



Governing risks from emerging technology : IRGC's approach

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NANOTRUST

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Policy advice for safe and sustainable innovation - technology assessment to support innovation

1. Emerging risks – IRGC's approach
2. Emerging technologies
3. Policy and regulatory issues
4. Advanced materials
5. Particular challenges for ensuring the environmental sustainability of emerging technology outcomes

1. Emerging risks

New risks or familiar risks that become apparent in new or unfamiliar conditions

<p>Risks with uncertain impacts</p>	<p>Risks in complex, interconnected systems</p>	<p>Risks resulting from changes in context</p>
<p>High uncertainty and a lack of knowledge about potential impacts and consequences (interactions with risk-absorbing systems).</p> <p><i>Examples in application of advanced biotechnologies</i></p>	<p>Increasing complexity, emerging interactions and systemic dependencies have the potential to lead to non-linear impacts and surprises.</p> <p><i>Examples in energy or ICT systems</i></p>	<p>Changes in context (in societal/behavioural trends, regulation, or the natural environment) may alter the nature, probability and magnitude of expected impacts of previously known risks.</p> <p><i>Examples: antibiotic resistance</i></p>

IRGC's emerging risk governance guidelines



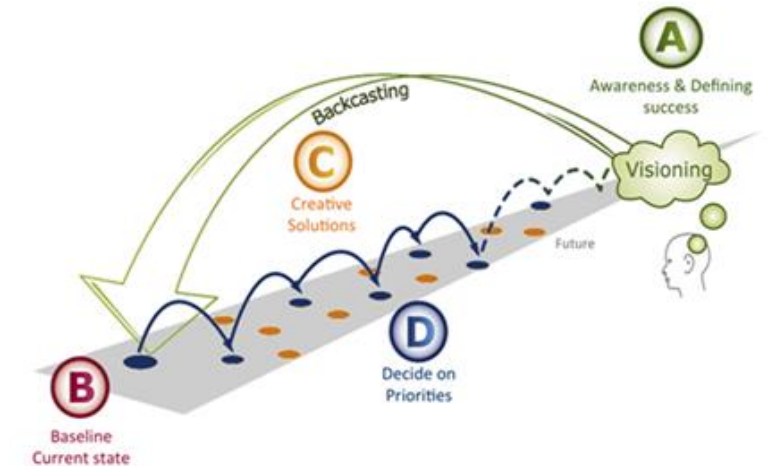
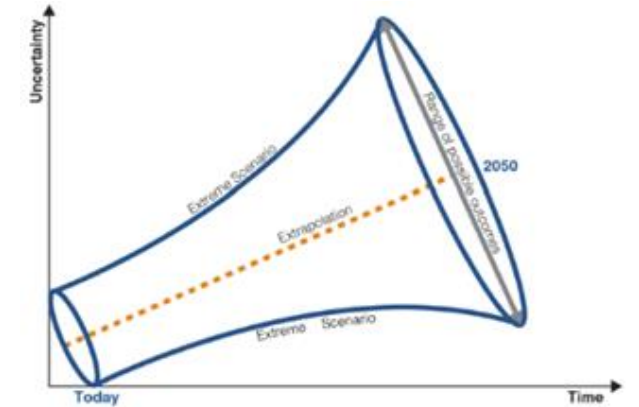
- | | |
|---|--|
| 1: Act on contributing factors to risk emergence | 2: Develop precautionary approaches |
| 3: Reduce Vulnerability | 4: Modify risk appetite in line with risk |
| 5: Use risk governance instruments for familiar risk | 6: Do Nothing |

2. Emerging technology

- New technologies or advancements in existing technologies that dramatically improve the performance of the technology. Some can be disruptive of existing industrial processes, or contribute to fundamental changes in the economy and society.
- **Five attributes** (Rotolo 2015)
 - (1) radical novelty
 - (2) relatively fast growth
 - (3) coherence
 - (4) prominent impact
 - (5) uncertainty and ambiguity
- Pose unique challenges to risk assessors and managers:
 - **there is generally a lack of procedures and tools to assess potential impacts**
 - **and a lack of data on which to build evidence.**

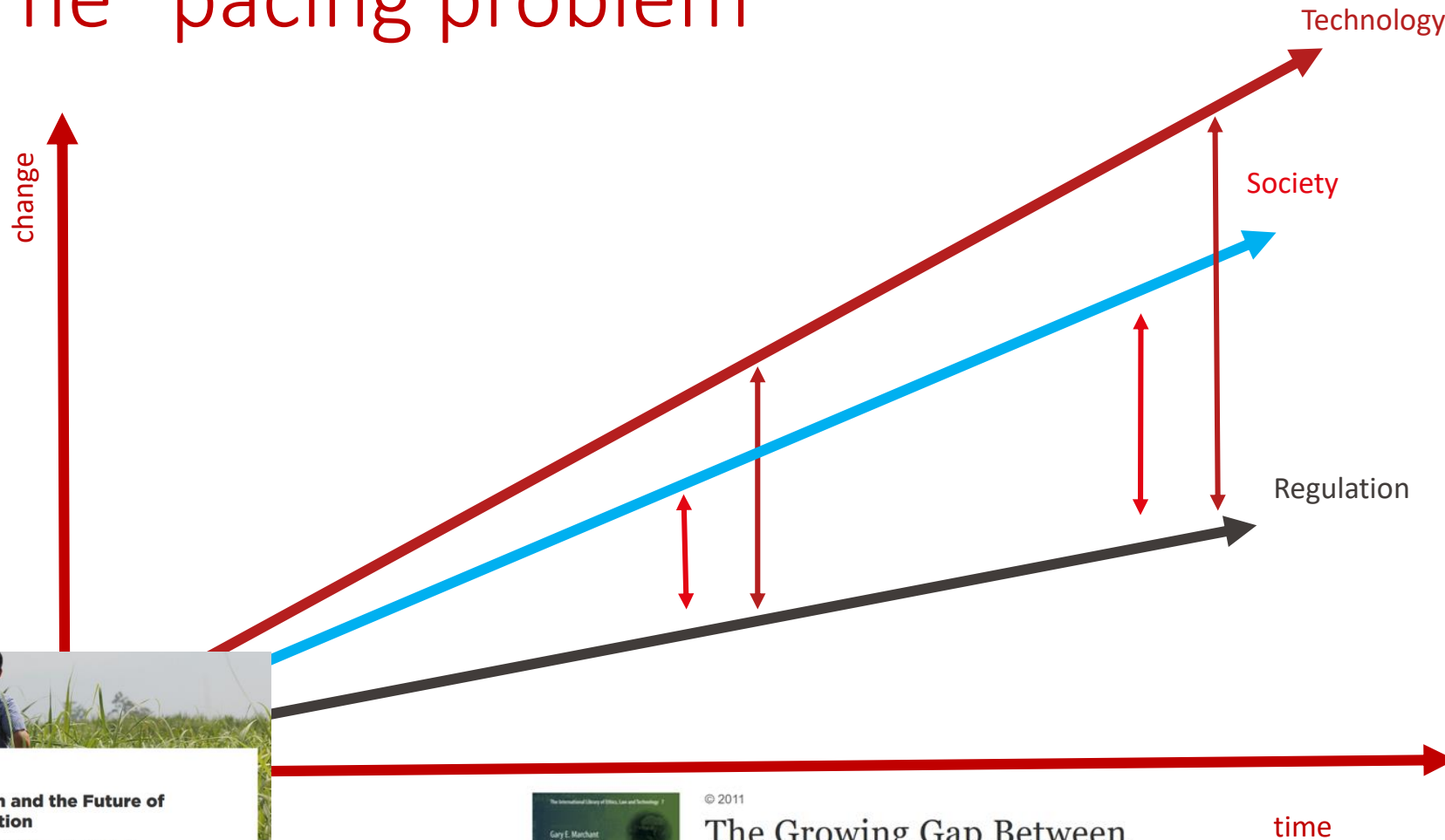
Emerging technology: future outcome, impact and consequences

- **Exploring** possible futures
 - possible outcome or new (emerging) technologies
 - possible application context in which they would deploy
 - possible outcome of various policy decisions
- **Visioning**, visualising and backcasting
 - Foresight: scenarios of possible futures
 - Backcasting
 - Do we like the future outcome?
 - If yes, how can we reach it?
 - If not, how can we avoid its materialisation?
 - Governing collaboration to reach the desired future vs. not achieve undesirable futures



3. Policy and regulatory issues

The "pacing problem"



- The problem is not the gap between S&T, regulation and society
- **The problem is when the gap is increasing**
- Can adaptive governance serve to "reset the clock" when and as needed?



The Bridge | Expert Commentary | Aug 8, 2018
The Pacing Problem and the Future of Technology Regulation

Why Policymakers Must Adapt to a World That's Constantly Innovating

By Adam Thierer Senior Research Fellow

What happens when technological innovation outpaces the ability of laws and regulations to keep up?

This phenomenon is known as "the pacing problem," and it has profound ramifications for the governance of emerging technologies. Indeed, the pacing problem is becoming the great equalizer in debates over technological governance because it forces governments to rethink their approach to the regulation of many sectors and technologies.

<https://www.mercatus.org/bridge/commentary/pacing-problem-and-future-technology-regulation>



© 2011
The Growing Gap Between Emerging Technologies and Legal-Ethical Oversight
 The Pacing Problem

Editors: Marchant, Gordon E. Allen, Braden R. Herrick, Joseph B. White (Eds.)

Planned Adaptive Regulation / Governance

Planned adaptive regulation is an approach in which a regulation is designed from its initiation to learn from experience and update over time.

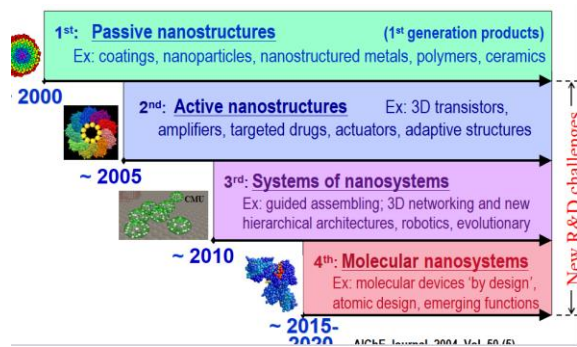
1. Planning for future review and revision of the governance arrangements
2. Funding of targeted research
3. Monitoring of performance and impact of existing arrangements
4. Review and revision

5. Vision of what the adaptability will enable to reach (goal)
6. Ability to respond to rapid changes
7. Trustworthiness between the actors that want to adapt the governance rules, together

Guiding principles

- 1. Regulate / govern applications: actors, products & specific domains**
 - Do not regulate technology per se
 - Do not regulate research, beyond scientific integrity / research ethics
- 2. Establish principles, but regulate on the basis of risk**
 - Focus on risk (of what, to whom, as a result of what),
 - Start with impact and risk assessment, produce risk-informed analytical outcome relevant to policy and industry
- 3. Try to be as operational as possible**
 - Produce hard and soft laws that make sense to a wide range of stakeholders, are acceptable, and established according to a legitimate process
- 4. When scientific evidence is low (uncertainty), substantive legitimacy of risk evaluation may be weak. Strive for procedural legitimacy of decisions.**
 - Engage with stakeholders

4. Advanced materials



Mike Roco, US NNI 2004; IRGC 2006

Zahra Mesbahi, André Gzásó,
 Gloria Rose, Daniela Fuchs,
 Anna Pavlicek*

Advanced Materials

Summary

Advanced materials are materials or material combinations with improved, novel or unique functionalities or properties. They are key technologies that are crucial for competitiveness and economic growth in the EU. The research framework programs of the EU, such as Horizon 2020 and Horizon Europe, reflect this importance. New developments range from innovative additives in food packaging and ultralight metal foams to transport systems for active ingredients in medicine or cosmetics. In many cases, these novel materials offer solutions to environmental problems, e.g. by saving energy and materials because of lighter weight. Consequently, they can contribute to a sustainable development of the environment, economy, and society. However, novel materials and/or new functionalities are also associated with uncertainties regarding human health and the environment. It is therefore important to highlight safety-relevant aspects at an early stage and identify potential risks in accordance with the precautionary principle. Because of the complexity of advanced materials, new approaches are required to gain all the necessary knowledge regarding their safety. The concepts of "safe by

Introduction

Materials with new or improved functionalities have always had great importance for humanity, evidenced by the fact that certain periods of time have been named after the available materials which shaped life (e.g. the Stone Age, Bronze Age, and Iron Age). Nowadays, rapid technological advances are resulting in material innovations at an even faster pace, i.e. the so-called advanced materials – a term that has been in use in the field of materials science for more than thirty years¹ – which bring about new functionalities and thus new possibilities, but also uncertainties in terms of their effects on humans and the environment. Because of their novel and advanced properties, it has often been pointed out that advanced materials can provide attractive solutions to global challenges, such as the need for continuous renewable energy, clean water, and transition to a low-carbon economy.

Advanced materials are promising in a number of ways: from new types of additives in food packaging and ultralight metal foams to transport systems for active ingredients in medicine or cosmetics (so-called "nanocarriers"), the applications cover various sectors and affect different industries. In many cases, these novel materials offer

There are several different approaches to define the term advanced materials, which have the following features in common: they concern materials or combinations of materials with improved, novel or unique properties or functionalities that are superior to currently existing conventional materials. As a result, the content of the term advanced materials depends on different points of reference and can vary contextually. For this reason, not only the material under consideration plays a vital role, but also the application and the selection of conventional materials as a reference basis. Moreover, the aspect of improvement or better suitability also includes a time component.

Advanced materials can be designed and developed from scratch by assembling atoms in new ways. However, they can also be developed by modifying traditional materials such as metals, ceramics, gels, and polymers, giving them new properties.⁴ These new properties, such as increased durability and elasticity, improve the performance of these materials which can therefore be superior to the conventional original materials. Materials used in hightechnology applications are sometimes also referred to as advanced ma-

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COMMISSION RECOMMENDATION

of 8.12.2022

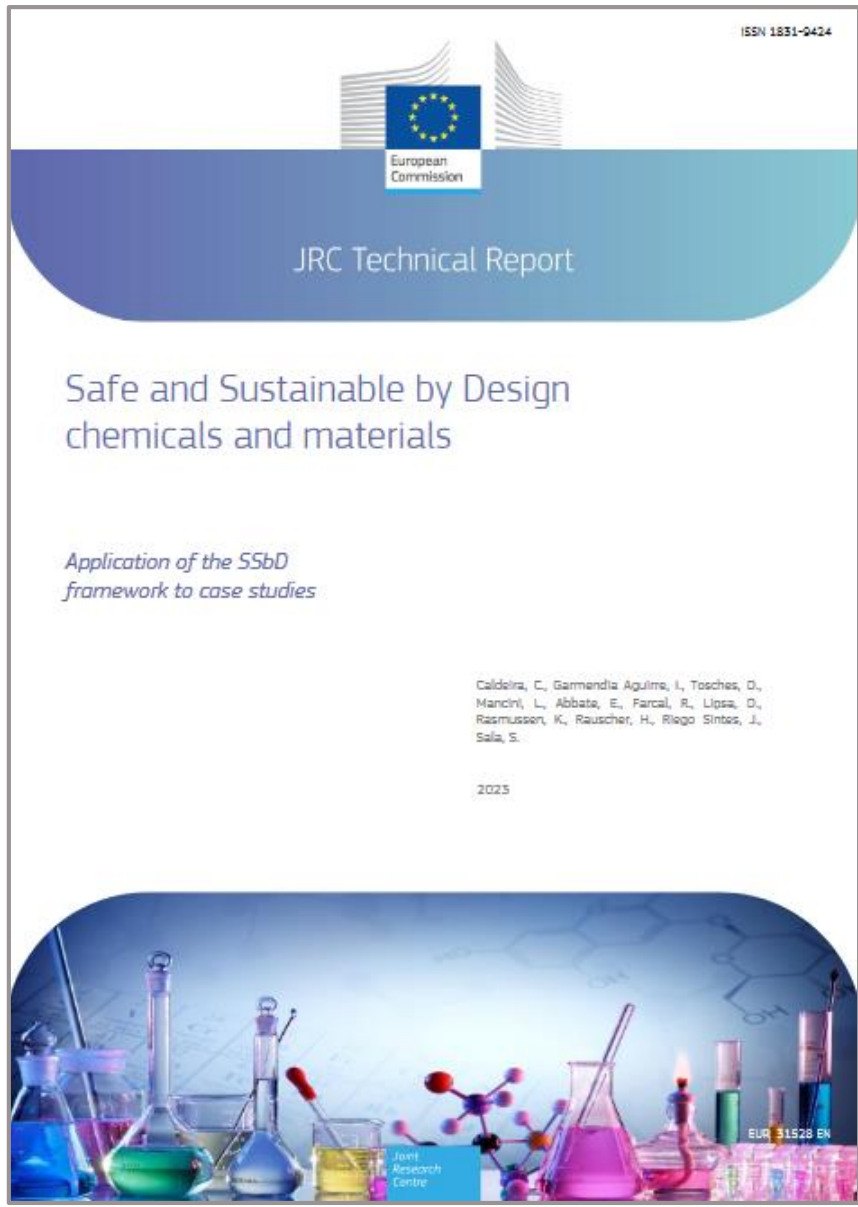
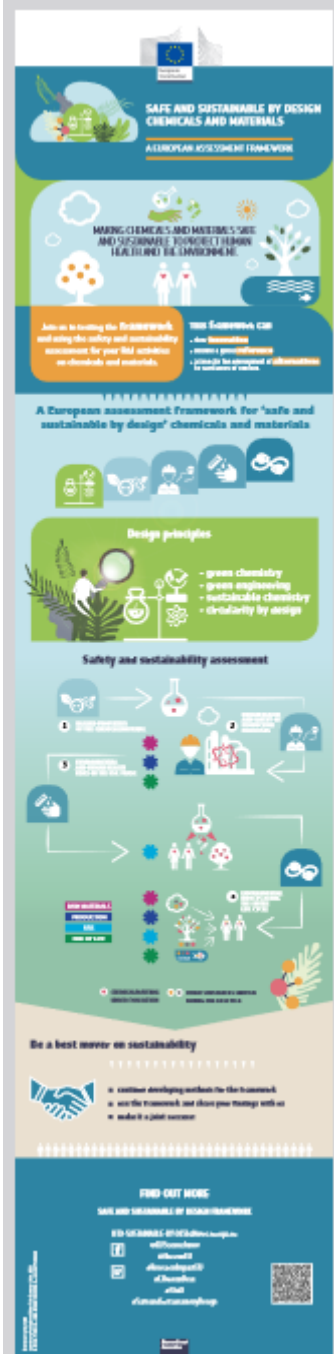
establishing a European assessment framework for ‘safe and sustainable by design’ chemicals and materials

ANNEX

Framework for the future definition of safe and sustainable by design criteria and the procedure for assessing chemicals and materials

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JRC Technical Report

Safe and Sustainable by Design chemicals and materials

Application of the SSbD framework to case studies

Caldola, C., Garmendia Aguilera, I., Tosches, D., Mancini, L., Abbate, E., Farcal, R., Lipsa, D., Rasmussen, K., Rauscher, H., Riego Sintes, J., Sala, S.

2023

EUR 31528 EN

Is it realistic to assume that *sustainability* can be established 'by design'?

- Sustainability is defined as the ability to meet today's needs without compromising long-term needs related to the environment, society and the economy.
 - Challenges related to biodiversity, ecosystems and the services they provide, the use of natural resources and climate, which can be adversely affected by chemical technologies
 - Damage would manifest in the medium to long term (i.e., not immediately), and are different from that affect short term human and environmental safety.
- Sustainability cannot be 'fixed' or 'controlled' in the same way as safety can.



Future-proof Approaches for Risk Governance

Horizon 2020 NMBP-13 projects



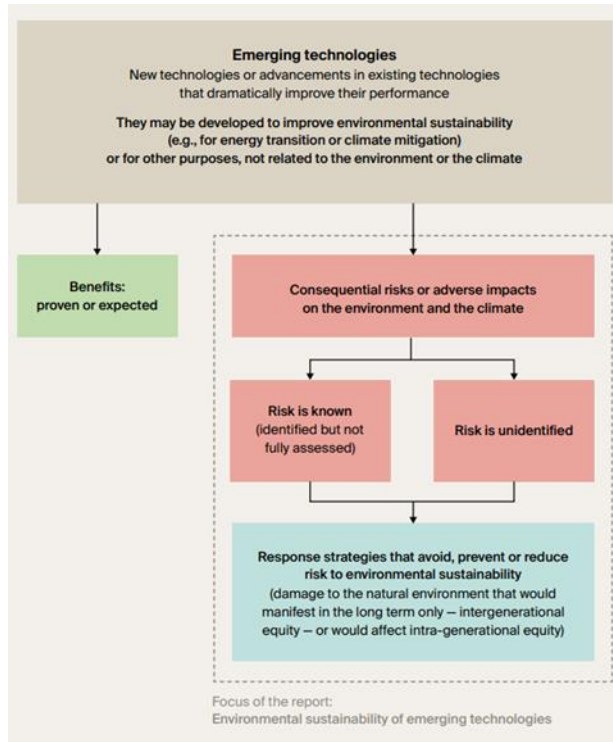
The three NMBP-13 projects have received funding from the European Union's Horizon 2020 Research and Innovation Programme under Grant Agreement No. 814401, 814530, and 814425.

Conference, 24/25-31 January 2023
Organised in collaboration with the OECD's Working Party on Manufactured Nanomaterials (WPMN).

Priorities for better governance of nanomaterials in the future

- **Priority #1: more connectivity and broader engagement with key stakeholders**
 - to collect opinions, concerns, and critical expertise that may not be captured in technical hazard and risk assessment alone, and need to be well understood to ensure effective risk management.
- **Priority #2: access to multi-disciplinary knowledge and expertise,**
 - in particular for more systematically integrating social sciences in assessment and decisions.
- **Priority #3: better quality data and easier access to data sets**
 - along with appropriate tools for risk assessment.

5. Ensuring the environmental sustainability of emerging technology outcomes (ESET)



- Can we ensure that outcomes of emerging technologies be environmentally sustainable?
- Guidance to various stakeholders



ESET



MATTERS OF CONCERN

- Uncertainties involved in emerging technology
- Lack of appropriate instruments to assess sustainability
- Solutions currently developed to today's challenges may not be sustainable
- Temporal mismatches and biases
- Limitations of containment approaches
- Ambiguities about societal preferences
- Pacing problem faced by regulation
- Lack of ethical guidance

CROSS-CUTTING ASPECTS

- Check the distribution of benefits and risks
- Differentiate foundational vs applied technology
- Explicit the concept of essentiality
- Various impacts from (e.g. energy consumption) and to (e.g. ecosystems)
- Cause-effect relationships may be hard to identify

OVERARCHING RECOMMENDATIONS

- Early-stage technology assessment
- Ex-ante (or prospective) life-cycle assessments
- (Safety and) sustainability by design
- Value proposition for sustainability
- Flexible and adaptive regulatory frameworks
- Compass to indicate the direction to sustainability

Anticipatory life cycle assessment for environmental innovation

- Modeling a future product in a future environment
- In contrast to conventional (ISO type) and *ex-ante* LCAs, *anticipatory* LCA could overcome the difficulty of gaining environmental insight into problems before they manifest at scale.
 - *Ex-ante* LCA aims to compare the assessment of pre-market technologies to determine expected or projected environmental gains relative to an incumbent. It is suitable for stage-gate / TRL innovation models.
 - *Anticipatory* LCA aims to identify uncertainties most critical to the environment. It is developed to match lean / agile innovation models that emphasize recursion and flexibility. It starts from an idea of how to solve a given problem or benefit from a market opportunity. The goal of anticipatory LCA is to rank-order environmental uncertainties for technology developers.

Guidance to various stakeholders

Lawmakers and regulators

1. Establish the necessary legal basis for sustainability
2. Consider precautionary approaches
3. Mandate the use of specific risk and impact assessment tools
4. Implement principles of planned adaptive regulation

Technology developers

1. Emphasize the benefits of adopting a long term view on benefits and risk of technological innovation
2. Build upon personal commitment to do good
3. Consider guidelines for RRI
4. Implement sustainability by design

Research funding organisations

1. Require the legal basis for mandating attention to ES in grant applications
2. Establish criteria to evaluate the attention of researchers to ES
3. Steer the thinking of researchers towards ES
4. Fund applied research on tools to identify, assess and manage risks to ES (inc. forward-looking LCA)

Technology investors

1. Request the provision of prospective LCA outcome, application of SSbD, etc.
2. Accelerate the design and implementation of ESG investing and, particularly, double materiality
3. Acknowledge and support the trend towards environmental sustainability
4. Reduce greenwashing and overcoming critics to ESG rating and investing

Industry

1. Select technologies with dual benefits: to business and to the environment
2. Implement business models that reward sustainability
3. Work with the future value chain operators
4. Share data with regulators

Standard-setting organisations

1. Steer practices that prioritise the long term
2. Encourage the formal adoption of methods for decision under certainty and high stakes
3. Intensify efforts to develop standards for forward-looking LCA
4. Develop principles or standards for emerging technologies risk governance



IRGC (2015). Guidelines for Emerging Risk Governance



IRGC (2022). Ensuring the environmental sustainability of emerging technologies 1 - Report



IRGC (2023). Ensuring the environmental sustainability of emerging technologies 2 – Edited volume



IRGC (2023). Ensuring the environmental sustainability of emerging technologies 3 – Guidance to stakeholders

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