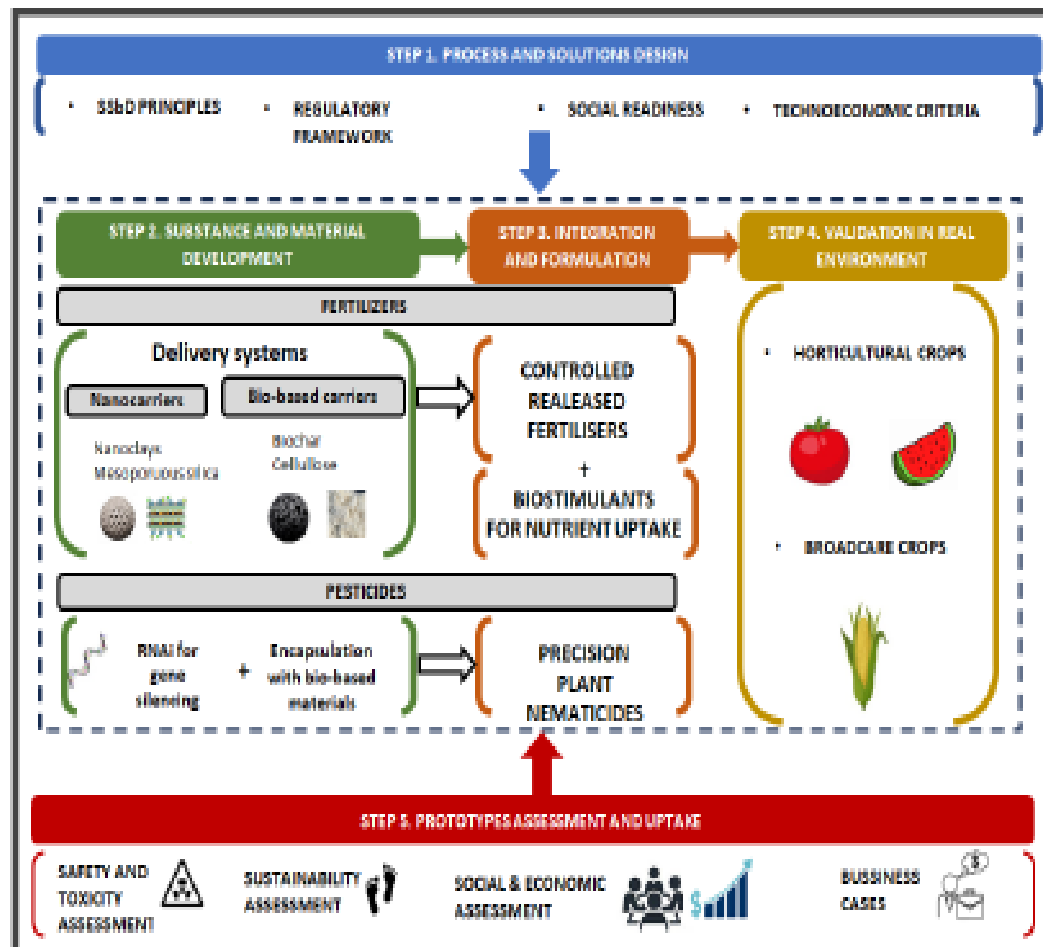


Figure 1 AGRO4AGRI concept



NEW SAFE AND SUSTAINABLE BY DESIGN AGROCHEMICALS DEMONSTRATED (TRL6) IN REAL ENVIRONMENT.

- Guidelines and recommendations
- EU roadmaps for agro-industry
- Business models

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), Bioaccumulative (B), Toxic (T) or Mobile



AGRO4AGRI

Thank you for your attention!

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