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Ensuring the environmental sustainability of emerging technologies – 2

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Ensuring the environmental sustainability of emerging technologies - 2

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Introduction

Marie-Valentine Florin[1]

In 2021, the EPFL International Risk Governance Center (IRGC) started work on a project about the issue of "ensuring the environmental sustainability of emerging technologies" (ESET)[2]. The project reviews concerns about the potential environmental unsustainability of some emerging technology outcomes, i.e., unfolding in the future, and evaluates the extent to which these concerns could be more effectively addressed in technology design and development, before large-scale deployment.

It is no longer sufficient to let people innovate and then address negative externalities with regulations. What is new is that the potential negative impacts of some of today's emerging technologies (e.g., machine learning, climate engineering, advanced chemicals, synthetic biology) could occur at an unprecedented scale and speed, and be irreversible. Some technologies could quickly impact major systems on which we depend (natural ecosystems, climate). Therefore, we cannot use the "trial and then correct the errors" method often used in the 20th century. Nor can we wait until we have extensive datasets. We must become better at anticipating, recognising patterns and intervening proactively, even with limited data available.

In this project, IRGC's goal is thus to improve the ability to detect and address a risk to environmental sustainability early in the technology development process, before usual risk and impact assessment is possible. IRGC's priority is not to explore conditions of success of emerging technologies developed *for* environmental sustainability, but to explore what could be done to ensure that *any* emerging technology does not appear later in its deployment to cause indirect, adverse consequences on the environment. A first report, "Ensuring the environmental sustainability of emerging technologies"[3], was published in March 2022. The report describes the current attitude towards the issue in various technology domains and instruments available or considered to help reach the goal of environmental sustainability.

In 2022, IRGC explored in more depth some emerging technologies and invited experts to describe what is being done in their domain toward the goal of the project. Papers 1 to 8 discuss specific emerging technologies and their possible applications. Papers 9 to 12 present types of instruments or approaches relevant across several domains to identify, assess and manage threats that new technologies in development could pose to environmental sustainability. The papers[4] focus on future applications or products and describe what is currently done or could be done to identify and anticipate risks earlier than conventional product assessment or regulators usually require.

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[2] IRGC is grateful to Chad M. Baum, Lucas Bergkamp, Carlos Felipe Blanco, Romain Buchs, Priscilla Caliandro, Martha Crawford, Christian Moretti, Arthur Petersen, Rainer Sachs, Christian Schwab, and Benjamin Sovacool for their contribution to writing this introduction.

[3] IRGC. (2022). Ensuring the environmental sustainability of emerging technologies. EPFL International Risk Governance Council (IRGC). See doi.org/10.5075/epfl-irgc-292410.

[4] On 27 June 2022, preliminary versions of the papers were reviewed in an expert workshop, which also included discussions around tentative cross-sectoral learnings about how ESET is being approached in various emerging technology domains.

Papers on technologies and their possible applications

- [1] **Risk governance of emerging technologies: Learning from the past** (R. Sachs, Sachs Institute)
- [2] **Gene drives: Environmental impacts, sustainability, and governance** (J. Kuzma, North Carolina State University)
- [3] **Smart materials and safe and sustainable-by-design — a feasibility and policy analysis** (S. F. Hansen, F. Paulsen, Danish Technical University, and X. Trier, University of Copenhagen)
- [4] **Ensuring the environmental sustainability of emerging technologies applications using bio-based residues** (C. Moretti, ETH Zurich)
- [5] **Lithium-ion batteries for energy and mobility: ensuring the environmental sustainability of current plans** (P. Caliandro, A. Vezzini, Bern University of Applied Sciences)
- [6] **Ensuring the environmental sustainability of emerging space technologies** (R. Buchs, ClearSpace)
- [7] **Ensuring the environmental sustainability of emerging technologies for carbon dioxide removal** (B. Sovacool, C. M. Baum, Aarhus University)
- [8] **Is cultured meat environmentally sustainable?** (C. N. Schwab, M. Boursier, EPFL)

Papers on approaches for ensuring that outcomes or emerging technologies are environmentally sustainable

- [9] **Practical solutions for *ex-ante* LCA illustrated by emerging PV technologies** (S. Cucurachi, C. F. Blanco, Leiden University)
- [10] **Anticipatory life cycle assessment for environmental innovation** (T. P. Seager, Arizona State University)
- [11] **Liability's role in managing potential risks of environmental impacts of emerging technologies** (L. Bergkamp)
- [12] **Ensuring environmental sustainability of emerging technologies — the case for applying the IRGC emerging and systemic risk governance guidelines** (R. Sachs, Sachs Institute)

This section introduces the twelve papers of the edited volume and includes: (i) a brief analysis of common themes and (ii) specific observations and learnings from each paper transferable to other domains. Together, they complement the learnings and recommendations presented in the March 2022 report[3]. Readers interested in ensuring a "better safe [and sustainable] than sorry" approach are thus referred to that report, where they can find other cross-sectoral aspects relevant to various technology domains (chapter 3), possible response strategies (chapter 4), and overarching recommendations (chapter 5).

Common themes

Certain themes are recurrent across several of the twelve papers published in this volume. We present them briefly below, indicating which papers mention them [numbers in brackets refer to papers as numbered in the list on the left side of this page].

■ Uncertainty, in the sense of lack of knowledge, is the first aspect noted in all technology domains

There are uncertainties about many aspects, including which exact future applications will be developed, the large-scale deployment of new techniques that affect the natural environment [7], or the behaviour of new materials or organisms when they are or could be released into the environment [3, 2]. Uncertainty also concerns which aspects of an emerging technology could cause risk to environmental sustainability, risk pathways, and potential impact [2]. It is often linked to an incomplete understanding of causal links [11], unavailability of data [3, 6, 7, 9], insufficient data sharing [5] or poor data quality [3], suggesting that:

- more resources are needed for data collection [2, 10];
- currently available instruments for scientific assessment may not be able to provide the kind of data needed to assess future impacts of new technology outcomes [9];
- uncertainty assessment itself may provide valuable information to decision-makers; and
- regulatory requirements [5] and liability systems could be tuned as incentives to collect data regarding *ex-ante* assessment [11].

PERVASIVE UNCERTAINTY

■ New approaches are needed for assessing risk from a future technology application

There is no robust technical approach to estimate potential risks when products are not deployed yet, and systemic consequences have not materialised. One way to address the challenge of anticipatory risk assessment is to define very broadly the boundaries of the future system being assessed to include potential effects far away from the initial cause of risk [2]. However, broadening creates additional challenges.

The following recommendations have been developed by Devos et al. for risk assessment of gene drive organisms [2] and could be transferred to other technology domains:

- "developing more practical risk assessment guidance to ensure appropriate levels of safety;
- making policy goals and regulatory decision-making criteria operational for use in risk assessment so that what constitutes harm is clearly defined;
- ensuring a more dynamic interplay between risk assessment and risk management to manage and reduce uncertainty through closely interlinked pre-release modelling and post-release monitoring;
- considering potential risks against potential benefits, and comparing them with those of alternative actions (including non-intervention) to account for a more comprehensive (management) context; and
- implementing a modular, phased approach to authorisations for incremental acceptance and management of risks and uncertainty".[5]

NEW APPROACHES TO ANTICIPATE RISKS

■ Life cycle assessment (LCA) could become an instrument of choice for assessing the impacts and risks of emerging technology products and applications

However, because of the many challenges in evaluating future environmental impacts and comparing them with alternatives [4, 9], current LCA ISO standards[6] need to be updated and extended to guide towards harmonised practices in *ex-ante* LCAs.

Ex-ante LCA aims to model a future product or application of emerging technology and the economic system in which it will be deployed [9] and scale up manufacturing and related processes from lab/pilot scale to future large-scale production [8, 9]. *Ex-ante* LCA offers regulators, policymakers, and investors (including research funding agencies) a concise rationale for incentivising or constraining technology development projects that follow a conventional innovation model, such as the stage gate model [10].

However, many technology developers or innovators follow a more lean and agile model, for which other types of forward-looking LCA are needed. For example, *anticipatory* LCA is a type of LCA designed to be effective under conditions of extraordinary uncertainty. It searches for research priorities that would resolve the most critical uncertainties in environmental assessment [10]. Therefore, it complements the searching nature of lean and agile innovation models, whereas *ex-ante* LCA complements the planning and execution nature of technology readiness level (TRL)/stage-gate innovation models. It questions more than tries to provide quantitative assessments. This LCA approach can be relevant to most emerging technology domains, and especially for potentially disruptive technologies [10].

FORWARD-LOOKING LIFE CYCLE ASSESSMENT

■ It is not sure that environmental sustainability could ever be ensured *ex-ante*, given inherent uncertainties

Regarding employing LCA methods to assess sustainability, as suggested by currently proposed frameworks for assessing chemicals' "safety and sustainability-by-design" (SSbD) [3], a question is whether sustainability can be 'fixed' in the same way safety (or sometimes risk) can. This is a non-trivial

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[5] Devos, Y., Mumford, J. D., Bonsall, M. B., Glandorf, D. C., & Quemada, H. D. (2021). Risk management recommendations for environmental releases of gene drive modified insects. *Biotechnology Advances*, 107807.

[6] ISO. (2006a). *ISO 14044:2006 Environmental management – Life cycle assessment – Requirements and guidelines*. iso.org/standard/38498.html and ISO. (2006b). *ISO14040:2006 Environmental management – Life cycle assessment – Principles and framework*. iso.org/standard/37456.html

question because the concept of sustainability is multi-faceted, and its application can be relative and variable[7]. Furthermore, sustainability assessment can change over time and be subjective. For example, there is a broad consensus that electrifying transportation systems can accelerate the reduction of CO_2 emissions (climate change risk), and electric batteries are essential for that. However, without adequate large-scale plans to implement a complete life cycle approach to produce, reuse and recycle batteries in circular economies, the gains in sustainability can be significantly reduced [5].

IS ENSURING ENVIRONMENTAL SUSTAINABILITY A REALISTIC GOAL?

■ Technology assessment or LCA often highlights the presence of trade-offs

Ideally, the LCA of an emerging technology outcome should also help evaluate trade-offs with other uses and among different environmental impacts [6, 7, 9]. However, trade-offs also affect non-technical aspects such as cost and expected revenue, social acceptability, business priorities, and many others that are not captured in LCAs. Furthermore, LCAs can identify these trade-offs but are not tools to resolve them. When a technology is evaluated relative to another, decisions will usually involve several options, and techniques for trade-off resolution or decision under uncertainty will have to be employed.

IDENTIFY AND RESOLVE TRADE-OFFS

■ Decision-makers are confronted with challenges related to the substantive validity of risk evaluation

Risk evaluation concerns analysing risk assessment outcomes and asking whether a new technology's attendant risks will be acceptable, tolerable, or not. Risk evaluation is of utmost importance when there is deep uncertainty and ambiguity. It can help to determine the acceptable level of risk [2] in a specific case and directly informs the decision to authorise or regulate an activity that involves risks, or even to prohibit the development or application of new technologies in specific domains.

Scientific evidence or substantive validity of a risk assessment is often missing or inconclusive. This can be the case when outcomes of the risk assessment cannot be compared to what might potentially happen in the real world, either because large-scale deployment is not yet possible [7] or because a particular environmental release is not authorised [2].

Furthermore, even when done by scientists and other experts, risk analysis is laden with assumptions and interpretations based on values [2]. Science cannot determine whether a risk is "acceptable" in the abstract (as this requires a policy or political decision), and even scientists may have diverging views about the sustainability of new products. This is the case for example with advanced materials (especially so-called active materials), mainly because they are adaptive and gain their attractiveness precisely thanks to their ability to modify their effects when in their target environment [3]. It is also essential to recognise that matters of individual or societal preferences can (i) motivate the acceptability of new technology applications [8] even if there is no substantive validity of their environmental sustainability, (ii) discourage the adoption of a new technology even if the absence of environmental harm is proven, or (iii) trigger the use of technology even if its environmental unsustainability is proven. In other words, a particular technology outcome may be acceptable for some communities, societies, cultures or individuals, and not for others.

INSUFFICIENT SUBSTANTIVE VALIDITY OF RISK EVALUATION

■ Methods for making the risk evaluation process more acceptable and legitimate must be adopted to improve decisions about future technology applications [2]

When substantive evidence is insufficient, notably for regulatory purposes, the question of "how to decide" becomes more prominent. In that case, the procedural validity or legitimacy of the risk evaluation (that is, how the risk evaluation is conducted) becomes even more critical than attempting to ascertain the substantive validity of a particular risk

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[7] The concept of sustainability has been quite well described since 1987 (Brundtland Report), adopted in the Rio Convention in 1992 and then in many international conventions. There is no ambiguity in the concept, but specific applications can become challenging and ambiguous, primarily because of differing stakeholders interpretations and objectives.

evaluation prior to deployment [2]. Decision-makers can consider establishing procedural legitimacy by adopting formal and standardised frameworks and processes that are deemed sufficient to provide the necessary evidence and legitimacy to support a decision regarding future technology outcomes, especially taken under deep uncertainty.

IMPROVING PROCEDURAL VALIDITY OF RISK EVALUATION

■ Robust deliberative decision mechanisms can be helpful when scientifically-informed decisions cannot be made

Despite (and because of) the complications of producing relevant information for assessing the environmental sustainability of emerging technology outcomes, it seems crucial to pay attention and devote resources to developing robust and deliberative mechanisms for decision and governance. Examples from the past have shown that inappropriate decisions based on false negatives can have severe consequences for the environment [1]. In the face of deep uncertainty and ambiguity, decision-makers should engage with stakeholders and the public who can help them identify risk endpoints of concern (which may differ based on geography or culture) and determine acceptable levels of uncertainty or risk-benefit distributions. Stakeholders and the public should also be involved in developing and examining future regulatory frameworks [2].

NEED ROBUST DELIBERATIVE DECISION-MAKING

■ A particular decision challenge exists when an emerging technology is anticipated to generate private benefits while risks will be delayed or mutualised with the public

There is a problem of misalignment of benefit and cost when decisions are made on expectations of short-term private benefits prioritised over the potential collective burden of possible long-term costs. This involves resolving or deciding about some of the trade-offs emphasised during risk evaluation.

This raises first a moral hazard problem, i.e., a lack of incentive to guard against risk because adverse consequences would only affect others, such as next generations or people in other regions. In the former case, there is a risk to prioritise new technology whose adverse effects might manifest only in the longer term. For example, if we know that a gene drive organism can help to mitigate human diseases, but ecological risks would manifest only in the future, we may be less likely to invest in prevention or control methods today, as future generations will bear the risk [2]. In the case of chemicals, this would manifest if advanced materials with considerable short-term benefits but potential – yet non-conclusively proven – adverse effects were authorised [3]. In the case of carbon dioxide removal, we may incentivise the deployment of approaches that will quickly remove CO_2, without addressing the risk of impermanence or even reversal [7].

Second, this challenge exists when risks to environmental sustainability affect common-pool resources or public goods [2]. Common-pool resources face the challenge of the tragedy of the commons [6] when risks are shared (mutualised) while benefits are privatised. There is a risk that specific, often private, interests capture the value created by technology, and sometimes a risk of technology lock-in. Stakeholders affected by the risk have no direct control over the technology and may bear a more significant share of the harm [2, 7]. When those who deploy a new technology do not bear the cost of all the adverse impacts, they might make riskier decisions than would be socially desirable. A business may not prioritise environmental sustainability unless adequate incentives and governance rules can be established and implemented [6].

PROBLEMS ALSO OCCUR WHEN BENEFITS AND RISKS DO NOT ALIGN

■ Incentives for technology developers and investors to include environmental sustainability in their preferences are much needed

Regulation and liability can provide such incentives. Technology development should be steered towards paying attention to environmental sustainability [2, 3, 5, 7]. Significant uncertainties about the outcomes of emerging technologies and their impact on the natural environment often prevent regulators from intervening and prescribing specific management measures, except if conditions are deemed to be present for implementing a precautionary approach. However, such approaches are often seen as hindering innovation, so technology developers and those who support them prefer other types of solutions, for example, based on prevention, adaptive governance or resilience building.

In parallel, a question is whether liability systems could act as incentives to generate data about potential environmental risks, thus acting as an *ex-ante* incentive to prevent environmental harm. It may be possible to change liability rules and procedures to provide better incentives, but trade-offs also need to be made here. In any case, appropriate legislative amendments would be needed to establish the legitimacy of courts to use liability systems in this direction [11].

EX-ANTE REGULATORY INCENTIVES

■ Generic capabilities can help address risks that come with emerging technologies

For example, in its guidelines for emerging risks governance[8], IRGC suggests that organisations develop four distinct capabilities [12]:

- Enhancing proactive thinking to identify future threats and opportunities. This involves creative foresight capabilities, monitoring new technology deployment's impact and risk reduction measures.
- Evaluating the organisation's willingness to bear or avoid risk (act on its risk appetite) in its future strategies. Increasing risk appetite is an option that a business may choose to develop, provided it can afford potential downsides.
- Prioritising investments in specific key emerging technologies according to their potential to alleviate existing risks, and allocating equally sufficient resources to ensuring that new risks are not created without adequate prevention and reduction.
- Fostering internal communication and building a forward-looking culture to benefit the whole organisation, which could also expand to the public.

These capacities are relevant for addressing the challenge of ensuring the environmental sustainability of emerging technology outcomes [12].

BUILDING A FORWARD-LOOKING CULTURE

■ Is the question of environmental sustainability only an afterthought in emerging technology research and development?

In some cases, yes; in others, no. Examples of the latter include space technologies and carbon dioxide removal, which are domains where long-term sustainability concerns do not appear to be always prioritised. In contrast, environmental concerns are clearly at the centre of motivations for not releasing gene drive organisms in the open environment. Also, there is rapid catch-up in domains such as chemicals, with the EC 2020 Chemicals Strategy for Sustainability[9] and its ambitious plans to implement sustainability in decision criteria and frameworks for SSbD [3], and electric batteries, with large-scale plans for reusing and recycling millions of batteries in the years to come [5].

ENSURING "BETTER SAFE AND SUSTAINABLE THAN SORRY"

Conclusion

Altogether, papers in this edited volume demonstrate that, despite many efforts underway, there are still gaps in all domains to ensure that emerging technology outcomes do not produce risks to environmental sustainability. For example, ensuring "safety and sustainability-by-design" may be very challenging for all advanced materials. Technology developers should not see risk governance as an afterthought or a burden, only to be addressed if required by regulation or public pressure. Risk governance aims to avoid, prevent or reduce risk, and thus indirectly helps realise the benefits of new technology.

A next question concerns the extent to which specific guidance can be provided to allocate incentives and responsibilities in a way that technology developers, grantmakers, investors, policymakers and others have an intrinsic interest in caring for environmental risks.

The twelve papers are summarised below, with specific takeaways.

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[8] IRGC. (2015). Guidelines for emerging risk governance: Guidance for the governance ofunfamiliar risks. EPFL International Risk Governance Council (IRGC). doi.org/10.5075/epfl-irgc-228053

[9] EC. (2020). Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: Chemicals strategy for sustainability towards a toxic-free environment. eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2020:667:FIN

Paper 1

Learning from past examples

The first paper, written by Rainer Sachs, "Risk governance of emerging technologies: Learning from the past", reviews some examples from the past. Some technical products or applications have been abandoned after their risks to the environment were scientifically proven and recognised by stakeholders. This is the case with chlorofluorocarbons (CFCs) and large-scale biofuel production. CFCs have been used for some time without a sufficient understanding of the environmental damage they were causing. The case of liquid biofuels from agricultural products illustrates that large-scale application of known techniques can cause significant unintended impacts across system borders. Some others, like neonicotinoids, are still in use even though their environmental sustainability is contested by scientists, but farmers say they need them. In each case, Rainer Sachs notes facts and draws learnings for the risk governance of current and future emerging technologies.

Emerging technologies develop in a context of assumptions regarding expected future benefits and potential risks, and testing these assumptions. Testing is made in several stages, from early phases of laboratory experiments, during development, to small-scale experimentation in real-life conditions. Unfortunately, detrimental environmental impacts are often detected or recognised only late in the development and application phases, making risk mitigation measures complex and costly. There were early signs of adverse consequences that either were not acted upon until very late, after significant damage had occurred (ozone layer), or have not led to a complete ban or prohibition (neonicotinoids). Therefore, early risk assessment is instrumental to maximising net benefit to society.

The main types of errors in risk assessment are false positives, or type I errors, assuming that a technology is harmful, but further developments show no or insignificant harm in reality, and false negatives, or type II errors, where initial assumptions about no or acceptable potential harm turn out to be wrong. The case of type II errors is even stronger when deliberate efforts to search for potential harm do find reasons for concerns, but those are misinterpreted, not recognised or not acted upon (type III errors).

Furthermore, assessing risks in new technology is often affected by a bias towards relying upon pre-existing knowledge (data, models, methods), even if it is incomplete or inappropriate, and another bias where unfamiliar, unexpected, or even unwanted consequences of emerging technology are granted comparably little attention and resources, and are often anticipated based on bold assumptions.

In the case of CFCs, the accumulation of scientific evidence combined with public attention to the 'ozone hole' and the availability of substitutes catalysed cooperation between stakeholders towards banning the substance.

In the case of large-scale biomass production for biofuels, which many governments supported through subsidies around 2005–2012, and even mandated in the 'clean' transportation fuel mix, it is mounting evidence of adverse consequences on land use, food production, biodiversity, greenhouse gas emissions, social and other aspects, that triggered stricter regulation of biofuel production to ensure sustainability. The case of biofuels revealed the gap between initial expectations and actual outcomes in the form of unintended consequences. New technologies or applications are often introduced for a particular benefit or to achieve a specific goal. However, the benefit or goal may not realise because unintended or unanticipated consequences may arise due to deficits in risk assessment.

In the case of neonicotinoid pesticides introduced in the mid-1990s and increasingly used in agriculture, scientific evidence of harm accumulated progressively. However, due to the high political and economic stakes, the European ban in 2018 for outdoor use led to a flurry of exemptions ('emergency authorisations') at a national level. The growing observation of adverse effects on bees, in particular, has triggered an intense controversy about significance and causality among different stakeholder groups (beekeepers, environmentalists, manufacturers, scientists, and policymakers).
In public debates, scientists are judged on their position on the controversy, and scientific results are frequently misinterpreted. Conflicts of interests are still not managed in a way that satisfies all groups. Requests for exemptions on the use of neonicotinoids illustrate the principle of 'essentiality', i.e., even if detrimental to the environment, a technology can continue to be used if it is deemed 'essential' for the economy or society, and there is no substitute at a similar cost.

The three cases discussed in this paper show the presence of false negatives. CFCs were not expected to accumulate in the stratosphere, thus causing long-term effects. The growing of agricultural crops to produce biofuels to reduce fossil fuel consumption did not consider the full array of consequences in the ecological and societal systems. Risk assessment of neonicotinoids was based on inadequate methods, such as insufficient detection limits or a lack of understanding beehive system.

Learning from the past would ideally enable decision-makers to understand that, when not enough attention is paid to the downside risk of an emerging technology (countervailing risks, second-order consequences), its successful deployment may be compromised. Unfortunately, the cases of CFCs and neonicotinoids show that the industry could profit for quite some time before the substances were banned, and the industry can request exemptions if the product is deemed essential.

Specific learnings relevant to other sectors or technology domains

Generic recommendations for technology developers, industry and funders include providing sufficient resources to address *ex-ante* ignorance and uncertainty, engaging in foresight, early-warning systems and exploratory impact and risk assessment, and recognising and dealing with conflicts of interest.

In addition, obstacles or behavioural biases that can prevent learning and making risk-wise decisions must be addressed. The explicit acknowledgement and communication of what is unknown or unknowable is important and often neglected, although it is essential for effective risk governance. In particular, limitations of understanding and modelling must be made transparent.

Paper 2

Gene drives

Jennifer Kuzma's paper "Gene drives: Environmental impacts, sustainability, and governance" overviews gene-drive organisms (GDOs) and their potential impacts on sustainability and the environment, and suggests special considerations for governing associated risks.

Gene drive systems enable the genetic modification of entire populations in situ (within the ecosystem) by releasing just a few individuals of that species. Newer GDOs utilise gene editing technologies like CRISPR to bias the inheritance of genes with each generation towards 100%. Gene drives can be designed to cause the population to decline (e.g., via female killing) or be beneficial to the population (e.g., via genes that immunise against a disease). GDOs also promise to control agricultural pests with fewer pesticides, protect endangered and threatened species against pests and ecological hazards, and reduce the transmission of human and animal diseases.

However, their release in the open environment presents characteristics of emerging risks that are accompanied by significant complexity, uncertainty and ambiguity. Although gene drive systems can be designed to be limited in geography or spread, or to be reversible, it is difficult to predict the risks of environmental harm of GDOs prior to open release, and open release could cause widespread ecological impacts through complicated and sensitive ecosystems. Furthermore, unintended consequences to the environment or human health may arise from a lack of stability and efficacy of the gene drive molecular system, or from a spillover effect if the gene drive itself spreads into a nontarget population.

There are currently no approved field releases of GDOs. But there is also no agreement among gene drive developers and stakeholders about whether a moratorium on gene drive releases would be needed.

Risk analysis in this field is marked by a complex set of issues:

- Anticipatory evaluation of the risk is complex. First, problem formulation in the context of gene drives involves: identifying which endpoints must be protected (e.g., health, biodiversity, social or cultural systems, certain species, ecological services, etc.); considering pathways by which events can lead to harm; developing hypotheses about the likelihood and severity of the harm; identifying information and data needs for testing the risk hypotheses; and then developing a comprehensive risk and concern assessment plan. Second, societal impacts associated with GDOs will vary based on the type of GDO, geographical setting, governance system, social and cultural setting, ownership and power structures, and cultural and ethical principles. These factors are intertwined with each other and the socio-ecological systems into which they are deployed.
- Evaluating the substantive validity of risk assessments — where outcomes of the risk assessment are compared to what happens in reality — is not feasible prior to any novel full-scale environmental release. Therefore, the procedural validity of the risk assessment, which is how the risk assessment is conducted, becomes even more important than ascertaining the substantive validity of particular risk evaluations prior to GDO release and field data collection.
- GDOs risk analysis is laden with assumptions and interpretations based on values. For example, the endpoints that are evaluated in a risk assessment are based on what societies care about (e.g., certain species, specific natural resources, certain human illnesses, etc.). Also, uncertainty in risk analysis leads to various interpretations of the data to which we bring our own experiences, cultures, and worldviews.
- Regarding technical risk management, it is based on methods of molecular biology that can stop, recall, or reverse gene drives after release; and specific protocols for physical, reproductive, ecological and molecular barriers for biosafety.
- GDO-related risks to environmental sustainability may be characterised by moral hazard and affecting common pool resources or even public goods. Therefore, it is critical to consider communities' behavioural and value systems for managing risk through shared governance and collective action. Unfortunately, there are no globally established shared values and norms for gene drive governance, although conversations are emerging.

GDOs are developed in a field marked by significant uncertainties and large decision stakes, which suggests that legitimate and robust risk evaluation and decision methods must be used. As mentioned above, increasing procedural validity in support of decision-making is necessary. For example, the Procedurally Robust Risk Analysis Framework draws upon principles of responsible research and innovation (RRI), such as humility, procedural validity, inclusion, anticipation, and reflexivity. Also, approaches developed for “post-normal science” suggests that extensive consultation of stakeholder communities could help make sense of uncertain information and their interpretation, and draw policy implications. Democratic engagement is important for deciding what levels of risk are acceptable to affected communities.

Specific learnings from this case relevant to other sectors or technology domains

A fundamental lack of knowledge about unwanted side effects on other species and systemic causalities is generally a cause of concern.
The catastrophic risk potential is related to the complexity of ecosystems and the uncertainty of outcomes, related to temporal aspects.

In contrast to other technology domains where technologies are deployed before a sufficient understanding of their benefits and risks, the use of gene drive systems is marked by both enthusiasm about the potential to contribute to alleviating environmental and health hazards, and extreme prudence through the development of molecular control mechanisms for gene drives and staged field trial release guidance.

Every emerging technology developer would be advised to learn about how things are done in this field, as the paper provides examples of emerging conversations about global governance as well as investments in technical mechanisms to reduce risk.

Paper 3

Smart materials and safe and sustainable-by-design (SSbD)

The paper by Steffen Foss Hansen, Freja Paulsen and Xenia Trier, about "Smart materials and safe and sustainable-by-design — a feasibility and policy analysis", considers how so-called "smart materials" are — or could be — assessed and managed to ensure that their applications do not threaten environmental sustainability. The European Commission's Chemicals Strategy for Sustainability (2020c) aims to address this complex challenge, in particular through the concept of safe and sustainable-by-design (SSbD).

Chemical risks to environmental sustainability essentially cover the risk of damage to the environment that may manifest in the long term as a result of (i) unknown effects at the time of deployment (examples in some advanced materials) and/or (ii) the accumulation process, after a given material has accumulated and crossed some thresholds (examples with common pesticides) and/or (iii) a long time gap between the introduction and subsequent manifestation of consequences.

The term smart materials (a sub-group of advanced materials) is generally used for materials that obtain a new kind of functional property as a consequence of stimulation via external factors. Smart materials result from relatively new technologies or even emerging ones. Stimuli agents can be light, temperature, electricity, magnetic field, stress, pressure, pH, etc. These controlled abilities of smart materials make them particularly interesting for applications such as drug-controlled release, treatment of various diseases, biosensors, etc.

The authors examine if the frameworks and criteria currently considered for SSbD assessment are sufficient to address the specific challenges of emerging smart materials, particularly concerning environmental sustainability. In other words, will it be possible to assess smart materials on SSbD?

The SSbD concept underlines that both safety and sustainability should be addressed in the design phase — and not considered as an afterthought, e.g., when a material or product has been developed and is about to be used in the economy.

The paper compares several views and frameworks suggested for implementing the SSbD concept (JRC, CEFIC, Hauschild, ChemSec). All suggest first that the new technology design should follow certain essential principles. For example, CEFIC focuses on identifying the best alternative to existing products. Then comes the assessment of safety, and finally, an assessment of sustainability. Also, before assessing their risks and sustainability, analysts must understand the various kinds and compositions of smart materials (whether polymers, nanomaterials or micro- and nanorobots) and their unique properties when responding to specific stimulating agents during application.

The methodology proposed by JRC consists of a tiered approach, starting with applying cut-off criteria to avoid the use of the most harmful substances and substances of concern. Chemicals and materials that do not meet the initial cut-off criteria should only be allowed in uses deemed essential for society. How "essential use" is defined is subject to discussion, but it is generally understood as usage necessary for health, safety or the functioning of society, where there are no acceptable alternatives when considering the environment and health.

Safety assessment can be done with hazard and risk assessment methods. However, those have to be adapted for the 'emerging' feature of smart materials because the current methods may fail to capture the impact on environmental and health safety.

Sustainability assessment can be realised with life cycle (impact) assessment, noting though that, In order to use LCAs to evaluate environmental sustainability fully, further development of the method is needed to capture emerging features.

The authors conclude that the lack of reliable data and information about the sustainability of smart materials implies that it will not be possible to evaluate their performance concerning cut-off criteria for SSbD and subsequent safety and sustainability assessment. In particular, the lack of sufficient understanding of smart materials' long-term health and environmental impacts are significant obstacles to their deployment in non-confined environments. Their view is that it is not possible to evaluate the possible (anticipated, expected, potential) risks of smart materials to environmental sustainability (i.e., to biodiversity, ecosystems, natural resources and the climate) or indications of human health, social, ethical or other concerns that may influence the development of the technology or its uptake in industry and society. In their opinion, smart materials could, therefore, not be characterised as SSbD.

Some NGOs underline that the very concept of SSbD cannot apply to hazardous chemicals, as those are, by definition, neither safe nor sustainable to use. Because smart materials are built to change behaviour in response to external stimuli, the concept of SSbD will be challenging to implement in regulatory risk assessment.

Specific learnings from this case relevant to other sectors or technology domains

The attempt to treat sustainability as if the concept was similar to safety or risk is laudable but will meet significant obstacles regarding implementation, which must be overcome. Chemicals sustainability will be subject to different interpretations based on different business and value systems.

The interdisciplinary nature of smart materials (physics, biology, chemistry, engineering, material science and information technology) is challenging when it comes to risk assessment and governance. Therefore, holistic approaches for explorative technology assessment might be helpful when assessing smart materials and their broad applications in distinct domains.

In general, it seems evident that avoiding the use of harmful chemicals, such as substances of concern, and, when used, ensuring their potential reuse, safe disassembly, and recycling are key considerations for introducing smart materials in the economy and environment.

Paper 4

Emerging technologies applications using bio-based residues

Locally sourced bio-based residues are promising to expand the number of bio-based products produced sustainably in the EU. In "Ensuring the environmental sustainability of emerging technologies applications using bio-based residues", Christian Moretti discusses how to guide investments in future emerging technologies using bio-based residues and avoid finding out adverse environmental impacts at a late investment stage.

Bio-based residues are by-products from agriculture, the food and wood processing industries, biorefineries and bioenergy plants. The feedstock does not generate concerns about competition for food and land, is usually cheaper than dedicated crops and is locally available. Products from bio-based residues are expected to be the core of future bio-based innovation to move towards a circular economy via better valorisation of natural resources. Emerging applications include plastics from used cooking oil, fuels from potato peels, fuels from biogenic carbon emissions, and asphalts from lignin. However, environmental trade-offs might emerge when residues are (i) already highly demanded by the market for high-value applications, (ii) already sold for other lower revenue uses, or (iii) currently used by their producers (not sold). Furthermore, there is a risk that the environmental burden is shifted towards another environmental impact, e.g., higher eutrophication or toxicity than their petrochemical counterparts.

Life cycle assessment (LCA) methodology is the key tool to assess environmental impacts over the product life cycle. It is thus incorporated in various policy regulation mechanisms to incentivise bio-based products based on their environmental performance. However, bio-based residues are regularly produced from multi-output or multifunctional processes, i.e., processes yielding more than a single function or product to society. So, conducting an LCA of a product from a bio-based residue regularly requires allocating a fraction of the environmental impact to the bio-based residue. Despite the existence of ISO LCA methodology standards, modelling multifunctional processes is one of the most controversial methodological aspects in the LCA literature, with low convergence in recommendations in LCA guides of different countries and sectors. It is, therefore, not uncommon to find the life cycle environmental impact of the same bio-based residue varying from highly positive to highly negative as a consequence of adopting different multifunctionality approaches.

This paper uses several prospective LCAs as illustrative examples to discuss the environmental benefits and trade-offs of products from bio-based residues and their uncertainty caused by multifunctionality approaches. These LCAs show that the climate impact of emerging products from bio-based residues is usually much lower than that of their fossil counterparts. For example, climate change impact reductions of 30–70% can be achieved by replacing current asphalts with lignin-based asphalts and 40–62% by replacing petrochemical polypropylene (PP) with PP from used cooking oil. However, the following considerations apply:

- High climate change mitigation performance achieved by specific conversion technologies and bio-based residues cannot be generalised since it depends significantly on regional variability and the kind of energy used. Using renewable energy and green chemicals is key to achieving high climate change impact reduction.
- Bio-based residues are scarce, and many technologies compete for the same bio-based residue. Therefore, decision-makers must be careful when diverting bio-based residues from other uses, especially in the case of low-yield technologies.
- The selection of the so-called multifunctionality approach significantly affects the environmental impacts of products from less economically valuable or physically smaller streams.
- A slight change in the allocation share of the main product can significantly change the allocation share of the by-product and, consequently, its environmental impact.
- It is not trivial to evaluate and quantify the environmental sustainability of an emerging technology to convert bio-based residues before investment and production have begun.

Specific learnings from this case relevant to other sectors or technology domains

The following conclusions obtained in this case can also be valuable for other emerging technologies:

- It can be misleading to generalise conclusions obtained in any specific LCA for any specific

product and wrong to transpose their outcomes into other settings.
- Key decisions are often taken based on pilot demonstrations. However, future large-scale deployment might significantly differ. Potential process design changes and size scaling effects depend on optimising process synergies and future technological learning.
- Attention is needed when diverting a scarce resource from another use which might be more environmentally attractive. A consequential LCA is the most appropriate tool to detect counterfactual impacts on the environment in these cases. However, evaluating the best use for constrained resources requires a complete understanding of the context of supply chain systems and competing markets, which may not exist until a market is created. So like in many other domains, decision-makers may see choices in terms of trade-offs, whose resolution may also need other analytical methods than LCA.
- Objectives regarding environmental impacts and economic outcomes may not align. Environmentally sustainable products generally have a (much) higher production cost than conventional products relying on (often) cheaper fossil resources for their production.

Paper 5

Lithium-ion batteries

In their paper "Lithium-ion batteries for energy and mobility: Ensuring the environmental sustainability of current plans", Priscilla Caliandro and Andrea Vezzini discuss current concerns raised by policy and industry decisions to develop large-scale plans to produce electric batteries for the mobility and energy sectors without adequate large-scale plans being made upfront for recycling, reusing or disposing of. Ultimately, this may contribute to aggravating specific environmental challenges.

Current lithium-ion batteries (LIBs) pose environmental, economic, social, legal and even ethical challenges in the different stages of the value chain. There are risks during manufacturing, using and reusing, and recycling/remanufacturing and disposal, which the paper reviews in some detail.

The main challenges for LIBs recycling are (i) separating small cells from other e-waste and (ii) current low volumes of large-format batteries that make operating plants at a scale not profitable. This calls for a business model that will enable a sustainable and circular value chain.

The paper delves into three major aspects that affect the environmental sustainability of current plans to ramp up the electrification of the individual transportation sector: the size of the battery recycling problem, ways to share information needed to process batteries into reusing and recycling, and the circularity strategy.

First, we need to scale up recycling facilities. Looking at the scale of the battery market, the expected evolution of the technology and the resources needed to achieve them, more coordination is needed between economic, environmental, social, and regulatory entities to ensure the environmental sustainability of LIBs. According to sources, the percentage of LIBs that are currently recycled ranges from 15% to 50%. Given the projection of LIBs deployment in the following years, many more additional recycling facilities will be needed. In June 2022, there were over 21 million EVs on the road globally, but by the end of the decade, this number could increase to 350 million.

Second, we need to increase the chances that every battery can be reused and recycled by making available specific information about each battery that is currently not made available by manufacturers and users. For that purpose, the Global Battery Alliance and the EC promote the "Battery Passport" as a global solution to share information and data on battery systems needed for reuse and recycling. This could enable resource efficiency across the battery life cycle while simultaneously demonstrating responsibility and sustainability to consumers. The Passport is anticipated to act as a standard-setting instrument to enhance transparency through sharing data on materials chemistry, battery origin, the state of health of the battery, or the chain of custody. It can also provide a powerful means to identify and track batteries throughout the life cycle and, hence, support the establishment of systems for life extension and end-of-life-treatment. Eventually, it can support industry marketing strategy, branding and reputation, and serve as an incentive towards the environmental sustainability of the entire industry. The Battery Passport is expected to allow for the reduction of sustainability risks and reach the following targets: (i) the reduction and/or the sustainable procurement of critical metals, (ii) the reduction of waste, (iii) an efficient manufacturing and recycling process, (iv) the exchange of data among key stakeholders to improve the economics of life extension through repair, refurbishment and recycling, and (v) the promotion of product design and technical development to facilitate disassembly for repurposing, repair and recovery of materials.

Third, LIB is an excellent candidate for circular economy practices. The EU Circular Economy Action Plan identified batteries as one of the resource-intensive sectors with a high potential for circularity to be addressed as a matter of priority. The EU created a proposal for a regulation on batteries and waste batteries oriented towards modernising the EU battery legislation to ensure the sustainability and competitiveness of the EU battery value chain. Circular economy principles can guide the sustainable management of the rising volume of end-of-life LIBs via a hierarchy of recovery pathways: reuse in less demanding applications (such as stationary energy storage) and material recovery through recycling, reducing the burden of mining raw materials. Each of these reuse pathways offers the potential to minimise the magnitude and pace of LIB waste generation while simultaneously reducing the life cycle environmental impacts of energy and vehicle storage systems.

Specific learnings from this case relevant to other sectors or technology domains

This case illustrates well the challenge of implementing circular economies and aligning manufacturing with reusing and recycling at chemicals' end-of-life. Given current plans to electrify the mobility and energy sector, it would be a mistake not to ramp up quickly on LIBs' reusing and recycling phase.

The solution proposed by the EU and other stakeholders, a "Battery Passport" designed to address one by one each of the deficiencies in the current battery life cycle, looks promising. The Passport will serve to share information and enable the implementation of reusing and recycling batteries.

Paper 6

Space technologies

In the paper "Ensuring the environmental sustainability of emerging space technologies", Romain Buchs reviews current and possible ways to ensure the environmental sustainability of emerging space technologies.

The size of activities in space is increasing dramatically, and their impacts on space and terrestrial environments are of growing concern. While stakeholders are generally more focused on the impact on the safety and security of operations, broader impacts on overall sustainability begin to raise more attention. A thorough understanding of those impacts is instrumental to informed decision-making, helping funders, developers and regulators take appropriate decisions to set space activities on a sustainable course.

It may come as a surprise to some to address the emerging concerns related to space technologies in terms of sustainability. However, near-Earth space is a finite resource and space activities have impacts across the terrestrial, atmospheric and space environments. The value of near-Earth space is increasing due to technological advances and demand for new satellite-based services on Earth, but there are no clearly established and shared rules for how to access and use space.

In many respects, the concept of environmental sustainability can be extended to space as applied in the Earth context. In this regard, it is helpful to refer to the concept of ecosystem services, i.e., the benefits that human populations directly or indirectly derive from ecosystem functions.

The concept of sustainable space activities often refers to the concerns addressed in the 2019 United Nations Guidelines for the Long-Term Sustainability of Outer Space Activities. The goal is to ensure that space activities can be performed safely and without interference so that the benefits they provide on Earth are sustained and that the outer space environment is preserved for current and future generations. The paper goes beyond this understanding and encompasses impacts from space activities on the atmosphere and the terrestrial environment.

The paper discusses the types of risks that could affect the sustainability of emerging space technologies and ways to assess and manage them. Risks to environmental sustainability from space activities include collisions with space debris, optical and radio interferences, marine pollution, atmospheric pollution, and interplanetary contamination.

Space debris is at the heart of the concerns regarding the sustainable use of outer space. These non-functional human-made objects cause a collision risk for operational spacecraft, threatening valuable assets. Congestion in near-Earth space is intensifying, especially in low Earth orbit (LEO), increasing the cost of space operations and potentially limiting future benefits. Properly managing near-Earth orbital space is thus becoming ever more crucial to protect critical infrastructure and give access to new benefits from space activities.

Methods are being developed to better assess the impacts of space activities. Life cycle assessment (LCA) is increasingly used in the space domain for assessing the ecospheric impacts. However, conventional LCA requires benchmarking to compare technologies, which is often difficult in the case of space technologies, and LCA rarely encompasses impacts beyond the atmosphere. Environmental impact assessment (EIA) is mainly used to assess impacts associated with launches and spaceports. Extensions of this tool are being developed to address the impacts of space activities on other celestial bodies. The space sector is only starting to use these tools, which are commonly used in other sectors, highlighting the sector's lateness in its consideration of the environment.

However, addressing the uncertain impacts of emerging technologies will also require other tools more capable of coping with uncertainty and a long-term perspective. Regarding space debris, in particular, the paper briefly reviews the concept of space environment capacity. This approach assumes that near-Earth orbital space is a limited shared resource and aims to indicate how much of this resource is used by space missions and objects. Similarly, a "Space Sustainability Rating" system can steer space actors towards sustainable and responsible behaviour. The paper concludes that, overall, instruments developed so far to assess the sustainability of space activities are not comprehensive and are not routinely implemented.

For spacefaring nations, national interests and security are the primary drivers of space policy. For commercial actors, the anticipated market size and business opportunities drive the risk management priorities. For example, there might be a risk that some private actors try to appropriate certain orbits (on a first-come, first-served basis). It might also be that commercial actors address the risk of loss of their satellites organised in constellation simply by creating more redundancy, which could increase the number of future debris if removal at their end-of-life is not correctly done.

Specific learnings from this case relevant to other sectors or technology domains

Technology-related risks to environmental sustainability in space are currently shared with others, but benefits are privatised. Furthermore, emerging space technologies that can create value for all might end up being captured by a few.

Like in other economic domains, specific interests thus outweigh concerns regarding the environmental impacts of space activities. For now, sustainability is only an afterthought and is not prioritised. However, the growing share of commercial applications and greater environmental consciousness can help move space sustainability higher on the political agenda.

Major threats to environmental sustainability from emerging space technology have global consequences, and will thus require a global collective response. However, due to the nature of international space law, national contexts and sovereignty must be recognised. Despite divergences among stakeholders, recognising that near-Earth is a limited shared resource with the characteristics of a common-pool resource is a stepping stone to managing it effectively globally.

Paper 7

Carbon dioxide removal (CDR)

In “Ensuring the environmental sustainability of emerging technologies for carbon dioxide removal”, Benjamin Sovacool and Chad M. Baum discuss the challenges posed by the potential deployment of emerging techniques for the large-scale removal of carbon dioxide (CO_2) from the atmosphere. Carbon dioxide removal (CDR) is likely to prove critical for stabilising and eventually reducing CO_2 atmospheric concentration in keeping with the targets of the Paris Agreement. However, while some technologies such as afforestation and soil management are already relatively mature from a development perspective, others such as biochar and direct air capture have not yet been deployed at scale. When deployed at a large scale, these techniques could substantially damage the environment or the climate itself, i.e., constituting an environmental sustainability risk.

The paper describes some potential risks of deploying four CDR techniques — bioenergy and carbon capture and storage (BECCS), direct air capture with carbon storage (DACCS), enhanced weathering, and biochar — alongside future benefits. It also emphasises the insufficient knowledge available today to inform policy decisions on the extent to which the deployment of some of these techniques should be encouraged or mandated.

BECCS involves harnessing specific energy crops or increasing forest biomass to replace fossil fuels and remove carbon dioxide by capturing and storing underground the emissions that result from burning the biomass. Because this technique is so tightly coupled to bioenergy systems, large-scale deployment could adversely affect land, water and food. However, it could also catalyse more resilient local bio-economies.

DACCS refers to capturing carbon dioxide from the air via engineering or mechanical systems, and then using solvents or other techniques to extract it before storing it underground. DACCS technology faces fundamental challenges, including high cost, energy requirements and the permanence and security of the long-term storage and sequestration of CO_2. On the other hand, DACCS could, in principle, be installed almost anywhere and would require relatively little land.

Enhanced weathering works by increasing the ability of rocks to absorb CO_2 from the atmosphere. It employs alkaline materials (such as basalt or lime), which naturally interact with carbon to draw down and provide long-term CO_2 (in the form of solid carbonate minerals). Reasons for concern include the sheer quantity of rocks that would probably be required (and mined), especially if we aim to remove multiple billions of tons annually. In addition, when done in marine environments, as is the case for ocean alkalinity enhancement, there are potential issues with how this might (adversely) impact oceans, life below water and/or water security. However, it could provide a means for helping to address the pressing problem of ocean acidification.

Biochar is a form of carbon removal that works by managing the thermal degradation (i.e., heating it) of organic material, such as tree branches or cornstalks, inside a container with no oxygen. A primary risk — one common to all carbon-removal methods reliant on biomass — is the prospect of adverse impacts on terrestrial ecosystems and land management. In particular, there is the potential for trade-offs and competition for scarce biomass resources. However, biochar could also contribute towards more carbon-rich soils, providing co-benefits for agriculture and food, and more sustainable forms of building materials.

These four CDR approaches still must be broadly considered as emerging, given that they remain at the stage of experimentation and testing and, moreover, since there is no demonstration or deployment on the scale that would be needed to reach the potential levels necessary to help reduce climate change. Each of the four techniques presents potential threats that may manifest only in the long term and remain challenging to identify clearly and assess fully, based on what we now know — even though such knowledge is crucially needed to support evidence-based decisions. However, at a high level, we know that the balance of risks and benefits will depend to some extent on how and where the techniques are applied. We also know that the complementarity and interoperability of some CDR options imply that risks may accumulate when multiple innovations are linked together in ways that improve their functionality and attain economies of scale.

The question of ensuring that emerging CDR technologies, if deployed on a large scale, would not lead to adverse consequences for environmental sustainability is complex. There are various reasons for concern, including that (i) existing instruments such as life cycle assessments are insufficient to assess and encapsulate the full range of risks that may unfold, (ii) some other potential risks may be ignored or neglected, and (iii) more sophisticated modelling, policy analysis, and even research designs capable of understanding and capturing the risk-risk trade-offs of carbon removal are missing.

Some learnings from this case relevant to other sectors or technology domains

The case of CDR-related risks to environmental sustainability indicates that deploying the most promising CDR options in terms of CO_2 removal potential would involve a diffuse collection of risks and benefits. No benefits come without some degree of countervailing risks elsewhere. No single technology is risk-free.

CDR is likely to be critical for stabilising and eventually reducing CO_2 atmospheric concentration. Therefore, the expected risks of CDR must also be compared with the risks that might come with not deploying the technology as a way to deal with climate change risks, along with benefits in terms of climate change reduction. Analysts and policymakers should recognise the difficulty in predicting risks and embracing the intersectionality and coupled nature of risks and benefits. It may even be that some CDR techniques could come to be declared ‘essential’ despite their risk. In such a scenario, the level of acceptable risk associated with CDR would be increased.

Trade-off negotiation and resolution will be at the core of decisions for the long term.

Paper 8

Cultured meat

In the paper "Is cultured meat environmentally sustainable?", Christian Nils Schwab and Marine Boursier discuss that cultured meat (also called in vitro, artificial or lab-grown meat) is presented as a promising alternative to conventional meat for consumers who seek to be more responsible towards the environment without moving to vegetarian food. Cultured meat is produced from a small tissue sample, and the cells can be taken from a living animal, so the process does not require killing animals.

Regarding environmental issues, the main anticipated advantages of cultured meat are lower greenhouse gas emissions (GHG) and reduced water consumption because much less conventional farming for livestock, ruminants in particular, will be needed. However, this can be a matter of controversy because cultured meat can impact the environment and the climate through its energy consumption, primarily electricity used during production, or through the production of the growth medium. Currently, there is no large-scale production facility.

LCA studies conducted on cultured meat are thus based on hypothetical production processes and simulation models. Attributional approaches are recommended to evaluate or compare processes or products and identify the most impacting process parameters and the technical optimisation potential. In addition, consequential approaches can be used to evaluate the societal and economic consequences. Also, prospective LCA that includes scaling-up technology application and the context in which it would apply would be very appropriate to inform decision-makers about potential environmental impacts.

Overall, most studies so far conclude that cultured meat could offer environmental gains compared to conventional meats (beef, pork, chicken) and would obviously use much less land and natural resources than conventional meat. It has a much lower carbon footprint than beef and is comparable to the global average footprints for pork and chicken when produced using conventional energy.

The paper also indicates that health and safety aspects may need to be considered even before environmental aspects, and that many other factors will influence industrial deployment, adoption, consumer choices and regulation. For example, the economic aspects of cultured meat will also determine whether the agrifood sector will find it beneficial. If conventional meat from livestock is progressively replaced with cultured meat, several services provided by livestock farming systems will be reduced or even disappear. Livestock provides essential income for rural populations, from meat, milk, eggs, wool, fibre, and leather. Current cost estimates indicate production costs above those of conventional meat. However, they could be lowered if agriculture waste could be used to produce the energy needed for cultivated meat, thus enhancing circular economies, but assuming this does not imply diverting agriculture waste from other uses. Another factor that could change the relative price of cultured vs traditional meat could be an evolution of the legal framework towards the inclusion in the consumer price of adverse externalities (True Cost Accounting for food). Finally, consumer acceptance is not established, and cultured meat is often perceived as unnatural, in contrast to so-called "vegetarian meat".

Specific learning from this case relevant to other sectors or technology domains

Regarding the specific question of what potential impact emerging technologies for cultured meat could have on environmental sustainability, researchers, technology developers, and investors would be advised to consider prospective LCAs, which will become easier to carry out as actual products become available on the market.

However, a range of other aspects than sustainability are involved in the adoption of an emerging technology.

Paper 9

Ex-ante life cycle assessment

In "Practical solutions for ex-ante LCA illustrated by emerging PV technologies", Stefano Cucurachi and Carlos Felipe Blanco discuss strategies to address the challenges of taking an *ex-ante* approach to life cycle assessment (LCA), which is the method of choice to assess the environmental impacts of products and services that span the global economy and trigger environmental trade-offs across multiple life cycle stages and impact pathways.

For over three decades, traditional LCA studies have been widely used to guide decision-makers and consumers regarding the environmental performance of products and services. LCA studies can be used to compare environmental benefits and trade-offs between competing product systems performing a similar function, such as electricity generation, passenger transport, or food provision. A series of ISO standards (ISO 14040) formalised the use and application of LCA. However, these standards were developed with *ex-post* assessments in mind, focusing on well-defined product systems for which sufficient data and knowledge are available, given that they have already been deployed at an industrial scale.

In contrast, the recently introduced approach of *ex-ante* LCA attempts to apply LCA already in the early research and development stages of technological products and services. In this novel application, *ex-ante* LCA aims to address the methodological quandary known as the Collingridge dilemma, which postulates that impacts cannot be easily predicted until the technology is extensively developed and widely used, while control or change is difficult when the technology has become entrenched.

Written from the perspective of LCA analysts, the paper highlights the practical challenges of conducting and interpreting *ex-ante* LCAs, using case studies of emerging photovoltaic (PV) technologies. It explores — amongst other aspects — the importance of product performance optimisation during technological development, and how it is directly linked to environmental performance. It also describes the implications of process optimisations required to mass-produce an emerging technology at an industrial scale and how such optimisations can be considered in an *ex-ante* LCA.

The *ex-ante* LCA approach can be very valuable in supporting early design improvements and sound investments, providing information about potential future large-scale environmental impacts, avoiding technological lock-ins in non-desirable technologies, identifying early comparative advantages/disadvantages, and warning decision-makers about critical material and process choices in the technologies' designs.

To be applied successfully, *ex-ante* LCA requires close collaboration between LCA analysts, technology developers and other stakeholders to overcome numerous challenges encountered in each of the LCA phases:

- **Goal and scope definition**. Identification of the functional unit and the system boundaries of the *ex-ante* study may be difficult and can be contested.
- **Life cycle inventory (LCI)**. The analyst must model manufacturing processes that are still at the lab or pilot scale and will probably change when the technology reaches the industrial scale. Information on how these lab/pilot processes will be upscaled is usually unavailable but highly relevant for LCA models. In addition to this, the recycling potential or end-of-life behaviour of the technological components and materials is difficult to anticipate.
- **Life cycle impact assessment (LCIA)**. Potential environmental impacts of new technologies are not always covered by the existing impact categories commonly used in *ex-post* LCA studies. Standard characterisation models used at the LCIA phase may not be entirely suited to assess novel chemicals/materials (e.g., microplastic and nanomaterials) and their impact pathways. As a result, the *ex-ante* LCA models will underestimate the impact scores in such cases.
- **Interpretation**. Due to significant uncertainties in forward-looking models, *ex-ante* LCA results may be prone to imprecise, inaccurate and/or ambiguous conclusions that are difficult to convey and act upon. Scenario analysis and sophisticated uncertainty and global sensitivity analysis techniques aid the analyst in stress-testing the assumptions in the system and identifying the relevant inputs in the model that are potential drivers of uncertainty.

Furthermore, the challenges listed above are encountered in the context of dynamic and rapidly evolving technology designs, giving limited time to adjust and reinterpret the models. Despite this, *ex-ante* LCA, combined with adequate screening and computational tools, can already guide decisions in the earlier phases of technology development.

Learnings from this case

Ex-ante LCA is a practical instrument adapted from standardised *ex-post* LCA that can provide support to technology developers who need to understand environmental impacts. However, the absence of process data, impact models, and uncertainty of future developments, are key obstacles which may hamper the usefulness of the *ex-ante* LCA approach. Various practical strategies are currently being developed to overcome obstacles. Currently, no strategy fully resolves the overall *ex-ante* challenge or even the specific issue it intends to tackle. However, the combined application of these strategies demonstrably provides a more robust basis for sustainable decision-making and technology appraisal.

Paper 10

Anticipatory life cycle assessment

In this paper, Thomas P. Seager discusses "Anticipatory life cycle assessment for environmental innovation". He adopts the perspective of technology developers rather than LCA analysts, and reviews the features and relevance of anticipatory LCA in contrast to conventional (ISO type) and *ex-ante* LCAs.

The principal difficulty regarding LCA for innovation is overcoming the challenge of data gaps and uncertainties with methods that steer novel technologies towards environmentally preferable outcomes. Several theoretical or methodological advances have been made, including prospective LCA, *ex-ante* LCA, anticipatory LCA, and LCA of emerging technologies. While each approach is motivated by the same problem — i.e., the difficulty of gaining environmental insight into problems before they manifest at scale — the specific goals and unique features are different. Prospective LCA aims to improve environmental forecasting. *Ex-ante* LCA aims to compare the assessment of pre-market technologies to determine expected or projected environmental gains relative to an incumbent. Anticipatory LCA aims to identify uncertainties most critical to the environment.

Any method of environmental LCA that seeks to inform questions relevant to innovation must be organised with a model of innovation in mind. The most popular model cited in the scholarship of LCA is the Technology Readiness Level (TRL) model, which presumes a linear progression from lower readiness levels to higher ones, as knowledge from research and development accumulates. This approach has been elaborated upon for private industry as "stage-gate" innovation, in which ideas are progressed through five stages of an innovation "pipeline". However, TRL fails to account for actual, messy, non-linear product development practices that are often carried out without TRL or stage-gate processes in mind. It also fails to acknowledge the significant resource constraints under which innovation often occurs, given the enormous costs of gathering complete information.

As a result, the linear TRL/stage-gate model has now been superseded in many domains and companies by agile and lean innovation models that emphasise flexibility, recursion, and minimising capital requirements. Rather than beginning with curiosity-driven basic science, the lean/agile innovation model typically starts with customer problems or market opportunities. Then, it asks what research or experiment is needed to identify ideas, possible improvements or other features that should be prioritised for the next iteration.

The lean/agile innovation model needs environmental LCA inquiry methods that are suitable for it. The most important distinction between *ex-ante* and anticipatory LCA as they are currently practised is that *ex-ante* seeks to provide answers, while anticipatory seeks to prioritise questions. The goal of anticipatory LCA is to rank-order environmental uncertainties for technology developers. Examples of questions:

Lean/agile	Anticipatory LCA
What problem is the technology solution attempting to solve?	What functional unit represents the effectiveness of the technology? What boundaries of analysis correlate to that unit?
Who has this problem?	Which stakeholders should be engaged?
What alternatives, competitors or incumbents offer solutions?	What alternatives shall be included in a comparative analysis?
What are they willing to pay for the solution?	What environmental values represent stakeholder concerns?
What is the lifetime value of customers to the business enterprise?	What environmental liabilities (e.g., end of life) might be hidden from technology developers?
How is the product or technology created & delivered?	What are the technology's thermodynamic (material & energy) requirements at each life cycle stage? How shall environmental risk assessment models/parameters be modelled for novel materials?
What are the minimum viable features to incorporate into the next product release? What is the next set of experiments necessary to develop those features?	To what processes or parameters is environmental assessment most sensitive?

Anticipatory approaches to LCA are designed in concert with technology developers and researchers seeking to incorporate environmental considerations into new technology development. However, the required exploration of sensitivity and uncertainty is not available in standard commercial LCA platforms. The burden of custom software development is the biggest obstacle to the broader adoption of anticipatory LCA.

Learnings from this case

It seems evident that the outcome of an anticipatory LCA could be used in a decision-making process where funding agencies, technology investors in industry or grant-making organisations, and regulators are confronted with the question of having to decide on enabling, funding, or authorising an emerging technology development. This analysis suggests that continuing to explore and develop anticipatory LCA will be valuable to help identify and do an early assessment of possible environmental risks and threats to environmental sustainability embedded into emerging technologies.

However, it is too early to recommend that funding agencies and investors suggest or mandate the use of anticipatory LCA by technology developers. Nevertheless, from their perspective, formulating the guiding questions that would be asked during an anticipatory LCA process could help reveal the uncertainties embedded in the vision of the emerging technology design and possible outcomes. Anticipatory LCA offers funding agencies and other investors a basis for identifying those environmentally relevant hypotheses or research questions that are immediate, compared to those that are either purely curiosity-driven (e.g., at TRL 1) or made necessary by the TRL/stage-gate criteria approach — and may have little environmental relevance to the agile/lean innovation process that characterises today’s technology world.

Paper 11

Liability regimes

The possible "Liability's role in managing potential risks of environmental impacts of emerging technologies" is discussed by Lucas Bergkamp, who asks whether liability regimes could take a more prominent role and complement a portfolio of strategies, including regulation, to manage emerging risks of emerging technologies and novel, innovative products. For liability systems to do so, they would have to be tuned to generate adequate *ex-ante* incentives for the good governance of innovation, which they are currently not designed to do.

Regulatory approaches to managing the risks of emerging technologies can face several limitations. They generally require deep knowledge of the industries and technologies involved, which is present within the regulated industry but not necessarily in the regulatory agency. Liability systems can complement regulation when emerging technologies create uncertainty and experience with them is limited. In contrast to regulation, civil liability is a corporation's exposure to an obligation to pay compensation (or to do some action or refrain from doing some action) when the corporation breaches a duty of care under civil law. Regulation is an *ex-ante* approach that may also impose some *ex-post* obligations (e.g., an obligation to report if harm is caused), while civil liability is an *ex-post* approach (it kicks in only after there is harm or imminent harm) that ideally generates *ex-ante* incentives. Because liability law threatens to hold companies that cause harm liable, companies have incentives to reduce the risk of harm. This specific feature of liability could be harnessed to handle risks from new technologies.

In this respect, a key issue (and limitation) is data generation before and after introducing new technologies and innovative products. Civil liability law imposes a duty to investigate possible risks and disadvantages of new technologies. In theory, a technology developer or industry could be exposed to liability in two cases: if (i) data is generated and (ii) no data is generated. However, it is hard to identify in a specific case whether the risk of liability exposure is larger in the first or the second case.

In addition, there are other limitations to liability's proper functioning to this end. First, it requires damage, negligence, and a causal link, which may be hard to prove for the environmental impact of technology applications. Other limitations include the cost of lawsuits, the burden of proof and, as noted, that there may also be liability associated with the generation of data. The more remote the risks (i.e., how far into the future a possible risk will materialise), the harder it will be for the court to identify them, as causal links may be complex due to fundamental uncertainty, threshold issues, bioaccumulation, synergistic effects, etc. So-called "long tail" damage, which is characterised by a long time gap between the time of introduction of a technology and the manifestation of consequences, presents serious challenges to the liability system

Possible remedies or approaches to mitigating the limitations of liability law exist, but many will be difficult to implement. First, remedies may have a chilling effect on inventors, innovators and technology developers — the fear of exposure to potentially large claims may deter them from engaging in invention and innovation. Further, for liability to play a role in ensuring the environmental sustainability of emerging technologies, the judiciary should be both normatively and epistemically legitimised in expanding its mission.

The paper concludes that, given the self-interest of potentially liable entities and the epistemic and normative limitations of courts of law, liability law is an inherently limited instrument in managing emerging risks of emerging technologies and new products. Effective ways to eliminate some barriers to expanding liability exposure are likely to impose high costs that must be weighed carefully against their benefits. Despite these issues, the liability system can, to some extent, be adjusted to improve the management of the risks of emerging technologies, while not discouraging desirable innovation. The balance is delicate and adjustments are best made carefully and iteratively, while learning from their effects and adapting the system progressively. As a general rule, legislatures, not courts, are best placed to take the lead and make incremental changes to better equip the liability system to manage the risks of environmental impacts of emerging technologies.

Learnings from this case

Lucas Bergkamp concludes that certain conditions must be met for liability (specifically, the most common form of liability based on negligence) to work well as a system for creating *ex-ante* incentives for prevention. These conditions include that (i) the risk must be foreseeable (i.e., the causal link must be fairly precise), (ii) there must be a reasonably available option to protect against the risk (other than not engaging in the activity at all), (iii) the damage that results from the activity must be unambiguous, not inherently tied to economic and social benefits, and constitute an injury to legally protected interests, (iv) the standard of care requiring preventive measures must be knowable (i.e., identifiable) beforehand, and (v) the question presented to the court must not be a politically charged issue with which the legislature occupies itself.

In the context of ensuring the environmental sustainability of emerging technologies, the inability to anticipate long-term environmental risks is an important issue. Assessment is generally scientifically complex, tainted with significant uncertainties about causal relations, ambiguity in the interpretation of available information, and frequent conflicting interests. These problems do not disappear if liability is triggered and courts of law are called upon to make decisions. Overall, liability can make a modest but, in some cases, an important contribution to controlling the environmental sustainability risks of emerging technologies.

Paper 12

Emerging technologies as emerging or systemic risks

The final paper in this series, "Ensuring environmental sustainability of emerging technologies — the case for applying the IRGC emerging and systemic risk governance guidelines", written by Rainer Sachs, reviews IRGC's guidelines for governing emerging and systemic risks published in 2016 and 2018, respectively. It assumes that emerging technology may create emerging risks and, thus, that some of the guidelines could be useful to govern risks from future applications of emerging technologies, many of which are also pervasive or systemic.

The specific properties of emerging technologies, i.e., radical novelty, uncertainty, ambiguity, fast growth and prominent impact, make a plausible case for applying the IRGC guidelines for emerging and systemic risks governance.

Emerging risks are either new or known risks that become apparent in new, unfamiliar, or changing context conditions.

Emerging technologies are applied in a world characterised by an increasing interconnectedness within and between complex adaptive systems, where risks can be 'systemic', i.e., they arise from the complexity of the technology itself and/or their interaction with the environment.

Due to the interconnectedness and complexity of systems, conventional risk governance approaches often reach their limits. For example, risk management by fragmenting risks into individual categories or isolated systems works well for many traditional risks but is no longer adapted to systemic risks characterised by contagion and proliferation processes (ripple effects).

The paper uses examples of emerging technologies to illustrate risk governance strategic priorities. Recommendations from IRGC guidelines suggest:

- Overcoming obstacles to the systematic consideration of early warning signals and future scenarios. Concerns about long-term environmental sustainability require attention to early warning signals and preparation for unexpected events. Hence, proactive governance of emerging technology aims to enhance anticipation and forward-looking capabilities. Explorative scenarios are particularly relevant if they can help decision-makers structure and organise the many uncertainties arising from emerging technology.
- Understanding and embracing complexity. Low predictability, limited modelling capabilities and emergence are prominent features of complex adaptive systems, which could adversely impact the long-term sustainability of the environment or the climate.
- Implementing strategies to resolve uncertainty and ambiguity. When little is and can be known about a technology that potentially has severe negative consequences, precaution-based strategies must be considered, and a large spectrum of values and beliefs must be included in risk assessments. The consultation of extended peer and stakeholder communities is necessary to understand and interpret the limits of knowledge, particular opinions that impact risk acceptability, and their influence on strategic decision-making.
- Developing strategies to prepare for unexpected events. Preparation is required for sudden events with adverse consequences (crises, disruptions, accidents), which may also prevent the effective deployment of technology and mitigation strategies. Therefore, the risk governance process must contain specific measures to build resilience to prepare for uncertain and unknown shocks and stresses.
- Striving for broad framing of risks and opportunities. The framing of emerging technology as a potential environmental threat may have significant strategic consequences, which should be weighed against the risk of not deploying the technology. Benefit-risk trade-offs are most often involved. In this case, it is necessary to explore and communicate expected benefits, potential exposure and vulnerability to risks across system boundaries and different time horizons. It also happens that developers of new technologies prioritise short-term private benefits over the collective burden of possible long-term costs. Like in many other domains, short- and long-term negative externalities are rarely internalised in calculating actual costs.

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Paper 1

Risk governance of emerging technologies: Learning from the past

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Introduction

This paper is written in the context of EPFL International Risk Governance Center's (IRGC) project on "Ensuring the environmental sustainability of emerging technology applications" (ESET). As defined in the ESET project, emerging technologies are characterised by radical novelty, noticeable impact, relatively fast growth, coherence, uncertainty and ambiguity (Rotolo et al., 2015). The range of emerging technologies is broad, with applications in many domains.

Ensuring the environmental sustainability of an emerging technology outcome is challenging in two main dimensions. First, it is about understanding and managing the sustainability aspects of technology. Outcome and impact on the environment, both hypothetical and actual, need to be identified and mitigated. The second challenge relates to the emerging features of newly developed and deployed technology. The lack of knowledge and experience with emerging technologies makes the *ex-ante* assessment of environmental risks even more difficult.

This analysis focuses on what can be learned from past examples of technologies, substances or applications that have been used for some time without sufficient understanding of their detrimental impact on the environment. Early signs of concerns or indications of potential adverse consequences were not acted upon until very late, after significant damage had occurred. This paper reviews historical cases of new products or their application on a large scale and their risk governance from an *ex-post* perspective. The objective is to reduce the risk of repeating mistakes from the past.

Three cases are reviewed: chlorofluorocarbons (CFCs), liquid biofuels and neonicotinoids. The analysis aims to distil patterns from these past cases for improving the risk governance of current and future emerging technologies and expand the range of lessons learned in previous reviews conducted by, for example, the European Environmental Agency (EEA, 2001, 2013).

The paper starts by summarising aspects of errors and learning in the context of emerging technologies. Then, for each of the three examples, we review their development background and evolution of risk assessment and regulation process, and provide some risk governance observations. Finally, the analysis concludes with lessons to be drawn from these selected examples. They should be reflected in applying and developing risk governance approaches for emerging technologies.

1.

Learning lessons – why and how?

Learning in the context of emerging technology is about forming beliefs (hypotheses) regarding potential future risks and benefits and testing these hypotheses. Most likely, testing will happen in several stages, from early phases of laboratory experiments, during development, and small-scale applications (sandboxes) to real-life applications. As observed in the past (EEA, 2001, 2013) detrimental environmental impacts are often detected or recognised only late in the development and application phases, making risk mitigation measures often complex and costly. Early assessment of risks is, therefore, instrumental.

1.1 Hypothesis testing

We briefly summarise below the most critical aspects of hypothesis testing to understand the outcomes and limitations of the process. We will need statistical terminology to make the argument as straightforward as possible. The first step in the process is the definition of a null hypothesis. The null hypothesis (H_0) is that the emerging technology under consideration does not cause harm to the environment. In the testing framework, we aim to reject this null hypothesis, i.e., we look for evidence of environmental harm. If we cannot reject H_0, we can assume that the emerging technology can be safely developed and applied within the significance level and parameters of the testing framework.

In general, there are two types of errors in hypothesis testing, which are briefly explained here:

- False positives or Type I errors occur if we reject H_0 and assume that the technology is harmful (and we either adapt or stop the development), but further research shows no or insignificant harm in reality. However, too many false positives will undoubtedly stifle innovation because technology might not be developed further based on risk concerns, which turned out to be "false alarms" *ex-post*. While this is undoubtedly a valid concern, an analysis by the EEA (2013) revealed that only a few examples of this type of error can be found for past emerging technologies.

- False negatives or Type II errors are the opposite, i.e., we do not reject H_0 and assume the technology is not harmful beyond acceptable limits, but it turns out the conclusion was wrong. This paper aims to extract lessons from past cases where technology caused harm despite prior expectations that it would not. We are mainly concerned with false negatives, where an emerging technology was deployed, and initial assumptions about no or acceptable potential harm turned out to be wrong. The overwhelming majority of past examples are false negatives, i.e., risk management and/or regulatory response was too late or too little.

There is, unfortunately, no way of minimising both errors individually, as they are not independent. Minimising Type I errors increases Type II errors and vice versa. The cost of being wrong determines the test strategy and sets the test parameters accordingly. If we could consider environmental (and societal) costs due to harmful application of technology appropriately, we would probably be more inclined towards reducing Type II errors. The concept of Safe and Sustainable by Design (SSbD) aims explicitly at reducing Type II errors right from the initial development process. We refer to a recent report from the Joint Research Centre (2022) for a comprehensive review of SSbD.[2]

Table 1 below summarises the possible outcomes of hypothesis testing.

In reality, there can even be another type of error rooted in an erroneous interpretation of the hypothesis test framework and results, sometimes called Type III error. In the hypothesis testing setting, we aim to disprove the null hypothesis, i.e., find evidence that the emerging technology does indeed cause harm to the environment. The failure to reject the null hypothesis does not prove that the null hypothesis is, in fact, true. While we can falsify H_0 for sure, it is simply impossible to prove H_0. For example, we might fail to imagine possible consequences and/or application cases and, therefore, cannot reject or even define the null hypothesis. Finite resources (time, funding, people) will also limit the search for counterevidence. In other words, the hypothesis testing framework cannot produce proof of no harm but only a plausible assumption with pre-defined target specificity. The absence of proof of harm is not equal to the proof of no harm. This needs to be reflected in the discussion and setting of test parameters ("Are our limits conservative enough?") and the communication of results with policymakers and the public.

1.2 Limitations of learning

In quite general terms, learning is about trying something new, experiencing feedback and adjusting behaviour. Moreover, learning involves mental models to project into the future possible outcomes of action in the present. In radically innovative situations, when a particular technology and its impact on the environment are hitherto unknown, this frequently amounts to the task of thinking the unthinkable. However, systematic barriers have been analysed in organisational decision-making, for example by Gowing & Langdon (2016). These barriers will ultimately contribute to Type I and Type II errors.

Table 1 | Confusion matrix

		Null hypothesis H_0 is	
		TRUE (harm not realised)	FALSE (harm realised)
Decision about null hypothesis H_0	NOT REJECT (harm not expected)	**Specificity**	**Type II error** (false negatives)
	REJECT (harm expected)	**Type I error** (false positives)	**Sensitivity**

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[2] See also the paper written for the ESET project by Steffen F. Hansen, Freja Paulsen and Xenia Trier, "Smart materials and safe and sustainable-by-design – a feasibility and policy analysis" (2022).

Successful learning and designing appropriate hypotheses and testing frameworks, therefore, require addressing three classes of barriers:

1. **Complexity of the situation**. Governance of emerging technology often involves "wicked problems" (Chandran et al., 2015) from a policymaker's perspective. These types of problems:
   - are difficult to clearly define in the first place because of the complex internal relations and unclear system boundaries,
   - are challenging to frame, understand sufficiently and raise awareness so that the problem gets the attention it deserves,
   - have no clear, unambiguous solution,
   - have no clear owner or do not sit within the responsibility of a single organisation, either administration or country, due to the transboundary effects,
   - often lead to unforeseen consequences if solutions are attempted.
2. Effective mitigation of wicked problems involves radically changing **organisational structures** within which we operate and new combinations of hierarchical power, solidarity and individualism (EEA, 2013).
3. On the **individual level**, many factors can lead to systematic over or underestimation of risks and benefits. Behavioural scientists point out the impact of heuristics leading to suboptimal decisions, particularly if scientific knowledge is scarce or unavailable, as is often the case with emerging technologies. Risks that are perceived far away (e.g., in time, space, or social distance) are systematically underestimated. Table 2 below contains several examples of typical situations in which heuristics may unconsciously influence our decisions.

In addition, two strategic mistakes commonly occur in risk analysis, and these might be relevant for the risk governance of emerging technologies as well:

1. **False precision**: there is a bias towards pre-existing knowledge – data, models, methods, even if they are incomplete or inappropriate – while explicit consideration of the unknown is neglected or even ignored. Being human, we tend to focus on already well-understood and familiar aspects of the problem and the tools at hand. The precision of selected risk aspects may thus be significantly advanced, but the analysis's overall accuracy is only improved apparently at best.
2. **Reckless approximation**: unfamiliar, unexpected, or even unwanted consequences of an emerging technology are granted comparably little attention and resources, and they are often anticipated based on bold assumptions. Because of limits in knowledge, understanding and imagination we may unintentionally neglect or underrepresent risks that arise from domains outside our knowledge and expertise. Accuracy goals of the unknown are typically not made transparent and much lower than in the focus area of pre-existing knowledge.

Both effects appear quite naturally in many research contexts. For example, extensive efforts to improve understanding in a narrowly defined field may co-exist with unintentional or even deliberate ignorance of the outside world. Moreover, the necessary focus in research on specific questions, which should be answerable, at least in theory, can contribute to an imbalanced allocation of resources. Overall this can lead to a false sense of security in risk assessments of emerging technologies.

Table 2 | Example situations where heuristics may have an impact on decision-making

Observation / Situation	Effect / Heuristic at work
… others are engaged in the same activity	social proof, peer pressure
… key people have been successful in the past, also in unrelated fields	expert halo
… we focus on successful examples only and ignore the failures	availability heuristic, base rate neglect
… we have already invested in the project (time, money, resources)	sunk cost effect, prospect theory
… we have positive feelings about the idea, technology, people	affect heuristic
… the decision is consistent with past decisions and successful results	hindsight bias, escalation of commitment
… responsibility is distributed within groups (committee decisions)	risky shift, social loafing

There is a need to address the issue of lack of knowledge by, for example, systematically using concepts of uncertainty, complete ignorance and ambiguity, and describing different levels and features of uncertainty. Research helps to increase knowledge and thereby reduces epistemic uncertainty. Additionally, it is necessary to acknowledge that perfect knowledge is not possible. There will rarely be complete scientific certainty when assessing risks related to emerging technologies. Knowledge gaps are opportunities for learning and drivers for scientific progress and innovation. If everything is known there is little need for risk governance. Thus imperfect knowledge is a raison d'être for risk governance.

Risk governance of emerging technologies has specific challenges caused by the defining properties of complexity, uncertainty and ambiguity. The following case studies illustrate lessons from the past and how we can deal with these challenges. Risk management based exclusively on data and models is problematic for emerging technologies. Understanding the limits of models and knowledge is essential for further developing risk (or uncertainty) governance frameworks. Learnings can help improve decisions about the governance of emerging technologies. Good decisions come from experience, and experience may come from bad decisions. The importance of learning in the context of risk governance, particularly for foreseeing and responding to crises, has been analysed by Haldon et al. (2022). They provide past examples of how societies responded to environmental changes and either succeeded or failed in their efforts to adapt.

> "History can offer something altogether different from [scientific] rules, namely insight. The true function of insight is to inform people about the present [...] We study history in order to see more clearly into the situation in which we are called upon to act [...] The plane on which, ultimately, all problems arise is the plane of 'real' life: that to which they are referred for their solution is history."
> (Collingwood, 1939)

2.

Case studies

This paper reviews analyses of three cases from the past. Chlorofluorocarbons and neonicotinoids are products that have been used for some time without a sufficient understanding of the environmental damage they were causing.The case of liquid biofuel from agricultural products illustrates that large-scale applications of known techniques can cause significant unintended impacts across system borders.

The three examples have been selected from a range of technologies and substances analysed by, for example, the EEA (2001, 2013), to distil important patterns for the governance of emerging technologies. These patterns relate notably to responding to the complete absence of knowledge, epistemic uncertainty, preparation for surprises in the sense of unexpected adverse outcomes, understanding complexity and vested interests, and communication and framing.

In each case described below, some or all of these aspects have not been adequately considered, and the technology eventually caused unintended environmental harm. Our analysis highlights learnings and conclusions from a risk governance perspective.

Each review starts with a summary of environmental impacts, as known today, after several years of large-scale deployment, and how the different stakeholder groups (technology developers, regulatory authorities, and the public) acted during the development phase, i.e., before full-scale deployment.

2.1 CFCs, the ozone layer and the Montreal Protocol

Background

Chlorofluorocarbons (CFCs) were synthesised in the late 19th century, and have been used in the industry as propellants, cleansing agents, air-conditioners, and refrigerants since the 1920s. However, the lack of comprehensive scientific knowledge about the detrimental effects in the upper atmosphere, where CFCs accumulate over time, caused inappropriate regulation of their production and use.

In 1974 scientists discovered that CFCs are causing the breakdown of ozone in the stratosphere and, consequently, the depletion of the ozone layer, which is a fundamental shield against UV radiation from the sun (Molina & Rowland, 1974). This observation triggered the systematic measurement of ozone and monitoring of CFC production. However, because of a lack of compelling scientific evidence, the chemical industry and governments did not severely restrict the production and use of CFCs. In other words, the early warnings provided by scientists in 1974 were not sufficiently acted upon.

It was not until 1985 that Farman et al. (1985) discovered the severe depletion of the ozone layer over Antarctica. First, the term "ozone hole" was coined in the media, and then the topic attracted sufficient attention and created growing public concern (Farman, 2001; IRGC, 2009).

Risk assessment & regulation process

After scientific evidence increased, the US government took measures to govern CFCs. At the same time, the industry tried to deny the existence of reputable evidence until the discovery of the Antarctic ozone hole (Farman, 2001).

A coalition of governments initiated a push for binding regulation on CFCs, followed by the United Nations Environment Programme (UNEP) in 1982. The UNEP inter-governmental negotiations led to the Vienna Convention on Protection of the Ozone Layer in 1985. The Montreal Protocol to this convention (signed in 1987 and enforced in 1989) imposed a strict timetable for phasing out ozone-depleting substances (IRGC, 2009).

The Montreal Protocol on Substances that Deplete the Ozone Layer was a ground-breaking international environmental agreement indeed. All major stakeholders were consulted during the negotiations and could cooperate effectively despite differing perspectives and interests. The Montreal Protocol was adopted more than a decade after the first discovery of harm in 1974, but only two years after the public started paying attention to the ozone hole.

The protocol adopts the principle of common but differentiated responsibility among industrialised and developing countries, thereby recognising the origin of the problem and the industrial and economic capacity to use substitutes. In addition, the industry was incentivised to develop replacement substances, thus fostering innovation. The development and availability of alternatives to CFCs was a critical enabling factor to the phasing out of CFCs.

The ozone depletion problem is on its way to being solved, and the ozone hole has started healing due to the protocol. However, the stratospheric ozone layer still bears the impacts of ozone-depleting substances because atmospheric concentrations decrease very slowly: atmospheric lifetimes of CFCs can be 50–100 years (WMO, 2006). The 2014 scientific assessment identified a stable ozone layer since 2000 and predicted a full recovery by the end of the century (WMO, 2014).

However, recent observation has identified that the ozone layer is shrinking again. In 2021, the hole was larger and deeper than 70% of ozone holes since 1979, reaching a maximum area of 24.8 million km^2 (WMO, 2022).

Risk governance observations

Before the 1970s and based on the previous 30 years of experience, risk assessment outcomes would not have raised serious concerns. CFCs have been designed to be chemically inert. Chemical inertia is generally regarded as a safety property but also leads to long environmental persistence times. Hence, the safety design of CFC involves a risk-risk trade-off: mitigation of a particular risk can lead to ancillary risks and unforeseen consequences. Because CFCs remain stable in the environment for very long times, they accumulate in a region where they eventually interact with the environment and cause harm. Practices that appear to be reasonable when introduced (in this case, when there were considerable gaps in the understanding of atmospheric processes) may later (as understanding improves) be seen to lead to a major global problem that can neither be avoided nor rapidly resolved (Farman, 2001).

The early scientific findings of Molina and Rowland in 1974 brought only limited action. It was the overall accumulation of scientific evidence combined with public attention to the ozone hole and the availability of substitutes that catalysed cooperation (Albrecht & Parker, 2019; Parson, 2003). While authoritative scientific assessments alone had been crucial in constraining the policy debates and shaping negotiations and, finally, the agreement, the key trigger was detecting the ozone hole in 1985. This finding was the outcome of systematic monitoring, which is hence of fundamental importance for the eventual adaptation of technology after deployment. Even the responsible scientists were surprised to find the extreme depletion of ozone over Antarctica, both in concentration and spatial extension (Farman, 2001) and created public awareness and pressure on policymakers.

Not only natural science was necessary, but also the social interaction between individual stakeholders. The development and implementation of the Montreal Protocol were based on an evolving community of experts. Participants developed human and social capital through networking activities, enhancing their environmental expertise and internationalism. They adopted global self-identities and established trustworthy relationships worldwide (Canan & Reichman, 2002).

A range of challenges common to international environmental agreements were successfully addressed in the process that led to the Montreal Protocol. The following aspects were instrumental and should be key objectives for multi-stakeholder discussions in general, and also regarding the environmental sustainability of emerging technologies (Albrecht & Parker, 2019):

- attract sufficient participation,
- promote compliance and manage non-compliance,
- strengthen commitments over time,
- neutralise or co-opt potential "veto players",
- make the costs of implementation affordable,
- leverage public opinion in support of the regime's goals, and
- promote the behavioural and policy changes needed to solve the problems and achieve the goals.

The negotiations, the agreement and the implementation of the Montreal Protocol demonstrate that it is feasible to trigger collective action on a global scale, even when the problems in question are difficult to understand, and even if the measurable effects of policies enacted to address the problem have relatively long time horizons before their benefits are apparent (Albrecht & Parker, 2019).

Hence, it is plausible to ask whether the approach and success of the Montreal Protocol can be transferred to other environmental challenges. There are limitations, however.

First, the availability of alternative chemical substances was a key enabler for the phase-out of CFCs. This may not be applicable elsewhere, although it is the approach taken by the EU Chemicals Strategy for Sustainability adopted in October 2020, which aims to require substituting harmful chemicals with less toxic chemicals.

Second, the political context of the 1980s was open to precautionary measures, creating a promising situation for addressing potentially disastrous global environmental threats. Since then, the political context has been claimed to have changed over the years to focus on profit, not precaution, into a "neoliberal" stance, in particular in the US, where concern for individual (and corporate) freedom is more substantial (Gareau, 2015). The EU, however, attempts to progress on both seemingly conflicting objectives simultaneously and aims to reconcile innovation and precaution. The political background must be kept in mind when one attempts to draw lessons from the CFC case and apply them to current and future situations.

2.2 Liquid biofuels in the EU

Background

Biomass has been a source of energy for millennia. Since the 1970s, government policies and programmes in many countries have led to the increased use of a broad range of biological resources as feedstocks for bioenergy. There are many different types and uses of bioenergy. This paper focuses on the case of liquid biofuels for transportation.

In the early 2000s, biofuels began to be actively considered as innovative use of existing agricultural technology that could contribute to reducing CO_2 emissions from fossil fuels. In addition, it brought an innovative change in agricultural production — mainly sugarcane, soy, maise and oil palm — leading to new products.

Three main interests drove the increasing production of biofuel (Hunsberger et al., 2014):

- **climate change mitigation** — attempts to reduce greenhouse gas (GHG) emissions raised interest in biofuels as a substitute for fossil fuels,
- **energy security** — fluctuating oil prices and uncertainty over future supplies drove interest in biofuels, and
- **economic growth in the agriculture sector.**

As a result of these interests, many governments provided financial support to producers (through subsidies) and even mandated the use of some biofuels in the transportation fuel mix. As a result, the production of biofuel crops increased rapidly.

Obviously, growing crops to produce energy also poses a threat to food production. Existing cropland is either converted to grow specific biofuel crops or so-called “flex crops” are converted into biofuel rather than food/feed. Since agricultural food production is still necessary, it may also cause an extension of agricultural land into previous non-cropland, possibly including areas with high carbon stock such as forests, wetlands and peatlands. CO_2 stored in trees and soil may be released, and biodiversity may be threatened. This process is known as indirect land-use change (ILUC).

The food versus fuel debate and growing concerns about social conflicts, e.g., changing ownerships from the local community to international organisations (land grabbing), drove a strong push for the development and implementation of sustainability criteria and frameworks (Chum et al., 2011). A promising initiative for providing frameworks for sustainable bioenergy is the Roundtable for Sustainable Bioenergy (RSB)[3]. The RSB is a multi-stakeholder organisation with members from the industry, NGOs, academia and government, with the common objective of providing global standards and certification to ensure the sustainability of all biomaterials.

Risk assessment & regulation process

Bioenergy policies, particularly biofuels, have changed rapidly and dramatically over time. We briefly summarise the regulation processes in the EU as an illustration of adapting regulation when unintended and previously unconsidered consequences surface and increase the need to act (Jordan & Moore, 2020).

In the late 1990s, the EU did not have a coherent, Europe-wide policy to promote the use of biofuels. Instead, driven by the three policy challenges mentioned above – rising GHG emissions from the transport sector, energy insecurity, and agricultural overproduction in some EU Member States – policies were designed to increase the production and use of biofuel.

The transportation sector was an obvious first target. The assumption was that greater biofuel use would not be overly disruptive from a technological perspective. In other words, the benefits of this transition were clear, and the ancillary side effects were regarded as acceptable.

The 2003 Biofuels Directive (EU, 2003) marked the EU’s first significant attempt to actively govern the production of biofuels for use in the transport sector. When it became clear that stricter regulation of biofuel production would be needed to ensure sustainability, the directive was revised in 2009, and its scope was broadened (EU, 2009). The new directive included sustainability criteria that addressed social issues related to land rights and labour and environmental considerations beyond climate, such as biodiversity.

The diversity of private biofuel certification schemes also warranted EU-level control. Continued problems with the diversity of private schemes resulted in additional procedural regulation in the 2015 ILUC Directive (Renkens, 2020) to reduce the risk of indirect land-use change and prepare for the transition towards advanced biofuels. There were limits on high ILUC-risk biofuels, bioliquids and biomass fuels with a significant expansion in land with high carbon stock. The directive also introduced an exemption from these limits for biofuels, bioliquids and biomass fuels certified as low ILUC risk.

The revised Renewable Energy Directive (EU) 2018/2001 (EU, 2018) established an overall policy for promoting and using energy from renewable sources in the EU. The current directive reinforces the sustainability criteria of bioenergy, including the negative direct impact due to ILUC.

Risk governance observations

The case of biofuels reveals the frequently observed gap between initial expectations and actual outcomes in the form of unintended consequences (e.g., ILUC, social injustice, biodiversity) and unmet targets (e.g., questionable impact on GHG reduction) (Hunsberger, 2015). This observation relates to the common lesson from studying the risk governance of emerging technologies. New technologies or applications are introduced for a particular benefit.

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[3] See www.rsb.org.

However, this benefit may not realise because unintended or unanticipated consequences may arise, and deficits in risk assessment and mitigation may occur.

From a risk governance perspective, bioenergy has complex societal and environmental interactions (e.g., health, poverty, biodiversity), which may be positive or negative depending on local conditions and the design and implementation of specific projects.

Hence, biofuel regulation needs to consider broader issues like land rights, food, rural livelihoods and ecologies, not simply focusing on the benefits and apparent risks. The systemic nature of the food-energy nexus demands different forms of governance (IRGC, 2015). Early biofuel policies shared a common weakness: "by treating complex problems as though they were separate, these policies apply pressure on narrowly-defined situations in a way that does nothing to prevent problems from simply moving" (Hunsberger, 2015).

A second risk governance observation relates to the concept of "hybrid governance," an approach linking public regulation, private governance and certification arrangements (Ponte, 2014). Regulators in the EU have used a range of measures to initiate and support private biofuel certification schemes and incorporate them into their regulatory frameworks. This has led to a hybrid regime in which public and private approaches are closely intertwined (Schleifer, 2013), and a more comprehensive range of actors have become involved.

Commonly used formats of hybrid biofuel governance are "sustainability roundtables", which aim to establish democratic legitimacy as multi-stakeholder platforms.

While this is valuable in principle, it leads to even more complexity in the governance process. It allows industry-led initiatives (quicker, less democratic) to compete in the sustainability certification market (Ponte, 2014). Instead of yielding an increasingly stringent sustainability framework, the hybrid EU governance arrangements resulted in a "proliferation of relatively lax, industry-driven, sustainability standards" (Stattmann et al., 2018).

Delegating responsibility for social and environmental regulation to the private sector has led to voluntary standards and certifications. In the past, the private certification market has been largely ineffective for the following reasons: (1) rush to the minimum: producers who pursue certification tend to choose the least demanding schemes, and (2) enforcing and availability: many producers cannot or choose not to seek certification (Hunsberger, 2015).

There is also evidence that social criteria were treated as less important than production, and environmental or social practices have not improved in many places where biofuel crops are grown (Hunsberger, 2015; Hunsberger et al., 2014).

It appears easy to criticise the role of the private certification market. However, there is no realistic alternative to multi-stakeholder approaches in risk governance of emerging technologies. Hybrid governance certainly has its benefits, particularly orchestrating the different stakeholder groups with diverging interests towards a common framework. Furthermore, there are successful public-private partnerships in the form of roundtables that provide platforms for successful dialogue and cooperation, e.g., RSB. These can be instrumental in addressing uncertainty and aligning stakeholder interests for the design of public regulation.

Critical success factors in "hybrid governance" appear to be the clear allocation of responsibilities, the execution of controls, adequate resources for all stakeholders involved and transparency about individual interests. This resonates well with key factors bringing the Montreal Protocol to life, as explained in the previous section.

2.3 Neonicotinoids and honey bees

Background

Neonicotinoid pesticides (neonics) were first introduced in the mid-1990s, and their use has proliferated. They belong to the class of systemic pesticides, i.e., they can be applied to the seeds and taken up by the plant during growth (seed dressing). While losses are smaller than through aerial dispersion, only approximately 5% of the active ingredient is taken up by crop plants, and the majority disperses into the wider environment (Wood & Goulson, 2017).

Bees are critically important in the environment, sustaining biodiversity by providing essential pollination for a wide range of crops and wild plants. The Food and Agriculture Organization of the United

Nations (FAO) estimates that of the 100 crop species that provide 90% of food worldwide, 71 are pollinated by bees. Most crops grown in the EU depend on insect pollination.[4]

Several factors will impact the health of bee populations, acting in combination or separately. These include the effects of intensive agriculture and pesticide use, starvation and poor bee nutrition, viruses, attacks by pathogens and invasive species (e.g., the Varroa mite) and environmental changes (e.g., habitat fragmentation and loss). As commonly observed, complex causal relationships call for systemic risk governance.

This paper focuses on the effects of neonics on honeybees only (EEA, 2013). However, we note that the unintended effects of systemic pesticides are much broader and potentially also impact human health (Zhang & Lu, 2022).

Risk assessment & regulation process

After the introduction of neonics to the market in the 1990s, the first signs of detrimental effects on non-target organisms were observed. Beekeepers reported unusual weakening of bee numbers and colony losses, particularly in West European countries. However, at the same time, the manufacturers considered that there was no risk to honeybees under proper use, i.e., for seed-dressing.

The observation of adverse effects triggered an intense controversy about significance and causality among different stakeholder groups (beekeepers, environmentalists, manufacturers, scientists and policymakers). Scientific evidence mounted and, due to the high political and economic stakes, was discussed fiercely, both in public and within the scientific community. The positions of opposing stakeholders hardened, and science was increasingly instrumentalised. Scientific work was sometimes not judged according to its scientific merit but based on whether or not it supported the positions of some stakeholders (Maxim & van der Sluijs, 2013).

In 2012, the European Food Safety Authority (EFSA) was commissioned to produce risk assessments for three different types of neonics (clothianidin, imidacloprid and thiamethoxam) and their impact on bees. Based on the EFSA results, the EU severely restricted the use of these substances in May 2013 (EU, 2013). It prohibited the outdoor use with bee-attracting crops, including maise, oilseed rape and sunflower.

Following further assessments based on additional research and data, the EFSA published an updated risk assessment in 2018. The EC and EU Member States concluded that the EFSA findings confirm previously identified outdoor use risks. Consequently, the decision was that all outdoor use is banned, and only the use in permanent greenhouses remains possible.[5]

Several EU member states have granted so-called Emergency Authorisations for the continued use of neonicotinoids after 2013 and 2018. The assessment of validity for these authorisations is currently ongoing. A recent report from Greenpeace reveals that EU member states have issued Emergency Authorisations in more than fifty cases since 2018, sometimes even unrelated to food production, but purely for economic interests.[6] Most other countries worldwide have not restricted the use of neonics, and farmers still prefer neonics for their minimal cost and their benefits, i.e., low to moderate resistance and strong insecticidal effects.

The EC's decision to ban neonics in the EU was recently confirmed by the Court of Justice of the EU on 6 May 2021[7]. In 2018 producers of neonics filed an appeal on the ground that such a ban could have "far-reaching consequences" for the certainty and predictability of active substance approvals in the EU. However, the Court decided that the Commission was within its rights and entitled to use the recent findings of the EFSA, despite not yet being validated by EU member states.

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[4] See efsa.europa.eu/en/topics/topic/bee-health.

[5] See ec.europa.eu/food/plants/pesticides/approval-active-substances/renewal-approval/neonicotinoids_en.

[6] See unearthed.greenpeace.org/2020/07/08/bees-neonicotinoids-bayer-syngenta-eu-ban-loophole/.

[7] See euractiv.com/section/agriculture-food/news/eu-court-backs-commissions-ban-on-controversial-neonicotinoid-pesticides/.

Risk governance observations

The case of neonics offers an excellent opportunity for risk governance lessons (Maxim & van der Sluijs, 2013), which broadly fall into four categories:
(1) dealing with knowledge and uncertainty,
(2) stakeholder management and communication,
(3) structures and processes, and (4) essentiality.

1. Knowledge and uncertainty

The development of neonics and its initial risk assessment by the manufacturers happened in a sandboxed environment, as is usually done. The conclusion was that neonics do not cause harm to pollinators if used for seed dressing. The risk assessment overall results from a Type III error: no proof of harm equals proof of no harm. As it turned out, much lower detection limits were required to measure the presence of neonics in pollen and nectar. Moreover, the risk assessment methods used were initially designed for sprayed pesticides, which are inappropriate for systemic pesticides. For example, the latter also needs to consider chronic effects on bees, not only acute effects.
There was also a lack of long-term environmental and health monitoring, inadequate research into early warning and insufficient use of lay and local knowledge, e.g., beekeepers.

Scientific advice was ambiguous for the following reasons: (1) divergent data came from different sources, (2) sufficient expertise on honeybee biology was lacking and (3) there was not enough time nor rigorous criteria for evaluating the submitted information.

2. Stakeholder management and communication

Stakeholder groups had to cope with increasing mistrust and lack of access to information. Scientists were judged on their positioning in the public debate, and scientific results were frequently misinterpreted.

Stakeholder groups were (and most likely still are) lacking competencies and methods to process and communicate uncertainty and ambiguity. This led to ambiguous and inappropriate communication of scientific results.

3. Structure and processes

Conflicts of interest were not properly managed. The risk assessments were performed both by privately and publicly funded scientists. This distinction was blurred, as some publicly funded laboratories also received funding from the industry, and researchers held consulting positions in the industry. While this is not unusual given the low public funding levels, it puts scientists in a challenging position if research results are controversial.

The risk assessment process lacked clear methodological guidance on the scientific assessment of risks, regarding field vs. laboratory results, and risk measurement (lethal, sublethal effects, accumulation, chronic effects).

The available resources for risk assessment were inadequate. For illustration, the number of applications for authorisation was much too large for the number of public servants available to process the submissions (20,000 applications processed by three servants).

4. Essentiality

If a technology is deemed “essential” for the economy or society, this justifies its ongoing use even under proven detrimental impacts on the environment. The technology may be regarded as essential if there are no substitutes and expected benefits are considered to outweigh possible risks or costs. The validity of the “essentiality argument” needs careful consideration involving all stakeholders’ perspectives.

There were (and still are) diverging views regarding the essentiality of neonics among stakeholders. Industry and farmers maintain that using neonics is essential for their mandate to ensure food availability and security. Manufacturers take the number of Emergency Authorisations as an argument that farmers lack alternatives and neonics should be treated as “essential.” However, the existence of possibilities to circumvent the ban deters resources from developing viable alternatives.

Beekeepers regard the use of neonics as an existential threat to their economic existence in particular and the functioning of the ecosystem in general. So far, the EC has not adopted the view that neonics are essential chemicals.

3.

Common lessons

New technologies or applications are introduced for certain expected benefits. However, benefits may not realise, and unintended consequences may arise, which may not have been anticipated and/or adequately assessed and mitigated.

It can be helpful to consider emerging technologies in the context of transition risks (see figure 1 below) because their dynamic structure is similar to a systemic transition (Collins et al., 2021). The analogy comes from the emerging aspects during the development phase and the disruptive potential in the application phase. Both factors can potentially lead to a system's transition. The resources allocated to define, understand and enable the technology's target benefits often outweigh the available resources to anticipate, model and mitigate the possible countervailing risks. The main argument from IRGC's previous work on transition risk governance[8] is that when not enough attention is paid to the downside risk of an emerging technology, its successful development and deployment may be compromised.

The three cases reviewed in this paper are different in the science and technology they rely on, their development and implementation paths, as well as their public reception and regulatory responses. However, some common lessons can be distilled from a risk governance perspective, which we summarise here. These factors contribute to either the success of risk governance, or its failure if they are ignored or remain neglected. The summary of lessons is meant to offer for consideration a possible set of rules for improving the risk governance of current or future emerging technologies.

Emphasize the common lessons: ensure adequate personnel (in number and competence) and financial resources to design efficient regulatory procedures for early risk identification, assessment and governance and thus reinforce their ability to manage risks effectively. Roundtables appear to give equal rights to all voices, but there is often an imbalance of power and resources. High economic interests of individual stakeholders, e.g., as evident from the neonics example, create an imbalance and make scientific risk assessments difficult.

Address ignorance and uncertainty by engaging in foresight and exploratory impact and risk

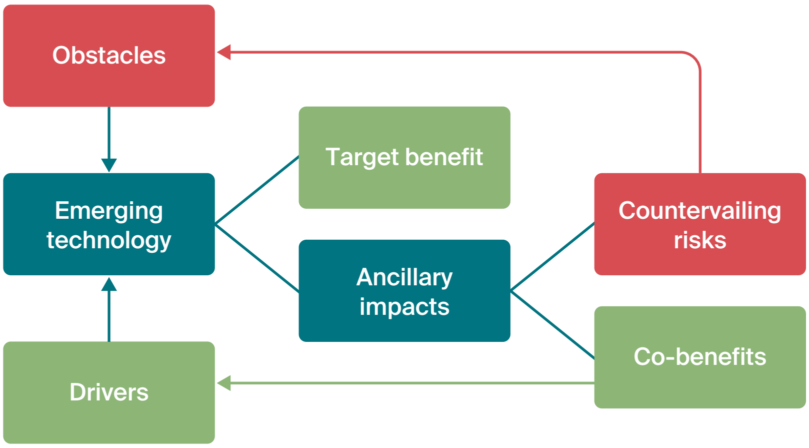

Figure 1 | Elements of the technology development and deployment process. Countervailing risks may adversely impact the target benefits if they are insufficiently addressed

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[8] See epfl.ch/research/domains/irgc/concepts-and-frameworks/transition-risk/.

assessment: risk governance must contribute to identifying future properties of emerging technology and anticipating potential adverse outcomes that may arise from them. Reasonable efforts must then follow to prepare for foreseeable risks. When dealing with new technologies or applications, methods already in use for risk assessment of existing technology may not be relevant, given the new risks' specific properties and characteristics. For example, in the neonics case, risk methods were not adequate; in the CFC case, adequate methods were not even available initially. Limits of understanding, risk assessment and modelling must be made transparent: "In the end, there are few certain and enduring truths in the ecological and biological sciences, nor in the economics, psychologies, sociologies and politics that we use to govern them." (EEA, 2013)

But prepare for unexpected events, too: even the most sophisticated risk assessment will have gaps, for example due to a lack of knowledge and imagination or changing conditions of the environment where the technology is applied. In the first decades of CFC use, there were no concerns regarding adverse effects on the environment, until after more than 30 years when researchers found the first evidence of harm. The development of redundancy, capacities for adaptation and a priori development of alternative strategies and designs is of utmost importance. The case of liquid biofuels illustrates the willingness and possibility to adapt existing regulations to act upon the availability of improved knowledge and understanding.

Understand and embrace complexity: emerging technologies, as defined in this paper, have the potential to change market practices in radical ways (transformational power) and can lead to risks in different sectors (social, political, etc.) through contagion and interconnectedness. Because of their non-linear character, technological "solutions" to complex problems, e.g., the promotion of liquid biofuel production to reduce GHG emissions from the transportation sector, may lead to unintended consequences when scaled up at the system levels. Extra caution must be paid to the differences between laboratory/sandboxed environments and the real world.

Systematic monitoring for early warning signals: early warning requires proactive searching for possible risks in many different directions, e.g., by using an interdisciplinary network of specialists. Ideally, these networks have already been operational for some time, and social capital has been accumulated. While quantification of risk is beneficial and a desirable goal, the lack of possibilities, capabilities and/or capacities for quantification could be compensated by a sound qualitative assessment of the risk. For example, in the case of CFC, the implementation of systematic monitoring led to the detection of the ozone hole, which was instrumental for the Montreal Protocol.

Address conflicts of interest: the independence of science and regulation from economic and political special interests must be maintained or established, e.g., by sufficient transparency about stakeholders' involvement, their interests and financial connections. The stakeholders' vested interest in neonics contributed to the challenge of arriving at an agreeable result. Nevertheless, even with the most outstanding efforts, conflicts may persist and may not be resolved ultimately. For example, some stakeholders regard neonics as essential chemicals (allowing for possible regulation exemptions), while others consider them too harmful to be authorised. Public-private partnerships offer valuable platforms for aligning interests and sharing benefits and risks, but this type of entanglement of private and public actors in regulation (hybrid governance) has its own challenges.

Communication and framing: the debate on the risks from emerging technology applications must usually not be restricted to the scientific community alone. It must involve a broader range of actors, including the general public. Communication rules and procedures must be carefully defined and adhered to to enable a constructive debate and produce balanced solutions. What appears to be important is how the issues are framed in the first place, which parts of the problem are delegated to experts, and which parts fall under the responsibility of democratic institutions. The factors contributing to the success of the Montreal Protocol offer valuable insights into how collaboration between scientists, policymakers, industry and the public can be established. This type of collaboration can provide the foundation for constructive debates and success.

4.

Recommendations and conclusions

In this paper, we have conducted a brief review of analyses of several selected past cases. Each case was characterised by significant economic impact, uncertainty about the consequences of its use on environmental sustainability, and ambiguity concerning the interpretation of its evaluation. The objective of the review was to generate lessons and recommendations for the risk governance of current and future emerging technologies, and to provide a historical perspective relevant to IRGC's ESET project.

We started with the question of why lessons from the past are helpful and how they could be included in the learning process. We highlighted several obstacles, e.g., behavioural biases, that can prevent learning and risk-wise decisions if unaddressed. The explicit acknowledgement and communication of what is unknown or unknowable is important and often neglected, although it is essential for effective risk governance. In particular, limitations of understanding and modelling must be made transparent.

The costs of false positives (Type I error) and false negatives (Type II error) must be carefully assessed to balance benefits and risks. Technological innovation must be possible and environmental concerns must be taken seriously simultaneously.

The risk assessment showed evidence of Type II errors in all three cases of CFCs, biofuels and neonicotinoids. CFCs were not expected to accumulate in the stratosphere, thus causing long-term effects. Growing agricultural crops for producing biofuels to address, among others, GHG emission reduction targets, did not consider the total bandwidth of consequences in the ecological and societal systems. And risk assessment of neonics was based on inadequate methods, such as insufficient detection limits or a lack of understanding of beehive systems.

We believe more awareness is also needed for Type III errors: these occur if we misinterpret the results of hypothesis testing and assume there would be no harm if we cannot find evidence for it. In other words, the inability to prove harm is often understood as proof of no harm. Many reasons can cause the failure to prove harm, e.g., lack of determination and imagination of possible adverse impacts, insufficient resources, methodical deficits, etc. Education of non-scientific stakeholders and unambiguous communication can help to reduce the risk of Type III error reasoning.

The analysis concludes with a compilation of elements to inform the risk governance of current and future emerging technologies.

The common lessons result from a review of past examples, with a particular focus on the risk governance for current and future emerging technologies and expand the range of lessons compared to previous, such as those from the EEA that focused on applications of the precautionary principle.

It is also worth asking which events or factors led to concrete action in the past. Table 3 below summarises key drivers that triggered risk identification, formal assessment, and management decisions. While systematic scientific research appears to be the main factor for action early in the process (risk identification), management decisions also require adequate social structures and value systems in addition to science.

Table 3 | Summary of triggers for action as observed in the past examples

Risk identification	Formal assessment	Management decision
Accidental observations	Amounting evidence	Compelling evidence
Systematic monitoring	Public concerns	Public pressure
Scientific research	Social interaction	Alternatives
Improved understanding	Multi-stakeholder platforms	Unrealised target benefits
		Political context, values, beliefs

We believe the following recommendations are instrumental in improving the sustainability of current and future emerging technologies. These are at the core of the common lessons and address scientific / technological as well as social/structural challenges in the risk governance process:

- Imagine and expect harm in seemingly unconnected systems, possibly (very) remote in time and space;
- To the extent possible, assess the total costs of Type I and Type II errors to balance necessary investments in interdisciplinary foresight and early warning;
- Be aware of the false sense of security through limits of knowledge and understanding;
- Increase transparency about stakeholder interests, allocate responsibilities, execute controls, and invest in social capital (trust) for successful conflict resolution.

Neglecting risk governance can not only cause avoidable harm to the environment, but also puts the successful implementation of the technology and its target benefits at stake.

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Paper 2

Gene drives: Environmental impacts, sustainability, and governance

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Table of contents

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Introduction

This paper, produced in the context of EPFL International Risk Governance Center's (IRGC) project on ensuring the environmental sustainability of emerging technology outcome, overviews gene drive organisms (GDOs), their potential impacts on sustainability and the environment, and special considerations for risk governance. GDOs are designed to spread their genes throughout a population in an ecosystem. Newer GDOs utilize gene editing technologies like CRISPR to bias inheritance of genes with each generation towards 100%. Gene drives can be designed to cause the population to decline (e.g., via female killing) or be beneficial to the population (e.g., via genes that immunize against a disease). Theoretically, the release of just a few organisms could change populations in ecosystems permanently. However, gene drive systems are also being developed and designed to be limited in geography or spread, or to be reversible. GDOs hold promise for controlling agricultural pests with fewer pesticides, protecting endangered and threatened species against pests and ecological hazards, and reducing the transmission of human and animal diseases. However, their open release presents characteristics of emerging risks that are accompanied by significant complexity, uncertainty and ambiguity. It is difficult to predict the risks of ecological release of GDOs prior to open release, and open release could cause widespread ecological impacts through complicated and sensitive ecosystems. This situation presents significant challenges for risk assessment, mitigation, management and international governance of GDOs. Given the near impossibility of amassing risk-relevant data prior to release, GDOs make the procedural validity of risk analysis and decision-making even more important in comparison to many other technologies and risks. More robust risk analysis methods and global governance systems are needed to ensure their safe, sustainable and equitable use.

1.

Gene drive technologies

Gene drives are "selfish genes" that bias their own inheritance greater than the typical 50% predicted by Mendelian inheritance. Naturally occurring gene drives, such as homing endonuclease genes (HEGs), have been proposed as ways to suppress or modify populations that carry disease for several decades (Burt, 2003; Curtis, 1968; Deredec et al., 2008; Sinkins & Gould, 2006). However, in recent years, with the advent of gene editing technologies biologists have been using the tools of molecular biology to engineer gene drive systems into animals, plants and microbes (reviewed in Bier, 2022). Most gene drive systems currently under development capitalize on CRISPR-Cas molecular tools (Esvelt et al., 2014). Cas proteins are nucleases that cleave

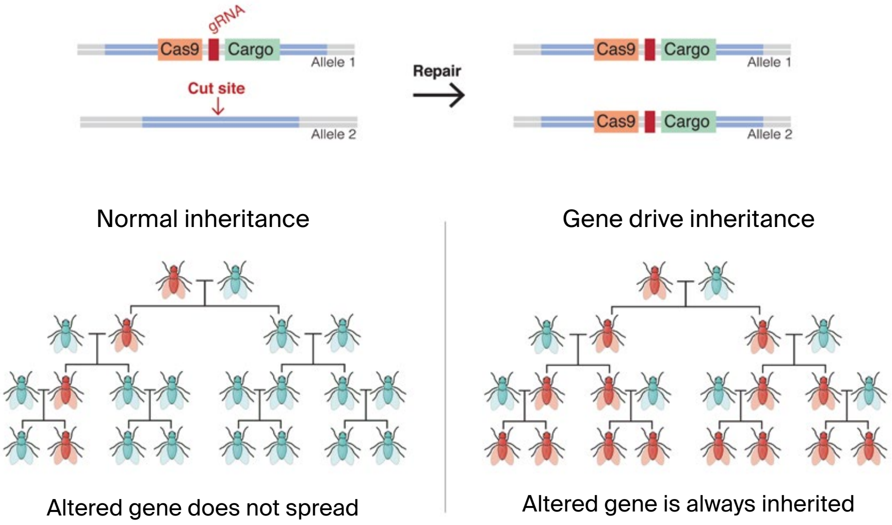

Figure 1 | How gene drives bias inheritance (reprinted from Mariuswalter, 2017)

DNA at “clustered regularly interspaced short palindromic repeats” (CRISPR) frequently present in genomes (Kuzma, 2020). CRISPR-Cas systems can be targeted toward any site in the DNA by “guide RNA” (gRNA) sequences. After the CRISPR-Cas system (with the gRNA) cuts the target DNA site, a double-strand break results, which can either be repaired by the cell or result in a mutation. However, if engineers provide an additional DNA template sequence with homology to either side of the break at its ends, it can be used for repair instead and copied into the break site. If the repair templates include DNA sequences coding for the CRISPR-Cas system and the gRNA, the gene drive system copies itself into cleavage sites via homology directed repair. When this gene drive system is introduced into germ-line cells, it biases inheritance away from 50% (predicted by Mendelian inheritance) towards 100% (depending on the efficiency) (Bier, 2022; Esvelt et al., 2014) (figure 1).

The shorter the generation time of an organism, the faster the engineered gene drive will spread in populations that interbreed. “Cargo genes” confer any type of trait that can be genetically linked to an engineered gene drive system, and even with some fitness cost, these genes will spread through the population along with the gene drive (Bier, 2022). Cargo genes can be designed that confer desirable traits, like disease resistance, or harmful traits that cause the population to decline (e.g., female killing). In the latter case, theoretically, the release of just a few individuals with gene drives could cause the whole population to decline or collapse (given full population mixing and mating) (Esvelt & Gemmell, 2017). In theory, cargo genes can come from any species and be introduced into any host.

The efficacy of gene drives has been studied via mathematical modeling (see also Section 3.1). Efficacy is dependent on factors such as the fitness cost of the gene drive or gene drive/cargo system compared to wild-type genetics; the ratio of the number of organisms released to the total target population; the dominance of the genes targeted or introduced; and mating characteristics and spatial features of the population (Bier, 2022). Gene drives require sexual reproduction to work, as well as short generation times to fixate into the population within a reasonable time frame. With ideal assumptions like complete population mixing and mating, models have predicted it would take 10–20 generations to fix gene drives into wild populations when the initial frequency of GDO individuals released to the wild population was 0.001 (Unckless et al., 2015).

Scientists are working on a variety of types of gene drives (Bier, 2022). Technological choices associated with gene drives include (1) whether the gene drive is designed to suppress the target population or to replace it with a genetically modified population; (2) the rate of its spread; (3) whether it is locally confined or not; (4) whether it has a fitness cost; (5) the rate of DNA sequences resistant to the gene drive with each generation; (6) whether it is reversible; and (7) whether it can be reversed to the original wild-type sequence (Champer et al., 2017). Some gene drives are designed to act globally with no limitations on spread. These are termed “global drives”, and theoretically, the release of one individual can drive the genes through the target population to achieve fixation. Other gene drives can be engineered to be “limited” in theory (e.g., reduce only 20% of the population as “self-limited” gene drives, or target only certain genetic variants of the organism in a particular geographic region as “local” gene drives). Others can require a certain proportion of individuals to be released to drive the gene into the population (e.g., 1,000 individuals per 10,000 wild population need to be released to achieve full spread – a “threshold drive”). However, getting gene drives to work in the field as they are predicted to behave mathematically or as they behave in the laboratory may be challenging (see Section 3.1).

2.

Use of gene drives

Gene drive systems enable the genetic modification of entire populations in situ (within the ecosystem) through the release of just a few individuals of that species. Given their potential power to control or protect species, gene drive research and projects have grown extensively in the past 5 to 10 years, and GDOs are being developed for multiple purposes and societal goals. No gene drives have been released yet into the ecosystem; however, several laboratory cage trials have occurred. To date, synthetic gene drives have been developed in yeast (*Saccharomyces cervisiae, Candida albicans*), fruit flies (*Drosophila melanogaster*), the plant *Arabidopsis thaliana*, diamondback moths (*Plutella xylostella*), mosquitoes (*Anopheles gambaie*, *Aedes aegypti*, *Anopheles stephensi*) and mice (*Mus musculus*) (Verkuijl et al., 2022).

Technology developers are contemplating GDO releases for disease control (e.g., malaria, Dengue, Zika, Lyme’s), pest control (e.g., mice on islands, diamondback moths or fruit flies in agriculture), and conservation (e.g., prevent bird malaria in Hawaii, control mice on islands to protect endangered birds, protect black-footed ferret from plague) (Anthony et al., 2017; Baltzegar et al., 2018; Bier, 2022; Buchman et al., 2018; Davies & Esvelt, 2018; Fidelman et al., 2019; Medina, 2017; Reynolds, 2021). Other places where gene drives are being considered include coral reefs so that they can withstand rising sea temperatures and invasive species programmes of countries like predator-free New Zealand (Dearden et al., 2018; Rode & Estoup, 2019).

Each GDO purpose will have multiple types of ways that gene drives could be designed to accomplish the protection goal. For example, strategies for reducing the disease impacts of insect-transmitted pathogens could involve reducing the population of the insect (i.e., population suppression) or immunizing the insect from carrying the disease (i.e., population modification) (Bier, 2022). Many population suppression approaches rely on using gene drives to cause most or all genetic offspring to be male or members of one sex to be infertile (Bier, 2022). This allows for gene drive spread via one sex (e.g., males) that can mate with the wild-type organism in ecosystems, while also reducing the population (e.g., by killing females before emergence). Gene drives are being developed not only for eradicating agricultural pests (population suppression) (Devos et al., 2021; National Academies of Sciences, Engineering, and Medicine (NASEM), 2016; Romeis et al., 2020), but also to add beneficial genes (e.g., immunizing genes) to protect desired populations (population modification) (Devos et al., 2021; National Academies of Sciences, Engineering, and Medicine (NASEM), 2016).

General applications for gene drives introduced into populations in the environment fall into general categories of eradicating vector-borne human disease, enhancing agricultural safety and sustainability, protecting threatened species, and controlling invasive species (Esvelt et al., 2014; Kuzma & Rawls, 2016). Categories of modes of action include populations suppression (e.g., GDOs with global, self-sustaining gene drives that prevent reproduction), enhancement (e.g., with cargo genes that confer an advantage to the GDO), immunization (e.g., with cargo genes that protect GDOs from disease), or sensitization (e.g., with cargo genes that make an invasive species susceptible to pesticides) (Kuzma & Rawls, 2016). Risk, ethical, societal, regulatory, and ecological issues depend at least in part on the purpose and mode of action of gene drives (Sections 3 & 4).

Human health applications have been the focus of much research on gene drives, especially gene drives to control human disease vectors like mosquitoes transmitting Zika, dengue and malaria. A CRISPR gene drive has been developed that achieved a total population collapse of *Anopheles gambiae* mosquitoes, the carrier of the malaria parasite, in laboratory cage trials (Kyrou et al., 2018). This was achieved by designing the gene drive to insert itself into (and thus disrupt) a sex determination gene (*doublesex*). The females were less fit and not able to reproduce, leading to an eventual crash of the population within 7 to 11 generations in the trials. How these lab trials translate to the field remains to be seen. A separate theoretical modeling study found that the impacts of GDO mosquitos on malaria control in West Africa are likely to vary — from population suppression to complete elimination — depending on sub-regional environmental and physical characteristics (North et al., 2019).

To harness and promote gene drives for controlling mosquito-borne diseases, research consortia have arisen. Target Malaria is a group of scientists and stakeholders joining together in a non-profit consortium to develop *Anopheles* malaria-reducing GDOs for use in sub-Saharan Africa (Target Malaria, n.d.). GDOs are also being developed for other insect-borne diseases like Chagas, sleeping sickness, Leishmaniasis, West Nile virus, and other encephalitic viruses (Bier, 2022).

Gene drive systems in vertebrates, plants, and bacteria are also under research and development (Bier 2022). Gene drives have been successfully developed in mice. Grunwald et al. (2019) reported on the use of a split CRISPR-Cas9 system with female mice carrying the gene Cas9 and males carrying the gene for the gRNA and a gene that modifies the mouse's coat color (Grunwald et al., 2019). They were able to increase inheritance for coat color from the predicted 50% for Mendelian inheritance to 72%.

A research consortium is tackling the conservation application of gene drives for controlling mice on islands. The Genetic Biocontrol of Invasive Rodents (GBIRd) project aims to reduce rodent populations on islands where endangered birds and other species are being destroyed by invasive mice[2]. Currently, rodenticides like Brodifacoum are dispensed through bait stations or aerial methods, and they not only cause a painful death of internal bleeding in the mice but also harm nontarget species that may be endangered. The GBIRd group is harnessing a natural gene drive that works during meiosis, called the t-haplotype, and inserting into it a male-determining gene called Sry to reduce mouse fertility and cause population suppression (Leitschuh et al., 2018). Gene drives with an immunization mode of action have also been proposed in mice to control Lyme's disease in the U.S. on Nantucket Island. Gene drives would be used to spread antibodies toward the parasite causing Lyme's disease in the reservoir species, white-footed mice (Davies & Esvelt, 2018).

Population suppression drives are being considered and developed for agricultural pests. CRISPR-Cas9 gene drives have been proposed for New World screwworm (a pest of livestock still a problem in tropical South America and on some Caribbean islands), the fruit fly *Drosophila suzukii*, the diamondback moth, and the red flour beetle (Scott et al., 2018). Companies are starting to commercialize gene drives for such purposes. For example, one company is pursuing a gene drive for population suppression of the fruit pest, Spotted Winged Drosophila (SWD) (*D. suzukii*). The gene drive system uses a synthetic *Medea* drive with a maternal toxin and an antidote in the zygote (fertilized egg) to kill females with each generation (Buchman et al., 2018). This drive system can bias inheritance up to 100% in the laboratory, but modeling studies suggest that in the field, a relatively high number of GDOs may need to be released.

Other groups have proposed gene drives for the control of agricultural weeds. Genes that confer susceptibility to herbicides could be introduced into weeds that are resistant to the herbicides (National Academies of Sciences, Engineering, and Medicine (NASEM), 2016). However, a challenge with plant-based GDOs is that gene drives rely on sexual reproduction and many plants self-cross, reproduce asexually, have perennial life cycles, or produce seed banks that are dormant (Neve, 2018).

3.

Risk pathways and endpoints of concern

Gene drives seem to present characteristics of all three types of emerging risks (IRGC, 2015): "(1) high uncertainty and a lack of knowledge about potential impacts and interactions with risk-absorbing systems; (2) increasing complexity, emerging interactions and systemic dependencies that can lead to non-linear impacts and surprises; and (3) changes in context (for example social and behavioral trends, organizational settings, regulations, natural environments) that may alter the nature, probability and magnitude of expected impacts". Gene drives involve the complicated context into which they are deployed (socio-ecological systems); uncertainty, as field-level effects cannot be well characterized until ecosystem release; and ecological disturbances that may lead to ecological surprises or non-linear impacts.

One of the first steps of risk analysis is problem formulation. Problem formulation in the context of gene drives involves identifying endpoints to be protected that are of societal value (e.g., health, biodiversity, social or cultural systems, certain species, ecological services, etc.); considering pathways by which events can lead to harm; developing hypotheses about the likelihood and severity of the harm to the endpoints from those pathways; identifying information and data needs for testing those risk hypotheses; and developing a risk assessment plan bringing together data, information, and public engagement in the process (Devos et al., 2021; Roberts et al., 2017). As problem formulation presents value judgements, engaged models for risk analysis of gene drives and other emerging technologies have been recommended so that diverse experts, stakeholders, communities, and marginalized or indigenous groups are consulted (Devos et al., 2021; IRGC, 2015; Kofler et al., 2018; Kuzma, 2019; Kuzma et al., 2018).

Subsequent steps in risk analysis involve exposure assessment, hazard and risk characterization, risk mitigation and management, and risk communication. However, the state of the field of risk analysis for gene drives is still very much in the problem formulation stage, as data and information are lacking, especially on the impacts of field releases of

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[2] See geneticbiocontrol.org.

gene drives. A detailed problem formulation for gene drive risk assessment was recently published that focused on a population suppression GDO designed to combat malaria-transmitting mosquitoes in West Africa. It reported 46 plausible pathways of harm, most of which involved increased human or animal disease transmission as the risk endpoints (Connolly et al., 2021).

Although the ultimate adverse outcomes associated with GDOs may be the same kind as those associated with related technologies like biocontrol or first-generation genetically engineered organisms (e.g., species loss, increased disease), the causal pathways that lead to those outcomes — and their likelihood and magnitude — are likely unique (Hayes et al. 2018). Two approaches to hazard identification for gene drives have been suggested: (1) evaluate hazards identified for more or less similar situations like biocontrol or genetically engineered organisms (GEO) in a "checklist-like approach", and (2) structured hazard identification to anticipate what might go wrong, such as fault-tree analysis (Hayes et al. 2018). With respect to the first approach, a study by Hayes et al. (2018) outlines hazardous occurrences or pathways that could arise at three different levels — the molecular, population or ecosystem level (summarized in table 1). In the following sections, this paper considers some of these pathways from molecular to population and ecosystem levels.

3.1 Molecular risk pathways

Unintended consequences to the environment or human health may arise from a lack of stability and efficacy of the gene drive molecular system.

Table 1 | Hazardous events that could lead to adverse outcomes (adapted from Hayes et al., 2018; also appearing in Kuzma 2020)

Scale	Hazardous events	Examples of potentially adverse ecological outcomes
Molecular	Cas9 cleaves loci with similar, but not identical, homology to the target loci	New phenotype with a different (possibly increased) capacity to spread diseases or pathogens
	Mutated gRNA causes Cas9 cleavage of nontarget sequence	New phenotype with a different (possibly increased) capacity to spread diseases or pathogens
	Cas9 fails to edit or target all alleles	Changes the target organism's ability to survive, reproduce or spread
	Mutations occur during repair of multiple cleavage sites	Changes the target organism's ability to survive, reproduce or spread
Population	Assortative or non-random mating between new phenotypes	Drive is reduced and/or competitive advantage accrues to a more virulent phenotype leading to an increase in the incidence of the disease or pathogen of concern
	Intraspecific (admixture) and interspecific hybridization	Gene drive is acquired by, and spreads within, nontarget population or nontarget species leading to the suppression or modification of this population or species
	Unpredicted phenotypes from gene by environment interactions	Gene drive fails to produce refractory organisms in the wild but increases target organism's capacity to spread diseases or pathogens
Community ecosystem	Population/species suppression changes competitive relationships	Release from competition allows a detrimental population or species to increase in abundance
	Population/species suppression causes extinction of (prey) species	Cascading effects on food web caused by decrease in abundance of predators leading to possible loss of ecosystem services
	Horizontal (lateral) transfer of gene drive to distant species	Gene drive is acquired by, and spreads within, nontarget species, leading to suppression or modification of the nontarget species

Molecular failure pathways can lead to adverse consequences or undesired outcomes related to risk endpoints. For example, with introduced genes for population suppression designed for pest eradication (like female-killing systems), resistance to the gene drive may develop over time depending on the mutation rate of the target site for the gene drive nuclease, fitness costs of the introduced genes like the CRISPR-Casx system or cargo genes, and the likelihood of non-homologous end joining (NHEJ) occurring prior to copying the gene drive into the homologous chromosome (Bier, 2022). The design of gene drives to include target sites that have lower genetic variation in the population (low polymorphisms) can both increase the probability that the drive will be propagated through the intended population and decrease the chance that it will disrupt nontarget species in the ecosystem (a population or ecosystem risk).

In experimental studies, one of the main reasons that gene drives fail, or disappear from the population, is due to emergence of mutations causing resistance to cutting at the DNA recognition or target site (Unckless et al., 2017). The rapid evolution of resistance could present an important risk for disease eradication and suppression drives, as the released GDOs would not lead to a population decrease but instead would increase the population size (from released GDOs adding to the wild population) and thus potentially increase the chance of disease transmission. Mutations can make the wild-type chromosomes resistant to further cleavage by the Cas9 endonuclease and cease the spread of the gene drive. To combat resistance, it has been proposed to use several gRNAs that target multiple sites (Bier, 2022; Noble et al., 2017), much like using multiple antibiotics to combat bacteria resistant to disease treatment. Experimental studies have found that targeting multiple sites does indeed decrease resistance (Champer et al., 2018). However, multi-site targeting might also lead to greater unintended effects by increasing the potential for the gene drive to cut and mutate off-target sites (discussed below).

Another molecular risk pathway stems from off-target binding, cutting, and edits or deletions in DNA regions with some homology to the target site for the gene drive system. Furthermore, the gRNA used to target sites with CRISPR-Casx gene drives could also mutate, causing additional off-target effects (Scharenberg et al., 2016). These off-target edits could have a variety of impacts, including fitness costs, which would be undesirable for immunization or protection drives designed to increase species survival. CRISPR-Cas gene drives are designed to be active over many generations, and with every one, the chance of mutation at off-target sites increases. With each generation in the gene drive heritance chain, mutations could therefore accumulate, increasing the likelihood of detrimental effects.

Cutting at off-target sites could disrupt genes that are important for survival. If the gene drive is meant to immunize a valuable or endangered species for example against a disease, an off-target mutation that is detrimental to the organism could spread and lead to a substantial risk to the health and survival of the species instead of achieving the intended benefit of increased survival. Furthermore, the gene drive could be transferred to another species or subspecies that is important to the ecosystem either through mating (if sexually compatible with the GDO) or horizontal gene transfer, albeit there is a low probability for the latter. Off-target mutations in the recipient species could then accumulate and cause a reduction in fitness. On the flip side, with gene drives intended to suppress or eradicate a population, off-target mutations could instead counteract this goal and make the organisms more fit or a bigger threat to the ecosystem. The unexpected survival of the population, despite the suppression drive, could lead to increased pestilence, disease transmission, or predation of other important species.

Some studies have shown no off-target mutations after careful selection of unique target sequences and optimization of both the gRNA and Cas nuclease (Cho et al., 2014). However, a meta-analysis of mouse studies using CRISPR-Cas9 for gene editing found off-target edits in 23% of the experiments (Anderson et al., 2018).

3.2 Population and ecosystem risk pathways

Changes to populations of important species in an ecosystem may have wide-ranging effects on biodiversity, food webs and ecosystem services (Connolly et al., 2022; Devos et al., 2021; Esvelt & Gemmell, 2017; Greenbaum et al., 2019; Hayes et al., 2018; Webber et al., 2015). For population suppression or eradication gene drives, where the goal is species decline, the demise of that target population could lead to decreases in their predators or increases in species on which they prey. If the GDO with the suppression drive is a predator that keeps another pest population in check, increases in pestilence or disease may result from the overabundance of the prey. In the case of disease-carrying organisms being suppressed or eradicated with gene drives, this might lead to the filling of the ecological niche with organisms that carry even worse diseases (Bier, 2022).

Furthermore, if the GDO is an invasive species to an ecosystem and is eradicated through a population suppression drive, another more harmful alien invader could take its place, potentially causing more damage to the ecosystem. For example, the eradication of feral goats and pigs on the Sarigan islands in the Western Pacific led to the proliferation of a new invasive vine in the region (Kessler, 2002). In summary, removing a species (whether native or invasive) with gene drive technology "could produce unintended cascades that may represent a greater net threat than that of the target species" (Webber et al., 2015).

Unanticipated ecological impacts may arise from a gene drive itself spreading into a nontarget population of the same or a different species, which is referred to as a "spillover" (Greenbaum et al., 2019). Spillover effects can be beneficial, neutral, or detrimental to the ecological health of the recipient species, predators or symbionts that depend on the species, or ecosystem services to which the species contributes. Risk has two components: the likelihood of exposure to a hazard and the severity of adverse effects stemming from that exposure. The ecological risk from gene drive spillover depends on both. In other words, the mere presence of gene drives in nontarget species does not necessarily lead to harm. Rather, it is the effects of those events that matter. Three risk pathways leading to unanticipated gene drive movement and exposure to non-target populations are migration, hybridization, and horizontal gene transfer.

A species that is invasive or considered a pest in one geographic region may be native or desired in another region. If a GDO containing an eradication or suppression drive migrates outside the target area, it could cause beneficial populations in those areas to crash. Migration patterns and other ecological or weather-related variables are difficult to model and predict (Greenbaum et al., 2019). In addition, human travel patterns and commodity trading in a global market could lead to the movement of a GDO far beyond the expected range.

Hybridization of GDOs with sexually compatible species could also be problematic. There is precedent for transgenes from genetically engineered plants in field trials to contaminate native populations. For example, glyphosate-resistance genes originally present in contained field trials of genetically engineered bentgrass have been found in native grass populations on National Parklands and in intergeneric crosses with other grass species (Zapiola & Mallory-Smith, 2012). Likewise, population suppression drives introduced into an invasive species may be transferred to a beneficial native species in that area through sexual hybridization. If the target DNA site for the gene drive is conserved between the two species, the gene drive would be active in the native population, and if it is a suppression drive the desired population could also decline. Even if the target site for the gene drive is carefully selected to be unique to the invader, the transfer of the gene drive may lead to off-target mutations in the native species and potentially cause harm if essential genes are inactivated.

In addition to migration and hybridization, gene drives could be transferred from one species to another through horizontal gene transfer. Horizontal gene transfer can occur via symbiotic or parasitic viruses, bacteria, fungi, and insects which can act as vehicles to transfer DNA between species. However, transfer from prokaryotes to eukaryotes seems to be more common than the reverse (Keeling & Palmer, 2008). The horizontal gene transfer of the gene drive system would be a low-probability event but potentially has high consequences. These "fault tree" events are largely unpredictable in risk analysis, although better understanding of genomic regions with propensity for horizontal gene transfer may assist with prediction in the future (e.g., Clasen et al., 2018).

Another potential risk pathway is the gene drive system itself causing toxicity to nontarget organisms from contact or consumption. For humans, the likelihood of consuming or coming in contact with a gene drive is low, and the adverse effects of such small exposures are likely to be close to zero. However, for predators or prey that feed on large numbers of species with a gene drive, this could be a significant pathway.

3.3 Social, cultural, and economic risk pathways

Societal impacts associated with GDOs will vary based on the type of GDO, geographical setting, governance system, social and cultural setting, and ownership and power structures. Furthermore, societal impacts of GDOs are intertwined with each other and the socio-ecological systems into which they are deployed (Kuzma et al., 2018). As discussed above, a population targeted by a population suppression gene drive in one geographic area could be a culturally or economically desirable species in an adjacent area. Political and social discord could then ensue over the deployment of a gene drive (Reynolds, 2021). Eradication of an important species could cause direct or indirect economic damage. Direct economic damage could result if the target species for the GDO has economic value itself (e.g., for food, fiber, timber, or fuel). Indirect economic damage may arise from broader ecological consequences. For example, if the target species plays an important role in maintaining ecosystem services or keeping human diseases under control, its decline could result in economic costs such as lost revenues from natural products or increased expenses in health care. It is important to take not only the health and ecological risks into consideration, but also the broader socio-economic impacts, in making decisions about whether to release a GDO organism. Integration of social, cultural, and economic values has been previously recommended for decision modeling of biocontrol of invasive species (Maguire 2004), and these should be considered for GDOs as well.

Non-use values of species are also important to consider in deploying GDOs. For example, if GDOs become pervasive and persist in the environment, as would be the case with population replacement or immunization to protect endangered species, people may view the natural world as tainted. Public rejection of current GMOs often relates to a lack of “naturalness” (Lull & Scheufele, 2017). Even if the species is preserved and can provide ecosystem services through the use of GDOs, current and subsequent generations may obtain less enjoyment from their natural-world surroundings knowing that they are genetically engineered (Kuzma & Rawls, 2016). On the other hand, if no other options exist for saving an endangered species, these impacts may be tolerable to the communities surrounding GDO deployment. Arguments can be made that there is an ethical obligation to deploy GDOs in cases where no alternatives exist for saving human lives or endangered species (e.g., Kuzma & Rawls, 2016).

Animal welfare is another important consideration for GDOs. In some cases, a gene drive approach may be harmful to an animal (Reynolds, 2021). Alternatively, for population control, a GDO could be superior to chemical or other eradication measures that cause greater suffering (Leitschuh et al., 2018). For example, the anticoagulant Brodifacoum has been used to eradicate invasive rodents on islands to protect endangered birds. This chemical kills the animals over a period of days and can cause great suffering to them. Gene drive options that affect rodent fertility may be a superior approach with regard to animal welfare (Leitschuh et al., 2018).

Negative public perception is sometimes seen as a societal risk to be mitigated. Scientists developing GMOs in the past have expressed the need to educate the public so they do not fear genetic engineering. These views are in line with the “deficit model” thinking of risk communication, which espouses that with more education, laypeople will be convinced of the lower risk of the technology in comparison to alternatives (e.g., Ahteensuu, 2012). Public backlash and pressure could stall or even stop GDO development and deployment, however, most of the gene drive community recognizes the failures of deficit model thinking and unidirectional risk communication (Kuzma et al., 2018). Instead, they are turning toward public engagement and bidirectional communication to allow the public to learn more about the risks and benefits of GDOs so they can make their own informed decisions about any future releases in their communities (Gusmano et al., 2021; Harmon, 2016; Kaebnick et al., 2016; National Academies of Sciences, Engineering, and Medicine (NASEM), 2016; Target Malaria, n.d.).

It will be important for the impacts of gene drives to be fairly and equitably distributed. Environmental justice includes making sure that marginalized or under-represented communities do not bear the risks of GDOs disproportionately (distributive justice) and have a voice in decision-making affecting them (procedural justice). Another issue is economic justice. For example, if GDOs are deployed in agriculture for pest control, organic farmers may suffer lost sales and revenue due to contamination by GMOs. Target genes and CRISPR-based gene drives are under consideration for controlling the fruit fly Drosophila suzukii on soft fruits such as cherries, blueberries and raspberries (Scott et al., 2018). It is currently not clear if the presence of GDO insect parts in organic berries would impact organic certification and associated product premiums (Baltzegar et al., 2018).

4.

Risk governance

GDOs raise new and magnified challenges for risk governance in comparison to the deployment of other genetic engineering technologies. Current governance systems for first-generation GEOs have been designed to limit their spread in natural ecosystems through bioconfinement strategies or limited use in managed agricultural settings (Kuzma et al., 2018). In contrast, gene drives are meant to spread through populations, leading some to call for precautionary approaches to the release of GDOs (Kaebnick et al., 2016). The goal of GDO spread also presents challenges to field monitoring and testing, requiring wide boundaries and more resources for data collection. The escape of even one GDO from a laboratory or limited field trial could in some cases (depending on gene drive design) spread a gene throughout an entire population (Min et al., 2018). How we mitigate the chance of escapees from the lab, make decisions about the first open releases, conduct risk assessments under uncertainty, manage potential risks, and include diverse experts and communities in decision-making, are considered below under the umbrella of risk governance.

4.1 Molecular confinement strategies

Methods based on molecular biology have been proposed for stopping, recalling, or reversing gene drives once GDOs are released (Vella et al., 2017). Development of these risk mitigation technologies is important given that GDOs are designed to spread and impact entire populations in ecosystems, yet their adverse impacts are difficult to assess prior to release. One strategy for reversibility after a GDO is released is to subsequently release drive-resistant individuals that carry a synthetic yet functional copy of the targeted gene without the Cas9 (or other GD nuclease) recognition sequence. These are called synthetic resistant (SR) drives (Vella et al., 2017). This approach is likely effective for eradication drives that impose significant fitness costs, but not for gene drives that have mild, neutral, or advantageous fitness costs.

A second strategy is to release a GDO with a different guide RNA to alter the recognition site of the original gene drive so that it is no longer recognized by the original nuclease. This is called a reversal drive (RD) (Esvelt et al., 2014). This strategy could be used to immunize a species in a certain geographic area against the spread of the GDO from another area (Esvelt et al., 2014). However, theoretical modeling studies have shown that SRs and RDs are not guaranteed to eliminate an unwanted gene drive from a population and could instead result in a mixture of organisms containing the unwanted gene drive, wild type, and RD or SR allele in the species (Vella et al., 2017).

Another scheme for limiting the spread of gene drives involves the use of CRISPR-based “daisy-chain drive” that contains genetic drive elements that are not linked (e.g., on different chromosomes) and are serially dependent or arranged to work in a chain (Esvelt & Gemmell, 2017; Min et al., 2017). Each element drives the next, but their ability to spread is limited due to the successive loss of the elements from the end of the chain via natural selection (Noble et al., 2019). Daisy-chain drives could theoretically drive a useful genetic element to local fixation in a population, while making the changes temporary and limited in geography. However, like SRs and RDs, modeling studies have suggested that daisy-chain drives would only work under a limited set of conditions (Dhole et al., 2018). Other split gene drive systems and “gene drive neutralizing” molecular systems strategies have been proposed with suggestions that they may require less stringent laboratory confinement conditions if employed (Bier, 2022).

Regardless, there is significant worry that molecular approaches to counteract gene drives based on gene drive technology would not only fail in the field given the ecological complexities, but also potentially lead to additional, unintended adverse effects. The public may also be uncomfortable with using a technological fix to prevent future technological failures. For example, with reversal and immunizing drives, the “wild” population would continue to carry engineered genes for Cas nucleases and guide RNA. This could perpetuate off-target mutations in the species, leading to potential ecological, health, or societal impacts (Section 3). Robust physical confinement and good risk assessment methods are still of utmost importance for preventing premature release.

4.2 Biosafety and biosecurity

Specific protocols for physical, reproductive, ecological and molecular barriers for biosafety in laboratory studies using GDOs have been proposed (Akbari et al., 2015). Ecological barriers include performing experiments outside the habitable range of the GDO, or in areas without potential wild mates, so that in the event the GDO escapes from the laboratory, the spread would be unlikely. Reproductive strategies involve using strains in the lab that cannot reproduce with wild relatives in the surrounding area. Molecular containment methods include using strains with specific target sequences for the gene drive that do not exist in the wild population. It has been recommended that physical barriers occur at multiple levels, along with reproductive and molecular barriers. Redundant containment is important so that if one level fails, another barrier could stop an escapee from spreading the gene drive (Akbari et al., 2015; Esvelt et al., 2014).

Stepwise guidelines for testing gene drives have been proposed to allow for time for anticipating risks before full-scale release (Bier, 2022; James et al., 2018; National Academies of Sciences, Engineering, and Medicine (NASEM), 2016). Phase 1 involves laboratory development and cage trial testing. Phase 2 consists of confined outdoor tests (either in large cages in the area of proposed release or in isolated environments such as islands). In Phase 3, there is limited open-field testing in areas of release. Finally, in Phase 4, there is full release and implementation with monitoring. However, the guidelines remain unclear on the exact criteria, types of risk studies, nontarget endpoints to be assessed, or tolerable risk levels that would be used in decision models to move from lab or cage trials to the first open-release field trials (particularly from Phase 1 to 2 or Phase 2 to 3). The uncertainties associated with GDOs are immense, and more specific decision protocols are needed to help determine when the first open release does not present an unreasonable potential risk.

Attributes of social and economic systems will also influence the spread of gene drives. Human patterns of movement may carry GDOs into unwanted areas via passive transport across national borders through trade or travel (Esvelt & Gemmell, 2017; Gloria-Soria et al., 2014). Unfortunately, the unintended movement of species via humans or goods can be sporadic, causing great uncertainty in the probability of occurrence. To minimize risk from these stochastic events, it has been suggested that the first open releases of GDOs should be on isolated islands with no-to-low human traffic, good border control, and large physical distances from the shore (Webber et al., 2015). Others have recommended that self-sustaining and global gene drives should only be used on target species for which global eradication of the species would not be seen as a problem (Esvelt & Gemmell, 2017; Noble et al., 2018).

Deliberate unapproved releases of GDOs by humans could occur and may be incentivized by potential economic or personal gain. For example, even if GDO rats are intended for release only on isolated islands, there would be little to prevent a rogue actor from smuggling a few GDOs to mainland areas for disseminating cheap and effective pest control (Esvelt & Gemmell, 2017). GDOs might also be released by rogue actors for more maleficent purposes to wreak havoc on ecosystems, agriculture, socioeconomic systems and human health.

Biosecurity to prevent intentional misuse of GDOs will be difficult in the future. Currently, the technical challenges with successfully engineering a gene drive that is effective in an ecosystem provide a significant barrier to misuse. However, once working GDOs are more readily available, they could be used to harm or eradicate desirable species. Some have called for the scientific research community to prevent the disclosure of instructions for making gene drives in scientific manuscripts or patent applications, citing the historical case in which nuclear weapons technology remained classified for 70 years after the Manhattan Project (Gurwitz, 2014). Others disagree, arguing that if GDO developments were kept secret, it would prevent the progress of science not only in addressing important health and ecological problems in the future, but also in defending against the misuse of gene drives (Oye & Esvelt, 2014).

The Defense Advanced Research Projects Agency (DARPA) in the U.S. has invested significant resources in the “Safe Genes” programme, upwards of $100 million, to develop tools and methodologies to “control, counter, and even reverse the effects of genome editing – including gene drives”[3]. However, DARPA’s leadership in this area could be met with the suspicion that the underlying purpose is really for future weaponization (Callaway, 2017). In parallel, a unit of the Office of the Director of U.S. National Intelligence, the Intelligence Advanced Research Projects Agency (IARPA), is working on capabilities to detect harmful GMOs and GDOs (Callaway, 2017).

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[3] See www.darpa.mil/program/safe-genes.

4.3 Risk analysis

Even with strict biosafety, biosecurity and countermeasures, 100% containment or prevention of risk is not likely. Risk analysis methods, such as fault-tree analysis, can be used to estimate low-probability and potentially high-consequence adverse events associated with GDOs and seem well-suited for thinking about the risks of GDOs from laboratory or confinement breakdowns. However, our current ability to quantify such failures is severely limited by the significant uncertainties associated with GDOs in part stemming from a lack of relevant ecosystem and biological studies (Section 1).

Risk analysis is laden with assumptions and interpretations based on values. For example, the endpoints we choose to evaluate in a risk assessment are based on what we care about (e.g., certain species, certain natural resources, certain human illnesses, etc.). Also, uncertainty in risk analysis leads to various interpretations of the data to which we bring our own experiences, cultures, and worldviews. Even if we have good information, the level at which something is presumed "safe" is debatable as safety is a socially defined concept. Science gives us a guide, but what risks are acceptable are based on values, taking into consideration our experiences, culture, perceptions of the benefits, control over the situation, and trust in those managing the risks (Kuzma, 2017).

Furthermore, uncertainty due to natural-world variables stems from several dimensions discussed in Section 3. Ecological sources include, but are not limited to: (1) the low, but nonnegligible, probability of horizontal gene transfer of a population suppression drive to a desirable or beneficial species resulting in its demise; (2) the ramifications of population reductions of the target species on other species like predators; (3) the possibility that another, more harmful species could fill the ecological niche of the eradicated population; and (4) potential impacts on ecosystem services from reductions in the target population. As previously discussed, a significant challenge with GDOs, is that field trials are the best way to study such interactions and gather data. Yet, we want to do risk assessment prior to field trials as GDOs are meant to spread and field trials are likely to result in GDO spread via open release.

Not only do population, ecological, mating, and genetic characteristics matter for the impacts of gene drives, but so do biophysical attributes of weather and climate and geographic features of habitats such as barriers (Kuzma et al., 2018). Sporadic and severe weather and climate events make the prediction of risk difficult. These events will affect the spread of GDOs and their distribution for mating with other subpopulations. Even if a field trial can be confined, it is unlikely to capture the range of physical conditions under which gene drives will be deployed. These conditions will impact interactions with and potential risks to other species, such as predators and prey. There is a need for better ecosystem and population models of GDOs that account for variability in biophysical parameters across temporal and geographic scales.

GDOs have features of "emerging risks" that are "characterized mainly by uncertainty regarding their potential consequences and/or probabilities of occurrence" which "can be due to a lack of knowledge about causal or functional relationships between new risk sources and their environment or to the insufficient application of available knowledge to the case in question" (IRGC, 2015). For these situations, evaluating the "substantive validity" of risk assessments —where outcomes of the risk assessment are compared to what happens in reality— is not feasible, especially prior to any environmental release. Therefore, "procedural validity" of the risk assessment, that is how the risk assessment is conducted, becomes even more important than attempting to ascertain the substantive validity of particular risk evaluations prior to GDO release and field data collection.

Methods for making the process of risk assessment for GDOs more legitimate and robust have been suggested. These approaches make use of ideas from post-normal science (PNS) (Brossard et al., 2019; Funtowicz & Ravetz, 1994). PNS suggests that when the "decision stakes are high and the system uncertainties great, extended peer and stakeholder communities (beyond scientific researchers) should be consulted to interpret what is known and what it means for the policy decision at hand" (Funtowicz & Ravetz, 1994, as cited in Kuzma 2021). Diverse values become an explicit part of risk assessment as the "facts" are uncertain and require interpretation for their meaning (Funtowicz & Ravetz, 1994). People with "on-the-ground" knowledge, who are "interested and affected" (National Research Council [NRC]), 1996), are invited into the deliberations about risk and safety measures, along with a broader range of scholars such as ethicists and social scientists. Scientific experts and government managers still provide important technical analysis, but democratic engagement opens up the policy process for characterizing risk to communities in areas of potential GDO deployment, giving them not only a voice but also a choice in deciding what levels of risk are acceptable to them (National Research Council [NRC], 1996). Bayesian approaches to estimating the risk, drawing on the mental models of a diverse group of experts and stakeholders, can provide important information on parameters for which little is known and thus signal areas where more research is crucial (Hayes et al., 2018). Another framework for conducting risk analysis on GDOs to increase the procedural validity in support of decision-making has been proposed. The Procedurally Robust Risk Analysis Framework draws upon principles of responsible research and innovation, such as humility, procedural validity, inclusion, anticipation, and reflexivity (Kuzma, 2019).

The following recommendations for GDOs risk assessment have recently been made by Devos et al. (2021): “(1) developing more practical risk assessment guidance to ensure appropriate levels of safety; (2) making policy goals and regulatory decision-making criteria operational for use in risk assessment so that what constitutes harm is clearly defined; (3) ensuring a more dynamic interplay between risk assessment and risk management to manage and reduce uncertainty through closely interlinked pre-release modeling and post-release monitoring; (4) considering potential risks against potential benefits, and comparing them with those of alternative actions (including non-intervention) to account for a wider (management) context; and (5) implementing a modular, phased approach to authorisations for incremental acceptance and management of risks and uncertainty.”

4.4 Risk management considerations

The use of gene drives could present a “moral hazard” in precluding other approaches to protecting ecosystems and combating disease (e.g., Lin, 2013). For example, if we know that a GDO can help to mitigate human diseases or ecological risks in the future, we could be less likely to invest in prevention or control methods today, as future generations will bear the risk. Without comprehensive cost-benefit analyses of GDOs deployment that account for a range of health and environmental externalities into the future (Kuzma & Rawls, 2016), we might naively forgo investing in safer, better known, and more effective control methods for disease prevention like bed nets or vaccine development (Kuzma & Rawls, 2016). In the context of GDOs designed to conserve species, the moral hazard may come from undermining efforts to conserve biodiversity through non-technological approaches like habitat protection, reducing greenhouse gases, or ecosystem services protections (Reynolds, 2021).

Gene drive governance has parallels to the governance of other common pool resources (Brown, 2017; Kuzma et al., 2018; Ostrom, 2011). They also share features with public goods, in that their impacts, both positive and negative, are likely to be nonexcludable. Parties without direct control over deployment are likely to experience benefits or harm from GDOs as they spread across landscapes. Likewise, because the deployers of gene drives might not bear all the adverse impacts, they might make riskier decisions than would be socially desirable to release a gene drive (Mitchell et al., 2018). Given the shared features of GDOs with common pool resources and public goods, behavioral and value systems of communities will be important for managing risk through shared governance and collective action (Kofler et al., 2018; Ostrom, 2009).

Gene drive release will require ongoing cooperation between different sectors and geographic regions to plan for, execute, and monitor gene drive releases and their impacts. Shared goals are important for collective-action settings, and in limited geographic areas, goals are more likely shared. As self-sustaining gene drives are designed for greater geographic areas and even for crossing national borders, the potential for shared values and norms is lower (Kuzma et al., 2018). Risk management and governance for gene drives will be a greater challenge across national or cultural boundaries, than for local, self-limited gene drives unlikely to travel outside of a defined area within a nation.

Policies and regulations may limit the types of impacts considered in risk management and governance. In current U.S. regulatory decision-making about GEOs, direct harms, such as toxicity to humans or nontarget organisms, are a primary (and often sole) focus of decision-making (Meghani & Kuzma, 2018; Thompson, 2007). For certain GDOs, the types of risks considered in regulatory decision-making may be further limited depending on the assigned federal agency, the rule evoked, and the GDO species (e.g., Kuzma, 2019; Meghani & Kuzma, 2018). However, non-governmental actors, such as the non-profits and academics developing gene drives, are broadening the scope of governance questions beyond formal regulatory authority (e.g., James et al., 2018; Target Malaria, n.d.).

At the organizational level, capacities among regulators, risk managers, and technology developers to assess and manage risks associated with GDOs need to be bolstered. As discussed, gene drives present the features of emerging risks (IRGC, 2015). IRGC guidelines for emerging risks (2015) suggest that governance institutions should implement four distinct key capabilities: "(1) Enhancing proactive thinking to identify future threats and opportunities; (2) Evaluating the organisation's willingness to bear or to avoid risk (risk appetite) for the definition of future strategies; (3) Prioritising investments in certain key emerging issues according to their potential impact; and (4) Fostering internal communication and building a forward-looking culture to benefit the whole organisation".

4.5 Global governance

There are currently no approved field releases of GDOs, and several national and international bodies have been developing reports and guidelines to make recommendations about their governance in order to prepare for proposals for release. The most relevant international agreement to govern GDOs is likely to be the Convention on Biological Diversity (CBD) and its Cartagena Protocol on Biosafety (Biosafety Protocol, BSP) (Reynolds, 2021). The CBD BSP governs the transboundary movement of living modified organisms (LMOs) as well as providing risk assessment guidance for LMOs and their movement. Also under the CBD is the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress, which requires signatories to create mechanisms for responses and civil liability in the case of significant damage to biological diversity that resulted from the transboundary movement of LMOs.

Since 2018, the CBD has been dealing with risk assessment and other issues surrounding GDOs. The CBD's Ad Hoc Technical Expert Group (AHTEG) on Synthetic Biology has been tasked with undertaking "a review of the current state of knowledge by analyzing information, including but not limited to peer-reviewed published literature, on the potential positive and negative environmental impacts, taking into account human health, cultural and socioeconomic impacts, especially with regard to the value of biodiversity to indigenous peoples and local communities, of current and near-future applications of synthetic biology, including those applications that involve organisms containing engineered gene drives" (Convention on Biological Diversity [CBD], 2018). In the interim, the Conference of the Parties to the CBD calls on governments to apply a precautionary approach to introducing GDOs and to obtain the prior informed consent of indigenous and local communities where appropriate (Convention on Biological Diversity [CBD], 2018). Although GDOs will likely come under the UN CBD-BSP framework for LMOs, this framework is not focused on GDOs; not all countries are party to the CBD-BSP (including major actors in GDOs such as the U.S.); and it mainly provides for advance notice of GMO importation and risk assessment guidance.

Safe, sustainable and equitable deployment of GDOs will require governance across national borders (international) to respect diverse values (especially those of indigenous and marginalized groups), world views, and perspectives on species, ecosystems, and technology. Political conflicts between groups or nations might ensue from GDO deployment. For example, pigs were brought to Hawaii by the Polynesians, and later the Europeans when settling the Hawaiian Islands. The pigs soon established themselves in the wild. In doing so, they disrupted native ecosystems and allowed for other invasive species to move into the area, which ultimately impacted the health of native birds and forests (Maguire, 2004). The eradication of wild pigs in Hawaii using population suppression by conventional techniques (traps, shooting, etc.) is seen as desirable from an ecosystem damage perspective, but Native Hawaiian communities, relying on the feral pigs for cultural events and food, value the pigs for cultural preservation (Maguire, 2004). Wild pig eradication remains a contentious issue. GDOs may face similar situations where cultural and ecological values conflict.

Identifying possible risks through global governance is important, but ethical principles also need to be integrated into processes for determining whether a field trial or release should take place. Many believe that scientists have a social responsibility for informing and engaging publics that will be affected by a gene drive (e.g., Thompson, 2007). However, recommendations have been made that engagement should not be hosted by those who have a conflict of interest in seeing the technology progress, but rather should be led by local communities in areas that are candidates for deployment, while supported by global governance structures to provide the resources and expertise for deliberative engagement

(Kofler et al., 2018). To date, such global governance systems for supporting engagement, conducting procedurally robust risk analysis, and comparing gene drives to other technological and non-technological alternatives are lacking.

5.

Lessons for other emerging technologies

Given that GDOs present a leap in our capabilities to engineer wild populations and come with great uncertainties about their potential impacts, it seems crucial that we provide as much attention and resources to the development of robust and deliberative mechanisms for risk analysis and governance as we do to the development of gene drive technologies. In the face of high uncertainty and ambiguity, stakeholder and public communities should be consulted to identify risk endpoints of concern (which may differ based on geography or culture), define concepts of "safety", and determine acceptable levels of uncertainty or risk-benefit distributions. Equal funding for risk studies and assessment methods (compared to the funding for gene drive development and efficacy studies) also seems warranted, as well as efforts to conduct ecological studies in field cages in the area of release (confined, mesoscale field trials). Stakeholders and publics should also be involved in developing and examining future risk-based scenarios for GDO deployment to inform risk assessments and governance options.

Further guidance is needed for risk assessment of GDOs, along with specific risk-based decision criteria for moving from confined laboratory or caged field trials to open releases. Regardless, the staged model for GDOs release proposed by their developers may provide a good example for risk governance of other emerging technologies. Technology communities for artificial intelligence, nanomaterials, and alternative energy might find the staged release guidelines useful for developing their own approaches for stepwise, responsible technological deployment. Another positive lesson from the GDOs case study is the value of a concomitant investment in technology to reverse or limit gene drives should the need arise based on risk-based monitoring (e.g., the DARPA "Safe Genes" programme). Other technological areas should consider this model for ensuring the reversibility of their technologies should adverse impacts arise.

Although global mechanisms for governance are currently not sufficient for GDOs, there are efforts to address GDOs at international levels, for example, through the UN CBD and BSP, as described above. Other emerging technological areas that are even less far along with international governance could learn from these emerging experiences with GDOs. The UN CBD also provides a mechanism for liability and redress under the Nagoya Protocol for LMOs, which likely applies to GDOs and can provide an example for the governance of other emerging technologies.

Currently, there is disagreement among gene drive developers and stakeholders about whether to impose a moratorium on gene drive releases. Some suggest a moratorium on any GDO release, while others propose a moratorium only on global or self-sustaining gene drives (but not self-limited gene drives). Other developers are more cavalier about open release of gene drives, maintaining faith in the low probability of harm, as well as in reversal drives or other molecular confinement strategies to mitigate risk. There is even more disagreement among global conservation groups, NGOs and civil society actors. GDOs bring to surface the many diverse values associated with ecological protection and restoration, human health protection, technological optimism versus pessimism, and the inherent or non-use value of ecosystems and species. Most agree, however, that gene drives illustrate the need for precautionary approaches, postnormal science, and responsible innovation paradigms, given their ability to widely and permanently alter ecosystems (much like geoengineering).

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Paper 3

Smart materials and safe and sustainable-by-design – a feasibility and policy analysis

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Introduction

Written in the context of EPFL International Risk Governance Center's (IRGC) project on ensuring the environmental sustainability of emerging technology outcomes, this paper considers how so-called "smart materials" are – or could be – assessed and managed to ensure that their applications do not threaten environmental sustainability. In the IRGC project to which this paper contributes, the concept of sustainability is broadly defined as the expectation that both current and future generations can meet their needs (IRGC, 2022). In this context, risks to environmental sustainability essentially cover the risk of damage to the environment that may manifest only in the long term as a result of (a) unknown effects at the time of deployment (examples in some advanced materials), and/or (b) the accumulation process, after a given material has accumulated and crossed some thresholds (examples with common pesticides) and/or (c) a long time gap between the introduction and subsequent manifestation of consequences (for example, with gene-editing techniques).

In the case of many emerging technologies, those whose task it is to anticipate, assess and manage risks do not have the information they need to do so properly. This particularly includes regulators that have a duty to avoid or mitigate risk while also being expected not to stifle innovation.

This paper presents how the EU's Chemicals Strategy for Sustainability aims to address this complex challenge, in particular through the concept of safe and sustainable-by-design (SSbD), and applies it to the case of smart materials.

Smart materials result from technologies that are relatively new, or even emerging. We examine if the currently developed SSbD assessment and reporting criteria are sufficient to address the specific challenges of emerging smart materials, in particular in relation to environmental sustainability.

After introducing the EU Chemicals Strategy for Sustainability (section 1), the paper describes the concept of and current approaches to SSbD (section 2), and then discusses specific features of smart materials (section 3). In conclusion, it reviews some of the challenges that smart materials might raise from a regulatory science perspective in relation to sustainability, life cycles and the protection of human health and the environment (section 4).

1.

EU Chemicals Strategy for Sustainability

In 2020, the European Commission adopted its new "Chemicals Strategy for Sustainability – towards a toxic-free environment" (CSS) (EC, 2020c). The CSS is part of the EU's zero pollution ambition – a key commitment of the European Green Deal – and aims to better protect citizens and the environment from harmful chemicals, as well as boost innovation by promoting the use of safer and more sustainable chemicals (EC, 2019). The CSS is also a key part of the European Green Deal and its associated strategies and policies to abate climate change (e.g., the Fit for 55 package), together with the Circular Economy Action Plan, the Farm to Fork Strategy, the Biodiversity Strategy and the Pharmaceutical Strategy. The CSS builds on previous ambitions to reduce the harm from chemical pollution to people and the planet, such as the European 7th Environment Action Programme (EAP), and a series of background studies supporting the call for a Non-toxic Environment Strategy (Milieu Ltd, Ökopol, Risk & Policy Analysts (RPA) and RIVM, 2017), including a list of potential policy responses (Camboni, 2017). While several of the ambitions of the CSS also relate to existing legislations such as REACH on industrial chemicals, the CSS applies more broadly to chemicals from all sources and to broader impacts, along with the life cycles of chemicals and associated products. The two supporting staff working documents (SWDs) on the combined exposure to mixtures of chemicals and on the per- and polyfluoroalkyl substances (known as PFAS) address chemicals across "vertical" product or environmental media policy silos and throughout their life cycles. The two overarching aims are to avoid harm to people and planet and to foster an industrial transition to safe and sustainable-by-design chemicals and materials, with the guiding principle of preventing pollution and harm, rather than cleaning up afterwards (prevention-mitigation-remediation-elimination).

To address chemicals across legislations, support innovation towards the development of safe and sustainable chemicals and to speed up their upstream regulation, the CSS introduces a number of new concepts, including safe and sustainable-by-design (SSbD), phasing out the most harmful chemicals for "non-essential uses" and the "mixture allocation factor" (MAF) (EC, 2020b). The CSS also calls for the Classification Labelling and Packaging Regulation (CLP) (EC, 2018) to include new hazard classes, with a focus on chronic effects such as developmental neurotoxicity and immunotoxicity, respiratory toxicants and chemicals with the intrinsic characteristics of being persistent and mobile (PMT, vPvM). Acute effects, such as physical hazards (e.g., explosions, corrosiveness, flammability linked to reactivity), and acute risks (e.g., suffocation, excessive nutrients) are not included. In addition, the CSS aims to achieve clean material cycles as well as several other objectives which are captured in the more than 60 actions in the Annex to the CSS (EC, 2020a). The SSbD concept is new in the sense that it brings together considerations on the health and safety of humans and the environment, as well as sustainability related to Earth systems (climate change, the ozone layer), biodiversity and the circular economy. As emphasised by the European Environment Agency (EEA), SSbD targets the upstream, pre-market design phase during technology development, aiming for fundamental changes in designs to deliver services in a tiered approach by (1) applying cut-off criteria to avoid the use of substances of concern and (2) a risk-based and multi-criteria decision approach to minimising impacts throughout chemical and product life cycles (EEA, 2021). This may involve other business models and eco-designs that allow for repair, reuse, upgrading, refurbishment, ease of maintaining and disassembling for recycling, which are energy and resource efficient, as captured in the Sustainable Products Initiative (EC, 2022a).

The CSS – and more specifically, the SSbD – is therefore highly relevant for emerging chemical technologies and smart materials, and it is thus important to analyse the challenges of ensuring their environmental sustainability.

2.

Safe and sustainable-by-design (SSbD)

The SSbD concept underlines that both safety and sustainability should be addressed in the design phase – and not considered as an afterthought, e.g., when a material or product has been developed and is about to be used in society. The scope of SSbD is currently a popular subject of discussion. The EEA (2021) published a briefing on SSbD, focusing on delivering services to minimise harm to the environment and people, which would require the consideration of chemicals, materials, processes and products. In contrast, the CSS only examines the molecular design of chemicals. Production process design and product design are to be addressed in a future sustainable products directive (EC, 2022b). This approach was taken in order to avoid double regulation on products.

The CSS called for the European Commission (EC) to set criteria and methodologies to support the SSbD in relation to chemicals and materials by early 2022, and several proposals have subsequently been made, albeit limited information is provided in the CSS about what these might be. Footnote 19 of the CSS (EC, 2020c), however, does state that the criteria should lay the foundation for a pre-market approach and could include considerations of whether the substance serves a function (or service), avoids volumes and chemical properties that may be harmful, avoids (eco)toxic, persistent, bio-accumulative or mobile substances and minimises the environmental footprint with regard to climate change, resource use, ecosystems and biodiversity from a life cycle perspective. As such, the CSS is clear in including only environmental sustainability aspects – and not societal or economic aspects.

2.1 Criteria and methodologies for SSbD: The JRC framework

The European Joint Research Centre (JRC), which is the EC's science and knowledge service, has been tasked with proposing a framework for the definition of criteria and evaluation procedures for chemicals and materials. In early 2022, a draft report was published and subsequently subjected to public consultation (Caldeira et al., 2022). The proposed methodology consists of a tiered approach, starting with applying cut-off criteria to avoid the use of the most harmful substances as well as substances of concern (SOC), followed by a life cycle (impact) assessment of the products' environmental footprint (PEF). SOCs are defined to some extent in the CSS as being those with chronic effects, although a specific definition of hazard classes is still being discussed internally in the EC. For chemicals and materials that do not meet the initial cut-off criteria, these are only to be allowed in uses proven essential for society. Just as we see with SSbD, how the term "essential use" is defined is subject to discussion, but it is generally understood as usage necessary for health, safety or the functioning of society, where there are no acceptable alternatives when considering the environment and health. Importantly, the Essential Use Concept (EUC) is only anticipated to be applied to known or suspected SOCs. The debate on EUC currently centres around the following: (1) if alternatives should be sought within the same technology group (drop-in substitution) or move to different (e.g., non-chemical) ways to provide the service and (2) if society should have the "right" to decide what is considered essential for the individual — a key example being if society has the right to decide if makeup with harmful substances should be allowed or not. The cut-off criteria follow the CSS's ambition to prevent the use of SOCs based on their intrinsic properties in order to avoid harm to people and the planet and to ensure clean material cycles. Continuing to wait for action until data is available for all chemical hazards and exposures to chemicals (mixtures), across all media and in multiple material cycles is simply unrealistic and has repeatedly proven to be ineffective in preventing the accumulation of pollution and harm (EEA, 2019b, 2019a). The cut-off criteria hence, arguably, represent a preventative and precautionary approach, which is combined with a traditional risk assessment for types of chemicals that currently are not known to be of concern.

Specifically, the JRC framework consists of two parts, namely the (re)design part and a safety and sustainability assessment. For the evaluations, the focus should fall on the functionality of the chemical/material, rather than its structure, which is supposed to make it easier to assess alternatives. Notably, the proposal also includes a consideration of social and economic aspects, which is not included in the original CSS ambition, so it is still unclear as to whether there will be policy support to include this in the final SSbD concept. While this is in line with the Sustainable Development Goals and what companies already do, the counter-argument is that finding agreement on all these complex matters, across technical and social dimensions, will slow down the implementation of the SSbD. A step-wise approach has therefore been proposed, starting with avoiding harmful chemicals and then adding the other dimensions as their frameworks become available (ChemSec, 2021).

To ensure that both safety and sustainability become part of the design process, the JRC framework proposes 13 design principles (Caldeira et al., 2022) (see table 1 below), drawing from the updated 12 principles of Green Chemistry (Anastas & Eghbali, 2009). Two of these are directly related to the development and safety of the chemical in question, namely No 2 "Design with less hazardous chemicals" and No 5 "Prevent and avoid hazardous emissions." Several of the other principles are also related to chemical substances, e.g., No 1 "Material efficiency," which includes all components in the production of the final product, in order to minimise waste, and No 8 "Consider the whole life cycle," which underlines the importance of taking into account every production, usage and end-of-life step. Principle No 4 "Use of renewable resources" is a contested point, since the current production/consumption of chemicals is at a scale whereby if it were moved to renewable feedstocks, it would compete with land set aside for nature as well as land, nutrients and energy used for food. Compared to fossil feedstocks, it also requires more energy and produces significant amounts of waste. Furthermore, it uses biomass, turns it into feedstock chemicals

Table 1 | SSbD principles for the design phase (reprinted from Caldeira et al., 2022)

1.	Material efficiency
2.	Design with less hazardous chemicals
3.	Design for energy efficiency
4.	Use renewable sources
5.	Prevent and avoid hazardous emissions
6.	Reduce exposure to hazardous substances
7.	Design for end-of-life
8.	Consider the whole life cycle

(e.g., ethanol or methane) and then starts the synthesis of chemicals. While principle No 4 “Use of renewable resources” might be a long-term aim, it would require a substantial reduction in global annual chemical production to avoid creating harm to, for instance, food supply ecosystems (Balan et al. 2022). Reducing the production and consumption of chemicals, on the other hand, is the one single action that would greatly reduce all risks across the board, from the extraction of resources through to life cycle emissions of chemicals.

2.2 Assessing safe SSbD

The sustainability assessment proposed by the JRC consists of five steps (see the first column of Table 2 below; columns 2 and 3 will be commented on in Section 2.3). In the first three steps, the safety of the chemical compounds is evaluated, whereas sustainability is examined in the final two steps.

Step four is the most encompassing step in the assessment, as it should include all aspects of environmental sustainability. The JRC suggests that a life cycle assessment (LCA) should be carried out and include toxicity, climate change, pollution and

Table 3 | Aspects to be included in the sustainability assessment (reprinted from Caldeira et al., 2022)

Impact category	
1.	Climate change
2.	Human toxicity, cancer
3.	Human toxicity, non-cancer
4.	Ecotoxicity
5.	Particulate matter
6.	Ionising radiation
7.	Ozone depletion
8.	Eutrophication, terrestrial
9.	Eutrophication, marine
10.	Eutrophication, freshwater)
11.	Ozone formation
12.	Acidification
13.	Mineral and metals resource depletion
14.	Fossil resource depletion
15.	Land use
16.	Water use

Table 2 | SSbD assessment steps and options, as presented by JRC, Cefic and Hauschild

JRC (Caldeira et al., 2022)	Cefic (2022)	Hauschild et al. (2022)
Step 1: Safety of chemical and material; hazard-based approach (cut-off criteria)	**Step 1**: Performance and functionality needs	**Option 1**: Develop an LCA and a risk assessment (RA), with two independent outcomes, without comparing their results
Step 2: Chemical or material processing safety; occupational safety and health approach (production focus)	**Step 2**: Identify scope through assessment dimensions (list of recommendations)	**Option 2**: Develop an LCA and an RA, and evaluate and compare the outcomes of using utility theory
Step 3: Human health and environmental impacts from the use phase; direct exposure (use focus)	**Step 3**: Select design principles along dimensions (list of recommendations)	**Option 3**: Develop an LCA and embed aspects of RA into it
Step 4: Environmental sustainability assessment (LCA)	**Step 4**: Perform comparative assessments	**Option 4**: Develop an LCA and embed RA to maximise the value of the LCA results
Step 5: Social and economic sustainability assessment (may be voluntary)	**Step 5**: Select solutions after having evaluated trade-offs	
Result: Either a class (poor, good, very good) or a numerical score (consider weighting)		

resources (a full list is provided in table 3). Life cycle assessment or analysis is employed to quantify the environmental impacts of a product, a material, a process or an activity. It is a cradle-to-grave approach that assesses all stages of a product's life cycle and estimates cumulative environmental impacts (IRGC, 2022). In order to use LCAs to fully evaluate environmental sustainability, further development of the method is required in order to include all other aspects (Packroff & Marx, 2022). It also needs to be noted that LCAs look at what is considered "normal" use and therefore fails to look at extreme cases, such as accidents (Hauschild et al. 2022). Moreover, in this regard, conventional LCAs apply to existing products and are thus not suitable for future applications of new technologies. For future products, methods for prospective LCAs are being developed, and data gap-filling tools are currently being researched in EU projects such as the Partnership for the Assessment of Risks of Chemicals (PARC). Such gap-filling will address the substantial data gaps in LCAs, i.e., a very data-heavy method where a lot of assumptions often have to be made. This means that more (and different) data is needed, and there is, therefore, a need for new data collection methods in order to generate accurate and useful results (Fantke et al., 2021).

2.3 Other suggestions for assessing SSbD: Cefic, Hauschild, ChemSec

Besides the JRC, other stakeholders have also presented alternative approaches to SSbD. For instance, Cefic (2022), which is the largest trade association for the chemicals industry in the EU, has proposed a framework that consists of five steps and focuses on the design phase in order to find the best alternative (see Table 2). Cefic defines SSbD as "chemicals, materials, products, processes and services that are safe, and deliver environmental, societal, and/or economic value through their applications". Furthermore, it interprets SSbD as a tool to facilitate innovation in which safety is evaluated based on a traditional risk approach, whilst the goal of the innovation in question is to improve environmental, societal and/or economic value, without negatively affecting any of the other aspects, thereby enabling the stepwise development of safer and more sustainable products. The definition and approach proposed by Cefic contrasts to the JRC framework in relation to two significant topics: risk-based safety evaluation and the fact that a "safe" chemical that delivers economic value is enough to be labelled SSbD under this definition. Since this is basically what industry is supposed to be doing now, the Cefic approach does not address how the approach would increase the prevention of repeated harm caused by pollution. Neither does it address how chemicals lacking in safety data can be risk assessed and therefore fed into the SSbD assessment. Avoiding the use of substances of very high concern is already a requirement and therefore does not advance the prevention called for by the CSS.

Another way of assessing SSbD has been proposed by Hauschild et al. (2022), who suggest that safety is evaluated via risk assessment, whereas sustainability is evaluated using an LCA (see Table 2). This would then lead to four options in relation to evaluating the results of each of these two assessments, namely (1) not safe/not sustainable; (2) not safe/sustainable; (3) safe/not sustainable and (4) safe/sustainable. After having weighed up the four options against a list of criteria, including feasibility, reliability, completeness, transparency and comparability with decision-making principles and the principles of "value of information", Hauschild et al. (2022) found that option 4, namely safe/sustainable, was the preferred option. The approach suggested by Hauschild et al. (2022) is in line with the JRC framework on using an LCA for evaluating sustainability and the suggestion made by Cefic (2022) to use a risk assessment to evaluate safety, albeit the latter would not prevent the use of SOCs, if data on hazard or exposure was missing.

Finally, the NGO ChemSec has published certain considerations that complement the other approaches. ChemSec interprets the idea of SSbD as a development guideline that can be used to determine what the EU should invest in (Lennquist, 2022). In line with the EEA approach and the JRC cut-off criteria, ChemSec underlines that hazardous chemicals can never be labelled "SSbD," as they are neither safe nor sustainable to use (ChemSec, 2021). Moreover, ChemSec argues that SSbD needs to have higher ambitions than current legislation that focuses on substances long established on the market being of very high concern; otherwise, the SSbD will not contribute with anything new (ChemSec, 2021). ChemSec also highlights the amount of data needed for evaluating SSbD and stresses that this must not result in "no data = no harm" whereby a lack of data results in positive assessments. To avoid this issue, ChemSec suggests a simple framework in the first years with a stepwise increase in the number of impact factors, in order to allow both academia and industries the time needed to produce methods and data (ChemSec, 2021).

2.4 Measuring, evaluating and reporting on SSbD

Besides questions about assessing SSbD, another question is how to measure, evaluate and report on the SSbD of chemicals. Evaluation, which is linked to the criteria setting, is a particular subject of interest in this regard. While consultations seem to indicate some agreement on communicating a relatively simple metric, there is also a desire to illustrate the performance of each protection goal outlined in the CSS. It has also been argued that it is essential to set minimum standards for each of the protection goals (EEA, 2021), to avoid burden shifting between risks, for example, to biodiversity, the climate or human health, and give credibility to the SSbD. Which level of harm is considered acceptable is linked to the carrying capacity and planetary boundaries of, for example, ecosystems and human health, which are still poorly understood in relation to chemicals (Persson et al., 2022). The final assessment uses a "multi-criteria decision-making" approach, which could allow for the weighting of different risks, potentially across different climatic and cultural regions. Ultimately, such evaluations involve societal value judgement and political decisions informed by science. To support the setting of criteria, funding has been given under the EU public-public research project PARC, involving scientists, national authorities and EU bodies. Other key points raised in the discussions on how to operationalise SSbD include the need to provide educational, financial and other incentives, such as having technical support centres (EEA, 2021), in addition to research funding going into the further development of the concept. In a global market, and to create a level playing field for products produced within or imported into the EU, it would also be key to develop analytical test methods, in order to demonstrate compliance with claims of SSbD.

3.

Smart materials

Before discussing how smart materials might compare with the ideals of SSbD, it is important to understand what they are and how they might be used in a variety of fields, such as construction, biomedical applications and food packaging. Often, references are made to smart nanomaterials — and here, it is important to note that smart nanomaterials are a subgroup of smart materials. In addition, nanomaterials are considered chemical substances in the EU and hence fall under the scope of existing legislation on, for example, industrial chemicals and biocidal and plant protection products. Sometimes, smart materials are labelled as "advanced materials" and here, it is important to understand that they are indeed a subgroup of advanced materials. Other examples of advanced materials subgroups include nanotechnology, advanced composites, light alloys and high-performance polymers (see Broomfield et al., 2016).

3.1 Definition of smart materials

The term "smart materials" is not new, and how to define such materials has been subject to discussion since the 1970s (Rogers, 1988). In the early days, they were often defined as man-made or natural materials that can respond in a timely manner to the surrounding environment (Ghosh, 2008; Rogers, 1988; Spillman et al., 1996). For instance, at a US Army Research Office consensus workshop in 1988, smart materials were defined as:

"A system or a material which has built-in or intrinsic sensor/s, actuator/s and control mechanism/s whereby it is capable of sensing a stimulus, responding to it in a predetermined manner and extent, in a short/appropriate time and reverting to its original state as soon as the stimulus is removed" (Rogers, 1988, p. 4).

Smart materials themselves are not necessarily new; for instance, magnetostrictive materials were first identified in 1842 by James Joule (Kumara & Arockiarajan, 2022), and the theory of thermoresponsive polymers originates from the 1940s (Thangudu, 2020). Nowadays, the term is more often associated with materials that obtain a new kind of functional property as a consequence of stimulation via external factors. These stimuli can be light, temperature, electromagnetic wave, electrical current, a magnetic field, stress, pressure, pH, etc. The new functional properties can vary in terms of shape, size, ductility, colour, etc. (Sharp & Clemen, 2004) (see figure 1).

In comparison to common materials, the response of smart materials is simple and immediate. Their versatility, aligned with the ability to control their properties via external stimuli, make them interesting for utilisation in a wide variety of applications such as aerospace, environment electronics, civil, electrical, medicine (controlled release of drugs, treatment of various diseases, biosensors), hospitality, agriculture, mechanical, sports, marine, defence, etc. (Mukherjee et al., 2021; Thangudu, 2020).

3.2 Types and classification of smart materials

Different types of smart materials exist, such as piezoelectric materials, magneto-rheostatic materials, electro-rheostatic materials and shape-memory alloys (see table 4). Each type has a different property that can be significantly altered.

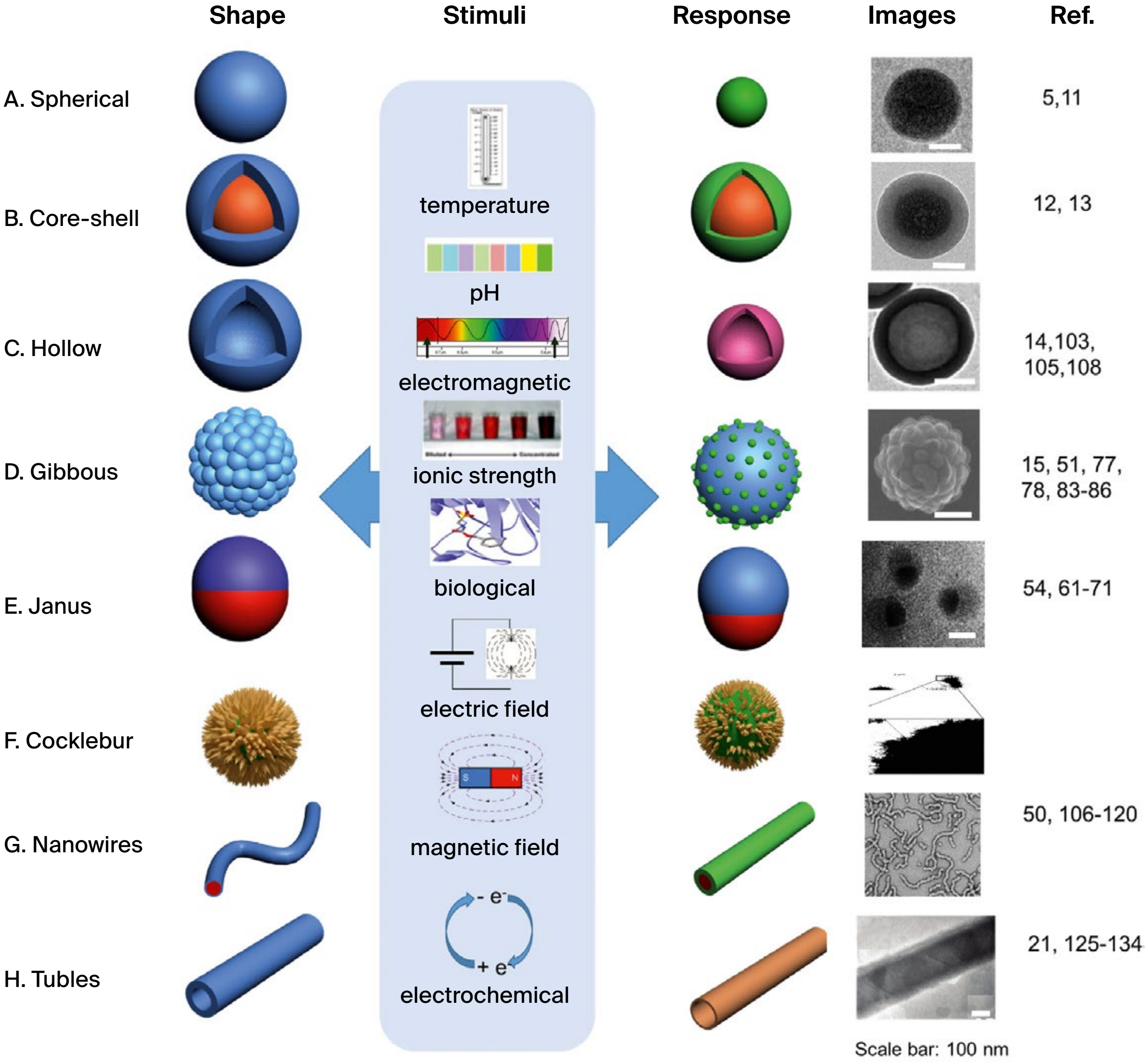

Figure 1 | Schematic representation of various shapes and morphological changes of nano-objects in response to physical or chemical stimuli, along with representative examples provided by electron microscopic images (from Lu & Urban, 2018, reprinted with permission)

Table 4 | Various types of smart materials (adapted from BBC, 2022; Mukherjee et al., 2021; TCE, 2022)

Smart Material	Altered property	Materials used	Applications
Piezoelectric materials	Change of properties when a force is applied on them	Quartz, $BaTiO_2$, $GaPO_4$, lead zirconium titanate (PZT)	Microscale energy harvesting, sensors, actuators, automobiles, clocks, stringed instruments, ultrasound machines, medical camera lenses
Electrostrictive materials	Change of properties when an electric field is applied	Lead magnesium niobate (PMN) lead magnesium niobate-lead titanate (PMN-PT) lead lanthanum zirconate titanate (PLZT)	
Magnetostrictive materials	Change in strain (deformation) when a magnetic field is applied on them	Fe, Co, Terfenol-D	Actuators and sensors, sonars, ultrasound transducers, sound bugs, vibration speaker technology
Rheological materials	Change in physical state when a magnetic or an electrical field is applied	20–40 % Fe nanoparticles suspended in mineral oil, synthetic oil, water or glycol as well as substance that prevent Fe-nanoparticles from setting	Automobile sector
Thermo-responsive material	Polymers that change form and physical properties when exposed to any temperature variation		Vehicles, aircrafts, thermostats
Shape-memory polymer and alloys	Polymer and alloys that can be returned to their original shape when heated	NiTiNol (NiTi-alloy), NiMnGa, Fe-Pd, Terfenol-D, CuZnSi, CuZnAl, CuZn, Ga, CuZnSn	Helmets, car bumpers, medical stiches, surgical plates, robotics, spectable frames, braces
Thermochromic pigments	Change in colour at specific temperatures		Mugs, spoons, battery power indicators, forehead thermometers, ink on eggs and beer
Electrochromic materials	Change in optical properties when an electric current is passed through it		Lithium-ion batteries
Fullerenes and carbon nanotubes (CNT)	Highly stable and versatile hexagons and pentagons of caged spheres consisting of carbon atoms	C_{60}, SWCNTs, MWCNTs	Electronics, corrosion resistance, crack prevention to mechanical durability
Graphite fibres	Thin, inflammable, lightweight carbon strands with excellent tensile strength, and conductance with a low coefficient of thermal expansion		Aircraft, ships and satellites to mobile phone covers, concrete, timber and steel structures
Biomimetic materials	Materials that are inspired by nature and its simple and effective geometric shapes to obtain desirable properties		Used to obtain strength, camouflage, waterproofing, mobility and self-sensing to self-repairing in buildings
Photochromic pigments	Change colour when exposed to light		Lenses for glasses, glass for welding glasses
Hydrogels	Able to absorb and release water in response to changes in temperature or pH		Artificial muscles, hair gels, nappies, expanding snow, granulates to retain water for plants

Many stimuli exist, including pH, enzymatic, redox, glucose, thermal, photo, magnetic, electrical and mechanical, and smart materials are often classified with respect to specific stimuli (Thangudu, 2020).

3.3 Application and uses of smart materials

The application of smart materials is very broad and ranges from use in composites (Gobin et al., 1996), polymers (Roy et al., 2010), aeroelastic and vibration control (Giurgiutiu, 2000), nanotextiles (Coyle et al., 2007) and nanocellulose-enabled electronics (Sabo et al., 2016), through to health (Brei, 1998), biomedical applications (Thangudu, 2020), micro- and nanorobots (Arvidsson & Hansen, 2020; Soto et al., 2022) and engineering (Aher et al., 2015) and civil engineering in general (Mukherjee et al., 2021). Some everyday items already incorporate smart materials, such as coffee pots, cars, the International Space Station and eyeglasses — and the number of applications is growing steadily (Industry Research, 2022).

Use of smart materials in the development of buildings

The use of smart materials is said to be changing the face of traditional engineering materials due to their widespread and multidisciplinary applications across all domains of human invention. When it comes to the development of buildings, they can be utilised individually as well as incorporated into existing materials to enhance a plethora of desirable properties. Major advantages of smart materials include that they can, for instance, increase resistance against corrosion, cracks, fire, chemicals and fatigue, as well as provide means to implement more environmentally friendly and energy-efficient building designs (Mukherjee et al., 2021). Examples of smart materials often mentioned include graphite fibres, which can be used in wind turbines and mouldings, transparent materials (such as aluminium and concrete), self-healing materials (such as concrete and coating), shape-memory metals (such as shape-shifting materials for use in concrete), resistant structures and pipe couplings, and aerogels used for heat and sound insulation and for capturing bacteria and dust particles. Some smart materials are already in use in the construction industry, such as self-sensing concrete, consisting of carbon fibre-reinforced concrete, smart bricks that have electrodes or basic electronic components (sensors, signal processors and a communicator) embedded along with conductive nanofiller, smart wrap, consisting of carbon nanotubes and various smart layers, for instance, to control temperature, and smart glass stimulated by sunlight, heat and electrical current (Mukherjee et al., 2021).

Use of smart nanomaterials in biomedical applications

Within the field of smart materials for biomedical applications, smart nanomaterials have received special attention due to their ability to overcome passive retention mechanisms and non-specific cellular uptake. They have been widely used in diverse biomedical fields, including cancer therapy, the delivery of drugs, genes and proteins, tissue engineering, biological imaging and biosensing, and antimicrobials (Mele, 2018).

Thangudu (2020) reviewed the applications and characteristics of smart nanomaterials in biomedical applications. Piezoelectric materials such as polydimethylsiloxane single-walled carbon nanotubes, boron titanate nanoparticles, PZT nanoribbons and enzyme/ZnO nanoarrays can be used to monitor human conditions, detect minute cellular deformations and engage in real-time biosensing, due to characteristics such as fast response times, high stability, chemical and temperature resistance and minimal invasiveness. AuNPs-PF127-HPMC and single-walled carbon nanotubes (SWCNTs) are examples of thermo- and photo-responsive materials used in drug delivery and in vivo imaging, respectively, whereas Au nanoparticles have been used as a pH-dependent material and photo-responsive material for in vivo therapy.

Use of smart materials in biodegradable packaging materials

A final area of application that has received increasing attention is the use of smart materials for developing biodegradable forms of packaging materials as an alternative to synthetic polymers (Cvek et al., 2022; Halonen et al., 2020; Sani et al., 2021). Smart packaging consists of biodegradable, film-forming materials, such as proteins, polysaccharides and lipids, and a natural pigment. The packaging can be designed to undergo a colour change in response to alternations in the ripeness, quality or safety of a food item, such as, for instance, a change in pH, temperature, moisture content, gas levels, light exposure, chemical composition or enzyme activity. Designing the packaging material so that it releases active ingredients, such as antioxidants or antimicrobials, into the food in order to protect it is also an option that is being explored. Such applications can help to reduce food waste, including animal products, and hence lower greenhouse gas emissions and the need to deploy land for food production. Nanoparticles, such as nanoclays, iron oxide (Fe_2O_3), titanium dioxide (TiO_2), silver (Ag), zinc oxide (ZnO), chitin and cellulose can be used to enhance the functional performance of these packaging materials.

The most common sensors that have been developed for applications in smart packaging materials suitable for food applications are indicators for pH, gas and time temperature (Halonen et al., 2020; Sani et al., 2021). pH indicators provide a measurable change in the pH of a packaged food that may be caused by enzymatic activity, chemical reaction or microbial growth. Natural pigments are preferred over synthetic dyes due to the increasing consumer demand for clean-label products. Anthocyanins are currently the most used natural pigments due to their ability to exhibit colour changes over a broad range of pH values. Examples of pH-sensitive indicators using anthocyanins derived from various botanical sources include saffron petal, black rice bran, purple corn and black soybean coat (Halonen et al., 2020; Sani et al., 2021). Anthocyanins are incorporated into biopolymer-based smart packaging materials and have been shown to be useful in a number of applications, including for pork, shrimp, chicken and fish. Other natural pigments include carotenoids that have been incorporated into polylactic acid films to monitor and control the oxidation of sunflower oil, whilst betacyanin has been incorporated into glucomannan/polyvinyl alcohol films as an indicator of the freshness of packaged fish. When it comes to the detection of gases, different kinds of natural pigments can be used in this regard and be incorporated into packaging materials in a variety of ways, including adhesive labels, printed layers or on the interior of films. As a result, these smart packaging materials can provide a cheap and quick way to detect different kinds of gases, including oxygen, carbon dioxide and hydrogen sulphide. Finally, the use of natural pigments as temperature sensors includes various types of anthocyanins isolated from vegetable extracts, blue flowers, pomegranate juice and the like. One example of such sensor is anthocyanin incorporated in a chitosan/cellulose matrix (Halonen et al., 2020; Sani et al., 2021).

4.

Conclusion: Health and environmental impacts and SSbD of smart materials

One of the greatest challenges when it comes to assessing safety early in the design phase of, for instance, smart materials is that data is often not available (Mech et al., 2022). However, if the new chemical is originally registered under REACH and used in a quantity above 1 ton/year, it will already have been assessed in terms of its risks (dependent on the expected tonnage) before being placed on the market. This is partly one of the culprits in current risk governance, in that for foreseen uses below 1 ton, there is not a great deal of incentive to avoid the use of SOCs.

Another challenge relates to the need for reliable data, as stakeholders need it to evaluate the safety and sustainability of chemicals. Accessible and open databases, for example, with hazard profiles for both existing and novel chemicals, are often suggested by the industry and other stakeholders but are rarely available (H&M Group et al., 2022; van der Waals et al., 2019). Many innovations, however, do not require the use of new chemicals but can make use of existing options known to be safe (i.e., not belonging to the SOCs group).

Health and environmental impacts, as well as our current lack of understanding of long-term effects, have been pointed out as some of the disadvantages of smart nanomaterials (Mukherjee et al., 2021; Thangudu, 2020). For instance, when it comes to piezoelectric nanostructured materials, Thangudu (2020) points out that "[…] further research efforts are still necessary for the evaluation of the nanomaterial biocompatibility, retention, degradability, accumulation in complex in vivo systems before actual exploitation in clinical context". Similarly, concerns about health and environmental impacts of fullerenes have been noted by Mukherjee et al. (2021). Furthermore, some smart materials consist of elements such as Ni and Cu that are well-known to be environmentally toxic and even more toxic at the nanoscale. These materials are classified according to EU regulations relating to the classification and labelling of chemical substances and could potentially be considered as causing, for instance, "chronic environmental toxicity (chronic aquatic toxicity)". Hence, they would not be considered as SSbD, as they would not meet the initial cut-off criteria in Step 1 of the framework proposed by the JRC.

For chemicals and materials that do not meet the cut-off criteria, these should only be allowed in uses proven essential for society. Although the term "essential use" is subject to discussion, it seems safe to say that there are many applications of smart materials that cannot reasonably be argued to be necessary for health, safety or the functioning of society and that there are no acceptable alternatives. These applications include inks on beer cans and eggs (see table 4). Although smart materials are often said to come at a high cost, and require delicate designs and sensitive work for high-end project applications (Mukherjee et al., 2021), it is not always what it seems, and many initial applications of emerging materials appear to be gadgets and quite meaningless. Many smart materials, furthermore, lack research and practical evidence on their application and efficiency. In general, the practical utility of smart materials has not yet been studied (Mukherjee et al., 2021).

Specific studies on the sustainability of smart materials are lacking. Mukherjee et al. (2021) mention that one kind of smart material, namely graphite fibre, is costly, low in compressive strength and non-recyclable, and hence it should not be used for general application. It is often mentioned that its use could help minimise energy consumption and CO_2 emissions, reduce waste, increase sustainability and improve economic viability (Mukherjee et al., 2021; Sani et al., 2021). However, these claims about environmental benefits are often unsubstantiated, and no data and information are currently available to support these claims. The lack of data and information about the sustainability of smart materials means that it is not possible to evaluate their performance with regard to the subsequent steps and cut-off criteria for SSbD proposed by the JRC and others — and smart materials can therefore, not be classed as SSbD.

Consequently, it is not possible to evaluate the possible (anticipated, expected, potential) risks of smart materials to environmental sustainability (i.e., to biodiversity, ecosystems, natural resources and the climate) or indications of human health, social, ethical or other concerns that may influence the development of the technology or its uptake in industry and society.

When scanning the literature on types and categories of smart materials, it is evident that many of them are based on polymers, nanomaterials or microrobots. The risk assessment and regulation of each of these has historically been challenging, and even when in their "benign" version, one can only imagine the additional challenges the smart version of a material might pose. For instance, Broomfield et al. (2016) pointed out that the regulatory definition of polymers may not be adequate for high-performance polymers that have been modified and reinforced with bio-fibres and/or nanocharges that result in materials with very advanced properties. Information on the effects of polymers on human health is still in the preliminary stage, whilst limitations in current methodologies prevent accurate human exposure/risk assessments (Paulsen et al., 2021). In addition, there is a mismatch between the technical definition of polymers and the ECHA definition of a polymer. Technically, polymers are defined as being large molecules with specific material properties and which are too large to be bioavailable from, for example, food. In contrast, ECHA defines a polymer as three repeat monomer units, which may easily be of a sufficiently small size to be bioavailable upon transfer in the gut or over intestinal barrier, regardless of their weight exceeding 1000 Da, as in the case of fluorinated compounds (Trier et al., 2011).

The (eco)toxicity of several nanomaterials used in smart materials, such as Cu, Ni and CNTs, is well-known (Denkhaus & Salnikow, 2002; Hansen, 2016; Hansen & Lennquist, 2020b, 2020a; Kjølholt et al., 2015), but establishing the (eco)toxicological hazard profiles of many nanomaterials has been challenging despite substantial effort in this regard. For instance, it remains unclear whether — and to what extent — the interactions between particle characteristics (e.g., particle size distribution, surface chemistry, volume-specific surface area) affect the overall hazard of a given nanomaterial, which again hampers its ability to be classified as SSbD (Clausen & Hansen, 2018; Hansen et al., 2022). With regard to nanorobots, Arvidsson and Hansen (2020) identified two potential hazards, namely the use of hazardous materials, such as foreign DNA, Ni, Ag and UV light, and the loss of propulsion/targeting control. The latter could be termed a novel hazard associated with nanorobots and relates to the control of their propulsion and navigation — whether by chemical propulsion, magnetic fields, sound waves, bioreceptor binding and/or light — potentially making these nanorobots travel to places in the human body and elsewhere where they are not supposed to be, for instance hazardous drugs being delivered to healthy cells. It also remains an open question as to whether the body can excrete advanced drug delivery systems, such as soft nanoparticles and amphiphilic polyfluorinated miktoarm star polymers and if not, how this may affect organs and other functions. Obtaining approval for medical products and devices is arguably one of the most lengthy, thorough and expensive regulatory processes, due to various phases of clinical testing and safety and benefit assessments. Nevertheless, regulations in the EU and elsewhere have been criticised for being insufficient when it comes to more complex drugs (Editorial, 2007). According to Arvidsson and Hansen (2020), it even remains unclear whether nanorobots should be considered a medical device or a medicinal product in the EU, which is important, as different sets of regulations would apply. The "mechanism of action" is used to decide on whether a product should be regulated as a medical device or a medicinal product. The mechanism of action can be pharmacological, immunological or metabolic. For nanorobots, this means that their categorisation according to mechanism of action is challenged by the fact that they use complex mechanisms of action combining mechanical, chemical, pharmacological and immunological properties, and they can also have both diagnostic and therapeutic functions (Hansen & Baun, 2012).

Whether polymers, nanomaterials or micro- and nanorobots, it is very important to understand the various kinds and compositions of smart materials and their unique properties with specific stimulating agents during application (Thangudu, 2020) before assessing their risks and sustainability. This is important as the kind and composition as well as unique properties of specific stimulating agents used during application influence the hazards and the potential exposure routes of a given smart material. Gaining access to this kind of information early in the development process can be very challenging. Similarly, it is not clear whether one would need to assess the materials used to form the smart materials, such as Cu, Ni and CNTs, or the smart materials themselves, as they come with and without (multi-)stimuli. When it comes to their components, hazard and/or risk assessments can be informative, although risk assessments do seem inadequate. Besides the lack of data and the challenges in this regard, the interdisciplinary nature of smart materials (physics, biology, chemistry, engineering, material science and information technology) is challenging when it comes to risk assessment and governance — as noted previously (Gee et al., 2013; Harremoës et al., 2001). More holistic approaches, such as technology assessments (similar to the one proposed by UNEP (2015) might be more helpful when it comes to assessing smart materials and their overall application. In general, it seems obvious that avoiding the use of harmful chemicals, such as substances of concern, and ensuring their potential reuse, disassembly and recycling are key considerations in making smart materials part of the solution rather than preventing zero pollution and a circular economy in which clean materials are safe to recycle.

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Paper 4

Ensuring the environmental sustainability of emerging technologies applications using bio-based residues

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Table of contents

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Introduction

The European Green Deal with related EU chemical and bioeconomy strategies aim to accelerate the development of innovative conversion technologies to produce bio-based alternatives in European sectors traditionally dominated by petrochemical products. As a result of this effort to reduce fossil fuel dependence and climate change impacts, the growing global trend of innovative bio-based commodities is expected to continue. The significant investments in future emerging technologies for bio-based products should be guided towards those that are environmentally sustainable. This is possible only with science-based evidence on their environmental impacts at an early stage.

In particular, unlocking the full potential of locally sourced bio-based residues is crucial to expanding the number of bio-based products produced sustainably in the EU. This feedstock does not generate concerns about food security and land competition. Furthermore, it is usually cheaper than dedicated crops and does not require transoceanic imports. For these reasons, products from bio-based residues are expected to be the core of future bio-based innovation to move towards a circular economy via better valorization of natural resources. Moreover, avoiding dedicated cultivation with required fertilizers, fuel consumption in tractors, irrigation, etc., bio-based residues are expected to have a lower climate change impact than dedicated crops.

Life cycle assessment (LCA) methodology is an internationally standardized method to assess products’ and services' life cycle environmental impacts. Various policy regulation mechanisms already rely on LCA results to incentivize bio-based products based on their environmental performance. However, these policy instruments mostly cover climate change impacts, i.e., incentives are based on greenhouse gas mitigation potentials (Edwards et al., 2017). So, other environmental tradeoffs typically existing between bio-based and petrochemical products are neglected. When the scientific literature considered additional environmental impact categories, bio-based products often showed higher eutrophication and water depletion impacts than their petrochemical counterparts due to biomass cultivation (EC, 2019). So far, there is still a lack of comprehensive understanding of environmental tradeoffs of emerging products made from bio-based residue streams not requiring dedicated cultivation.

This paper aims to reflect on critical considerations necessary to avoid that a greenness claim of a future technology utilizing a bio-based residue is challenged at a late investment stage for its adverse environmental impacts.

1.

Background

Based on the findings of recent LCA literature, the calculated environmental impacts of bio-based products from less economically valuable or physically smaller streams are expected to be more affected by the selection of a so-called multifunctionality approach than the impacts of products from dedicated crops. Bio-based residues are regularly produced from multi-output or multifunctional systems. So, conducting an LCA of a product from a bio-based residue regularly requires multifunctionality solutions (also commonly referred to as "allocation practices") to allocate a fraction of the environmental impact to the bio-based residue. Suppose an LCA expert is investigating the environmental impact of a bio-based product made from wheat straw, this expert needs to divide the environmental impact of wheat cultivation between wheat grain and straw, since only the straw is part of the life cycle of the bio-based product. Economic allocation is often used to make this distinction, reflecting the difference in price between straw and grain. Wheat cultivation exists primarily to provide grain to the market and not straw. Accordingly, taking an example from the literature, 17.7% of the total cultivation emissions of wheat are allocated to straw and 82.3% to grain (Lokesh et al., 2017).

Despite the existence of ISO LCA methodology standards (ISO, 2006b, 2006a), modelling multifunctional processes is one of the most controversial methodological aspects in the LCA literature, with low convergence in recommendations in LCA guides of different countries and sectors. For example, an LCA guide used in a certain country or sector might recommend mass allocation between wheat straw and wheat grains. Another LCA guide might recommend the subtraction of the impact caused by the production of the product replacing wheat straw from its current use. Using these methods instead of economic allocation significantly changes wheat straw's environmental impact. As a result, it is not uncommon to find the life cycle environmental impact of the same bio-based residue varying from highly positive to highly negative as a consequence of adopting different multifunctionality approaches (Hermansson et al., 2020).

The system modeling approach is one of the key methodological decisions/preferences influencing multifunctionality practices. There are two major, well-distinguished modeling approaches: attributional and consequential (Schaubroeck et al., 2022). Information regarding the definition and critical differences between these two modeling approaches can be found in table 1. The same table also provides the definition and main features of "prospective LCA", which is another system modeling approach often mentioned in this paper. The selection of a prospective LCA modeling approach is linked to the technology under assessment and its temporal scope (Cucurachi et al., 2018)[2]. Adopting a prospective LCA modeling approach has no direct effect on multifunctionality choices. A prospective LCA can be either a prospective attributional LCA or a prospective consequential LCA, with multifunctionality approaches selected accordingly. The relevance of a prospective LCA approach in this paper originates from the fact that most conversion technologies for bio-based residues have not yet been commercialized. Prospective LCA allows one to determine the environmental impacts of these technologies at a future large-scale commercial level.

2.

Aim

In discussing critical considerations necessary to avoid that a greenness claim of a future technology utilizing a bio-based residue is challenged at a late investment stage for its adverse environmental impacts, this paper considers two primary aspects. The first aspect concerns the shift of environmental burden towards another environmental impact (e.g., a product incentivized based on its low climate change impact that might cause higher toxicity exposure for the environment and humans) or sector (e.g., diverting a bio-based residue from its current application might have some counterfactual impacts). The second aspect regards the effect of adopting a different multifunctionality modeling approach for bio-based residues in the LCA of a product. This reflection provides a deep dive into challenges in evaluating and quantifying the environmental sustainability of an emerging technology which converts bio-based residues before investment and production has started. Various examples of emerging conversion technologies to convert bio-based residues into a heterogeneous range of high-value products, designed for different markets and competing for these bio-based residues are presented in this paper.

Table 1 | Definitions and critical differences in LCA system modeling approaches mentioned in this paper

Attributional	Consequential	Prospective
Attributional is a system modeling approach in which the environmental impact is attributed to a product by partitioning the system's processes via allocation methods commonly based on economic, mass or energy values. So, if the allocation method is consistently chosen in all LCAs, summing up the environmental impacts of all worldwide products in the temporal scope of the LCA leads to the total observed environmental burdens globally at that time. Attributional LCA is the most applied modeling type in EU policies and ecolabeling given that it has lower uncertainties than consequential LCA (Giuntoli et al., 2019).	Consequential is a system modeling approach which measures the environmental impact of a product through any expected changes in impact due to the production of that product. The systems modelled in consequential LCAs include all processes affected by the decision to produce such a product. The processes to include are determined based on the cause-and-effect chain initiated by the decision to produce the product. The chains may include processes outside the supply chain, or avoided environmental burdens indirectly caused by introducing the potential co-products in the market, leading to the displacement of conventional market products (UNEP/SETAC, 2011).	The LCA community uses different names and definitions to refer to prospective LCA. Among the most common alternative names are *ex-ante* LCA and early-stage LCA. A prospective LCA is a particular type of LCA investigating an emerging technology and having a future temporal scope. An LCA can be defined as prospective "when the (emerging) technology studied is in an early phase of development (e.g., small-scale production), but the technology is modeled at a future, more-developed phase (e.g., large-scale production)" (Arvidsson et al., 2017). So, compared to conventional LCAs, it is important to avoid a mismatch.

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[2] See also the paper written for the ESET project by Stefano Cucurachi and Carlos F. Blanco, "Practical solutions for *ex-ante* LCA illustrated by emerging PV technologies" (2022).

The following emerging products are considered based on recently published prospective LCAs:

1. **Plastics from used cooking oil** (Moretti et al., 2020)
2. **Fuels from potato peels** (Moretti et al., 2022)
3. **Fuels from biogenic carbon emissions** (Falter et al., 2020)
4. **Asphalts from lignin** (Moretti et al., 2021)

The LCAs of these products determined the environmental impact reduction compared to their conventional counterpart, i.e., petroleum-based plastics, fuels and asphalt. While investigating climate change impacts is a common practice in the LCAs of bio-based products, the four prospective LCAs used here as examples considered a broad spectrum of potential environmental impacts. This allows understanding whether typical environmental tradeoffs of products from cultivated biomass compared to their conventional (fossil) counterparts (such as higher eutrophication impacts) also apply to products from bio-based residues (not requiring dedicated agricultural activities).

The insights gained from these four LCAs (e.g., on environmental hotspots and tradeoffs of the products analyzed) are used to provide recommendations on how to produce products from bio-based residues sustainably, which would be preferable from a long-term environmental standpoint to the current situation, considering the risks of existing processes to environmental sustainability. Given the holistic overview of applications and environmental impacts considered in these four LCAs, they are used to draw general lessons and recommendations (that are potentially applicable also to other domains) for guiding investment and research toward environmentally sustainable technologies.

Furthermore, to avoid severe consequences in investment decision-making for future technologies utilizing bio-based residues, the effect of multifunctionality practices on the environmental impacts of these emerging products needs to be well understood. The four bio-based residues investigated in the selected LCAs are key examples since they reflect the entire spectrum of relevant cases from an LCA multifunctionality perspective:

1. **Residues already highly demanded by the market for high-value applications**. This is the case of used cooking oil which is used worldwide for renewable diesel (Mandolesi De Araújo et al., 2013).
2. **Residues already sold for other lower revenue uses**. For example, potato peels are sold as animal feed but could be valorized into fuels (Moretti et al., 2022).
3. **Residues currently polluting the environment**. For example, carbon emissions of biological origins released into the atmosphere could be captured and transformed into high-value products (Falter et al., 2020).
4. **Residues currently used by the potential producer (not sold)**. This is the case of lignin (black liquor) which is currently burned for internal energy needs by pulp mills and lignocellulosic biorefineries (Hermansson et al., 2020).

3.

Data: Outcomes of the considered LCAs

Figure 1 shows the life cycle climate change mitigation potentials of the four products derived from the respective bio-based residues considered by this paper.

3.1 Plastics from used cooking oil

The prospective LCA of polypropylene (PP) from used cooking oil (UCO) (Moretti et al., 2020) showed a 40-62% climate change impact mitigation potential compared to petrochemical PP. This range reflects different allocation methods applied for UCO at the process level. PP from UCO also showed a much lower climate change impact than bio-based PP made from sugarcane and woody biomass (up to 80% lower). PP from UCO is a better alternative to both petrochemical and bio-based PP from dedicated crops. However, UCO is a very limited feedstock and is already largely used to produce renewable diesel. The reduction of climate change impact allowed by renewable diesel from UCO compared to oil diesel is 80-90%, which is much higher than 40-62% obtained with UCO PP replacing petrochemical PP. Thus, it is questionable if using UCO to produce more PP than renewable diesel is beneficial, especially considering that other bio-based types of diesel have a much lower climate mitigation potential (Edwards et al., 2017).

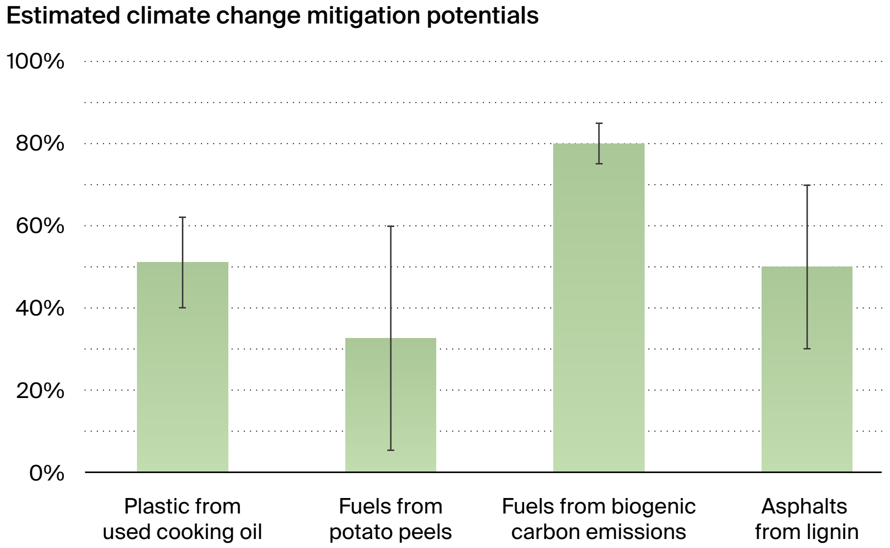

Figure 1 | Climate change mitigation potentials of the considered products expressed as a percentage compared to the conventional (fossil) counterparts taken as 100%. Error bars represent both data and methodological uncertainties. Data uncertainties include prospective uncertainties (primarily due to future energy mixes) and methodological uncertainties (primarily due to multifunctionality approaches).

Nonetheless, the LCA performed by Moretti et al. (2020) concluded that the climate change mitigation potential for PP from UCO could be further improved by recycling the embedded biogenic carbon content in durable plastic applications over different life cycles. The same LCA also concluded that the climate change impacts of both UCO-based PP and diesel could be significantly improved by using renewable electricity to power the process and produce renewable hydrogen via electrolysis. For PP from UCO, renewable gas produced as a co-product could be used to partially replace liquefied petroleum gas (LPG) consumption for steam cracking. However, renewable gas is currently sold on the market. So, there might be tradeoffs with natural gas replacements allowed by renewable gas.

The same LCA also showed that petrochemical PP from UCO has a much lower fossil fuel resource use (80-86%) than petrochemical PP. The LCA did not lead to robust conclusions due to both data and methodological uncertainties for other impact categories such as toxicity, ozone depletion, and freshwater eutrophication.

While multifunctionality uncertainty was relatively low for climate change and fossil resource depletion, it was much higher in other categories. Therefore, multifunctionality uncertainties on the environmental impacts of the final products are regularly much higher for several environmental impacts than others. For example, if UCO is no longer considered waste (free of burdens) but a by-product (given its high market value today), an allocation method is necessary. The so-called 50/50 allocation method applied to UCO open-loop recycling would increase the environmental impacts of UCO-based PP between 25% and 160% (on a weighted basis), depending on the impact category and type of primary vegetable oil, with higher variations observed for particulate matter, human toxicity, ecotoxicity, eutrophication, land use, and depletion of non-fossil resources (minerals and metals). This example also shows the complexity of analyzing an LCA outcome in cases when more than one option is possible for a key modeling parameter, such as allocation for bio-based residues. In the case of circular processes like the recovery of a residue (or waste), a deeper interpretation of LCA results becomes necessary due to the inconsistency of current multifunctionality practices and and how sensitive the outcomes are to the practice chosen.

3.2 Fuels from potato peels

The prospective LCA of jet fuel from potato peels applied both attributional and consequential approaches. According to the attributional LCA, the fuel could achieve a 60% lower climate change impact than conventional jet fuel (hence, it could be catalogued as sustainable aviation fuel and be incentivized). The high climate mitigation potential of this jet fuel assessed via attributional LCA is favored by the fact that the environmental impact of the potato by-product is only a minor fraction of the impact of the potato food processing industry. Since potato peels are a minor fraction of the economic revenues of this industry, a minor impact is allocated to them. This would not be valid if mass allocation was applied instead of economic allocation. In fact, mass (or energy) allocation would allocate impacts of similar magnitude to the potato peels and the potato food products, neglecting the fact that the potato processing industry works to generate revenues by producing food products and not energy or animal feed products. Therefore, mass allocation does not respect the allocation causality principle that should be followed according to the ISO standards at the base of LCA practice. However, for practicality, various LCA guides generally prefer allocation based on mass or energy over economic values.

The consequential LCA showed that this fuel could achieve a maximum of 40% climate change impact reduction (too low to be considered for EU incentives). Adopting consequential modelling, the impact of the potato by-products corresponds to the animal feed needed to replace the potato by-products diverted from their current use. This fact is the main reason for the lower performance assessed via the consequential LCA than via attributional LCA. In an extreme case, if imported soybean meals (with associated land-use changes) are used to replace potato peels, the climate change impact of the bio-jet fuel could become higher than kerosene. With respect to other environmental impacts, opposite outcomes between the attributional and consequential LCAs were obtained for photochemical ozone formation. Conversely, both LCAs concluded that the investigated fuel causes lower fossil fuel depletion but higher terrestrial eutrophication and acidification than kerosene. Since worldwide policy incentives could be based on LCA tools following either one or the other approach (or a mix of the two), the same fuel could be considered sustainable and receive an incentive following the method applied in one country but not in another country.

Since the system analyzed in attributional LCAs is only made of processes directly linked to the product's supply chain, displacement effects on the animal feed or markets are not captured using this type of modeling. Thus, applying a consequential LCA when the plan is to divert a bio-based residue from another market is highly recommended to avoid issues at a later investment stage. In this way, it is possible to change a technology design in time (e.g., targeting the design to convert a different bio-based residue) to avoid potential adverse environmental and economic impacts in the long term.

However, capturing counterfactual aspects makes the consequential LCA more uncertain. This is even more valid for prospective LCAs. In fact, since this fuel technology has a low technological readiness and will take years before being marketed, forecasts of future markets are more uncertain than current marginal markets. This also applies to the substitution of the fuel's co-products. Therefore, given this additional complexity in consequential LCAs, the case of conflicting prospective consequential LCAs will not be rare. Despite these challenges, a prospective consequential LCA is the most powerful tool to detect counterfactual burden-shifting of environmental issues due to the utilization of a constrained resource.

3.3 Fuels from biogenic carbon emissions

A recent prospective LCA of innovative jet fuel from biogenic carbon emissions estimated a climate change mitigation potential of about 80% (Falter et al., 2020). The captured biogenic carbon emissions are converted into jet fuel via a solar thermochemical fuel pathway. To achieve such a high mitigation potential, solar energy produced in a location with high direct normal irradiance is a key choice.

It is fair to acknowledge that this LCA mostly investigated the production of fuel from carbon emissions captured via direct air capture. The solar thermochemical fuel production from a biogenic carbon emission point source is only discussed as a sensitivity analysis in this LCA. Besides generating low climate change impacts and fossil resource depletion, the LCA of fuels from biogenic carbon emissions showed high particulate matter formation, terrestrial acidification, freshwater consumption and human toxicity impacts. The main source of these impacts is found in the chemical process of capturing carbon dioxide (CO_2).

Fuels from biogenic carbon emissions are a key technology for carbon neutrality. However, the high climate change mitigation potential for this type of fuel relies on the methodological assumption that those carbon emissions would be emitted if this fuel is not produced. An allocation by physical causality or consequential modeling is necessary to account for this fact. As it was recently well illustrated in a scientific article on this specific matter (Müller, Kätelhön, Bringezu, et al., 2020), simple allocation methods based on mass or economic shares cannot properly account for avoiding these emissions or any other waste of concern. They would lead to a completely different outcome penalizing this type of fuel.

Driven by this need to increase the comparability of outcomes of LCAs of CO_2-based products, a recent guideline has been internationally developed (Müller, Kätelhön, Bachmann, et al., 2020). However, the recommendations of this guideline are far from being broadly known and implemented at an international policy level. Furthermore, it must be kept in mind that the recommended method (physical causality allocation or consequential approach) does not distinguish between CO_2 sources. Based on this method, fossil CO_2 sources whose use leads to waste streams with high CO_2 concentrations, which are easier to separate and capture, are environmentally favored over biogenic CO_2 sources whose use results in lower CO_2 concentrations or direct air capture technologies. So, for the same energy source, investing in capturing and utilizing biogenic CO_2 sources or capturing CO_2 directly from the air is penalized by this approach. This would not be true utilizing a different approach distinguishing between fossil and biogenic sources.

3.4 Asphalts from lignin

The prospective LCA of bio-based asphalts using lignin to replace bitumen estimated a climate change impact reduction of 30–75% compared to conventional asphalt. Hence, storing the high biogenic carbon content of lignin in asphalts has a high potential to mitigate the climate change impact of asphalts. With lignin extraction in pulp mills, there would be the need to use natural gas and hog fuel (low-value biomass) to replace the black liquor no longer available for steam production. Besides the fuel for heating the steam source to replace the no longer available fraction of black liquor from which lignin is extracted, the percentage of lignin replacing bitumen is a key factor influencing the environmental performance of bio-based asphalts. Therefore, lignin-based asphalt needs to be carefully designed from this point of view. This LCA shows low environmental gains in replacing other components of the asphalts that are not bitumen with lignin. Hence, filling asphalts with lignin is not enough if a high percentage of bitumen is not replaced.

The production of lignin (excluding biogenic carbon intake) was one of the main sources of environmental impacts of lignin-based asphalts. Lignin with low climate change impact can be obtained using hog fuel to replace the black liquor. Conversely, using natural gas to replace the black liquor leads to a much higher climate change impact for the same lignin and lower climate change mitigation benefits for lignin-based asphalt. Besides steam production, the other main sources of the environmental impact of lignin production are the production of sulfuric acid and liquid CO_2.

The high climate change mitigation potential of lignin-based asphalts was also favored by using economic allocation at the level of the pulp mill since lignin has a lower market value than pulp. Applying mass allocation instead of economic allocation would have led to a much higher impact for the same lignin. This also applies to bitumen which is a residue of oil refining. Hence, the cradle-to-gate comparison between lignin-based and conventional asphalts is meaningful only if the same allocation principle is applied to both lignin and bitumen. However, guides for environmental footprint declarations in the construction sector often have a predefined value for bitumen's environmental impact, which is based on one or the other principle.

Furthermore, in the LCA, the physical biogenic content of lignin (which is high) was considered and preferred to an allocated biogenic carbon value which would have been lower. However, various LCA guides suggest allocating the biogenic carbon as any other process input, which would penalize this type of product compared to others.

4.

Lessons learned and recommendations for emerging technologies utilizing bio-based residues

The considered prospective LCAs were used to show that the life cycle climate change impacts of emerging products from bio-based residues are usually lower than their fossil counterparts. For example, climate change impact reductions of 30–70% can be achieved by replacing current asphalts with lignin-based asphalts and 40–62% by replacing petrochemical PP with PP from used cooking oil. However, the following considerations apply:

1. High climate change mitigation performances achieved by specific conversion technologies and bio-based residues cannot be generalized since environmental optimization of various factors plays a crucial role in achieving a positive environmental performance. Using renewable energy and green chemicals is key to achieving high climate change impact reduction. Low-value biomass or biogas are key choices for products from bio-based residues, although they might be more expensive than liquefied petroleum gas or natural gas. Using fossil energy in the production process of products from bio-based residues could lead to higher climate change impacts than their petrochemical counterparts used today. Suppose the pulp mill or biorefinery chooses natural gas to replace lignin as internal fuel, this could result in a higher environmental impact for bio-based asphalts than conventional asphalts. Besides green energy and fuels, the supply chain, production process, and composition (e.g., some products are only partly bio-based) are key aspects to be analyzed.

2. Positive performances in terms of climate change impacts are usually accompanied by savings of a similar magnitude for the impact category regarding depletion of fossil fuels. However, tradeoffs with conventional products from fossil resources regularly occur in some other impact categories. This fact has widely been observed for products from dedicated crops and is confirmed to apply also to products from bio-based residues. For example, significantly higher acidification and terrestrial eutrophication impacts than fossil products can also be expected for products from bio-based residues. Counterintuitively, this does not apply only to products made from dedicated crops. The allocation to bio-based residues of even a small percentage of agricultural activities such as fertilizer volatilization and combustion of fuels in tractors easily leads to higher eutrophication and acidification impacts since petrochemical products require no fertilizers or tractors. Furthermore, the conversion of bio-based residues into high-value products requires pre-treatment with chemicals (e.g., sulphuric acid), often leading to high toxicity-related human and environmental impacts, especially in the case of low conversion yield.

3. Bio-based residues are scarce, and many technologies compete for the same bio-based residue. Therefore, the decision-makers must be careful when diverting bio-based residues from other uses, especially in the case of low-yield technologies. Consequential LCAs are designed to understand this aspect and might lead to significantly different outcomes than attributional LCAs for the same bio-based residue. This is often the case if it is diverted for another application (e.g., animal feed), causing high indirect environmental impacts. Attributional LCAs cannot spot these potential burden shifts if the current use of the residue is not part of the producer's supply chain of the bio-based product. Therefore, the decision-makers should monitor with attention the effect on the current uses and the alternative chosen to replace them. However, this might be outside the supply chain and, therefore, not influenceable by the future producer of that bio-based product. Consequently, for maximized satisfaction of human and eco-systemic needs, it is necessary to involve a wide range of stakeholders (even beyond market actors) to understand which bio-based residues are appropriate for certain end uses.

4. For producers of durable applications such as bio-based asphalt, it is important to know that certain LCA methods recommended at the national or international level may not give any credits for permanent (and temporary) carbon storage. This could significantly penalize the environmental performance calculated for this type of bio-based product.

5. The environmental impact of bio-based residues is usually not trivial in the LCA of the derived products and is highly linked to the adopted allocation method. In fact, a small change in the allocation share of the main product can significantly change the allocation share of the by-product. For example, suppose the impact allocated to the main product is 90% with one assumption and a different assumption would lead to 85%. The allocation share of the by-product would increase by 50%, while the impact of the main product varies only by 5.5%.

6. Applying an allocation based on a physical parameter (e.g., a simple mass-based or energy-based allocation) to the bio-based residue often leads to a much higher environmental impact for the bio-based residue than economic allocation. In principle, these two allocation methods applied to bio-based residues often do not reflect causality as recommended by the ISO standard on top of which LCA practice is built. However, various international LCA methods and EU policies linked to alternative fuels recommend these methods over economic allocation with the goal of increasing simplicity of analysis. Therefore, producers of products from bio-based residues could be penalized in sectors or countries adopting these LCA methods. Furthermore, allocation based on a physical parameter is not suitable for mitigating undesirable use of scarce bio-based residues driven by financial return optimization instead of optimized environmental impact. If bio-based residues are increasingly demanded on the market, their price will adjust. A higher price for a bio-based residue leads to higher environmental impacts if allocated via economic value. This avoids incentivizing less efficient production of the primary product, i.e., optimizing for more "waste" production with unforeseen consequences and lower sustainability benefits in using waste feedstocks.

5.

General reflections and recommendations for future emerging technologies

In terms of observations or lessons that could be transferred to other emerging technologies, for the purpose of helping decision-makers better anticipate potential adverse impacts on environmental sustainability, the following aspects are noted:

1. Generalizations and conclusions are difficult to make and can be misleading if the outcomes of a single LCA (or a set of LCAs for a single product) are transposed into another setting (e.g., different country and, therefore, different energy mix).

2. Decision-makers generally face several tradeoffs at various levels. Products with lower climate change impacts than their alternatives might show other environmental tradeoffs, e.g., higher eutrophication or ecotoxicity impacts. These tradeoffs should be evaluated case by case and minimized as much as possible by changing the design choices in time.

3. Optimization and decisions may not be replicable. Key decisions are often taken based on pilot plants. However, pilot plants might significantly differ from future commercialized technologies. Potential process design changes and size scaling effects depend on optimizing process synergies and future technological learning. These aspects also depend on external factors such as future infrastructural changes (e.g., in the energy mix, supply chains, etc.) In this case, prospective LCA modeling is a key tool.

4. Objectives regarding environmental impacts and economic outcomes may not align. Environmentally sustainable products generally have a higher production cost than conventional products relying on (often) cheaper fossil resources for their production. So, using natural-gas energy or certain petrochemical ingredients instead of greener alternatives in the production process of a future alternative product might be tempting. However, this could result in higher environmental impacts than the conventional products intended to be replaced.

5. Certain feedstocks or materials for future products have limited availability and their best use should be preferred. Attention is needed when diverting a scarce resource from another use which might be more environmentally attractive. A consequential LCA is the most appropriate tool to detect counterfactual impacts on the environment in these cases. However, evaluating the best use for constrained resources requires a full understanding of the context of supply chain systems and competing markets, which may not exist until a market is created.

6. Uncertainty in future incentives due to inconsistency in multifunctionality practices adopted worldwide to certify the environmental sustainability of future products can have severe consequences in making investment decisions about certain products. In this sense, ISO LCA standards have failed in their role to "standardize" (Schaubroeck et al., 2022; Weidema, 2014). So far, the consequences of this fact have been investigated only incidentally when dealing with the climate change impact of a specific product, and it is rare to take a holistic perspective on multiple products intended for different uses and sectors and at the same time on multiple environmental impact categories. Therefore, there is an urgency to provide clear and internationally acknowledged guidance to avoid generating arbitrary or extreme results with consequent erroneous recommendations to the study's commissioner. This applies especially to products from residual streams, residues, and wastes or emissions, which are at the base of a future circular economy.

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Paper 5

Lithium-ion batteries for energy and mobility: Ensuring the environmental sustainability of current plans

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Introduction

This paper, produced in the context of EPFL International Risk Governance Center's (IRGC) project about ensuring the environmental sustainability of emerging technology outcomes, presents concerns raised by policy and industry decisions to develop large-scale plans to produce electric batteries for the mobility and energy sectors without adequate large-scale plans being made upfront for recycling, reusing or disposing of them. Ultimately, this may contribute to aggravating certain environmental challenges.

The rapid improvements of lithium-ion batteries (LIBs) in terms of performance and lifetime over the past decade, combined with decreasing costs and increasing global demand, put this technology at the forefront of electrochemical energy storage markets. LIBs are everywhere: in consumer electronics, industrial machinery, home storage and electric vehicles (EV).

EVs are considered a key technology to decarbonise the transport sector and achieve the climate target defined in the Paris Agreement (International Energy Agency, 2021).

There were over 21 million EVs worldwide in June 2022 (BloombergNEF, 2022) but, by the end of the decade, this number could increase to more than 350 million (International Energy Agency, 2022). When those vehicles reach their end of life, there will be around 8.6 million tons of lithium-ion batteries per year (Ruiz Leotaud, 2021) that need to be disposed of, recycled, or reused in an economical and sustainable manner (Thompson et al., 2020). While the ease of collection and the vast quantities of electric car batteries that will reach end-of-life offers an excellent opportunity to create a more robust value chain, since recycled materials can decrease the pressure on mining, it also brings various technical and economic challenges. The different designs, different LIBs chemistries and the high voltage of EV batteries mean that safe dismantling remains complex, sometimes dangerous, and time-consuming.

Moreover, global decarbonisation will require the electrification of other sectors, i.e., the industrial, energy generation, commercial and residential sectors. Looking at the energy sector, greenhouse gas (GHG) emissions will be reduced by increasing the penetration of renewable energy sources. In countries like Germany, production from renewable sources will account for more than 50% of the electricity supply in 2030. Dealing with intermittent renewable energy sources will be facilitated by installing batteries that can balance production and consumption. Moreover, batteries can increase the flexibility of the grid by balancing short-term energy fluctuations, avoiding investment in upgrading the power transmission and distribution infrastructure, allowing a more decentralised energy system, and eventually bringing electricity to off-grid communities.

Looking at the scale of the market segment, the expected evolution of the technology and the resources needed to achieve them, the coordination between economic, environmental, social, and regulatory entities is essential to assure the sustainability of LIBs.

Currently, the percentage of LIBs that are recycled is uncertain but ranges from 15% (Gaines et al., 2021) to 50% (Maisch, 2019). As of late 2021, there are at least 32 established or planned facilities for LIB recycling with roughly 322,500 tons of recycling capacity (J. Z. Baum et al., 2022) but given the projection of LIBs deployment in the next years, additional recycling facilities will be needed.

The biggest challenges for LIBs recycling are (1) separating small cells from other e-waste and (2) coping with the currently low volumes of EV and other large-format batteries that make operating plants at scale not profitable. However, the current low recycling rate should not be considered the only bottleneck of the LIB value chain. Other challenges that should be considered are, for example, (1) the sourcing of critical materials for the conspicuous volumes needed in the EV market, especially considering the geopolitical conditions, (2) the importance of using the battery as long as possible (during the first and second life – the longer the use, the lower the material request for new battery systems as well as the lifetime emissions), (3) the necessity to improve dismantling and remanufacturing to increase the ratio of material that can be recycled and/or reused. All of these elements aim to build a business model that will allow for a sustainable and low-risk value chain around batteries by pivoting from the current linear trajectory of the value chain to creating a circular one. Globally, moving from a linear to circular economic model for LIBs "could result in a reduction of 34 Mt of greenhouse gas (GHG) emissions while creating an additional economic value of approximately US$35 billion" (World Economic Forum, 2019).

Table 1 | Some facts about the scale of LIB developments and needs for recycling and disposal, indicating the potential sheer size of the upcoming sustainability challenge

In June 2022, there were over 21 million EVs on the road globally, but by the end of the decade, this number could increase to 350 million.	(International Energy Agency, 2022; BloombergNEF, 2022)
Currently, the percentage of LIBs that are recycled is uncertain but ranges from 15% to 50%.	(Gaines et al., 2021) (Maisch, 2019)
Since 2010, the global manufacturing capacity of lithium-ion batteries has increased 33-fold, with the most significant increase in the automotive industry.	(Baker McKenzie, 2022)
The global battery demand is expected to increase 14-fold by 2030, and the European Union (EU) could account for 17% of that demand.	(European Parliament, 2022)
The expected supply increase for major raw materials in 2030, with respect to 2018 levels, is about 4 times for cobalt, 6 for lithium and 24 for class 1 nickel.	(World Economic Forum, 2019)
It is forecast that, in 2025, 27% of batteries from the automotive sector will have a second life in stationary applications, while the rest will be available for recycling.	(Curry, 2017)
By 2030 the total annual European LIB recycling market could reach about 130 GWh, equivalent to more than 700 kilotons of recycling capacity needed. This number is expected to increase three-fold by 2040 as more EV batteries reach the end of their life. Up to €555 million could be recovered by 2030 from the four critical materials (nickel, lithium, cobalt and graphite) from EV batteries. In 2040, these figures will increase up to €2.6 billion. Therefore, recycling, as opposed to extracting the raw material, may help reduce CO_2 emissions, with a net savings of over 1 million tons of CO_2-eq in 2040.	(Navarro et al., 2022) (Drabik & Rizos, 2018) (Dominish et al., 2021)
Moving from a linear to circular economic model for LIBs "could result in a reduction of 34 Mt of greenhouse gas (GHG) emissions while creating an additional economic value of approximately US$35 billion".	(World Economic Forum, 2019)

1.

Sustainability challenges and regulatory framework

Current LIBs pose environmental, economic, social, legal and even ethical challenges in the different stages of the value chain, starting from the production/manufacturing, passing through the use of these systems and down to the recycling/disposal.

The socio-environmental risks can be linked to the rapid growth of the volume of this technology on the market. Since 2010, the global manufacturing capacity of LIBs has increased 33-fold (Baker McKenzie, 2022), with the most significant increase in the automotive industry. As a result, the global battery demand is expected to increase 14-fold by 2030, and the EU could account for 17 % of that demand (European Parliament, 2022).

Given the segment's scale and strategic importance, different countries are issuing legislative proposals to create a regulatory framework to ensure sustainability along the entire value chain.

At the end of 2020, the EU created a proposal for a regulation on batteries and waste batteries that is oriented towards modernising EU battery legislation to ensure the sustainability and competitiveness of EU battery value chains (European Commission, 2020b). The proposal is part of the European Green Deal (European Commission, 2019), the new Circular Economy Action Plan (European Commission, 2020a) and the new industrial strategy (Berger et al., 2022; Global Battery Alliance, 2022). More precisely, the circular economy action plan identified batteries as one of the resource-intensive sectors with a high potential for circularity to be addressed as a matter of priority. Specifically, the Global Battery Alliance and the EU promote the Battery Passport.

This instrument can be used as a global solution to share the information and data of battery systems needed for recycling, which can prove responsibility and sustainability to consumers while enabling resource efficiency across the battery life cycle. The standardisation provided by the Passport could serve as an incentive and support industry marketing strategy, branding and reputation. Thus, the Battery Passport will not only enable transparency and standard setting but also support progress tracking of the entire industry over time.

In China, the world's largest lithium battery consumer market, the scale of the lithium battery industry reached 324 GWh in 2021, four times that of 2017. In the same year, the global LIB market reached 545 GWh and China accounted for more than half of the total. Moreover, by the end of 2021, China held 70% of the world's global total battery production capacity (Pandaily, 2022). At the same time, China is also leading the recycling market, with installed recycling facilities with up to 188,000 tonnes of battery recycling capacity (J. Z. Baum et al., 2022).

The first Chinese legislation about battery recycling, introduced in the mid-1990s, mainly focused on batteries containing mercury and cadmium. Only in 2018 was a regulation on EV end-of-life LIB management issued. Along with other successive and more recent guidelines, an overall policy framework for today's battery recycling industry in China was defined. The key elements of this policy framework are (1) encouragement of manufacturers to design batteries for easy disassembly; (2) obligation of manufacturers to provide the technical information necessary for end-of-life battery treatment; (3) promotion of cascaded application and second life of batteries; (4) responsibility of EV and battery producers for battery waste treatment; (5) responsibility of cascaded application companies, EV makers and battery producers for establishing waste battery collection outlets; (6) material recovery targets (Neumann et al., 2022). Despite the well-thought-out framework, current estimates indicate that only 30–40% of battery materials are recycled (Hampel, 2022).

As evident from the regulatory frameworks of the EU and China, taken as examples, progress in the sustainability of LIBs will not be effective if the challenges in a specific phase of their lifetime are addressed individually. Therefore, a systemic and holistic approach should be embraced to create feasible and genuinely sustainable solutions.

1.1 Risks during manufacturing

The sharp increase in battery production demand also requires the availability of certain raw materials for production to ramp up, which increases risks in the manufacturing process that can affect the availability, price and sustainability of the final product.

The materials used for batteries are numerous. Some are highly abundant (carbon), while others are scarce (cobalt) and concentrated in some geographical regions. The impact of mining minerals is inherently associated with social and environmental problems, and those mined for battery production are no exception, as has been well documented over the last years (Conde, 2017; González & de Haan, 2020; Kallitsis et al., 2022).

The expected supply increase for major raw materials in 2030, with respect to levels of 2018, is about 2 times for cobalt, 6 for lithium and 24 for class 1 nickel (World Economic Forum, 2019). Even if global reserves have been proven to exceed forecast demand (Buchert et al., 2018), lithium and cobalt mining sourcing is a well-known social, economic and environmental challenge and a possible bottleneck for the LIB supply chain (Olivetti et al., 2017).

Mining battery raw materials like lithium, cobalt and nickel is labour-intensive, requires chemicals, uses energy coming from CO_2-emitting fossil fuels (for every tonne of mined lithium, 15 tonnes of CO_2 are emitted into the air (Crawford, 2022)), requires enormous amounts of water, and can leave contaminants and toxic waste behind. Lithium extraction from salt brines in South America (Chile, Argentina and Bolivia hold 75% of the world's lithium resources (González & de Haan, 2020)) comes with concerns of contamination of local water basins and salinisation of fresh water. Cobalt mining in the Democratic Republic of the Congo (accounting for 70% of the world's total production (González & de Haan, 2020)) has raised numerous issues related to human rights violations such as child labour and environmental damage.

Other risks might occur for other metals as well. For example, the Russian-Ukraine conflict disrupted the EU nickel market, as Russia is the biggest exporter of this metal to Europe (Jain, 2022).

Even if the critical materials can and will be recovered by recycling, the volume will not be enough to compensate for the rising demand expected in the coming years (Zeng et al., 2022).

Along with raw materials sourcing, some details of the manufacturing processes can be taken into consideration. Energy intensity and pollution must still be addressed depending on how and where the battery is manufactured. After mining, raw materials are subsequently refined and processed to produce active electrode materials as core components of battery cells. Asia Pacific accounted for 81% of the global manufacturing capacity of LIBs in 2020 (with 73% of the global capacity manufactured in China) (Baker McKenzie, 2022). Electricity used in the battery manufacturing process accounts for about half of the emissions associated with battery production, so increased use of renewable energy and more efficient power plants will lead to cleaner batteries. The expected drop of 30% in the average carbon intensity of global electricity production by 2030 will translate to a 17% reduction in the emissions related to battery production (Hall & Lutsey, 2018). However, coal is the primary energy source in China, the biggest battery producer.

Different solutions and propositions on how to act around these risks exist, including to:

1. Increase efficient use of raw materials, limit waste and increase quality during manufacturing.
2. Propose raw materials governance (Bechberger & Vorholt, 2021).
3. Increase the use of synthetic fabricated material (as is already the case for graphite) or secondary metals (as is the case for platinum) (World Economic Forum, 2019).
4. Suggest regulatory programmes for mining, for example dictating the maximum level of extraction (Buchert et al., 2018).
5. Request transparency and identification of what materials have been used and from where they have been mined.
6. Include ethical aspects – such as human rights abuses and environmental risks in the product identification of batteries (Amnesty, 2019).
7. Switch towards different use of chemistries and electrode designs. For example, lithium iron phosphate batteries (LFP) have gained popularity, and different battery manufacturers are increasing the proportion of battery production with electrodes that do not contain cobalt. Moreover, recent developments have demonstrated that this formulation can reach higher energy density and battery lifetime compared to the past, decreasing the gap with nickel manganese cobalt batteries (NMC) and thus allowing their implementation for mobility purposes (Zeng et al., 2022).
8. Demand high levels of vertical integration so that original equipment manufacturers (OEM) or battery manufacturers become increasingly involved in the supply chain up to the mining stage (Bernhart, 2022). Occupying critical control points along the supply chain can provide a strong competitive advantage and mitigate supply chain risk and abuse.
9. Encourage public and large companies with high purchasing power to request sustainable and responsible manufacturing conditions in producing EVs. At the same time, appropriate purchasing criteria can promote the necessary transparency in supply chains (Bernhart, 2022).
10. Manufacture with renewable energy and scale up manufacturing sites to reduce energy waste (this is already the case for the EU market).
11. Move toward flexible, innovative and versatile plants that can accommodate or enable a change in technology toward the new chemistries of the future, especially in the EU, where major manufacturing plants are currently being built (Claussnitzer, 2020).

The most effective recommendations that can mitigate the sustainability risks linked to the sheer size of the problem include a long-term supply strategy, responsible sourcing, safe and energy-efficient manufacturing processes, and technologies that will allow enhanced resource efficiency and lower the dependence on primary raw material sourcing.

1.2 Risks during using and reusing

Efficient battery use during their lifetime can contribute considerably to the sustainability of the technology, as it decreases the environmental burdens associated with the production of new systems as well as the disposal of used batteries. If the battery systems can be used as long as possible, the use of materials needed to build new systems can be avoided, and the emissions originating from the mining, manufacturing and disposal processes can be spread over a longer lifetime.

By minimising exposure to conditions that accelerate degradation, batteries can last longer. The critical conditions are related to three main variables that impact battery health: temperature, state of charge and current. The battery management system (BMS) records and monitors these variables in real-time. For example, extreme temperatures (both high and low) when using or storing LIBs should be avoided. Elevated temperatures, in particular, can accelerate the degradation of almost every battery component and lead to significant safety risks, including fire or explosion. Likewise, the time the battery spends at a low or high state of charge should be limited. Especially the low state of charge could bring the battery to an over-discharge state that can be dangerous and require the battery to be replaced. Additionally, since high current for both charge and discharge contributes to performance degradation, fast charging and intense use should be metered (Woody et al., 2020).

When batteries reach the end of their first life (meaning that they reached the end of their usefulness and can no longer operate at sufficient energy and/or power for the intended application), they can still hold 70—80% of their initial capacity. Because considerable value is embedded in manufactured LIBs, it is recommended that their use should be cascaded through a hierarchy of applications to optimise material use and life cycle impacts. For this reason, before batteries are recycled to recover critical energy materials, reusing batteries in secondary applications (provided the battery's cells are undamaged) is a promising strategy that will allow them to operate for several more years in a less demanding function. However, deciding if a battery should be recycled or reused is a trade-off problem that should be solved by identifying the value-maximising path between the two options.

Batteries used in EVs lose roughly 2.3% of their energy capacity annually, meaning a new 64 kWh battery might have 48.4 kWh of its original storage capacity after 12 years (Berman, 2019). According to various studies, cars run for a full twelve years in the EU. A battery with 48 kWh capacity is still a useful product with the possibility of having a second life, even if it is insufficient for use in an EV. Energy storage systems can use these batteries after the EV itself has reached the end of its life (Casals et al., 2017). These batteries can be used in residences, microgrids and as utility-scale storage. Reuse can double the useful lifetime of the batteries. After that, they can be recycled.

It is forecast that, in 2025, 27% of the batteries from the automotive sector will have a second life in stationary applications, while the rest will be available to be recycled (Curry, 2017). The European Commission (EC) DG Joint Research Centre listed the main barriers to determining the suitability of a battery to be used in a second-life application (Hill et al., 2019). It stated that "only with professional diagnostic equipment used by experts who have the knowledge on how to get the history out of the battery management system (BMS), can that advice or decision be taken" to unlock the second life market potential.

Concerning the battery's first life with regard to use in EVs, charging time and range availability still limit their large-scale adoption. People are not yet in favour of a means of transportation that cannot offer the same benefits as an internal combustion engine (ICE), such as refueling in a few minutes and being able to travel over a longer range before needing to refill. For this reason, fast charging (that can decrease battery lifetime), as well as swappable battery stations (Siddiqi & Edmondson, 2022) (exchange a battery with a charged one), are some of the proposed concepts for improving EV acceptance, along with increasingly powerful batteries. Especially the last two points might suggest that if the consumer mindset is not changed, higher numbers and larger-sized battery systems than those needed will be produced, affecting the sustainability potential of the technology.

Moreover, battery data should be tracked and made available during the battery's first life. By doing so, real-time operating strategies can be suggested to increase lifetime and avoid improper use that might lead to the inability to use the battery for a second life or even create safety hazards.

Avoiding adverse conditions should be of particular interest to users, as there are significant financial incentives to extend the battery lifetime, as the cost of LIBs can range from 5% to over 50% of a product's cost (University of Michigan, 2022).

Other challenges and risks linked to the use/reuse phase are associated with several factors, including a large number of battery pack designs with different sizes, chemistries and formats, missing regulatory schemes for data exchange, improper use of batteries, no guarantees on second life battery quality or performance, and the absence of an incentive scheme that will allow higher battery reuse.

Thus, despite the promise of circular economy solutions for end-of-first-life LIBs, many unknowns still limit widespread adoption, especially related to liability issues and regulatory voids (Babbitt, 2020).

Different solutions and propositions on how to act around these risks include to:

1. Allow easy interexchange of complete BMS data recorded during use. With the Battery Passport, the EC is already moving in this direction even if it is not yet indicated which essential data (for the use phase) need to be recorded and made available, leaving space for non-uniformity and obstacles due to intellectual or proprietary data.
2. Define which data should be recorded during operation to allow an understanding of the wide variation in the state of health (SoH) across an EV pack during its life and its possible exposure to temperature extremes, overcharging and/or charging at high currents, all of which can increase the potential for thermal runaway and safety concerns (Mrozik et al., 2021).
3. Put in place an incentive scheme for people to return their batteries to allow for reuse and circularity.
4. Define standards for testing used batteries and create a market of second-life batteries without safety risks and with acceptable performance.
5. Formulate liability schemes for second-life batteries.
6. Define a target for reuse since it is not yet part of the EU proposal (Nature, 2021).

The main strategies to guarantee the sustainability of the expected large-scale market should focus on the definition and adoption of data storage standards and open protocol for data transfer, system design and sensing.

1.3 Risks during recycling/remanufacturing

When direct reuse of a LIB system is not possible, recycling it is the best option as it closes the loop of the battery value chain. End-of-life LIB recycling could provide substantial economic benefits, as it reduces the need for new mineral extraction and can improve weaknesses in the supply chain.

According to some estimates, by 2030, the total annual European LIB recycling market will reach about 130 GWh (equivalent to more than 700 kilotons of recycling capacity needed), and this number is expected to increase three-fold by 2040 as more EV batteries reach the end of their life (Navarro et al., 2022). A study conducted by the Centre for European Policy Studies (CEPS) estimated that up to €555 million could be recovered by 2030 from the four critical materials (nickel, lithium, cobalt and graphite) from EV batteries (Drabik & Rizos, 2018). In 2040, these figures will increase up to €2.6 billion. Recycling has the potential to reduce primary annual demand compared to total demand in 2040 by approximately 25% for lithium, 35% for cobalt and nickel and 55% for copper (Dominish et al., 2021).

However, the recycling processes are still far from optimal. While battery researchers and manufacturers have focused on lowering costs and increasing battery longevity and charge capacity, recycling processes are hazardous and often inefficient.

Traditionally, LIBs are recycled by means of three techniques: pyrometallurgy, hydrometallurgy and a combination of both. The first, more common, is a heat-based extraction and purification process in which the batteries are shredded and burned before the metals are extracted. In hydrometallurgy, metals are extracted from ore through a process that involves the use of a leaching agent, separation of impurities and precipitation of the metal. Neither is ideal: pyrometallurgy is energy-intensive, while hydrometallurgy uses potentially harmful chemicals (HDI Global SE, 2021). With the combination of the two approaches, batteries are shredded, heated, and then processed with an aqueous solution. Still, much can be done to improve the recycling process, especially considering the different processes needed for the various battery chemistries and the rising number of batteries that will reach end-of-life.

The efficiency of the recycling process is also limited by the battery design and the collection rate. Recently, a study from the Centre for Research on Multinational Corporations (SOMO) pointed out that battery manufacturers are currently not designing LIBs to optimise recycling (González & de Haan, 2020). Packs are not easy to disassemble, and cells are not easy to separate for recycling. LIBs are compact, complex devices of different sizes and shapes. Large battery packs in electric vehicles may contain several thousand cells grouped in modules. The packs also include sensors, safety devices, welded connectors and circuitry that controls battery operation. These elements add complexity and costs to battery dismantling and recycling. According to the International Energy Agency (IEA), “increasing collection and sorting rates is a crucial starting point to scale up recycling. Government policies can play a major role in facilitating waste collection, thereby ensuring a sufficiently large waste stream to justify infrastructure investment” (van Halm, 2022).

For these reasons, the EC is working on modernising the battery recycling directive 2006/66/EC (2006). The objective of the directive is to achieve an average LIB recycling target of approximately 70% by 2030, with the aim to recover 70% of lithium and 95% of nickel, copper and cobalt in end-of-life batteries. The updated proposals in the amended Regulation (EU) No 2019/1020 (European Commission, 2020b) also contain goals for recycled materials that must be used in new cells. These figures are 4% for lithium and nickel and 12% for cobalt by 2030.

Considering the main outstanding issues around the recycling process, propositions for dealing with uncertainties and risks include to:

1. Design new batteries for recycling so that materials can be easily separated and the recovery percentage can be increased. One of the significant challenges in setting up a performant collection infrastructure lies in the heterogeneity of battery types available on the market. LIBs are used for a wide range of applications, resulting in a large variety of battery designs that differ with regard to their capacity, shape, size and chemical composition (Neumann et al., 2022).
2. Make sure that sufficient recycled materials will be recovered, which is difficult due to the significant percentage of batteries going to second-life uses. A possible solution to obtain recycled materials to produce new batteries is to use the waste (material scrap) from battery manufacturing that can become the main source of recycled material as well as the ideal starting point (Boukhalfa et al., 2022).
3. Prevent manufacturers from being secretive about the materials and concentrations used in the batteries they produce. If the composition is not known, recycling them properly is harder. In this perspective, the Battery Passport and correct labelling will clarify which materials are used in a battery and thus facilitate recycling. Moreover, LIB chemistry is constantly evolving, making it even more challenging for those in charge of the recycling process to foresee future technologies.
4. Improve the recycling process as it remains energy-intensive and polluting because battery binders do not allow for easy separation. Thus, water-based solvents should be investigated (both for performance and durability) to allow easy recycling (Li et al., 2020). Moreover, there is a need for new technologies for material recovery that are less energy-intensive, cheaper and reduce secondary pollution. Improving the recycling process should also consider optimising the recycled materials' quality to maintain the properties needed for manufacturing new cells.
5. Define standards to decide which batteries are to be recycled and which should be used for other purposes, to avoid recycling batteries that can still serve in a second use.
6. Define responsibilities for recycling battery systems at their end-of-life, as is done for portable electronics. Furthermore, illegal disposal and informal processing that leads to severe pollution must be prevented. This could be achieved through better collection schemes, expansions and improvements in the current recycling infrastructure, and posing legal obstacles to exporting second-hand EVs or LIBs (Mrozik et al., 2021).

All of the proposed solutions will help handle the expected rise in the volume of LIB to be recycled, but especially the first points (1 to 3) will help achieve current policy targets (for collection and material recycling rates) and allow the recycling process to be economically viable with the smaller volumes of LIB available today. However, developing the recycling capacity to meet the expected needs will require a clear policy framework with strong monitoring to prevent the growth of informal markets. It will also require heavy investments in recycling infrastructure.

2.

Conclusion

Environmental, social and economic benefits are possible by expanding a sustainable battery value chain. However, this will not be possible without coordination and immediate action by policymakers, investors and companies in consultation with all stakeholders.

Sustainability risks for the LIB industry can arise in each stage of the battery lifetime, from production to recycling. Regulatory programmes have already addressed most of these risks, but there are still open points that need to be dealt with, especially considering the large volume of battery systems that will be created, used and recycled in the following years.

In Europe, as well as in other countries, the adopted strategy is grounded in circular economy principles that can guide the sustainable management of the rising volume of end-of-life LIBs via a hierarchy of recovery pathways: direct reuse of used LIBs in vehicle applications, followed by reuse in less demanding applications (such as stationary energy storage) and material recovery through recycling which reduces the burden of mining raw materials. Each of these reuse pathways offers the potential to minimise the magnitude and pace of LIB waste generation while simultaneously reducing the life cycle environmental impacts of energy and vehicle storage systems (Babbitt, 2020).

To reach this holistic approach and create a low-risk value chain around batteries, there is a need to create a circular business model not only for large but also for small/medium enterprises which are involved in the electrification of the vehicle fleet and faced with the task of offering solutions for their end-of-life batteries.

A concrete solution already in the EU regulatory plan that could enable a circular trajectory is the Battery Passport. The Passport would support data sharing on details such as materials chemistry, battery origin, the state of health of the battery, or the chain of custody. It could provide a powerful means to identify and track batteries throughout the life cycle and, hence, support the establishment of systems for life extension and end-of-life treatment (World Economic Forum, 2019). More specifically, the Battery Passport will allow for the reduction of sustainability risks listed above and reach the following targets: (1) the reduction and/or the sustainable procurement of critical metals, (2) the reduction of waste, (3) an efficient manufacturing and recycling process, (4) the exchange of data among key stakeholders to improve the economics of life extension through repair, refurbishment and recycling, and (5) the promotion of product design and technical development to facilitate disassembly for repurposing, repair and recovery of materials. More importantly, the new circular approach will offer storage solutions in an affordable, sustainable and more democratic way to keep pace with the expected electrification necessary for the decarbonisation of different sectors.

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Paper 6

Ensuring the environmental sustainability of emerging space technologies

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Introduction

As humanity's activities in space expand, their impacts on space and terrestrial environments should be scrutinised. A thorough understanding of those impacts is instrumental to informed decision-making, helping funders, developers and regulators take appropriate decisions to set space activities on a sustainable course. Space missions have very specific impacts as they involve the development and manufacturing of spacecraft on the ground, their launch through the different layers of the atmosphere, their operations in space or on other celestial bodies, and potentially their return to Earth. Space activities have long been the remit of governments focusing on national security and great-power influence. As they have only recently started to scale, notably due to the expansion of commercial ventures, the study of their potential negative impacts on the environment has been neglected. Important legislative and regulatory instruments pertaining to the environment often exclude space activities,[2] resulting in a lack of attention and the slow development of tools and methods to assess the space sector's impact on the environment.

The increase in space activities and concern about unsustainable practices have led the United Nations Committee on the Peaceful Uses of Outer Space (UNCOPUOS) to elaborate 21 Guidelines for the Long-Term Sustainability of Outer Space Activities (hereafter LTS guidelines), which were adopted in 2019. These voluntary non-binding guidelines are the result of a decade-long effort. They focus on (1) the national policy and regulatory framework for space activities, (2) the safety of space operations with an emphasis on collision risk and space weather, (3) international cooperation, capacity-building and awareness, and (iv) scientific and technical research and development. These guidelines also provide a definition of the "long-term sustainability of outer space activities" as "the ability to maintain the conduct of space activities indefinitely into the future in a manner that realises the objectives of equitable access to the benefits of the exploration and use of outer space for peaceful purposes, in order to meet the needs of the present generations while preserving the outer space environment for future generations." While we follow this definition in this paper, we also extend it to consider the preservation of the Earth environment, including the atmosphere,[3] and do not focus on equitable access to the benefits of space exploration and use.[4]

At the heart of the concerns regarding the sustainable use of outer space is space debris. These non-functional human-made objects cause a collision risk for operational spacecraft threatening valuable assets. Congestion in near-Earth space is intensifying, especially in low Earth orbit (LEO),[5] increasing the cost of space operations and potentially limiting future benefits. Properly managing near-Earth orbital space is thus becoming ever more crucial to protect critical infrastructure and give access to new benefits from space activities.

This congestion issue is the result of the properties of near-Earth orbital space; it is both rivalrous and non-excludable. A space actor's use of a particular orbit prevents other space actors from using it, and it is difficult to exclude actors from enjoying the benefits of orbital space. Common-pool resources (CPR), which are defined by these two properties, face a management problem known as the tragedy of the commons (Hardin, 1968). The tragedy stems from space actors' failure to integrate the costs they impose on others when consuming the resource, leading to an overconsumption of the resource. Moreover, the benefits of the efforts from one space actor to maintain the resource accrue to all, which disincentivises resource preserving activities.

Near-Earth space is a finite resource whose value is increasing due to technological advances and demand for new services. As the value of orbits increases, many governmental and non-

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[2] For example, the Montreal Protocol on Substances that Deplete the Ozone Layer does not specifically address emission sources that emit directly into the stratosphere, such as launch vehicles, and the US National Environmental Policy Act (NEPA) only applies to the "human environment," which US Federal Agencies have interpreted (so far) as not encompassing the outer space environment.

[3] See, e.g., Yap & Truffer (2022), who advocate for a more holistic view on sustainability challenges by looking at "Earth-space sustainability."

[4] See also the definition elaborated as part of the space sustainability roadmap for Scotland (Space Scotland, 2022, p. 10) which extends the LTS guidelines definition to the preservation of "both the Earth and the outer space environment" and includes the "promotion of the use and environmental benefits of space data."

[5] Low Earth orbit (LEO) is the orbital region around the Earth ranging from the upper atmosphere to an altitude of 2,000 km.

governmental actors want to benefit from them. The space sector has steadily grown from about $176 billion in 2005 to about $360 billion in 2019, with the vast majority of the growth in commercial activities (Weinzierl, 2018), and investment bankers project a $0.9–1.5 trillion space economy in 2040 (McKinsey & Company, 2022). While there are, as of January 1st, 2022, more than 4,800 satellites in orbit from 73 countries (Union of Concerned Scientists, 2022), space analysts predict the launch of tens of thousands of satellites in the next decade (e.g., Gleason, 2021). However, the rush for this scarce resource raises a number of environmental concerns which are highlighted in this paper.

This paper presents how the sustainability concept is used in the space domain (section 1), key trends in the space ecosystem that can have a bearing on the sustainability of space activities (section 2), threats to environmental sustainability from space activities (section 3), and what is being done or could be done to ensure sustainable space activities (assessment in section 4 and management in section 5).

1.

Space sustainability: A broad concept

The term “space sustainability” is commonly used in the space community but can be understood differently depending on the forum for discussion. Its primary meaning refers to the concerns addressed in the LTS guidelines, that is, to ensure that space activities can be performed safely and without interference, such that the benefits they provide on Earth are sustained, and that the outer space environment is preserved for current and future generations (Martinez, 2021). This meaning leans more towards the ability to sustain activities in space rather than considering outer space as an environment worthy of protection. However, space sustainability can have a broader meaning by taking a holistic view on the supply chain of space missions, thus encompassing environmental impacts from the design phase to the decommissioning of space assets, both on Earth and in space. Space sustainability can also expand more explicitly to the other two dimensions of sustainable development: the social and economic dimensions. Sustainable development is generally defined as “development that meets the needs of the present without compromising the ability of future generations to meet their own needs” (World Commission on Environment and Development, 1987) and is embodied in the UN Sustainable Development Goals (SDGs; Transforming Our World: The 2030 Agenda for Sustainable Development, 2015). It requires a delicate equilibrium between competing environmental, social and economic interests.

In her exploration of the space sustainability concept, Aganaba-Jeanty (2016) argues that its current conception “ties more clearly to global security than to sustainable development” with a focus on the needs of the present space actors. She also notes that space sustainability is sometimes “conceptualised as defining good behavior, its boundaries, and disincentives for negative behavior in space” thus limiting its reach.

Two adjacent and sometimes overlapping concepts are often used in the space community: space safety and space security. Space safety refers to “space mission hazards and relevant risk avoidance and mitigation measures” and “encompasses the safeguard of critical and/or high-value space systems and infrastructures, as well as the protection of orbital and planetary environments” (Pelton et al., 2020). It is often perceived as minimising hazards for space assets and humans in the short-term and is seen as a prerequisite for space sustainability. Space security is traditionally associated with the military security of states and encompasses the maintenance of peace and stability. This concept can include “the security of satellites and spacecraft in orbit, the security of access to space, and also the contribution to the security of people on Earth made by various types of satellites” (Sheehan, 2014). However, its meaning has broadened to include the freedom of access to and utilisation of space, blurring the distinction with space sustainability.

The space sustainability concept needs to be contrasted with the concept of space for sustainability which refers to space activities’ contributions towards the UN SDGs. Indeed, the growing space infrastructure is increasingly important for monitoring and improving the sustainability of many Earth activities. Satellite-based services can enhance the monitoring, assessment and management of environmental risks, such as fires or floods, and are thus key enablers of progress towards the SDGs (e.g., Anderson et al., 2017; Ferreira et al., 2020; Kavvada et al., 2020; Song & Wu, 2021; UNOOSA, 2018). The space infrastructure is also key in our response to climate change as many essential climate variables can only be measured from space.

This paper focuses on environmental sustainability and only touches upon the social and economic dimensions. It takes a holistic view on space activities and looks at their environmental impacts on Earth and in space. Currently, the most valuable region of space to humankind is near-Earth orbits as only limited activities happen beyond this region. Therefore, the environmental risks associated with the exploration and use of space beyond Earth orbits are only briefly addressed.

In many respects, the concept of environmental sustainability, as used in the Earth context, can be extended to space. In this regard, the concept of ecosystem services is particularly useful. Ecosystem services can be defined as “the benefits human populations derive, directly or indirectly, from ecosystem functions” (Costanza et al., 1997). The Millennium Ecosystem Assessment (2005) groups services into four categories: provisioning services (e.g., food, water, timber), regulating services (e.g., bees pollinating flowers, tree roots holding soil in place), cultural services (e.g., recreational, aesthetic, spiritual benefits) and supporting services (e.g., photosynthesis, nutrient cycling). Near-Earth orbital space is an ecosystem providing services. The vantage point above Earth’s surface enables services such as Earth monitoring and communications, which support human activities on Earth. The proliferation of debris can alter the ability of the ecosystem to provide those services. Similarly, the night sky provides cultural services that can be degraded by light reflected from human-made objects in outer space.

2.

Space industry trends affecting the environmental sustainability of space activities

The environmental impacts of space activities are more linked to the scale of those activities than to their characteristics. Emerging technologies are a driver of the growth in space activities and are thus indirectly affecting their sustainability. Some space applications are not intrinsically new but can now scale due to external factors, such as reduced launch cost or increased demand for space-based services. A bundle of new technologies is often required to make a new application emerge. For example, the combined emergence of partially reusable launchers, new constellation architectures, and smaller and cheaper user terminals is enabling large constellations of satellites for broadband internet, resulting in fundamental changes in the space economy.

Let us take a look at some important trends in the space ecosystem that can have a bearing on the sustainability of space activities, impacting the space debris issue but also other environmental aspects discussed in the next section:

- **Low-cost access to space** – The development of partially reusable launch systems by commercial companies has drastically reduced the cost of launching spacecraft. Whereas the Space Shuttle cost about $54,000 per kg launched in LEO, SpaceX’s Falcon 9 costs about $2,700 per kg, a twenty-fold reduction (Jones, 2018). Dropping launch costs is an enabler of new space activities.
- **Miniaturisation of satellites** – The use of smaller and lighter components, as well as commercial off-the-shelf (COTS) components, enables the production of smaller and cheaper satellites, such as CubeSats.

These two background trends have led to a 17-fold increase in the annual number of satellites launched in LEO over the last ten years and are fueling the following foreground trends:

- **Large LEO constellations for broadband internet** – Although satellite constellations for communications in LEO are not intrinsically new, more favorable market conditions are resulting in a proliferation of large systems (Portillo et al., 2019). SpaceX is leading the race with more than 3,000 satellites already launched, followed by OneWeb with 428 satellites.[6] Several other companies also intend to launch large constellations consisting of thousands of satellites. Not only has demand for high bandwidth low latency communication increased, but several technology developments, such as advances in antennas, inter-satellite links and artificial intelligence, have reduced the cost of LEO constellations (Daehnick et al., 2020).

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[6] As of August 2022.

- **Introduction of new actors** — The lower barriers to entry lead to a plethora of new operators, including academic institutions and startup companies. Operators are also more diverse geographically, with more than 73 countries owning or operating at least one satellite (Union of Concerned Scientists, 2022).
- **Emergence of in-orbit services** — The space industry operates under the launch, use and discard paradigm. Maintenance services in orbit, e.g., to deorbit, refuel or repair a satellite, are emerging and are likely to change this paradigm (ESPI, 2020).
- **Space tourism** — Suborbital and orbital spaceflight are democratising with the availability of various services (FutureLearn, 2022). Commercial destinations in the form of private space stations are also developing. Space tourism is bound to become a significant part of the space economy.
- **Resources exploitation** — The moon, asteroids and other celestial bodies are sources for natural materials that can be extracted for use in outer space (e.g., for refueling) and on Earth. There is growing interest and investment for mining in space (Gilbert, 2021).

3.

Risks to environmental sustainability from space activities

Throughout their life cycle, space missions have environmental impacts on the ground, in the atmosphere, in space and potentially on other celestial bodies (see figure 1). The development and production of spacecraft have impacts similar to other manufacturing activities on Earth. However, compared to other products, space technologies are often custom-made, need long development cycles, use specialised materials and industrial processes, and require thorough testing.

The unique nature of space missions starts with the launch. This paper thus focuses on the environmental impacts that are particular to space technologies, and are the result of the launch of spacecraft into space, their operations and decommissioning in space or on other celestial bodies, and their return to Earth (see, e.g., Boley & Byers, 2021, for a study of the potential impact of large LEO constellations throughout these phases).[7]

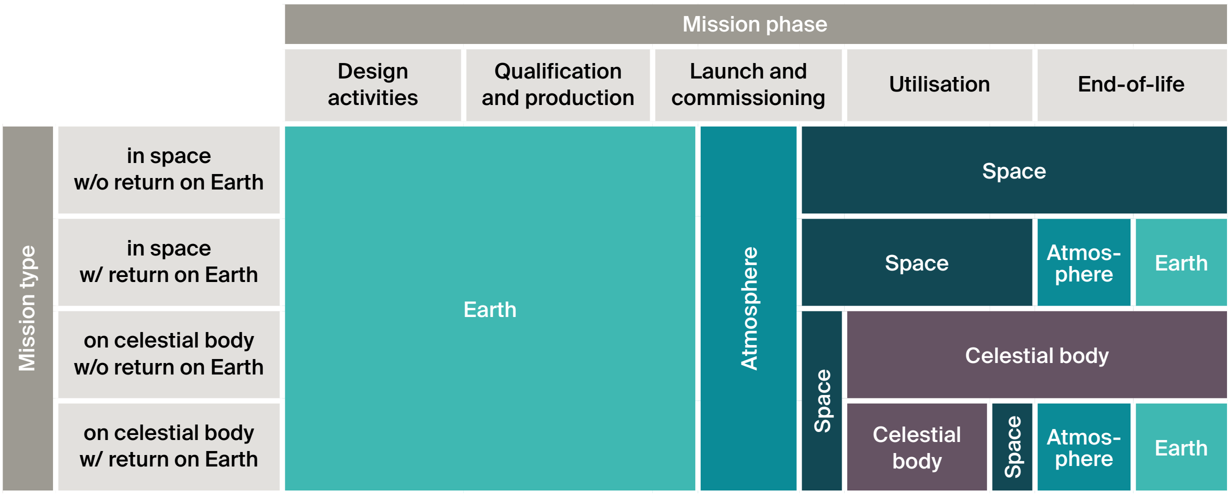

Figure 1 | Basic life cycle stages of a space mission and locations of impacts

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[7] For life cycle assessment of the Earth-based impacts (ecospheric) of space missions, see Wilson et al. (2022). They estimate that the global contribution from space missions to climate change is only 0.01% of total greenhouse gases emissions.

3.1 Collisions with space debris

The most unusual, probably most concerning, and thus most studied risk to environmental sustainability associated with space activities is space debris (see, e.g., Bonnal & McKnight, 2017; Buchs, 2021, for a general review). As a by-product of space activities, non-functional human-made objects, or space debris, are generated. Space debris ranges from sub-millimeter paint flakes to 9-ton rocket bodies.

With the current monitoring infrastructure, only space debris larger than 5–10 cm in LEO can reliably be tracked and catalogued. The population of more than 30,000 trackable debris pieces is dominated by fragments resulting from explosions and collisions, but there are about 3,000 derelict intact objects in orbit.

Operational spacecraft face a collision risk from the space debris population. A low-intensity collision can affect the performance of a spacecraft or disable some subsystems. If the collision intensity is higher, it can result in the disabling of the spacecraft or its complete fragmentation. As objects travel at 7–8 km/s in LEO, even a collision with a centimeter-sized object can have devastating consequences.

When equipped with manoeuvring capabilities, spacecraft can potentially avoid catalogued objects. However, not all spacecraft can manoeuvre, and the ability to accurately determine the position of space debris is limited. Objects with sizes below the tracking threshold are much more numerous and can disable or even fragment a spacecraft. Statistical modelling estimates a population of a million pieces of debris in the 1 to 10 cm size range (ESA Space Debris Office, 2021). Thus, these lethal non-trackable objects dominate the risk profile of operational spacecraft (Maclay & McKnight, 2021).

The large number of derelict objects abandoned in LEO have a significant risk-generating potential as they could create tens of thousands of lethal non-trackable debris if they were to collide or explode (Rossi et al., 2020). In 2009, the collision between the active commercial satellite Iridium 33 and a derelict Russian military satellite Cosmos-2251 generated about 3,000 trackable fragments and many more non-trackable ones. Collisions involving more massive objects would create much more debris. Military activities are also a major source of debris and an increasing cause for concern. In 2007, China deliberately destroyed one of its derelict weather satellites to test an anti-satellite (ASAT) weapon, generating more than 3,400 trackable fragments, and in 2021, Russia conducted a similar test generating about 1,500 pieces of trackable debris.

The evolution of the space debris population is a balance of sources and sinks. The sources are satellites that have reached their end-of-life and cannot be deorbited, satellites of which the operator has lost control, mission-related objects, such as rocket upper stages, and fragmentation debris resulting from on-orbit break-ups. Only two sinks are available to clear space debris from orbits: atmospheric drag and direct retrieval. The lifetime of a piece of debris increases with its altitude; while at 500 km objects take between a few years to a few decades to reenter the atmosphere, at 800 km the reentry can take centuries. Direct retrieval of large pieces of debris from orbit is in its infancy, with demonstration missions coming up in the next years.

The population of space debris has steadily increased over time. The sharp growth in space activities combined with poor compliance with commonly agreed-upon debris mitigation guidelines is a cause for concern (ESA Space Debris Office, 2022). Modelling of the space debris environment has shown that the environment has probably already reached the tipping point where even without new launches the population would keep growing as a result of collisions.

The loss of spacecraft due to collision with debris pieces can result in large disruptions on Earth as a result of the unavailability of critical satellite services. Space debris is also a threat to human spaceflight as a collision with a non-trackable piece of debris can result in the loss of human lives. Space debris uses some of the space environment capacity, augmenting the costs of conducting space activities and limiting the benefits we can extract from this resource.

3.2 Optical and radio interferences

Human-made objects in Earth orbit produce passive and active electromagnetic emissions (Dark and Quiet Skies II for Science and Society, 2022). All space objects passively reflect the sunlight and operational spacecraft actively communicate with stations on the ground using radio frequencies. Both types of emissions affect astronomical observations, but only the former impacts stargazing. They likely also have an impact on the wildlife, but very little about this topic is known.

These electromagnetic emissions scale up as the number of objects in Earth orbit grows. The plans to launch numerous large constellations consisting of thousands of spacecraft is thus a cause for concern given their impact on the appearance of the night sky and on astronomical observations (e.g., Hainaut & Williams, 2020; Massey et al., 2020; McDowell, 2020).

The visibility from the ground and the brightness of satellites depend on their altitude, surface reflectivity and attitude with respect to the observer. Only a fraction of the planned satellites will be visible by the naked eye, but all of them are potentially detectable by highly sensitive telescopes.

While research has recently focused on the discrete streaks produced by artificial objects on astronomical images, little information is known about the contribution of these objects to the diffuse brightness of the night sky. The cloud of artificial objects orbiting the Earth, comprised of both space debris and operational spacecraft, reflects and scatters the sunlight towards ground-based observers. Their combined effect is a diffuse night sky brightness component similar to that of the starlight background of the Milky Way. According to preliminary estimations, the contribution of space objects to the skyglow has already reached 10% of the luminance of a typical natural night sky (Kocifaj et al., 2021). The launch of large constellations of satellites is bound to exacerbate this light pollution.

The lack of a multistakeholder appraisal of the impact of large constellations is a concern. Venkatesan et al. (2020) argue that space is an ancestral global commons, and that the impact of humanity's expansion of activities in space on the essential human right to dark skies and on cultural sky traditions across all peoples needs to be properly evaluated.

3.3 Marine pollution

Two phases of space missions can result in pollution in the marine environment: the launch and the reentry of objects into the atmosphere. Expendable launch vehicles can only be used once. The stages of a rocket and its fairings are jettisoned at different altitudes. Some objects are discarded at sea before reaching space while others reenter the atmosphere in a short amount of time without fully burning. The development of reusable launch systems will reduce the amount of debris ditched at sea. For now, only partially reusable orbital launch systems have flown, but the first fully reusable orbital launch vehicles should be ready during the 2020s.

The development of the launch industry, with the emergence of small launchers in countries that were not used to launch rockets (e.g., the UK, New Zealand) has led to renewed scrutiny regarding this activity. Debris jettisoned during launch can have the following impacts on the marine ecosystem: direct strikes on the fauna, underwater noise and disturbance on impact, toxic contaminants (e.g., fuel, batteries), ingestion of debris, smothering of seafloor and provision of hard substrate (Lonsdale & Phillips, 2021). A report prepared for the New Zealand Ministry for the Environment regarding Electron Rocket launches from New Zealand assessed that for up to 100 launches the ecological risk is low for all ecological impacts identified (NIWA, 2016), and only flagged a high risk to the air breathing fauna with 10,000 launches. As highlighted by the case of the now-retired Russian Rockot launch vehicle which was powered by unsymmetrical dimethylhydrazine (UDMH), a highly toxic chemical creating potential environmental risks (Byers & Byers, 2017), new propellants require detailed assessment before authorising their use to avoid releasing toxic material in the natural environment.

Objects in Earth orbit are dragged down by the residual atmosphere. When reentering the atmosphere, objects do not always fully disintegrate – depending on their size, shape and materials – and can hit the ground. Objects which are likely to survive the reentry and cause a significant risk of damage or casualty on the ground require a controlled reentry. In such a case, Point Nemo, the farthest point from any land on Earth, in the South Pacific ocean is targeted (Lucia & Iavicoli, 2019). While this practice has raised concerns, as oceans should not be seen as a dumping ground, compared to the 11 million tons of plastic that end up in the ocean, the space debris contribution is negligible (David, 2022).

3.4 Atmospheric pollution

Like the marine environment, the atmosphere can be impacted by the launch of space vehicles and the reentry of objects into the atmosphere. Rocket engines emit different gases and particles into the atmosphere with potential local and global consequences (e.g., Dallas et al., 2020; Ross & Sheaffer, 2014; Ross & Vedda, 2018; Ryan et al., 2022; The Aerospace Corporation, 2022). Rockets are the only direct anthropogenic emission sources in the upper atmosphere. Although these emissions can affect Earth's climate and the ozone layer, limited scientific research has been conducted on them, as the space industry has for a long time been assumed to be too small to have a significant effect. Moreover, the number of launches had been declining from 157 in 1967 to only 42 in 2005, leading to a disinterest on the impact of rocket emissions. However, this trend is reversing, with an annual growth of about 6% in the past ten years leading to 135 successful launches in 2021. Given the plans to launch large satellite constellations and the emergence of space tourism, the number of orbital launches could reach 400 per year by 2030.

Emissions include gases such as water vapor and carbon dioxide (CO_2), but the quantities emitted by rockets are significantly smaller than those from other human sources. The emergence of space tourism has drawn public attention to the carbon emission of launches. However, CO_2 emissions from rockets are insignificant in the global picture, as rockets emit less than 0.01% of the CO_2 emitted by aviation (The Aerospace Corporation, 2022). More concerning are the emissions of small particles of soot (or black carbon) and alumina (aluminium oxide) directly into the stratosphere (Ross & Toohey, 2019). For comparison, in 2018, the amount of black carbon emitted in the stratosphere by rocket engines was similar to the amount released by global aviation. Black carbon and alumina particles reduce the intensity of solar flux entering the troposphere, and thus contribute to cooling the Earth's lower atmosphere and surface. Ross & Toohey (2019) estimate that "the magnitude of present-day cooling from rocket particles is about the same as the magnitude of warming from aviation carbon dioxide." However, the physics at play is different and Earth responds to stratospheric particle injections in complex ways which are not yet fully understood. More research is needed to unravel these complex effects and the potential impacts of an increase in launches. The effects of 400 launches per year could be unsettling.

Human-made objects reentering the atmosphere mostly burn up: about 60% of rocket bodies and 60 to 90% of satellite mass disintegrate during atmospheric reentry (Werner, 2020). While there are currently about 100 tons of hardware reentering the atmosphere per year, if the planned constellations materialise, the annual mass reentering Earth's atmosphere could eventually rise to between 800 and 3,200 tons. Historically, the concerns have been on the potential hazard to aircraft and people of objects surviving reentry. To comply with space debris mitigation guidelines requiring a probability of less than 1 in 10,000 that someone gets hit by a part of a space object reentering the atmosphere, manufacturers are pushed to implement design for demise practices. However, the disintegrated spacecraft deposit fine aluminum particulates which can damage the ozone layer and change the Earth's albedo, and thus change the radiative balance of the Earth.

The combined effects of rocket emissions and space objects' reentries is akin to uncontrolled geoengineering experiments, which are much debated (Pultarova, 2021). This raises more questions regarding the interplay of these effects and geoengineering, at both the research and governance levels, if geoengineering were to be deployed.

3.5 Interplanetary contamination

The exploration and exploitation of other celestial bodies and the return of spacecraft to Earth comes with the risk of biological contamination. "Forward" contamination, that is the transfer of life and other forms of contamination from Earth to another celestial body, could potentially harm extraterrestrial ecosystems and mislead scientific efforts to detect extraterrestrial life. "Backward" contamination, that is the introduction of extraterrestrial organisms and other forms of contamination into Earth's biosphere, might harm terrestrial ecosystems. Limiting the risk of these harmful contaminations is called planetary protection.

Recognising these risks, the Committee on Space Research (COSPAR) has been responsible for setting the international standards for planetary protection since the early 1960s. Following the launch of several Mars missions in 2020 and the progress of the Artemis programme which intends to return humans to the Moon during the 2020s, NASA and COSPAR have updated their planetary protection policy (COSPAR, 2021; NASA, 2020a, 2021). As the number and diversity of actors, especially private companies, involved in space activities on other celestial bodies expand, planetary protection is growing in importance (Cheney et al., 2020).

3.6 Cross-cutting aspects

Space actors tend to have a retroactive approach towards the sustainability risks discussed above. A reaction is often triggered by affected stakeholders, as was the case with the astronomy community for optical interference caused by satellites. Experts researching the environmental impacts of space activities often highlight that "sustainability has not been much of a concern for space systems development" (The Aerospace Corporation, 2022). Attention has been on national pride and security, rather than sustainability. While the approach is evolving, space endeavours remain closely linked to defence and national security interests, with sustainability hanging in the background.

While the different risks mentioned above were treated in silos, there is growing interest in considering them simultaneously, with the development of all-encompassing guidelines or best practices. The recognition of space as an environment worthy of protection will help extend approaches developed to address sustainability on Earth and produce a coherent approach to space sustainability.

The different risks discussed have interactions and trade-offs which will need to be addressed. For example, design for demise results in less marine pollution but more material deposited in the atmosphere. There might also be tensions in the measures needed to limit collision risk and to limit optical interference from satellites. Tools and agreements on how to quantify and balance those risks are far from being settled.

4.

Assessing the environmental impacts of space activities

As discussed in section 3, space activities have a large diversity of environmental impacts. As a result, the tools to assess them can be very specific to the impacts considered. In this section, we first briefly present two methods which are increasingly used in the space domain to assess environmental impacts: life cycle assessment (LCA) and environmental impact assessment (EIA). The space sector is only starting to use these tools which are commonly used in other sectors, highlighting the sector's lateness in its consideration of the environment. Addressing uncertain impacts of emerging technologies will require other tools, more capable of coping with uncertainty and a long-term perspective. We then discuss approaches developed to assess environmental impacts that are specific to space activities such as space debris. In particular, we look at the space environment capacity, an approach currently gaining traction to measure orbital use by active spacecraft and space debris.

4.1 Life cycle assessment

LCA has been identified as a practical tool to monitor and reduce the environmental impact of space activities, particularly in Europe (see Maury et al., 2020, for a review). However, only a limited number of studies are publicly available and even fewer have been published in peer-reviewed journals. The application and formalisation of LCA of space missions have been pioneered by the European Space Agency (ESA), which has developed a set of guidelines (handbook), a specific database and an eco-design tool.

The space sector has very unique impacts which are not captured in conventional life cycle models, making the application of LCA challenging. In their current form, traditional LCA models can only provide results with significant uncertainties and are often unable to come up with actionable results (Wilson et al., 2022). Furthermore, LCA typically requires benchmarking to compare technologies, which is often difficult in the case of space technologies. Efforts aimed at developing standardised approaches for declaring environmental impacts of space systems over their entire life cycle, thus ensuring accurate and verifiable impact quantification for regulatory and economic purposes are ongoing (Wilson et al., 2021).

ESA's efforts have been geared towards adapting current ISO standards on LCA to space specificities, as methodological rules were missing. The agency has also championed the development of methods to include impacts related to space debris within the LCA of space missions (Maury et al., 2019). Work conducted at the University of Strathclyde has attempted to not only take into account the environmental dimension of sustainable development, but also to include the social and economic dimensions (Wilson, 2019). The resulting integrated framework is aimed at improving concurrent engineering activities to help develop cost-efficient, eco-efficient and socially responsible technologies.

Sustainability requires looking into the long term, and assessing the environmental sustainability of emerging space activities or technologies will require tools that have the capacity to help anticipate future impacts (see Miraux et al., 2022, for an application of a streamlined LCA to future space activities over the period 2022-2050 under two scenarios). Not only do the outcomes of the technology need to be anticipated, but also the future system in which it will be deployed.

4.2 Environmental impact assessment

EIA is a tool used to assess the potential environmental consequences of a particular project or action. EIAs are currently performed to evaluate the impact of space activities on the terrestrial environment, in particular for the development of new spaceports (e.g., Lonsdale & Phillips, 2021; NIWA, 2016). However, in its current implementation in laws and regulations, as a requirement before undertaking major infrastructure projects, EIA is not meant to assess impacts in outer space.[8]

As humanity's horizon expands beyond Earth's orbit, and major actions, such as resource extraction, are undertaken on other celestial bodies, there is a need for the development of a comprehensive process to assess human impacts on extraterrestrial environments (Kramer, 2014). Different frameworks for extraterrestrial EIA have been proposed (e.g., Dallas et al., 2021; Kramer, 2020; Mustow, 2018) but their application in practice remains distant.

4.3 Special approaches in the space domain

To address the specific aspects of space activities, dedicated approaches are under development (see, e.g., Maury et al., 2020; Wilson, 2019, in the context of LCA). In particular, several metrics have been proposed to improve the management of near-Earth space, where most space activities currently happen (e.g., Letizia et al., 2018; Rossi et al., 2015). Of notable interest is the concept of space environment capacity (ESPI, 2022). It assumes that near-Earth orbital space is a limited shared resource and aims to provide an indication of how much of this resource is used by space missions and objects in a defined orbital region (see figure 2).

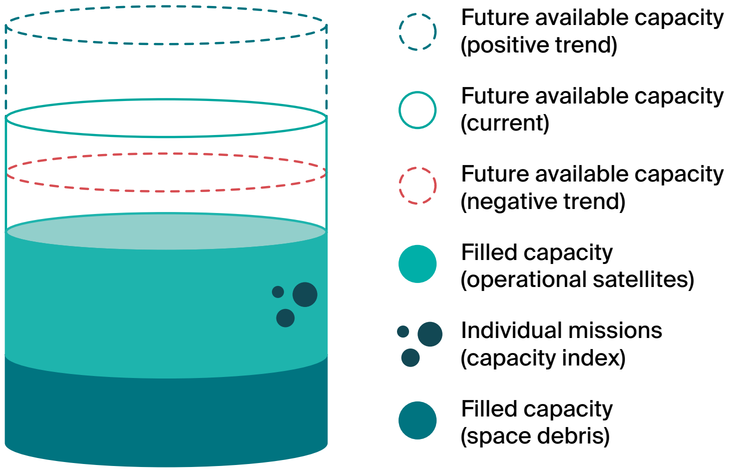

Figure 2 | Schematic depiction of the space environment capacity concept (reprinted from ESPI, 2022)

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[8] Reasons for not applying EIA to outer space infrastructure development include the perception that space is not part of the environment and the fact that space is not under the jurisdiction of any state.

Another effort worth mentioning is the development of the Space Sustainability Rating (SSR). This voluntary rating system for space missions relies on a composite indicator of a mission's footprint on the space environment which incorporates the space environment capacity (Letizia et al., 2021; Rathnasabapathy et al., 2020). The SSR was launched in June 2022 and is aimed at offering a transparent and data-based assessment of the level of sustainability of space missions. For now, the different modules forming the indicator are focused on the space debris issue, and do not address the other risks mentioned in this paper.

5.

Managing the environmental impacts of space activities

As some of the risks associated with space activities have only recently been identified and their quantification is insufficient, the response strategies are in most cases only emerging. Collision with space debris was one of the earliest risks identified and has benefited from some, albeit limited, policy and regulatory attention since the 1990s. The other risks discussed have been mostly left out of legislative and regulatory instruments.

5.1 Technical approaches

Identification and characterization of most of the risks described in section 3 are at a preliminary stage. As highlighted for a number of them, more research is needed to understand the significance of their impacts on environmental sustainability and to develop appropriate response strategies. Space debris has been identified early and thus has more mature technical approaches.

Collision risk from space debris is addressed through four sets of technical activities: impact tolerance, collision avoidance, debris mitigation and debris remediation (see, e.g., Buchs, 2021). The first two consist of minimising risk in the existing environment while the latter two involve changing the environment. Impact tolerance is reducing the probability of losing a spacecraft when it is hit by a piece of debris through, for example, shielding or redundancy (S. Ryan, 2022). Collision avoidance consists of manoeuvring spacecraft in the case of an approaching trackable piece of debris to avoid being hit (NASA, 2020b). Debris mitigation involves different activities, such as post-mission disposal or passivation, to reduce the likelihood that a spacecraft becomes or generates debris (ISO, 2019). Finally, debris remediation consists of minimising the chances that existing debris creates further debris, for example, by actively removing derelict objects (Bonnal et al., 2013) or upgrading them with manoeuvring capabilities (Marchionne et al., 2021).

5.2 Governance approaches

The only internationally binding instruments of public international space law are five UN treaties on outer space adopted in the 1960s and 1970s. Although they are legally binding on the states who have signed and ratified them, enforcement mechanisms are weak. Moreover, these treaties do not directly address the sustainable use of space. They have been complemented by non-binding guidelines on space debris mitigation (UNCOPUOS, 2007) and on the long-term sustainability of outer space activities (UNCOPUOS, 2019; see introduction).

The UN treaties render states internationally responsible for national activities in outer space whether such activities are carried on by governmental agencies or by non-governmental entities (Outer Space Treaty, 1966, Article VI). Thus, licensing for space launches and operations at the national level has a major role to play in ensuring the sustainability of space activities. International guidelines (e.g., IADC, 2021; ISO, 2019) are often integrated as part of the requirements in licensing procedures. However, so far the only risk mentioned in section 3 that is commonly assessed in the licensing process is collision risk from space debris, albeit only before launch, without mechanisms to address what actually happens once in space.

6.

Way forward

Apart from space debris, the space industry's contribution to adverse environmental sustainability impacts appears minimal at present. However, "these impacts may become more meaningful with the scaling up of space activities in the near-to-medium term future" (Wilson et al., 2022). In the case of space debris, most experts agree that tipping points have already been reached and that congestion in LEO is alarming, threatening the long-term use of these orbits.

There is a need for more in-depth research on all the risks discussed in this paper. Crafting effective response strategies requires more scientific evidence, technology developments and harmonised international governance. Some of the risks, such as atmospheric pollution, require more investigation into the impacts of space activities on the environment, while others, such as collision risk from space debris, would benefit from a better understanding of the cost-benefits of approaches to address it. In comparison to other sectors, research efforts to analyse the environmental impacts of space activities and potential response strategies are not commensurate with the size of the sector, even less so with the predicted growth of the sector in the coming decade.

Instruments developed so far to assess the sustainability of space activities are not comprehensive and are not routinely implemented. Efforts are needed to expand and operationalise them. Effective tools to anticipate future risks and address large uncertainty are typically absent. The space sector could benefit from findings in other sectors regarding foresight and long-term sustainability.

For spacefaring nations, national interests and security are the primary drivers of space policy, outweighing concerns regarding the environmental impacts of space activities. For now, sustainability is only an after-thought and is not prioritised. However, the growing share of commercial applications and greater environmental consciousness can help move space sustainability higher on the political agenda. The UK's recent announcement of a package of new measures to drive space sustainability goes in this direction (BEIS, 2022).

Major threats to environmental sustainability from space activities have global consequences, requiring a global response. However, due to the nature of international space law, national contexts and sovereignty must be recognised. Unilateral but coordinated action (e.g., by like-minded states) can be the way forward. Despite divergences among stakeholders, recognition that near-Earth is a limited shared resource with the characteristics of a common-pool resource is a stepping stone to managing it effectively at the global level.

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Paper 7

Ensuring the environmental sustainability of emerging technologies for carbon dioxide removal

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Introduction

Some technologies developed to combat climate change have adverse side effects in other domains, from the environment to society and geopolitics, as well as on different scales and time frames. They may not fully satisfy the conditions of sustainability, defined as the ability to meet current needs without compromising the ability of future generations to meet their own needs, along with supporting the aims of environmental protection, social equity and economic viability. This paper addresses the challenge posed by the potential deployment of emerging techniques for the large-scale removal of carbon dioxide (CO_2) from the atmosphere (grouped under the term carbon dioxide removal, CDR). While some technologies are already mature from a development perspective, they have not yet been deployed at scale. Deployed at large scale, these techniques could cause damage to the environment or the climate itself, i.e., constituting an environmental sustainability risk. Written for the EPFL International Risk Governance Center's (IRGC) project, the paper describes some potential risks of deployment of CDR techniques alongside prospective benefits, as well as emphasizing the insufficient knowledge available today to inform policy decisions on the extent to which we should encourage or mandate deployment of some of these techniques. There are reasons to worry today because, on the one hand, CDR is likely to be critical for stabilizing and eventually reducing CO_2 atmospheric concentration; on the other hand, it seems it will not be possible to do so without some degree of countervailing risks elsewhere.

Increasingly tense and fraught discussions are underway around the use of emerging technological options to help address climate change and stabilize the climatic system. For instance, direct air capture with carbon storage (DACCS) utilizes very large fans to remove CO_2 directly from the air. Bioenergy with carbon capture and storage (BECCS) emphasizes growing and harvesting plants as a source of energy and, by capturing emissions, a means for carbon storage. Enhanced weathering works by increasing the ability of rocks to absorb CO_2 from the atmosphere. Biochar removes carbon by converting organic material, whether from plants or animals, into a form of high-carbon charcoal.

Based on a large sample of expert interviews undertaken for the GeoEngineering and Negative Emissions Pathways in Europe (GENIE) project, which offers an interdisciplinary, holistic perspective of CDR technologies to understand conditions under which they might be deployed at scale, an early consensus seems to be emerging wherein risks abound no matter which emergent options are supported and/or deployed by scientists, policymakers, or the public. As one of our expert respondents put it:

> "Energy system transition is like a game of poker. We won't know which technology will work; we don't have good predictive skills for technologies like solar that are already a decade ahead. Think back: for technologies in the 1950s, how much predictive skill did we really have for 2050? Imagine how actors then would have distributed their bets. It's a monumental challenge."

Another explained that:

> "There are huge investment risks with deploying climate engineering: where to put the money, where to put the finance, where to create markets. There are risks everywhere. It comes down to how you talk about technology transitions, deal with futures, anticipate problems and integrate them into policy development."

Our systematic analysis of these interview data revealed no fewer than 12 different baskets of risk, which we have termed "risk-risk trade-offs" to underscore that climate action undertaken to mitigate the worst impacts of climate change does not ultimately eliminate all risks. As the diagram suggests, attempts to address risk in one area can exacerbate risk in another dimension. Moreover, these risk-risk trade-offs cut across different dimensions, including institutions and governance, technology and the environment, and behavior and future generations (see figure 1).

In this paper, we focus primarily on the environmental risks of four CDR technologies: BECCS, DACCS, enhanced weathering, and biochar, which are still "emerging" in the sense that most are at the stage of experimentation and testing, but there is no demonstration or deployment on the scale that would be required to reach the potential levels needed to help address climate change. Each of the four technologies presents potential threats that may manifest only in the long term and which remain challenging to identify and assess on the basis of what we now know – even though such knowledge is crucially needed to support informed (evidence-based) decisions. For each technology, and based on GENIE data, we identify and describe the environmental risks of deployment and some positive co-benefits, while also highlighting the possible environmental risks of not deploying, i.e., the risks of not taking action to try and mitigate climate change. This enables a broader and more comprehensive assessment of risk-risk trade-offs across space, time, and in diverse sectors.

1.

Bioenergy and carbon capture and storage (BECCS)

BECCS involves harnessing specific energy crops (e.g., perennial grasses, or short-rotation coppicing) or increased forest biomass in order to replace fossil fuels and to remove CO_2 by capturing and storing underground the emissions that result from the burning of the biomass. Similarly, if biogenic CO_2 is captured (e.g., CO_2 captured from a biogas plant or bioenergy), negative emissions are generated given that CO_2 is removed from the atmosphere. Because this technique is so tightly coupled to bioenergy systems, myriad environmental risks can accompany the deployment of BECCS. In particular, to reach the scale needed to help address climate change, it would have to expand to the scale of billions of tons of additional production of fuels or building materials per year (Parson & Buck, 2020). R093[2] added that BECCS would "need land and huge amounts of water," and R124 warned that "rivers could run dry with widespread deployment of BECCS." Studies have confirmed both the land intensity and water intensity of BECCS (Creutzig et al., 2012, 2015). R037 articulated that "large-scale BECCS and afforestation will negatively affect food security,

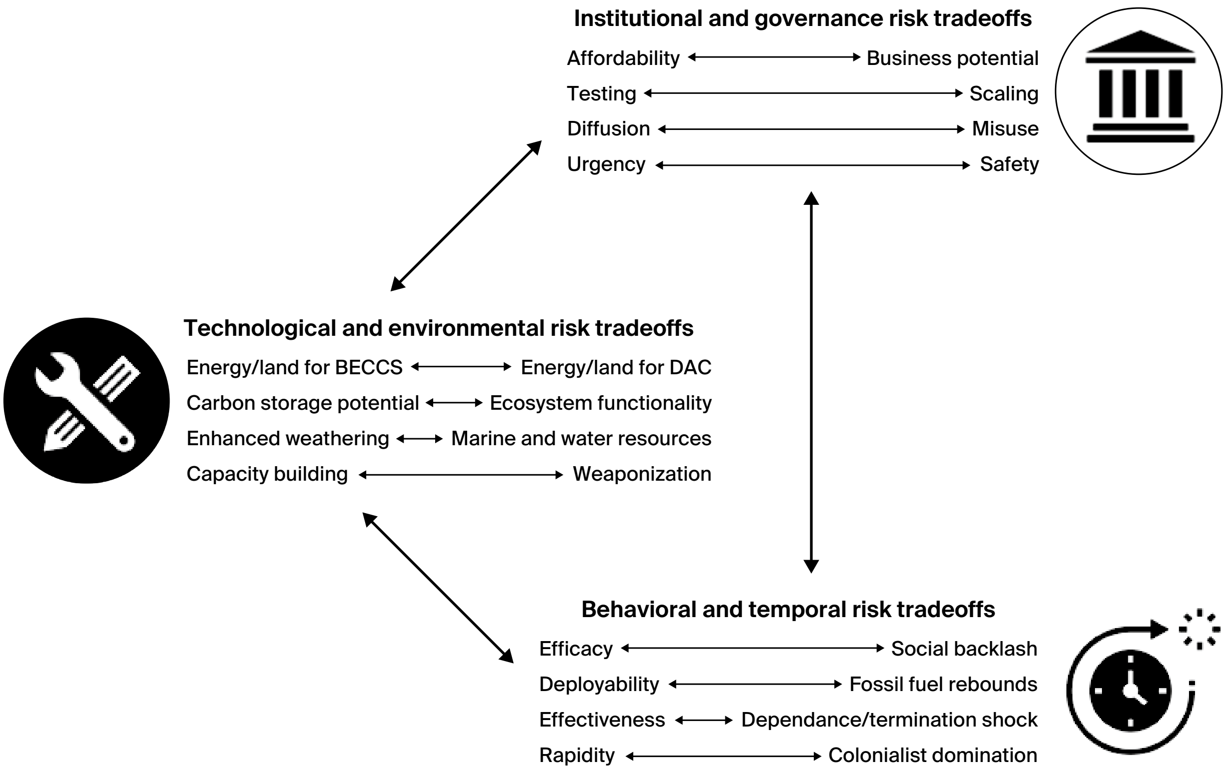

Figure 1 | Institutional, technological and behavioral trade-offs that may emerge from climate engineering deployment (reprinted from Sovacool, Baum, & Low, 2022b). Note: rationales for clustering each of the twelve risk-risk trade-offs are based on qualitative expert interview data. Some of the trade-offs relate to solar geoengineering alongside CDR, both of which are covered by the GENIE project, though the focus of this particular IRGC report is only on CDR.

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[2] In order to ensure anonymity while also helping to link interview participants with particular quotes, the GENIE project assigns interviewees a respondent number, i.e., R093 is the 93rd expert respondent. These numbers will be used in this paper as well.

because you are taking land out of production, and negatively affecting the ability for land to be used for poverty reduction or farming." R042 termed this as follows:

> ”I see the highest risk of carbon removal with impacts on land use. And land use is the main driver of anthropogenic mass extinction that we are currently witnessing which is arguably at the same level and scale as climate change. [...] If there are mass plantations and they are historically known to actually be led to land capture and land enclosures from societies that have traditional property rights on land, I'm skeptical that carbon removal will be able to deliver without hurting food production or agriculture."

R121 added that another dimension to this co-impact involved the pollution flows at the back-end, which could also negatively impact land. As they noted: "growing all of these bioenergy crops will generate large amounts of pollution, which could limit access to food or at least safe and healthy food."

Furthermore, existing supply chains for biomass are not extensive enough to move beyond the current deployment of smaller, more distributed BECCS facilities (Buck, 2019). Scaling up of both BECCS and direct air capture (see the next section) is thus limited and must confront challenges in the form of unclear standards and procedures for monitoring, reporting and verification (MRV) or high energy costs per ton of captured or avoided CO_2; increasing conflicts over land use or biodiversity; and competition from wind and solar as sources of renewable energy, which undercuts the need for storage (i.e., because mitigation is cheaper) or the need for bioenergy (since biomass is more expensive as an energy source) (Creutzig et al., 2019).

This is not to say that BECCS deployment is without positives, or that it cannot help mitigate the potential for other environmental risks. Multiple respondents discussed BECCS as an important part of a diversification insofar as it could help promote a portfolio approach to climate protection. R026 stated that:

> "CDR could consist of co-deployed options. For example, with enhanced weathering and genetically modified crops, enhanced weathering with BECCS, or enhanced weathering with clean coal, there are neat land-based couplings and interactions that can arise."

Indeed, R060 identified the co-deployment of various technologies as necessary, given not only the desire to avoid or mitigate certain negative co-impacts that would attend to scaling the use of any one option on a grand scale (also noted by R025, R043, R081, R083, R085) but also the scale of the problem itself:

> "The thing I always come back to is that there is no silver bullet. In practice [...] it's going to be a portfolio of things because some things will probably never scale to a global scale. [...] I think, practically, it's going to be more of a local to regional operation if it can get to that scale, and not a global solution, for all sorts of reasons."

In this vein, R055 spoke about how "obviously, BECCS needs massive upscaling of the bioeconomy, and it could revolutionize the biofuel, biomass, and biogas markets, along with transport networks and supply chains connected to them."

2.

Direct air capture with carbon storage (DACCS)

DACCS refers to the capture of CO_2 from the air via engineering or mechanical systems, and then using solvents or other techniques to extract it before storing it underground. However, DACCS technology faces important risks. The first of these risks is cost, which also affects environmental sustainability. Potential cost estimates for direct air capture are contested in the literature, ranging from $30 per ton CO_2 captured to $600 at the high end, with most estimates falling in the multiple hundreds (Godin et al., 2021; Gür, 2022). It should be noted that this is in addition to sequestration and transportation costs. Under optimistic assumptions, if direct air capture follows the cost-reduction trajectories of comparable technologies such as solar power, there would be significant economies of scale as well as the development of follow-up innovations, which could bring prices down and make direct air capture economically viable. In arguing for the merits of such a comparison, Lackner and Azarabadi (2021) contend that direct air capture, like solar power, is likely to be scaled up through the increasing production of small-scale modules and efficiency improvements instead of increasing size, as is the case with larger power plants. However, for such a "buy-down" to happen, a significant financial entry barrier beyond initial profitability would still need to be overcome. It is unclear where the money to sequester gigatons of CO_2 could come from under the current global economic structure, specifically the incentives available for carbon removal. Scaling up carbon storage, especially in saline aquifers or at other underground geological sites, will also face extreme limits; they need to grow at no less than 10% per year every year from 2020, and yet the National Academies of Sciences, Engineering, and Medicine (2019) warned that "scale-up could be limited by materials shortages, regulatory barriers, infrastructure development (i.e., CO_2 pipelines and renewable electricity), the availability of trained workers, and many other barriers."

The second major risk is the energy requirements of the technology (Madhu et al., 2021), which could give rise to severe environmental risks. Sequestering gigatons of CO_2 using direct air capture will require enormous amounts of electricity, some of which may have to come from fossil fuels. High energy needs and/or the need to compete for currently scarce amounts of renewable energy have the potential to reduce the carbon-capture efficiency of direct air capture projects, put pressure on efforts to decarbonize the electricity supply, and also put constraints on the location of direct air capture plants. The list of places in the world that are in close proximity to both good sources of renewable energy and to suitable injection sites is much smaller than the list of places in the world that have access to carbon sequestration sites alone. Fuss et al. (2018) identify four core challenges: capital investment costs, energy costs for capture, energy costs for regeneration, and costs related to sorbent (i.e., the materials used to absorb CO_2) loss and expensive maintenance.

A third environmental risk is the permanence and security of the long-term storage and sequestration of CO_2. Indeed, as concluded by one of our other studies, "issues of long-term storage intersect with other aspects of risk, including permanence, leakage, liability, and the pursuit of a more circular economy" (Sovacool, Baum, Low, et al., 2022). For example, if the cap rock that seals the top of reservoirs fails, the gas could leak — possibly at a rate that would be dangerous to anyone or anything on the surface — and aquifers may transport brines and CO_2 to the surface, necessitating monitoring and thorough hydrogeological assessments. R003 expanded on this topic as follows:

> "The entire system of direct air capture or storage of carbon presents geological risks. You're essentially trying to mine air, a very low-grade, low-value product: not gold, but CO_2. And once you've got it, you've got to compress it, you've got to pump it maybe hundreds or thousands of kilometers, and you've got to compress it down into rock strata which doesn't want to accept anything more, so you've got to use huge amounts of energy. Once it's down there, you're never quite sure whether a fault is going to happen and it's going to vent again and you're going to kill lots of people around about where it's venting because CO_2, you know, if you remember those lakes in Africa [the Lake Nyos disaster in Cameroon] which vented their CO_2 and they wiped out five villages worth of livestock and people."

There are also risks of seismic effects, not to mention questions around how this might affect the social acceptance of these projects. R027 explained that:

> "Lack of social license is a real risk for many techniques [...] we might not even know that these knock-on consequences are happening because the systems are so complex and so interconnected. We still don't fully understand how they work."

Nevertheless, DACCS does have benefits for environmental sustainability. DACCS technologies could, in principle, be installed almost anywhere, would require relatively little land (less than 0.001 ha per ton carbon per year, compared to 0.1-1.7 ha for BECCS plants, depending on the fuel stock; Sovacool, Baum, Low, et al., 2022) and, according to its advocates, would have only relatively small environmental side-effects, all while producing a verifiable, high-purity stream of carbon dioxide that can be permanently sequestered using existing carbon-storage technology. Fuss et al. (2018) add that DACCS could even be deployed proximate to storage facilities, and it could be co-located with attractive sites for renewable energy, thus minimizing transport and grid costs. The National Academies of Sciences, Engineering, and Medicine (2019, p. 8) identified DACCS as one of the few realistic technical options that "could be scaled up to remove very large amounts of carbon". Fasihi and colleagues (2019) project that if DACCS systems are commercialized in the 2020s, they could see “massive implementation” by the 2040s and 2050s, when they could be of a magnitude equal to existing sources of climate change mitigation, such as wind energy or solar energy.

A second benefit is potentially positive couplings with renewable energy, in particular between direct air capture and solar energy. R005 framed this by noting that “because solar power is very cheap, especially in deserts, it makes good sense to run DACCS on it.” R010 identified “a positive potential synergy between DAC and solar energy, given DAC could create demand for solar even more.” R051 also concurred that “solar […] is the cheapest form of energy that can be used to power future DAC facilities, and solar thermal in particular could provide water at 100°C and offers a very low-carbon, economic solution.”

3.

Enhanced weathering

Enhanced weathering, also referred to as enhanced rock weathering, employs alkaline materials (such as basalt or lime) which naturally interact with carbon in order to drawdown and provide long-term sequestration of CO_2 (in the form of solid carbonate minerals). Given that such processes when left to occur naturally (e.g., under exposure to natural processes like rain, wind, or the action of waves) work very slowly, on the scale of centuries to millennia, enhanced weathering aims to speed things up. Notably, by deploying physical, chemical, or even biological mechanisms to grind the rocks, the surface area that is exposed and which can react with CO_2 is increased — along with, potentially, the carbon-sequestration potential of the rocks. Enhanced weathering has gained prominence in light of recent estimates that it might be able to store CO_2, at a relatively low cost, on the magnitude of 2.9 to 8.5 billion tonnes per year by 2100 (Beerling et al., 2020; Hartmann et al., 2013; Strefler et al., 2018).

Regarding environmental sustainability, there are a few reasons for concern. First of all, there is the sheer quantity of rocks which would probably be required, especially if we aim to remove multiple billions of tons per year. Instead of simply making sufficient use of available resources or the by-products of the mining sector, it is highly probable that existing mining would need to be intensified and/or new mining sources would need to be excavated. Beyond the impact of the requisite mining on landscapes and local communities (let alone the questions of where such mines would be sited), notably on water and land resources as well as biodiversity, there is also the attendant demand for energy, e.g., for the crushing of rocks. A recent synthetic review of the literature (Sovacool, 2021; based on McLaren, 2012) has established that in order for enhanced weathering and BECCS to achieve significant carbon reductions, as much as 12% of total global energy consumption could be required. As stressed by one of the experts in our interview exercise, enhanced weathering would thus “have a very high energy demand” and, as such, calling it a “low-carbon” option was “disingenuous.” Around 10% of experts surveyed were concerned as a result about the extent to which this technology would be “material intensive” and with supply chains quite extended over large areas (Sovacool, Baum, & Low, 2022a).

Elsewhere, Cox et al. (2020) conclude that the level of effort envisioned could be “equivalent to the size of the current oil and gas industry” once all the impacts in terms of mining, extraction, processing and transport are considered. Among the experts we surveyed, one (R002) similarly stated enhanced weathering “will likely rival mining operations”, while another (R041) less optimistically predicted “a doubling of global mining activities”. The extent to which enhanced weathering can source its rock resources without dramatically expanding the need for mines thus emerges, in Cox et al. (2020) and elsewhere, as one “red line”. After all, if one of the aims of carbon removal is to foster a transition away from our reliance on oil and gas, not to mention the heavy impacts of the mining sector on biodiversity, then these linkages would seem to undercut any improvements here.

When done in marine environments, as is the case for ocean alkalinity enhancement, there are additional issues with how this might (adversely) impact oceans, life below water and/or water security. Although less of a concern than for BECCS and its high water demands, this trade-off between carbon-sequestration potential, water availability and water quality emerges as central (Sovacool, Baum, & Low, 2022b). Specifically, the risk may be that by adding additional nutrients to lands or coastal regions (or generally increasing acidity levels), this might unintentionally influence the balance of species within ecosystems, for instance, by stimulating and favoring the growth of certain organisms rather than others. In our large-scale expert-interview exercise

(Sovacool, Baum, & Low, 2022a), such risks were highlighted by more than one of every six experts questioned – making it one of the most frequently mentioned, non-general risks for a CDR technology. As an example, R036 reflected on the public's response if a "nice beach vacation" were spoiled by the leakage of "alkaline waters" or, in the words of R026, if the effects of enhanced weathering were perceived to infringe on this "last pristine environment".

Similarly, through surveys and focus groups centering on enhanced weathering, a group of co-authors have established over a few studies (Cox et al., 2020; Pidgeon & Spence, 2017; Spence et al., 2021) how perceived risks increase substantially, and public acceptability drops, as soon as the question of ocean impacts is mooted. Cox et al. (2020) specifically identified this as a "red line" for the public, in view of the emotional resonance of oceans for so many individuals as well as the ocean's status as a "fragile, interconnected ecosystem". The experts (e.g., R072, R080, R087) in our extensive expert-interview exercise were cognizant and critical of the specific risks of ocean-based approaches, notably, how this may lead to "the dissolution of other materials, potentially other bioactive materials from the rock" (R072) or "biomagnification through the food web where you have increasing concentrations of a toxin, or a metal, or what have you".

More positively, the prospective co-benefits for the environment and agriculture have also received attention. In this respect, enhanced weathering is increasingly viewed as a potential package (along with soil carbon sequestration and biochar) that can be jointly deployed to improve food yields, enrich soils and increase carbon stocks, foster biodiversity, and increase the health of ecosystems. This constellation of enhanced weathering, biochar and soil carbon storage already features in several early-stage climate-intervention trials (Low et al., 2022). Going one step further, many of the experts even envisioned a "triple win" (R125) if such practices were used to substitute for the use of costly industrial fertilizers, a strategy which would make use of the capacity for enhanced weathering to slowly release minerals over time, when they are then available for soils and their constituent micro-organisms (see also Cox & Edwards, 2019). Notably, enhanced weathering could serve as a kind of "slow-release fertilizer" (R015) in suitable climates and regions, such as the humid tropics, which have "poor soils because of the high rainfall and temperature [... and] are totally depleted." Given that it is farmers in such regions that struggle most to purchase expensive fossil-based fertilizers, enhanced weathering could thus provide assistance to those most in need.

Having looked at the attendant environmental risks and benefits of enhanced weathering, it is helpful to set this in relation to climate change. While the potential for materials to dissolve into water sources is a reason for concern for how it might impact ecosystem functioning, this has also been pointed to as a key benefit of enhanced weathering, namely, to help to tackle ocean acidification. Indeed, the experts interviewed were unanimous about how ocean alkalinity enhancement and enhanced weathering could help return oceans closer to their pre-industrial state. The fact that other methods, such as solar radiation management, cannot deal with ocean acidification renders enhanced weathering particularly important. A couple of experts even went so far as to adjudge this approach as synonymous with ecosystem restoration, though one (R060) still highlighted how much remains uncertain, particularly the extent to which the alkalinity level can actually be increased in this manner.

In any case, alongside its substantial potential to sequester carbon, there is much to speak for enhanced weathering as a way to address climate change. The above discussion makes clear, though, that the how, where and how much of enhanced weathering is crucial. First and foremost, if enhanced weathering can only be done at scale through a massive expansion in mining activities and/or through heavy reliance on non-renewable energy, the resulting environmental risks are likely to substantially offset (at a minimum) any gains that are achieved. On this point, several experts did however observe that, by using a combination of the various methods (e.g., enhanced weathering with soil carbon sequestration and biochar), the inevitability of the trade-offs might be mitigated somewhat. Otherwise, as reflected by questions over whether the co-benefits for local farmers and fisheries would exceed the potential damages to local ecosystems and the ecological balance of oceans, there is a definite need for more research here.

4.

Biochar

Biochar is a form of carbon removal which works by managing the thermal degradation (i.e., heating it) of organic material, such as tree branches or cornstalks, inside a container with no oxygen. The resulting black material is very similar to charcoal, thus the name. If we grind it up and add it to the soil, it is possible to remove CO_2 from the air and store it in soils for decades or longer, thereby increasing soil carbon stocks and improving soil fertility. Like its counterpart, enhanced weathering, biochar has received attention as a possible amendment to soils that could substitute for fertilizers and/or improve agricultural productivity. Pointing to the stability of biochar, i.e., as it tends not to interact with other forms of soil carbon — or, for that matter, processes of enhanced weathering — one expert (R019) described it as "safe, scalable shovel-ready, it's durable [and] it can keep forests healthy and reduce bio risks".

Having touched upon the prospective environmental benefits of biochar for carbon sequestration in terrestrial ecosystems (i.e., in concert with enhanced weathering), we focus instead on some of the other applications of biochar, e.g., as an input for concrete, steel, cement, animal feed and compost (Honegger et al., 2021; Sovacool, Baum, & Low, 2022a). Drawing on our expert-interview exercise, one out of every eight experts noted the relevance of biochar for net-zero and sustainable forms of concrete and cement production and, more broadly, for decarbonizing industrial processes (e.g., nuclear-reactor designs, buildings, or "green coal") and thus for the emergence of the bioeconomy. Another application receiving increasing attention is the potential of biochar to facilitate remediation. Whether in storm drainage systems, water-treatment plants, or even potentially for hospital waste, many of our experts also highlighted the role that biochar could play in addressing the issue of landfilling.

Turning to the environmental risks, a primary risk– and common to those carbon-removal methods that rely on biomass – is that of adverse impacts on terrestrial ecosystems and land management. In particular, there is the potential for trade-offs and competition for scarce biomass resources. Indeed, for biochar to play a scaled-up role in addressing climate change, lots of organic material would be required. Depending on how this is sourced, there is the risk that this could undermine food security or increase pressures on land use (e.g., to cultivate on more marginal lands or watersheds), that is, by literally burning potential food. As a result, it is crucial that circular principles such as cascade usage be adhered to, whereby high-value uses (such as food) are prioritized before those such as biochar, where the biomass would be burned and potentially locked away in soils. Here, one of our experts (R039) made explicit reference to how little attention is paid at the moment to the ultimate consequences of biochar for soils, land and oceans: "We have voluntary carbon market actors paying producers of biochar just for the production of biochar and for selling it, with entire disregard for whatever happens with it afterwards."

Similar to enhanced weathering, but again worth emphasizing, there are potential handling and disposal risks, such as the fact that biochar could potentially catch fire. Though discussed more in relation to industrial processes, these risks are worth monitoring in order to avoid leakage and impermanence of biochar when applied to agricultural purposes. Also, as one of our experts (R026) stressed, there are always the risks of chemical contamination, specifically, "if you take the wrong rocks or wrong materials [...] spread them on agricultural land, can contaminate food, pollute local rivers; they are also linked to ocean pollution." Lastly, the fact that biochar is fundamentally dependent on heating organic materials indicates that energy use, mainly how such energy is sourced, is a crux issue. If, for instance, renewable energy is available in sufficient amounts such that biochar is not a drain on scarce energy resources or produces a rebound effect – i.e., where, like direct air capture, the attempt to remove carbon becomes coupled with continued reliance on oil and gas – then the energy requirements of biochar become less problematic. At present, however, limited availability of renewable energy represents a notable constraint for biochar employing energy sustainably.

Again, as is the case for all the carbon-removal methods here considered, the main takeaway is that the balance of risks and benefits depends on how and where they are applied. Among other things, in the case of biochar, this entails ensuring that the organic materials are of a sufficiently high quality that they do not have contaminants or harmful ingredients. On the flip side, this could mean that there is a constraint on what can be used for biochar, and thus the scale that can be attained. As is generally true for many of the carbon-removal methods, there is a trade-off between how much carbon can be captured and sequestered and the kinds of impacts that can be expected, i.e., on land use and ocean ecosystems. The fact that biochar also lends itself to a number of other uses, such as water remediation and the decarbonization of industrial processes, simultaneously provides alternate avenues through which it might help address climate change. Accordingly, even if one avenue is closed down on account of being too environmentally risky or too demanding of scarce energy or biomass resources, there are potentially others that can still be pursued.

5.

What could be done to address the risks to environmental sustainability?

The question of “how to ensure” that emerging CDR technologies, if deployed on a large scale, would not lead to adverse consequences for environmental sustainability is a vexing one. Indeed, there are various reasons for concern at present, whether because existing instruments (such as LCAs) are insufficient to assess and encapsulate the full range of risks that exist, or because there are concerns about other potential risks to environmental sustainability, which have so far been ignored or neglected (Terlouw et al., 2021). This has two implications for research and policy.

First, we call for more sophisticated modeling, policy analysis, and even research designs that are capable of understanding and capturing the risk-risk trade-offs of carbon removal. This holds particularly true for some of the social and political risks, which are more prosaic and difficult to quantify or measure. And yet, the degree to which the views and perceptions of the public as well as insights from political science have been integrated into models remains minimal (Peng et al., 2021; Shen, 2021). This finding becomes even more pertinent when such risks have varying temporal timeframes, work on separate spatial scales, involve different actors, and have distinct effects on incumbency and democracy. As such, we confirm the findings arising from Ürge-Vorsatz et al. (2014) and Bhardwaj et al. (2019), notably, that the analysis of co-benefits, whether for energy or climate policy, demands a multiple-objective and multiple-impact framework.

Secondly, the complementarity and interoperability of some CDR options imply that risks may accumulate when multiple innovations are linked together in ways that improve their functionality, attain economies of scale, or when they are co-deployed by the same firm, programme, or actor. The implication is that future deployment is likely to require complementary innovations across an array of technologies, thereby further complicating the task of risk management. Examples here include:

- The reliance of BECCS and DACCS on intricate carbon capture and storage systems that must sequester carbon safely for thousands of years;
- The potential coupling of enhanced weathering and biochar as part of an emerging land-based bioeconomy;
- The dependence on intellectual property regimes or the use of inputs (fertilizers, materials) that could lend themselves to monopoly market structures or pose different environmental risks themselves.

Such complementarities between CDR options suggest the need to move beyond analyzing individual technologies towards entire systems. Yet, this would only be possible with highly sophisticated research designs that also utilize whole systems or sociotechnical approaches.

6.

Conclusion

The four forms of carbon removal identified here — BECCS, DACCS, enhanced weathering and biochar — could become instrumental parts of the transition to a net-zero, more carbon-resilient society. Our results indicate, however, that deployment of such options would involve a diffuse collection of risks as well as benefits (which could themselves represent risks for the climate if the technology is not deployed). As table 1 below summarizes, no single technology is risk-free. BECCS could lead to negative impacts on land and food while also catalyzing more resilient local bio-economies. DACCS may have high resource and energy requirements which could be (partly) offset if coupled with renewable energy. Scaling-up of enhanced weathering would likely depend on large mining operations and their environmental impacts but could help address the pressing problem of ocean acidification. Biochar poses handling and disposal risks but could also contribute towards more carbon-rich soils and more sustainable forms of building materials.

Table 1 | Summarizing the potential environmental risks and benefits of four emergent carbon removal technologies

	Estimates for carbon removal and sequestration	Risks of deployment	Benefits of deployment
BECCS	0.5 – 11 $GtCO_2$/year	Negative impacts on land use, competition with food security, pollution from reliance on fertilizers	Diversification and an integral part of a portfolio approach to net-zero, positive transformation of local bioeconomy
DACCS	5 – 40 $GtCO_2$/year	High cost, need for energy inputs, risks around sequestration and storage	Modularity, ability to be scaled up quickly, positive couplings to renewable energy
Enhanced weathering	2 – 4 $GtCO_2$/year	Need for mining and large quantities of rock, negative impacts on oceans and marine life, concerns over public acceptability	Co-benefits to agriculture including enhanced crop yields, reduction of ocean acidification
Biochar	0.3 – 6.6 $GtCO_2$/year	Handling and disposal risks including fires, intensity of land use	Potential to contribute to green buildings or more sustainable soils

Source: Authors, with estimates for carbon removal and sequestration from Table TS:7 from the IPCC AR6 WG3 technical summary report (IPCC AR6 WG III, 2022). Note: BECCS = bioenergy with carbon capture and storage, DACCS = direct air capture with carbon storage. Gt = Gigaton

We highlight the particular importance of considering the following three aspects:

1. There could be significant impacts on long-term environmental sustainability if and when large-scale climate interventions, including some CDR techniques, affect biological and Earth systems.
2. It would be useful to develop guidelines, criteria, and instruments to evaluate the outcomes for environmental sustainability of emerging CDR technologies, especially for those with high sequestration potential.
3. Equally needed are methods to evaluate and arbitrate between trade-offs and thereby facilitate decision-making about these trade-offs, in a manner compatible with legitimate democratic processes and acceptable to business and society.

Consequently, analysts and policymakers should recognize the difficulty in predicting risks and embracing the intersectionality and coupled nature of risks and benefits. No benefits come without risks, and vice versa, especially for novel climate-intervention technologies. From this perspective, the value of comprehensively entertaining and wrestling with the prospective risks of CDR is entangled with not only the potential of identifying which options can be co-deployed, or deployed in particular contexts, but also to vouchsafe, as much as possible, the very sustainability of the technologies themselves.

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Paper 8

Is cultured meet environmentally sustainable?

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Introduction

To satisfy the increasing demand for food from a growing human population, expected to exceed 9 billion by 2050 (Chriki & Hocquette, 2020), cultured meat (also called in vitro, artificial or lab-grown meat) is presented as a promising alternative to conventional meat for consumers who seek to be more responsible towards the environment without changing their diet (Chriki & Hocquette, 2020; Merck Group, n.d.; Robbins, 2020; Skye, 2021; The Guardian, 2011). To produce cultured meat, muscle tissue is grown in a laboratory setting. First, muscle stem cells (called “myosatellite” cells) are extracted from an animal and grown in a highly-processed raw calorie source (medium). Then, the tissue is fed, multiplied, shaped and structured in bioreactors to become what consumers can consider similar to a meat product and would typically be used for burgers or nuggets (Robbins, 2020). While cultured meat requires a small tissue sample, the cells can be taken from a living animal, so the process does not require killing animals (Pathak, 2021).

The questions that this paper addresses are: Assuming that all uncertainties and challenges regarding human health and safety (a priority), economics, regulations and other matters are resolved, are there possible adverse impacts on the environmental sustainability that have to be considered at the design phase? What is the outcome of a full life cycle assessment (LCA) of cultured meat compared to conventional animal meat? Is there a risk that environmental impacts, currently perceived as negligible, could eventually lead to adverse consequences on the environment if production reaches a large scale? Chriki and Hocquette (2020) produced a review of various issues related to cultured meat, upon which this paper is largely based.

1.

Expected impact on the environment

Regarding environmental issues, the main anticipated advantage of cultured meat is lower greenhouse gas emissions (GHG) because much less conventional farming for livestock, ruminants in particular, will be needed. However, this is a matter of controversy (Chriki & Hocquette, 2020; Robbins, 2020) because cultured meat can have an impact on the environment and the climate through its energy consumption; primarily electricity use during production itself, but also electricity and heat use in upstream production of the medium (Skye, 2021; Tuomisto & de Mattos, 2011).

Researchers began as early as 2010 to conduct LCAs of cultured meat (see Tuomisto & de Mattos, 2010). In a study conducted in 2011 by the University of Oxford (see Tuomisto & de Mattos, 2011), an LCA approach was adopted for assessing the environmental impacts of large-scale cultured meat production. In this research, nutrients and energy to grow muscle cells were provided by cyanobacteria hydrolysate. The results showed that “in comparison to conventionally produced European meat, cultured meat involves approximately 7–45% lower energy use (only poultry has lower energy use), 78–96% lower GHG emissions, 99% lower land use, and 82–96% lower water use depending on the product compared” (Tuomisto & de Mattos, 2011). The researchers conclude that despite high uncertainty, the environmental impacts of cultured meat production may be significantly lower than those of conventional meat production.

A complete comparison between cultured and conventional meat production will require considering other factors. Additionally, a comparison with other meat substitutes, especially plant-based alternatives, will also need to exhibit net benefits (Chriki & Hocquette, 2020).

2.

Prospective LCAs of cultured meat

Acknowledging the multitude of LCAs for cultured meat, but the limited number of environmental impact studies on actual cultured meat production, the Global Food Institute and Nova Institute published in 2019 a review and gap analysis of three LCA studies of cultured meat (see Scharf et al., 2019). According to the study, “all analysed studies [LCA] are based on hypothetical production processes and simulation models as, currently, no largescale production facility of clean meat exists. Hence, all studies heavily rely on assumptions, literature and calculations based on mathematical formulas”. The report provides a number of recommendations for future LCAs. Regarding the goal and scope of a relevant LCA, the authors recommend that “the LCA approach shall be selected depending on the goal and scope of the study. One can distinguish two approaches: attributional and consequential. An attributional approach is recommended to evaluate and/or compare processes or products. Moreover, this approach allows to identify the most impacting process parameters and the technical optimisation potential. In contrast, an evaluation of the (societal) consequences of the technology can be better performed in a consequential approach. The typical target audience here is policymakers. In order to provide feedback for the industry, an attributional approach is the most suitable. Moreover, a so-called prospective LCA might be suitable. This includes scale-up data as well as potential changes of the circumstances". The authors also emphasize that prospective LCAs are suitable and necessary to address questions like "what will happen?", "what can happen?" or "how can a specific target be reached?". They recommend that "a hypothetical scale-up and optionally an outlook into a future technosphere can be included (e.g., changes in the energy mix and transportation, feedstock provisions). This is especially relevant in comparative studies as a comparison on lab-scale may cause premature and potentially wrong conclusions".

A study from CE Delft published in February 2021 (see Odegard, 2021) used primary data from multiple cultured meat companies and associated companies in the supply chain, and compared several future production systems expected to be in place by 2030. The study concluded that cultured meat could offer environmental gains compared to conventional meats (beef, pork, chicken) and that it uses much less land than conventional meats. Moreover, it also has a much lower carbon footprint than beef and is comparable to the global average footprints for pork and chicken when produced using conventional energy, provided at least 30% of the energy used is produced sustainably. When using sustainable energy, cultured meat has a lower carbon footprint than ambitious production benchmarks for all conventional meats.

3.

Food safety and potential risks for human health

Health and safety aspects may need to be considered even before environmental aspects. Cultured meat is a new product, and there is incomplete knowledge regarding its impact on human health. Chriki & Hocquette (2020) showed at least four aspects to consider when evaluating potential health safety hazards:

First, advocates of cultured meat claim that it is safer than conventional meat, based on the fact that it is produced in a fully controlled environment. In contrast, conventional meat is produced from living animals and health and safety conditions may not be optimum. Cultured muscle cells are not confronted with various pathogens such as intestinal pathogens like E. coli, Salmonella or Campylobacter, three pathogens that cause millions of episodes of illness each year. Perfect health and safety control are not always possible. Contamination occasionally happens at slaughter, and incidents may occur during industrial production of chopped meat.

Second, cultured meat may be considered safer because it is not produced from animals raised in a confined space. There is no risk of an epidemic outbreak and no need for costly vaccinations against diseases like influenza. However, it is possible to argue that incidents may also occur with cells that live in high numbers in cultured meat incubators. There are uncertainties regarding the consequences of cultured meat on public health, as in vitro meat is still a new product. It may not be possible to control the cell culture process perfectly and some unexpected biological mechanisms may occur. For instance, given the significant number of cell multiplications, cell line dysregulation is likely to occur (as takes place in cancer cells). When in vitro meat is consumed, this may have unknown potential effects on the muscle structure and possibly on human metabolism and health.

Third, the abuse of antibiotics as a growth promoter in some countries and antimicrobial resistance are two significant problems in the case of livestock, which are absent in the case of cultured meat. The controlled environment and close monitoring can help stop any signs of infection. However, one cannot rule out that antibiotics would be added to prevent or stop early contamination.

Finally, it has been suggested that the nutritional content of cultured meat could be controlled in the production medium, which could be a highly desirable goal to improve nutrition standards. For example, the ratio between saturated fatty acids and polyunsaturated fatty acids can be easily controlled, and saturated fats can be replaced by other types of fats, such as omega-3 (although there is a risk of higher rancidity). However, new methods are being developed in conventional livestock farming as well to increase the content of omega-3 fatty acids in meat.

4.

Animal welfare and economic aspects

In addition to evaluating environmental and human health aspects, cultured meat can also be evaluated for its impact on animal welfare, which is a matter of concern in some parts of modern society. Although the process of producing cultured meat needs animal muscle samples, the number of slaughtered animals can be reduced dramatically.

Furthermore, economic aspects must be considered in evaluating cultured meat with respect to sustainability. If conventional meat from livestock is progressively replaced with cultured meat, several services provided by livestock farming systems will be reduced or even disappear: besides supplying proteins for human nutrition, livestock provides essential income for rural populations, from meat, milk, eggs, wool, fibre, leather, and socio-cultural services such as when transhumance is attracting tourism, or when local products with a sense of terroir are protected with various labels (Chriki & Hocquette, 2020).

5.

Regulation and norms

Another issue is uncertainty regarding regulatory frameworks. Cultured meat stands at the frontier between meat and non-meat (see Schneider for the US [2013] and Petetin for the EU [2014]). For example, regarding labelling, in April 2018, France banned the use of the terms “meat” and “dairy” in the communication about vegetarian and vegan products (as in “vegetarian-meat”). It has not been decided yet whether the term “meat” for cultured meat is authorised. In the US, several organisations are fighting over what cultured meat should be called, who tests for safety, and which governing body can regulate it (Chriki & Hocquette, 2020).

Finally, the nebulous status of cultured meat must be mentioned from a religious point of view. There is still some debate about whether cultured meat is Kosher or Halal (compliant with Jewish or Islamic dietary laws) (Chriki & Hocquette, 2020).

6.

Costs

In their seminal study, Chriki & Hocquette (2020) remind that the first in vitro hamburger was produced in 2013 by Professor Mark Post, Maastricht University, for more than $300,000. This high cost was due to the fact that products and compounds traditionally used in medical science were used, and it was anticipated that the price would go down if production were to be scaled up. The cost of the cell culture medium used to produce cultured meat is currently quite high and, furthermore, may not be ecologically sustainable. However, researchers consider that raw materials from large-scale agricultural production could serve as inputs for cultivated meat. This would mean it might be possible to turn a waste product into food. This could be a positive contribution to circular economies, assuming this does not imply diverting agriculture waste from other uses, or that there would be a net benefit at the level of the system.

At the end of 2020, Mosa Meat[2], a Dutch company created by Post, announced the development of a serum-free medium. No cultured meat has yet been sold to consumers, and more applied research and experimentation are needed before an acceptable price level is reached. The Dutch government announced in April 2022 that it would invest 60 million euros in “cellular agriculture”[3] (Biotech Campus Delft, 2022).

In February 2021, Future Meats[4], a US company, announced that its technology had advanced to the point where it could produce a cultured chicken breast for US$7.50, and in June 2021, they opened the world's first lab-grown meat factory in Israel, where it produces cultured chicken for $3.90 per pound (Lavars, 2021). In comparison, the US average price between May 2021 and May 2022 for a pound of chicken was around $3.80, according to the US Bureau of Labor Statistics (n.d.). If the price difference for actual products becomes small, then serious considerations must be given to the other aspects previously mentioned in this paper.

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[2] See mosameat.com/.

[3] See en.cellulaireagricultuur.nl/.

[4] See future-meat.com/.

7.

Consumer acceptance

Many factors will strongly influence consumer acceptance. Some authors have demonstrated that consumers tend to strongly reject the name “in vitro” or “lab-grown” meat. This is confirmed in a study conducted by Siegrist et al. (2018), which concluded that participants have a low level of acceptance of cultured meat because it is perceived as unnatural, in contrast to so-called “vegetarian meat”, which consumers generally know is produced with plants. A recent survey indicates that potential consumers of cultured meat could be young, highly educated meat consumers who are concerned about the negative impacts of conventional meat on the climate and are somehow familiar with cultured meat (Bryant et al., 2019). However, it is unclear if consumers may associate cultured meat with vegetarian food in their search for alternative sources of proteins. In addition, more work is still needed to optimise the technical aspects of cultured meat production. Currently, it is also impossible to reproduce the diversity of meats derived from various species, breeds and cuts, which impacts consumer acceptance (Chriki & Hocquette, 2020). So in many ways, the jury is still out.

Regarding the specific question of what potential impact emerging technologies for cultured meat could have on environmental sustainability, researchers, technology developers and investors would be advised to consider prospective LCAs, which will become easier to carry out as actual products become available on the market.

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Paper 9

Practical solutions for *ex-ante* LCA illustrated by emerging PV technologies

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Introduction

In this paper, we discuss practical challenges in *ex-ante* life cycle assessment (LCA) of emerging technologies, i.e., barriers to hands-on implementation, as opposed to the conceptual challenges that recent contributions to the literature have been focusing on (see Giesen et al., 2020; Thonemann et al., 2020; Villares et al., 2017). We will illustrate the discussion with the case of emerging photovoltaics (PV), namely multijunction III-V/silicon tandem cell (III-V/Si). This case application helps structure the *ex-ante* LCA exercise and highlights the challenges of applying LCA early on in technology development, while providing sufficient general elements that apply to other emerging technologies.[2]

Written from the perspective of LCA analysts, the paper is organized around the LCA method. LCAs can be conducted at various stages of a technology development process, requiring different types of information at the various stages. By illustrating with the case study of emerging photovoltaics, the paper explores the importance of product performance optimization during technological development, and how it is directly linked to environmental performance during the use phase. It also demonstrates how the design and manufacturing choices that technology developers are confronted with can greatly influence environmental performance over the future product's life cycle. The approach that emerges is one in which the LCA method remains flexible throughout the technology development process to accommodate its dynamic nature and the numerous uncertainties inherent in it.

1.

Why we need *ex-ante* LCA

LCA is the method of choice to assess product and service systems that span the global economy and trigger environmental trade-offs across multiple impact pathways. For several decades now, LCA has been used to quantify the environmental impacts of products or services across their full life cycle, from the extraction of raw materials up to the end-of-life (EOL), and across a wide range of impact categories, from climate change to toxicity and acidification (Hellweg & Canals, 2014). A series of ISO standards (ISO, 2006b, 2006a) formalised the use and application of LCA. These LCA studies have mostly been *ex-post* assessments of well-defined systems, namely systems for which sufficient data and knowledge were available, given that the systems have already been operating at an industrial scale. *Ex-post* LCA studies can guide decision-makers and consumers on the environmental hotspots in the life cycle of a product system and can be used to compare environmental benefits and trade-offs vis-à-vis an incumbent product system performing a similar function. While useful for decision-makers, *ex-post* LCA studies can have limited use when they call for changes that are likely to be costly or unfeasible (Cucurachi et al., 2018).

Assessing a system that is still being designed or that is still in development has the advantage that changes are still possible. A designer of a novel or emerging technology, for instance, would have the choice to use the results of an LCA study to avoid designs that require manufacturing processes or features that lead to an increase in environmental sustainability impacts from a sustainability perspective. Furthermore, *ex-ante* LCA accounts for the process optimizations required to mass-produce and deploy an emerging technology at an industrial scale (Bergerson et al., 2020; Giesen et al., 2020). Additional advantages of performing an *ex-ante* LCA are the close collaboration with technology developers and other stakeholders, the ability to put claims of environmental sustainability to early scrutiny, to support early design improvements and sound investments with information about potential large-scale environmental impacts at hand, to avoid technological lock-ins, to identify early hotspots or comparative advantages/disadvantages, and to warn decision-makers about critical material and process choices. *Ex-ante* LCA has been gaining traction, and scholars and practitioners have been working in the past few years to develop new methods that are suited to assess emerging systems and technologies (we refer the reader to Bergerson et al. (2020) and Giesen et al. (2020) for the classification of alternative modes of LCA to assess systems prospectively).

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[2] See the paper written for the ESET project by Christian Moretti, "Ensuring the environmental sustainability of emerging technologies applications using bio-based residues" (2022).

2.

Background: *Ex-ante* challenges

Ex-ante LCA studies fall into the methodological quandary known as the Collingridge dilemma (Buckley et al., 2017), which postulates that impacts cannot be easily predicted until the technology is extensively developed and widely used, while control or change is difficult when the technology has become entrenched.

Several scholars have highlighted the different nature and challenges of conducting an *ex-ante* LCA compared to the standard practice of LCA, as defined by the ISO 14040 standards (see Guinée, 2001 for an operational guide to the ISO standards). Technology-specific guidelines are also available. For example, readers can consult Langhorst et al. (2022) for guidelines on the LCA of CO_2 utilization technologies and the report published by the European Commission's Knowledge Centre for Bioeconomy (2022) for the application of *ex-ante* LCA to bio-based systems. In the next sections, we will assess some of the challenges in turn. Here, we provide a short review of the challenges and the phases of LCA in the order of which they need to be tackled.

Several aspects of the goal and scope phase, the initial phase of any LCA study, become critically important to define for emerging technologies due to the need to understand the product's ultimate *functional performance*, i.e., how much service it can deliver or needs it can satisfy per unit of product and under what conditions. By calculating impacts on the basis of a specific *functional unit*, the analyst is able to capture trade-offs between the *functional performance* of the system and the related environmental impacts. Giesen and co-authors (2020) stress the difficulties in defining a functional unit for technologies that are yet to be implemented on the market, as well as in finding a relevant incumbent technology performing a similar function for benchmarking (see also Arvidsson et al., 2017; Hetherington et al., 2014; Wender & Seager, 2011). This challenge of comparing an emerging vs. an incumbent technology is highlighted by several review studies (Arvidsson et al., 2017; Hetherington et al., 2014; Moni et al., 2020; Thonemann et al., 2020). A screening of alternatives should be conducted (Langhorst et al., 2022), and Moni and co-authors (2020) suggest defining and assessing multiple functional units and their alternatives, if needed, so that the full spectrum of potential alternatives can be covered. The identification of the functional unit(s) for the system under assessment is also strictly connected to the expectation of the developer of an emerging technology regarding the functional performance of the system both in the lab and at an industrial scale. An important decision that the analyst needs to make during the goal and scope phase of LCA relates to the identification of the system boundaries of the *ex-ante* study. System boundaries set the criteria and specify which unit processes are part of the product system (Thonemann et al., 2020). When assessing alternative systems performing a similar function, but which are at different technology readiness levels (TRLs), the system boundaries should be as broad as possible and must be harmonized between alternatives. A clear point of attention regards the EOL of emerging technologies, and whether the EOL should be included in the assessment given the uncertainty of which EOL will become available in the future.

During the life cycle inventory (LCI) phase, the analyst faces challenges related to data availability and coverage (Giesen et al., 2020; Moni et al., 2020; Thonemann et al., 2020). This mainly concerns data on material and energy inputs and outputs (flows) in all processes that will be part of the product/service's life cycle, and which ultimately trigger the environmental impacts. Data available in standard LCA databases might be obsolete, unavailable, or not representative, thus requiring the analyst to rely on scenarios, proxies, or gap-filling strategies. As for the specific technology under assessment, the analyst may face the challenge of modelling processes that are still at the lab scale, and that are bound to change should the technology penetrate the market and become industrially available. A parametrized system, where inputs/outputs are expressed as a function of variable parameters, may be better suited in conducting an *ex-ante* assessment (Blanco, Cucurachi, Guinée, et al., 2020). Additionally, upscaling techniques may be used to upscale processes from lab to industrial scale (Piccinno et al., 2016).

The life cycle impact assessment (LCIA) is dedicated to the characterization of potential impacts from the system of interconnected processes inventoried at the LCI stage. This is generally done by multiplying the aggregated input/output exchanges of materials and energy with the environment by characterization factors that quantify the impact resulting from each exchange. Standard characterization models used at the LCIA phase may not be fully suited to assess novel materials in emerging technologies, thus leaving unclassified flows and impacts as a result (Giesen et al., 2020). Due to a lack of data, such unclassified flows and results leave the decision-maker with a false sense of confidence about the realistic performance of the emerging technology under assessment (we further refer the reader to Moni et al., 2020).

In the final interpretation phase, the analyst evaluates the results of the study and assesses the implications of modelling choices on the results and the potential impacts of uncertainty and assumptions on the results of the study. In an *ex-ante* LCA study, scenario techniques (Bisinella et al., 2021) and advanced techniques of uncertainty and global sensitivity analysis aid the analyst in stress-testing the assumptions in the system and identifying the relevant inputs in the model that are potential drivers of uncertainty and key to make an informed decision on the system under assessment.

In the remainder of this paper, we discuss the above challenges in more detail and use the case of an emerging solar PV technology, the multijunction III-V/silicon tandem solar cell, to illustrate the following practical strategies to overcome the challenges:

1. Parametrized use-phase modelling (goal and scope phase)
2. Upscaling based on process engineering principles (LCI phase)
3. Expert elicitation (LCI phase)
4. Modelling technological pathways (LCI phase)
5. Using future background scenario LCI databases (LCI phase)
6. Assessing future impacts (LCIA phase)
7. Modelling EOL scenarios (goal and scope, and LCI phases)
8. Recognizing what matters in the LCA model (interpretation phase)

2.1 Case study of emerging photovoltaics

Crystalline silicon cells (c-Si) have been dominating the photovoltaic electricity (PV) market for over two decades, largely due to the availability and low cost of silicon and their relatively good performance in converting energy from sunlight. Industrially available c-Si cells today have conversion efficiencies of ca. 22%, while the record-holding lab prototypes are pushing towards the thermodynamic limit of 29.4% (Ehrler et al., 2020). Cost reduction has been exponential, reaching $0.20/Wp in 2020 (Benda & Černá, 2020). But after decades of research and development (R&D), marginal increases in c-Si efficiency and decreases in cost are more difficult to attain. Still, solar PV is expected to be a key player in the energy transition, and the most optimistic scenarios see installed capacity reaching 70 TW in 2050, up from 760 GW in 2020 (Jaxa-Rozen & Trutnevyte, 2021). In such a future, the market dominance of c-Si may be challenged by higher-efficiency cells if they can achieve a lower cost per watt. The emerging PV landscape is dynamic and diverse, with many novel combinations of materials and processing methods being proposed to achieve the lowest cost-per-watt ratios. At the same time, the focus on the cost per kW ratio could distract from the original goal of reducing the environmental burdens of energy systems. Emerging PV is, therefore, a very well-suited and justified domain for the application of *ex-ante* LCA.

The multijunction III-V/silicon tandem cell (III-V/Si) concept is an emerging PV technology that combines c-Si bottom cells with top absorber layers made from group III-V materials (gallium, indium, arsenide and phosphide) (Cariou et al., 2018). This combination allows such cells to reach conversion efficiencies well beyond c-Si's theoretical limit. With significantly less time and resources invested in R&D, III-V/Si cell efficiencies close to 36% have already been demonstrated at the lab scale (Essig et al., 2017). Recent R&D efforts have targeted potential pathways to improve cost and environmental competitiveness via more efficient III-V layer deposition, enhanced waste treatment, recycling of metals, and low-cost preparation of the c-Si growth substrate (Blanco, Cucurachi, Dimroth, et al., 2020; Fraunhofer ISE, n.d.). In this paper, we use such advancements to illustrate the challenges of applying LCA to an evolving system at a low TRL.

3.

Goal and scope

During the goal and scope definition phase, important choices are made, and boundary conditions are defined for conducting an LCA study. The objective of an *ex-ante* LCA is to quantify the future environmental impacts of an emerging technology (Moni et al., 2020), e.g., to require funding or benchmark a system in comparison to an alternative. In comparative studies, the emerging technology is frequently compared to an incumbent technology, defined as the system in the technology landscape that performs a similar function as that of the emerging technology (Giesen et al., 2020). While in conventional LCA the incumbent systems are typically well-defined (European Commission's Knowledge Centre, 2022), in an *ex-ante* LCA study the incumbent systems may become clearer to the analyst only as the technology evolves, thus after iterations of the assessment are carried out in close coordination with technology developers. This process could take years, making finding a balance between timeliness and accuracy challenging but necessary.

The transparent definition of a reference year for the analysis, geographical context and technological landscape allows for modelling scenarios that consider all the relevant operating conditions (see also Bisinella et al., 2021; European Commission's Knowledge Centre, 2022). It is recommended at this stage that the analyst formulates the expected delay until there is industrial production, together with the specific TRL of the system under assessment (Moni et al., 2020). In the case of low TRL levels, the system is considered to be in the conceptual development phase and, thus, extensive process changes are expected due to further research developments (Gavankar et al., 2012). In comparative assessment, it is important to account for the TRL of the emerging technology and the related incumbent technology and to discuss the implications of TRL on the potential performance of the systems.

3.1 Functional performance

Once the objective of the study is clearly defined, a functional unit (FU) can be defined, i.e., a "quantitative description of the service performance (the needs fulfilled) of the investigated product system(s)" (Rebitzer et al., 2004). Challenges in *ex-ante* LCA may arise regarding the precise identification of the function of the technology under assessment. At the earliest stages of innovation, it might be challenging for the analyst and technology developer to fully define the ultimate function of emerging technology, and this may be influenced by future consumer behaviour, i.e., how they use the technology. It is also possible that multiple functions may be identified and studied, and they may require comparison with multiple incumbent technologies, e.g., batteries may be used for frequency/voltage regulation of the energy grid or for energy storage in residential units.

Another key challenge is that the functional performance (i.e., the efficiency in delivering the required function) of the technology, once it is market-ready, is often uncertain. Performance improvement is often the main target of R&D, and performance gradually (sometimes significantly) improves as the technology progresses from one TRL to the next (see Table 1).

Table 1 | Examples of emerging technologies typically evaluated in *ex-ante* LCA and how their expected functional performance can evolve throughout R&D

Technology	Functional unit example	Example performance improvements targeted in R&D
PV panels	1 kWh generated electricity	Increase panel conversion efficiency, reduce degradation
Batteries	1 kWh delivered electricity	Increase roundtrip efficiency, increase cycle life
Electric vehicles	1 km transport	Increase engine efficiency, increase components' lifetime
Carbon capture and storage	1 kg captured carbon	Increase adsorber efficiency and lifetime
Bioproducts	1 kg biomass	Increase bioreactor yield

Functional performance — and its determining factors — are often the most influential unresolved aspects for LCAs of emerging technologies. In an LCA model, the performance of a service (such as generating electricity, transporting passengers, or providing novel nutrition sources) is a use-phase activity that is downstream of most other activities in the value chain. Better performance will demand less from the upstream supply chain to deliver the same amount of service. Therefore, it is of the utmost importance that this aspect is carefully modelled and analysed via uncertainty and sensitivity analysis (see section 6).

As can be gathered from above, we recommend detailed modelling of functional performance aspects, which can then be subject to comprehensive uncertainty and sensitivity analyses (section 6). We also recommend erring on the side of over-parametrization rather than under-parametrization in this part of the model, as important opportunities for optimising designs for increased sustainability may be revealed.

Ex-ante practical strategy 1: Parametrized use-phase modelling

The relevance of functional performance is well illustrated by the case of emerging PV. For PV, the functional unit is often defined as "1 kWh (kilowatt-hour) of DC electricity generated by a photovoltaic module" (Directorate-General for the Environment of the European Commission, 2020). The key quantity of interest for calculating life cycle impacts is the size of the PV installation required to generate this amount of electricity. This size will depend on several performance-related factors, according to the formula:

$$A = E/(I \cdot \eta \cdot PR \cdot LT)$$

Where A is the size of the PV installation (in m^2), E is the required electricity given by the FU (i.e., 1 kWh), I is the incoming solar irradiation ($kWh/m^2 \cdot a$), η is the panel's conversion efficiency, PR is a performance ratio expressed as a percentage, and LT is the expected useful lifetime of the panels, in years. Any performance improvement in conversion efficiency, performance ratio, or panel lifetime will proportionally reduce the installation size A required to generate 1 kWh of electricity, therefore reducing the consumption of materials and reducing the impacts of these materials per kWh of electricity generated.

Furthermore, solar cells can be expected to degrade over time, lowering their efficiency (η). Degradation is thus an additional key performance factor. The Product Environmental Footprint Category Rules (PEFCR) put forth by the European Union prescribe a degradation rate of 0.7% each year for all PV technologies, only to be revised if a different value can be substantiated by long-term testing (> 10 years). In the context of emerging PV technologies, this is naturally not feasible. Yet our goal of understanding *potential* impacts and improvement pathways requires an analysis of *potential* performance, especially if improved solar cell efficiency and stability (and/or panel lifetime) are key features of the PV technology being evaluated.

The III-V/Si technology can offer important improvements in several of the factors which should be captured by an *ex-ante* LCA. Figure 1 shows the comparative LCA impacts for III-V/Si PV vs c-Si, taking the PEFCR recommended baseline values: annual irradiance (1700 kWh/m²), PV system lifetime (30 years), performance ratio for roof-mounted systems (75%) and a degradation rate of 0.7% per year. The initial conversion efficiency of 27% is taken based on what has been achieved to date for III-V/Si. Technically feasible and foreseeable performance optimizations are assessed by extending lifetime to 35 years, increasing efficiency to 30%, reducing degradation to 0.5%/year and increasing the performance ratio to 80% (see figure 1: LT_opt, Eff_opt, Deg_opt, PR_opt, respectively).

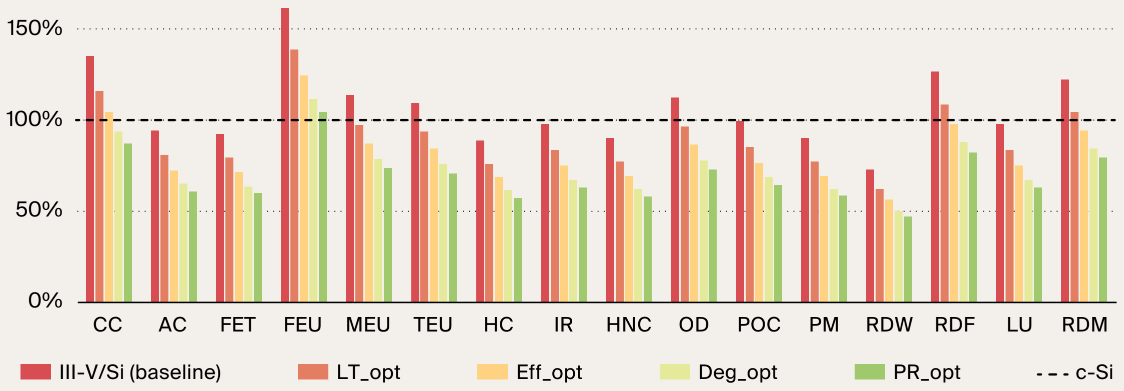

Figure 1 | Comparative impact results of III-V/Si future scenarios compared to the reference c-Si system with an improved panel conversion efficiency of 30%, degradation rate of 0.5% per year, extended lifetime of 35 years and performance ratio of 80%. CC: climate change; AC: acidification; FET: freshwater ecotoxicity; FEU: freshwater eutrophication; MEU: marine eutrophication; TEU: terrestrial eutrophication; HC: human toxicity, cancer effects; IRH: ionising radiation; HNC: human toxicity, non-cancer effects; OD: stratospheric ozone depletion; POC: photochemical ozone formation; PM: particulate matter; WRD: water resource depletion; RDF: fossil resource depletion; LU: land use; RDM: mineral resource depletion.

4.

Future LCI: Foregrounds and backgrounds

The emerging technology system and incumbent system/systems under assessment can be defined as the foreground system, i.e., the part of the system that the analysts model themselves. For the case of emerging technologies, the foreground system is also typically under the direct control of the technology developer with whom the LCA analyst collaborates, meaning that specific processes in the emerging technology product system could be influenced and changed given adequate resources and guarantees of acceptable trade-offs on the functional performance. For example, nitrogen could be used instead of hydrogen when non-reactive gas streams are required in a chemical processing step, should the LCA analyst signal an environmental preference for the first option as compared to the latter.

The technological context in which the emerging technology and incumbent technology (or technologies) are embedded can be defined as the background system, i.e., the part of the system for which LCA analysts typically use LCI databases (e.g., ecoinvent Wernet et al., 2016). An example of unit processes in the background is the service of electricity provision from the grid, which does influence the performance of the emerging technology, but depends on policy decisions and a country's macro-economic context.

While modelling choices related to the foreground and background systems are decided upon during the goal and scope phase, they do have an impact on the inventory data used at the LCI phase. The literature suggests avoiding temporal mismatches between foreground systems and background systems (Arvidsson et al., 2017; Giesen et al., 2020; Mendoza Beltran et al., 2020; Thonemann et al., 2020), although this is often not possible.

4.1 Upscaling the foreground

Lab- and pilot-scale processes are often how technologies are built up and transformed during R&D. However, these processes are highly inefficient in their use of energy and materials, and as a result, would likely have disproportionate environmental impacts if introduced in an LCA model. Given that such processes will not be used to manufacture the technology at an industrial scale, the results of a lab/pilot-scale LCA model could provide, at best, limited insight and, at worst, distorted conclusions as to the future environmental performance of the technology. One of the foremost challenges encountered by *ex-ante* LCA practitioners is, thus, the lack of knowledge of how each lab/pilot-scale process being tested by technology developers will be optimized for industrial mass production.

Ex-ante practical strategy 2: Upscaling based on process engineering principles

Piccinno et al. (2016) offer excellent guidance for upscaling chemical processes in LCA models, based on process engineering principles and well-known practices in the chemical industries. The approach can be illustrated with the front metal contacts (fingers and busbars) of the III-V/Si cells case study. Current industry practice is to screen-print the metal contacts using silver paste. However, silver is expensive and is ranked high vs. other metals in terms of potential ecotoxicity impacts in LCA impact assessment models. A proposed innovation is to replace it with copper nano ink, with the caveat that copper ink must be sintered (dried and consolidated) in an oxygen-free environment to avoid damage. This environment is provided by a constant flow of nitrogen gas with formic acid (Hermerschmidt et al., 2018). A laboratory setup for this sintering step is depicted in figure 2.

An LCA of III-V/Si including this lab-scale process would quickly raise a flag since sintering would introduce climate change impacts orders of magnitude larger than all other processes and components of the PV installation. Most of the burden would be traced to the large consumption of formic acid per solar cell processed (figure 3, top). But this is an unrealistic representation, as such a process is by no means scalable. Following the guidance of Piccinno et al. (2016), we establish that the formic acid is mostly non-reacting and therefore would likely be recirculated in an industrial setting, greatly reducing the environmental burden of this step (figure 3, bottom). The reader is referred to Piccinno et al. (2016) for additional strategies regarding the consumption of energy and reactants, as well as reactor geometry and waste handling.

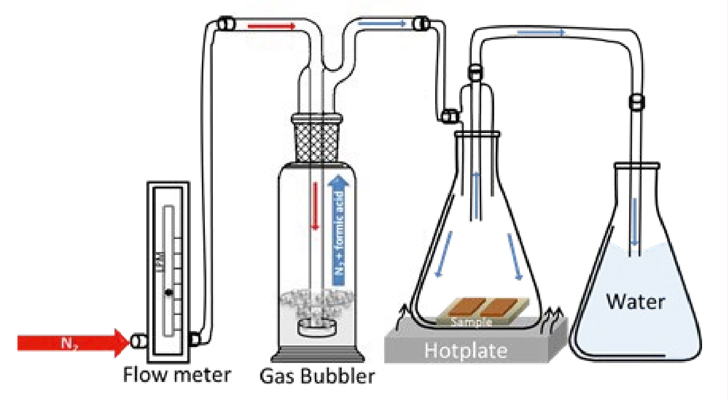

Figure 2 | Lab-scale demonstration of copper ink sintering of front contacts in sample 1 cm² sized solar cells (credits: Mirella El Gemayel).

Figure 3 | Process contributions to climate change impacts of III-V/Si panels with lab-scale (top) and industrial-scale (bottom) sintering of front contacts (left) and upscaled sintering (right) (credits: Mirella El Gemayel).

Ex-ante practical strategy 3: Expert elicitation for hotspots

A similar situation is encountered in the deposition step of PV cell fabrication, where the top III-V layers are placed on top of the silicon wafer (Blanco, Cucurachi, Dimroth, et al., 2020). With current technology, this deposition is done in metalorganic vapour phase epitaxy (MOVPE) reactors operating at high temperatures (> 900°C) with low throughputs (e.g., 31 round 4-inch wafers per 2.5-hour run). The combination of low-throughput and high-energy demand in a manufacturing step is likely to make it an LCA hotspot and is something for *ex-ante* practitioners to be on the watch for. This is confirmed for the III-V/Si case, as seen in figure 3. Thousands of MOVPE reactors would be required to reach the targeted industrial-scale production capacity of billions of cells per year. The capital expenditure and operational costs of such a reactor fleet would render the III-V/Si technology technically and economically inviable. The MOVPE reaction will necessarily have to be optimized, and the question then is how to do so and to what extent.

In a European project in which the authors were involved (Fraunhofer ISE, n.d.), a focus group involving engineering experts was created to discuss what improvements are necessary and also feasible and foreseeable in the MOVPE process. The output of this expert elicitation was a roadmap with eight milestones, each representing an optimization of the MOVPE process needed to approach industrial-scale production and cost targets.

Table 2 | Description of future foreground scenarios for MOVPE optimization

Milestone	Description
III-V/Si P	Present MOVPE reactor configuration with a throughput of 31 small 4-inch round wafers per run and runtime of 2.5 h
M1	Change shape and size of wafer handled by the reactor to larger 156.75 x 156.75 mm square wafers
M2	Increase throughput to 50 wafers per run
M3	Reduce runtime to 1 h by minimizing intermediate steps and increasing some deposition rates
M4	Reduce runtime to 0.5 h by minimizing intermediate steps and increasing some deposition rates
M5	Increase reactor deposition efficiency from 50% to 60% (reduce III-V material consumption)
M6	Reduce equipment power load of MOVPE reactor from 15 kW to 5 kW
M7	Reduce cooling power load from 16 kW to 5 kW
M8	Reduce facilities ventilation power load from 39 kW to 20 kW

Recalculation of the LCA for each milestone showed that a combination of steps would suffice to achieve a comparative environmental advantage for the III-V/Si tandem cells (see figure 4). This result is remarkable, considering that the incumbent c-Si cells are already mass-produced in assembly lines that handle > 5000 square wafers per hour. Such an approach can be replicated in additional contexts in which an LCA analyst is collaborating with technology developers early in R&D to elicit feasible technological roadmaps to assess via LCA. The reader is referred to (Morgan, 2014; O'Hagan, 2019; Wang et al., 2012) for in-depth descriptions of structured elicitation protocols.

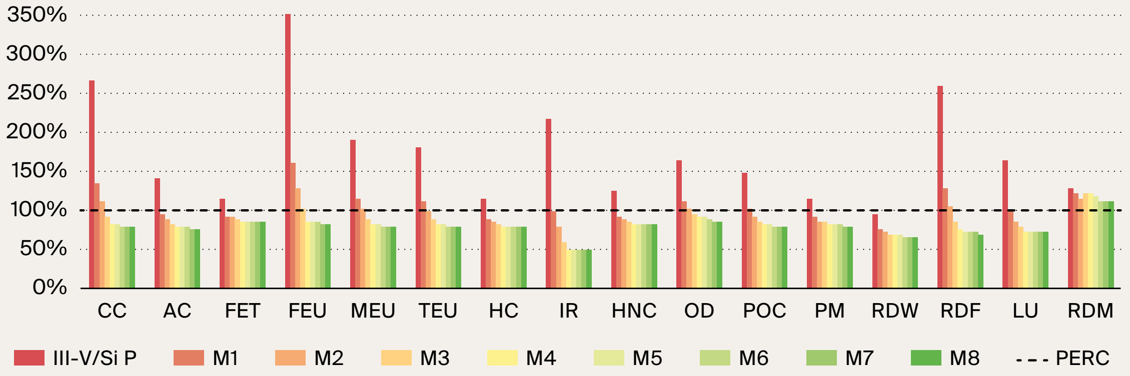

Figure 4 | Life cycle environmental impacts of generating 1 kWh with a III-V/Si tandem module on a slanted-roof installation, following MOVPE process optimizations M1—M8 (Table 2). Impacts are shown relative to incumbent c-Si modules (red dashed line = 100%). CC: climate change; AC: acidification; FET: freshwater ecotoxicity; FEU: freshwater eutrophication; MEU: marine eutrophication; TEU: terrestrial eutrophication; HC: human toxicity, cancer effects; IRH: ionising radiation; HNC: human toxicity, non-cancer effects; OD: stratospheric ozone depletion; POC: photochemical ozone formation; PM: particulate matter; WRD: water resource depletion; RDF: fossil resource depletion; LU: land use; RDM: mineral resource depletion

4.2 Projecting changes in the background

As technologies progress from TRL1 to 9 (usually 10+ years), background supply chains can also be expected to evolve. For example, most global scenarios agree that energy grids around the world will likely turn towards less carbon-intensive sources, and economies will become more circular, reducing waste and consumption of raw materials. The number of interconnected processes in any product's background can easily exceed 10,000. Background LCA databases such as ecoinvent (Wernet et al., 2016) take a long time to compile and update, and even the most current databases often reflect technologies from 5—10 years ago. However, a technology may be better situated to take advantage of background trends than the incumbent technology. For example, this would be the case if it uses a material with a better outlook towards recyclability and reusability in the future. If future recycling trends are expected to better incorporate the materials in novel technology designs, this competitive advantage should be captured by an *ex-ante* LCA.

The matter of static or outdated background data has received considerable attention from LCA practitioners in recent years. One of the first practical solutions was proposed by Mendoza-Beltran et al. (2020), who translated future scenarios from the Integrated Model to Assess the Global Environment (IMAGE) models, developed and maintained by PBL Netherlands Environmental Assessment Agency (Stehfest et al., 2014), into future background LCA databases. The implementation of Mendoza-Beltrán et al. (2020) is based on the Shared Socioeconomic Pathways (SSPs) scenarios, which represent five storylines on possible human development trajectories and global environmental change in the twenty-first century. For example, the SSP2 scenario, "medium challenges to mitigation and adaptation" represents a balanced, leaning toward conservative, view of how energy markets may evolve over the next decades (O'Neill et al., 2014, 2017; Riahi et al., 2017; Stehfest et al., 2014).

Figure 5 illustrates how applying the SSP2 background scenario affects the climate change impact scores of III-V/Si panels over the next three decades. The improvements are gradual, suggesting that the SSP2 scenario is indeed conservative. We note that the incumbent technology (PERC c-Si) will also be subject to the same changes in the background energy supplies; therefore, it is of value to reveal whether and to what extent these changes are more beneficial to the emerging technology than to the incumbent one.

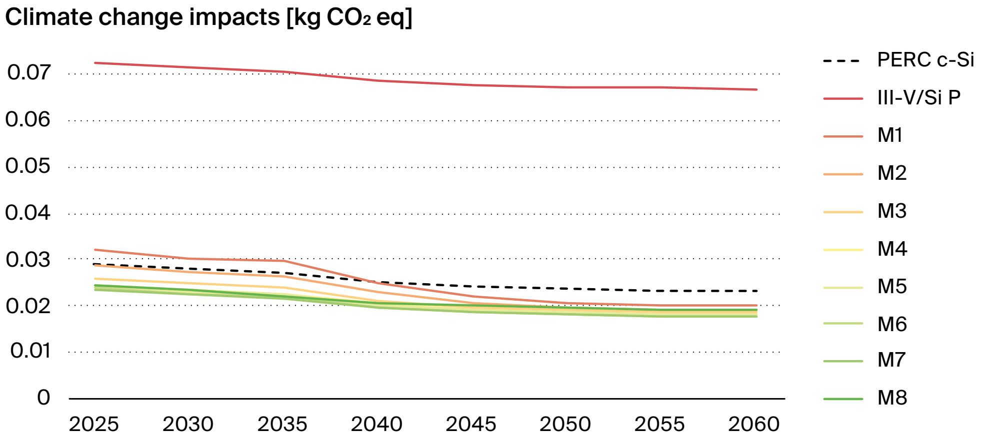

Figure 5 | Evolution of the climate change impact score of each future foreground scenario (milestones 1–8, see the previous section) modelled on future background SSP2-450 scenarios from IMAGE for the period 2020–2060

4.3 Competing processing and material alternatives

Another situation often encountered by *ex-ante* LCA analysts is that competing processing methods or materials will be tested by technology developers for different technology components. This will be evident in the foreground but may take place in background systems as well. The uncertainty, then, is not how much a given quantity such as energy consumption or processing runtime of a reactor will change, but whether an entirely different type of process, material, or equipment will be used to balance product performance with industrial scalability. Insofar as these decisions are not resolved (which may only happen at higher TRLs), the LCA analyst is challenged with assessing and communicating the impacts of numerous possible technological configurations, which can quickly become impracticable.

Ex-ante practical strategy 4: Defining and modelling technological pathways

Blanco et al. (2020) propose a probabilistic method for incorporating all possible combinations of process/materials choices (i.e., technological pathways) in a single LCA model, where the competing alternatives are selected stochastically in a Monte Carlo simulation according to their expected chances of success. The output of such a model (i.e., the impact score) is in the form of a probability distribution rather than a single-point value. The approach can be visualized in figure 6. The challenging aspect of this approach is justifying the expected chance of success that is given to each alternative. Here, the analyst can resort to expert elicitation protocols such as those applied in strategy 3. (Morgan, 2014; O'Hagan, 2019; Wang et al., 2012).

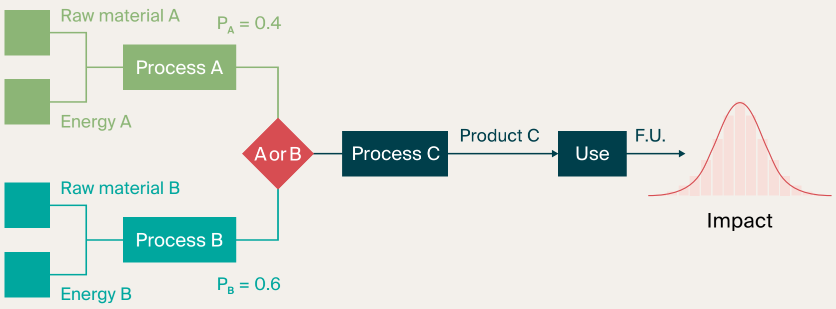

Figure 6 | Visualization of Monte Carlo propagation of competing for technological pathways.
P_A: expected chance of success of process A.
P_B: expected chance of success of process B

4.4 End-of-life treatment, emissions and impacts

Where the product or function of a technology (and its embedded system) serves a mature market, "cradle-to-gate" system boundaries may be appropriate for the goals of an LCA. However, emerging technologies may often provide a distinct product or service for which a market is not well established, which warrants careful consideration of market effects and the EOL phase (Bergerson et al., 2019). While a cradle-to-gate assessment of an emerging technology may require looking 10–15 years in the future, incorporating the EOL phase — which may take place 30 or more years later — really stretches the foresight capacity of the tools available to support LCA. Yet often the life cycle impacts of a technology are materialized in the EOL phase. This is especially the case for impacts such as ecotoxicity, acidification and eutrophication, which are triggered by chemical releases after incineration or landfilling of the technology's components. Other impacts, such as mineral resource depletion, will largely depend on the recyclability of such components, specifically if closed recycling loops are implemented. Emissions from waste streams in LCA are calculated from generic incineration/landfill models with a limited degree of product specificity (Wernet et al., 2016). Preserving a cause-effect link between the discarded product and its EOL emissions would require a specific emissions model to be developed, making this a very challenging aspect to model as no data can be collected for EOL situations, and recycling tests are seldom included in R&D programmes of novel technologies.

5.

Future impacts: Novel materials and evolving landscapes

LCA allows for the characterization of impacts across a broad set of impact categories and regions of the globe, accounting for a broad range of emissions and their potential impacts. However, technology develops faster than LCIA models (Temizel-Sekeryan & Hicks, 2021). As highlighted by Giesen and co-authors (2020), it is important to realize that in *ex-ante* LCA studies, potential environmental impacts of new technologies are not automatically covered by the existing impact categories commonly used in *ex-post* LCA studies. As a result, applying the current set of impact categories and characterization models to a novel or emerging technology may result in

Ex-ante practical strategy 5: Modelling EOL scenarios

A simplified model can be developed for the EOL phase by considering the different components of the product in terms of their separability and expected economic value upon eventual recovery. Scenarios can then be developed for the recovery of economically attractive materials. The analyst is encouraged to report on the potential benefits (avoided impacts) from eventual product recovery separately, clearly stating all assumptions. Separation techniques applied to similar technologies may be reported in patents, giving clues as to the types of processing required, e.g., mechanical crushing, chemical, or thermal treatment. Here, it may be possible to highlight potential hotspots if high temperatures or hazardous chemicals are involved. As for recycling rejects or components that are not expected to become economically/technically recyclable, modelling specific emissions in a landfill or incineration facility will typically be beyond the scope of an LCA exercise. At the very least, it is useful to map out potential waste streams; if the waste is hazardous, it will likely be disposed of in an underground or security landfill, where foreseeable emissions are negligible. Incinerated wastes will produce solid waste, such as ash, which is sent to secure landfills or, in some cases, reintroduced in construction materials (Blasenbauer et al., 2020). Other types of waste may end up in less stringent landfills; for these cases, the analyst can assume a conservative scenario where an important fraction of the waste is eventually released to the surrounding soil environment.

unclassified and uncharacterized flows, due to a lack of models and data.

While unclassified and uncharacterized flows may be deemed negligible in a comparative context with shared background and foreground data, the lack of specific characterization models or characterization factors does have an impact on the possibility of intervening early in R&D to avoid environmental burdens (Giesen et al., 2020). An LCA analyst, for instance, would not be able to calculate the potential toxicity impacts of an emerging technology that would make use of a newly synthesized chemistry. This is due to the lack of an adequate characterization model able to characterize the cause-effect impact pathway of the said chemistry. The exclusion of these impacts, in such a case, could communicate to the decision-maker an artificial sense of safety[3], which would only be due to an imperfect assessment. In a comparative assessment, such a sense of safety may also shift the preference from the incumbent technology to the emerging one.

Ex-ante practical strategy 6: Updating characterization factors

The case of front metal innovation discussed in strategy 2 also provides a good illustration of the uncertain impacts of novel chemistries. While metallization inks for commercial c-Si PV cells are made of bulk silver paste, R&D is pushing towards the use of copper, as well as smaller particle sizes in the ink formulation, i.e., nano inks. Smaller particle sizes mean increased surface area, which has been linked to different intrinsic toxicity potentials than the bulk version of the same metal. Furthermore, nano-sized particles are subject to different transport mechanisms once released (e.g., particle aggregation), resulting in different fate and exposure factors. Thus, the databases with toxicity characterization factors, which were developed over several decades, may significantly under/overestimate the toxicity potential of novel material structures.

Updating toxicity characterization factors involves extensive lab testing and knowledge of a complex domain that is often beyond the reach of LCA practitioners. Fortunately, there is a growing body of literature aiming to fill this gap for nanomaterials, see e.g., Temizel-Sekeryan & Hicks (2021) (silver), Salieri et al. (2015) (TiO2), Miseljic & Olsen (2014) (silver and carbon nanotubes), Pini et al. (2016) (TiO2), Pu et al. (2016) (copper). The characterization factor for bulk copper releases in freshwater, according to the commonly used USEtox database is 194,000 CTU (comparative toxicity units) per kg of copper (2017). In contrast, Temizel-Sekeryan & Hicks propose a range between 2.19 × 103 and 2.34 × 105 CTU for silver nanoparticles. In both cases, the underlying uncertainties are very large and any treatment of these types of impacts must give uncertainty and variability due consideration. Alternatively, Song et al. (2017) propose assessing novel chemistries and materials by using artificial neural networks, thus using current knowledge of existing chemistries to assess in silico the impacts of novel chemistries and materials.

Another important consideration related to characterization factors in LCIA is that several impact categories calculate impacts relative to an evolving baseline. The most obvious examples are biotic and abiotic resource depletion, where the existing reserves are likely to change considerably in the time it takes for a technology to climb the technology development ladder from low TRL to TRL 9. A resource consumption now may be less "damaging" than the same consumption in 10 years. Baustert et al. (2022) have addressed this for the case of water scarcity in recent work, offering characterization factors projected to the year 2050. To our knowledge, no similar work has been conducted to date for minerals or other types of resources.

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[3] See the paper written for the ESET project by Rainer Sachs, "Risk governance of emerging technologies: Learning from the past" (2022).

6.

Interpretation: Recent developments in uncertainty analysis and global sensitivity analysis

In recent years, the treatment of uncertainty in LCA has garnered increasing attention among LCA practitioners. While uncertainty analysis is mandated in the ISO 14040 standards for LCA (ISO, 2006b), it has been ignored in most studies or conducted only at a very superficial level. Current LCA databases have become much larger and more complex, and, as a result, the sources of uncertainty in the underlying data have increased significantly. Therefore, more comprehensive methods for analyzing and interpreting uncertainty in LCA models are needed, particularly when assessing emerging technologies.

7.

Outlook and generalization

Ex-ante LCA faces an overwhelming dearth of data, rapidly evolving technology designs, and limited time to adjust and reinterpret the models. In this paper, we used the case of emerging PV technologies to inventory, assess and provide practical guidance to tackle many challenges of conducting an LCA study at the earliest stages of technological innovation.

The traditional approach of only producing the assessments when a technology is fully developed, allowing for both models and data collection to be refined, has long been the standard of conventional *ex-post* assessments. Such an approach guarantees more accurate results at the expense of the risk of inaction because a technology is already

Ex-ante practical strategy 7: Recognizing what matters in the LCA model

Given the many different futures that can unfold, one of the key aspects of understanding and interpreting large uncertainties in an *ex-ante* LCA model is sensitivity analysis. Perhaps the most commonly applied method for sensitivity analysis in LCA is "one factor at a time" (OFAT) (Groen et al., 2017). OFAT analyses, which are a form of scenario analysis, consist of varying the values of selected input parameters and investigating how these variations are reflected in the model's output. OFAT analyses have several limitations, particularly their ad-hoc nature, given that the tested parameters are chosen subjectively by the practitioner.

A more thorough and systematic type of analysis is global sensitivity analysis (GSA) (Plischke et al., 2013), which systematically tests all of the model's uncertain input parameters and ranks them in terms of their contribution to the model output's uncertainty (e.g., contribution to variance). Several authors have argued strongly for the application of GSA in LCA, as it provides very valuable information on which input parameters should be investigated further to reduce the LCA model's output uncertainty (Cucurachi et al., 2016; Groen et al., 2017; Lacirignola et al., 2017; Ravikumar et al., 2018). Cucurachi and co-authors (2021) provide a protocol and software application to assess the importance of uncertain input parameters across all phases of an LCA model, including background and foreground contributions, and the use of the uncertain characterization model at the LCIA phase. The authors show, using a case study of III-V solar PV, that the proposed method and software application is suitable for the study of emerging technologies.

entrenched. We have shown that the *ex-ante* LCA alternative, combined with adequate screening tools and computational tools (e.g., for parametrization, uncertainty, GSA) can already guide decisions in the earlier phases of technology development. Such an approach requires close collaboration between LCA analysts and the relevant stakeholders, from the definition of the goal and scope of the analysis to all subsequent phases of LCA, including the interpretation of results. Similarly, substantial interdisciplinary work is required to build and extend the *ex-ante* LCA toolbox, calling for a necessary hybridization of LCA models with risk assessment models, technology and innovation theory, and data scientists, among other disciplinary experts.

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Paper 10

Anticipatory life cycle assessment for environmental innovation

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Introduction

Environmental life cycle assessment (LCA) has emerged as the preferred perspective from which to evaluate the prospective impacts of innovative technologies. However, conflicting methodological recommendations in the scientific literature may leave technology developers, policy makers, and research funding agencies confused about which approach(es) to adopt. This paper contrasts the features and relevance of *ex-ante* and anticipatory LCA for the purpose of informing EPFL International Risk Governance Center's (IRGC) preliminary recommendations regarding the environmental sustainability of emerging technologies. In particular, it details the advantages, methodological approach and challenges of anticipatory LCA.

The principal feature distinguishing the two methods is the model of innovation with which they are most compatible. Namely, *ex-ante* aligns with technology readiness level (TRL)/stage gate models of innovation, whereas anticipatory aligns with lean/agile. TRL/stage-gate is typical of large, well-funded bureaucratic organizations, such as government agencies, whereas lean/agile is typical of startup companies and teams seeking technology breakthroughs. Thus, anticipatory LCA better recognizes that disruptive innovation rarely follows the linear pathway for which TRL/stage-gate was originally developed (see Box 1).

This paper is divided into six sections. Section 1 reviews the historical development of environmental life cycle assessment and contrasts different approaches to prospective environmental modeling for emerging technologies. Section 2 describes how current ISO guidelines for LCA are consistent with the TRL/stage-gate model of innovation. Section 3 contrasts lean/agile models of innovation with TRL/stage-gate. Section 4 contrasts the *ex-ante* and anticipatory methods. Section 5 describes the different stages and steps of anticipatory LCA. Finally, Section 6 offers recommendations and conclusions.

1.

Historical development of environmental life cycle assessment

The intellectual antecedents of environmental LCA can be traced back to the 1970s when regulations were promulgated in response to an emerging environmental consciousness. In the United States, the Clean Air Act (Daniels et al., 2020) and the Clean Water Act (Murchison, 2005) exemplified the new regulatory approach. For example, when the US Environmental Protection Agency was established by the Nixon administration in 1970 it was organized, and is still organized, around different environmental media. In each regional office, one division regulates air pollution, another solid waste, and another water. Emissions limits and permit reviews are conducted separately by each division, complicating coordination across environmental media.

At the time, the separation of divisions made sense in two ways: (1) it allowed piecemeal, incremental construction of a regulatory structure, without the additional obstacles of having to conceive of a whole systems approach all at once, and (2) it mirrored the typical organizational structures of the large corporations that were the object of regulation.

Nonetheless, critics were quick to recognize shortcomings in a compartmentalized approach (e.g., Lapping, 1975). For example, incineration became a popular solution for the management of solid waste because it reduced waste volumes, conserved landfill space and could be used to generate electricity. However, it also shifted pollution problems from one environmental medium to another. Similarly, storing liquid waste in drums and burying them in the ground offered some protection to surface waters, but came at the expense of land and groundwaters (as the infamous case of Love Canal, New York, made clear to the public in 1977–1978). The separation of regulatory actions by environmental media permitted, if not encouraged, shifting problems from one media to another without considering what might reduce environmental burdens as a whole.

Environmental LCA emerged as an analytic solution to the problem-shifting that characterized early technological approaches. The principal advantage of LCA is that it incorporates broad, explicit boundaries designed to consider all environmental effects along the supply chain, including use and disposal, as a whole system.

The earliest applications of LCA were in the industries that dominated the industrial revolution and were perceived as relevant to its environmental legacy. For example, a famous article in "Scientific American" (Frosch & Gallopoulos, 1989) that popularized the term "industrial ecology" relied on examples from the automobile industry – partly because the authors were scientists at General Motors, and partly because the auto industry dominated manufacturing in the American economy for decades. The article emphasized potential material interconnections between industries, such that "waste" or by-products from one industry might become feedstocks for others. Later, this became known as "industrial symbiosis" (Grant et al., 2010) and, more recently, "circular economy" (Korhonen et al., 2018).

The advantages of the circular economy are exemplified by the industrial ecosystem in Kalundborg, Denmark, where cooperation between different industries has improved material and energy efficiency, reducing exchanges with the environment (Chertow & Park, 2016). Nonetheless, the disadvantage is that interdependent relationships typically exist only between mature, stable industries. They can take decades to develop, and once they are in place, they can become an impediment to innovation.

The historical development of LCA has made it natural to develop standardized methods applicable to mature industries, operating at scale, where data on production processes and emissions is both available and stable. LCA is less developed in steering the development of novel technologies, or guiding innovation. Several theoretical or methodological advances that go by different names have been made, including prospective LCA, *ex-ante* LCA, anticipatory LCA and LCA of emerging technologies. While each term is motivated by the same problem — i.e., the difficulty of gaining environmental insight into problems before they manifest at scale — the terms are not synonymous, and the approaches are different. Table 1 provides a high-level comparative summary focusing on critical differences rather than commonalities.

What often gets lost in the research regarding LCA for innovation is that attempts to force existing models of retrospective LCA, such as those codified by the International Standard Organization (ISO), into prospective applications will suffer from irredeemable shortcomings. Retrospective LCA methods were organized around an understanding of traditional manufacturing, distribution, use and waste collection processes. That is, the ISO standards that dominate thinking about LCA were developed to improve the environmental efficiency of mature supply chains, markets and processes. Consequently, they are structured with models of these industrial processes in mind, to address

Table 1 | LCA methods comparison

Descriptor	Goal	Unique features
Prospective	Improve environmental forecasting	Emphasizes: • absolute rather than relative assessment
Ex-ante	Comparative assessment of pre-market technologies to determine expected or projected environmental gains relative to incumbent	Emphasizes: • uncertainties related to scale-up • seeks compatibility with ISO 14040 series guidelines[2] for retrospective LCA
Anticipatory	Identify uncertainties most critical to the environment, and research priorities	Emphasizes: • sensitivity analysis by stochastic exploration of data uncertainties, including value-based tradeoffs between impact categories • environmental prioritization of critical uncertainties for technology developers

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[2] See ISO 14040:2006 www.iso.org/news/2006/07/Ref1019.html

questions for designers and managers concerned with improving the environmental efficiency of producing, delivering and recycling goods. However, at the early stages of innovation, different concerns dominate.

In research & development, life cycle questions related to manufacturing efficiency are often secondary to questions related to functionality in use. For example, a life cycle examination of single-walled carbon nanotube (SWCNT) production in a laboratory research setting revealed that carbon yield during laser ablation was a critical factor in determining overall environmental efficiency in the fabrication of experimental SWCNT battery electrodes (Ganter et al., 2009). In this case, the environmental analysis was not motivated by comparison to conventional battery electrodes (as *ex-ante* LCA suggests). Rather, analysts were guided by the technology developers' request to identify opportunities for environmental improvement. Subsequent anticipatory analyses revealed that the current research focus on improvements in use-phase functionality would do little to effect environmental life cycle improvements. As a consequence of communicating these findings back to the technology developers, research attention shifted to investigations that improve yield (Wender & Seager, 2014).

An analogous example is the anticipatory life cycle comparison of emerging photovoltaic (PV) technologies. Anticipatory LCA revealed that the most important uncertainty with regard to greenhouse gas emissions was the carbon intensity of the silicon manufacturing processes (Ravikumar et al., 2017). At the time, PV technology developers were preoccupied with making use-phase efficiency gains to increase avoided carbon-dioxide emissions from displaced coal-fired electricity. However, because greenhouse gas emissions were more closely associated with manufacturing than use-phase conversion efficiencies, environmental research priorities would have been better directed to technologies for minimizing or eliminating kerf losses in silicon wafer slicing.

The anticipatory approach can reveal insights into a technology development agenda that might otherwise be hidden by other approaches to LCA. For example, a comparative anticipatory LCA of three PV technologies (amorphous-Si, CdTe, ribbon-Si) indicated that metal depletion in amorphous-Si contributes more to absolute uncertainty than any other life cycle parameter. As such, intuition suggests investigating process improvements in amorphous-Si technology that reduce uncertainty in metal depletion. However, anticipatory testing of hypothetical improvements in metal depletion failed to resolve uncertainties in environmental rank-order preferences relative to other technologies. Instead, relative uncertainties in technology preferences are better addressed by investigating uncertainties in marine eutrophication (Ravikumar et al., 2018).

These examples illustrate difficulties with the assertions that "the ISO standard could and should also be used when LCA is applied in an *ex-ante* manner" (van der Giesen et al., 2020). Because the ISO standards were developed to address questions related to mature manufacturing industries, not the salient questions and uncertainties related to technology development, they place emphasis on goals that are in poor alignment with current trends in research and technology development.

2.

How is innovation modeled in prospective LCA?

Just like LCA was organized with a model of manufacturing in mind, any method of environmental LCA that seeks to inform questions relevant to innovation must be organized with a model of innovation in mind. The most popular model cited in the scholarship of LCA is called Technology Readiness Level (TRL). It has been adopted by NASA, the US Department of Energy and others (Straub, 2015), and is often cited with respect to *ex-ante* LCA (e.g., Moni et al., 2020). In TRL, technologies or products progress from Level 1 — Basic science without a commercial application in mind, to Level 9 — Product tested under real conditions.

The TRL model presumes a linear progression from lower levels of readiness to higher ones, as knowledge from research & development accumulates. It is understood that not all ideas or discoveries will progress all the way to the highest levels, as some will fail to find commercial or practical application. As such, TRL is typically compared to a funnel or pipeline through which many ideas flow in one direction from lower levels to higher. This approach has been elaborated upon for private industry as "stage-gate" innovation, in which ideas are progressed through five stages of the "pipeline" (Cooper & Edgett, 2009, p. 2), including:

1. Scoping,
2. Building a business case,
3. Development,
4. Testing & validation, and
5. Launch.

At the conclusion of each of these stages, prior to making investments that advance to the next stage, the quality of the idea, product, or technology is assessed relative to increasing detailed criteria. Hypothetically, life cycle environmental criteria can be included among any of the gates. For example, breakthrough ideas that require prohibited, tightly regulated, or critical materials might fail environmental criteria before progressing to the development stage. Prospective and *ex-ante* LCA may have been developed with this in mind.

Nonetheless, there are at least two difficulties with TRL: linearity and cost.

Linearity
The single-minded focus at each stage-gate is obtaining an answer to the question "Go or kill?" In its original formulation, the stage-gate process on which TRL was predicated did not encourage feedback loops or iterative cycles (e.g., Cooper, 1990). Although subsequent revisions to stage-gate recognize the importance of iteration (e.g., Cooper, 2014), these have yet to be formalized in TRL. Thus, TRL suggests that innovation success depends on increasing the number of ideas entering the funnel at Level 1 – Basic science. TRL fails to account for real, messy, non-linear product development practices that are often carried out without TRL or stage-gate processes in mind (Wender et al., 2014).

Cost
Progressing from basic science without guidance toward practical application requires long-term capital investment that is typically unaffordable to all but governments, universities with large endowments, and large corporations in dominant market positions. When ideas do emerge from basic science to enter a stage-gate funnel at higher readiness levels, additional research investment is required to assess go/kill at every gate. Because the funnel metaphor suggests increasing the number of new ideas at the beginning of the funnel, increasing the pace of innovation incurs both the increased cost of generating or obtaining these ideas and the cost of assessing them relative to stage-gate criteria. The more criteria added at each gate, the greater the cost. TRL fails to acknowledge the real financial constraints under which innovation occurs, given the enormous costs of gathering complete information.

3.

How does innovation really work?

The suggestion by Cooper & Edgett (2005) that the idea "pipeline was dry" in 2005 proved to be facile. For example, the most valuable American companies in 2005 placed Walmart at the top, followed by Exxon Mobil, two automobile companies, General Electric, two more oil companies, and a bank[3]. While it may be true that each of these corporations was lacking in strong, high-value ideas, revisiting the list in 2022 reveals some significant changes. Apple, Microsoft, and Alphabet (Google) now top the list, followed by Amazon and Tesla.

The linear TRL/stage-gate model that dominated industrial behemoths like General Electric has since been superseded by agile and lean innovation models that emphasize flexibility, recursion, and minimizing capital requirements. Although "lean" originally referred to production management practices that enabled Toyota to deploy quality improvements and retool production systems faster and cheaper than American automobile manufacturers (e.g., Womack et al., 2007), it was subsequently adopted by software and other start-up companies in Silicon Valley to accelerate the launch of imperfect products that could be further developed with the benefit of customer and market feedback (Blank, 2003). Meanwhile, the intellectual antecedents of "agile" innovation trace back to two Japanese business scholars who levied a critique of the linear product development, suggesting that "the traditional sequential or 'relay race' approach to product development exemplified by NASA's phased program planning system may conflict with the goals

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[3] Fortune magazine maintains rankings of the largest companies in the world, measured by market capitalization. Subscribers may browse the historical data at fortune.com/ranking/fortune500/2022/search/

of maximum flexibility" (Takeuchi & Nonaka, 1986). They advocated for a more holistic, team-based approach to innovation that emphasized speed, instability, learning and flexible controls.

Where agile innovation addresses the problem of linearity, lean addresses the problem of expense. As these alternative pathways to product development co-evolved, they have eventually become mingled to the extent that they may be referred to as a single lean/agile model.

Rather than beginning with curiosity-driven basic science, the lean/agile model typically starts with customer problems or market opportunities, iterating through pretotypes, prototypes, and "protoproducts" (Jensen, 2017) to create a continuous improvement loop of new product versions of releases. The lean/agile model emphasizes the launch, revision, and relaunch of inexpensive product innovations that improve ideas rather than discard them. Given the flexibility of the lean/agile innovation and the recognition of resource limitations, one of the central recurring questions lean/agile developers must confront is, "what experiment should we try next?" Lean/agile requires searching among the myriad of those features, improvements, or ideas to identify those that should be prioritized for the next iteration. By contrast, TRL/stage-gate presumes that the development criteria are largely known ahead of time.

While the lean/agile model is particularly well-suited to software companies that can rapidly reconfigure code for new releases, or fix "bugs" that are only discovered after products release, lean/agile has also been adopted at manufacturing companies – especially those like Tesla with close ties to Silicon Valley. Given the success of lean/agile models of innovation, it behooves LCA researchers to develop methods of environmental inquiry that are suitable for them.

The most important distinction between *ex-ante* and anticipatory LCA, as they are currently practiced, is that *ex-ante* seeks to provide answers, while anticipatory seeks to prioritize questions.

To advance an environmental technology development agenda within lean/agile organizations, LCA researchers had to develop new methods of environmental inquiry that are suitable for them. To this end, anticipatory LCA is designed to be effective under conditions of extraordinary uncertainty.

Not all questions or assessments that might be required by TRL/stage-gate will be investigated under lean/agile prior to launch. Rather, lean/agile must prioritize which questions or assessments are essential and which will be reprioritized after product releases. In this respect, only anticipatory LCA is explicit about being designed with a model of innovation that proceeds under high uncertainty, prioritizes uncertainties and responds to recursive feedback (Wender et al., 2014).

LCA methods organized around the TRL/stage-gate model of innovation demand answers before technology development is permitted to proceed. Because the stated goal of *ex-ante* LCA is a comparative assessment of the projected environmental benefits of pre-market technologies or products, relative to the incumbent, it is particularly well-suited for TRL/stage-gate approaches. In *ex-ante* LCA, a product or process that projects as a poor environmental comparison to incumbent technology should either be abandoned, or reprioritized to determine under what conditions the new technology might become superior.

By contrast, the recursive nature of the lean/agile model of innovation demands development of the next question, uncertainty, or experiment to prioritize. In this approach, every iteration is like testing a new hypothesis, and the subsequent product iteration is rarely worked out prior to gathering feedback on the current version from customers or the marketplace. Because the stated goal of anticipatory LCA is to rank-order environmental uncertainties for technology developers, it is particularly well-suited for the lean/agile approaches that currently dominate innovation at the world's most successful companies. For example, in anticipatory LCA, analysis can proceed without data by assigning probability distributions to LCA parameters for which no data exist (such as novel characterization factors). Then, proceeding via internal normalization (rather than external) and stochastic exploration of impact category weights, a global sensitivity analysis determines the uncertainties that are most relevant to undermining confidence in a comparison between novel and incumbent technologies. Thus, anticipatory LCA suggests which research and development questions might be prioritized next.

4.

Ex-ante vs anticipatory LCA

Several aspects of anticipatory LCA are inconsistent, if not in direct conflict with the current ISO guidelines that are the basis of *ex-ante* LCA. While the mathematical models constructed in each are identical in their form, the processes are distinct. Table 2 summarizes the distinctions. For example, in ISO, the interpretation phases that place characterized inventories in context are optional. However, anticipatory LCA cannot proceed without them.

Specific aspects

Uncertainty

One of the most challenging aspects of anticipatory LCA is proceeding in an environment of extraordinary data uncertainty. There are two aspects of the challenge. The first relates to the scientific training of typical LCA analysts, who are habituated to seeking definitive answers to data questions. Most are uncomfortable building LCA models based on hypothetical, probabilistic representations of unknown parameters. Rather than treating uncertainty assignments as scientific hypotheses to be revisited later, many analysts regard such analysis as guesswork that undermines their credibility. Nevertheless, closer coupling of LCA with methods of stochastic exploration already familiar in environmental risk analysis (e.g., Walker et al., 2015) allows anticipatory LCA to proceed even when uncertainties span several orders of magnitude (Eckelman et al., 2012).

The second aspect relates to the commercial software tools available to carry out analysis under conditions of high uncertainty. To date, existing software packages do not automate internal normalization, stochastic exploration of weights, global sensitivity, or rank correlation analyses. Thus, pursuing anticipatory LCA requires custom programming, which may be the single biggest obstacle to its adoption.

Relative vs absolute

When environmental impact assessments became part of regulatory review requirements in the 1970s, they expected absolute assessments of consequences related to stakeholder concerns in measurable units such as excess cancer deaths. By contrast, relative assessments can be reported as a dimensionless preference ordering of alternatives, with such alternatives defined by stakeholders. Thus, relative alternatives assessment has the advantage of being less burdensome for steering developmental pathways towards preferential outcomes. In anticipatory LCA, alternatives must be developed by technology developers in cooperation with analysts and stakeholders.

Normalization

External normalization seeks objective benchmarks beyond the scope of the analysis as context from

Table 2 | Comparison of ISO guidelines to anticipatory LCA

ISO guidelines	Anticipatory LCA
Organized for TRL/stage-gate innovation	Organized for lean/agile innovation
Difficulties proceeding in the absence of data for environmental inventories & characterization factors	Assigns hypothetical probability distributions to essential parameters, allowing analysis to proceed
Emphasizes absolute determination of environmental impacts in characterized inventory	Emphasizes relative comparison of environmental uncertainties in global sensitivity/uncertainty analysis
External normalization typical, albeit not required	Internal normalization typical, albeit not required
Normalization & weighting optional	Normalization & weighting mandatory
No requirement for stakeholder engagement	Stakeholder engagement essential
Reports back a product environmental profile reflecting quality of execution relative to planned performance criteria	Reports back product environmental research priorities reflecting search outcomes

which to interpret characterized inventories. Although external normalization dominates LCA wherever normalization is carried out, research has shown that it can introduce biases that mask significant environmental tradeoffs (Prado et al., 2017). Because elucidation of decision tradeoffs is essential in technology development, internal normalization is preferable to external in anticipatory LCA.

Weighting
Considerable uncertainty exists in application of the proper weights to apply in all types of LCA. For this reason, many analysts avoid applying any weights at all. However, the failure to weigh different impact categories encourages decision-makers to accept equal weights as their default view, which is rarely representative of stakeholder values. In fact, weights (like all LCA data parameters) are uncertain. Thus, they should be subject to the same kind of stochastic exploration and sensitivity analyses as other aspects of LCA (Prado et al., 2020).

Stakeholder engagement
One of the essential distinctions between TRL/stage-gate and lean/agile is the emphasis that the latter places on investigating and engaging with customers, suppliers and other stakeholders in the innovation ecosystem. This aspect is often overlooked in LCA. However, several aspects of any LCA method benefit from direct inputs from stakeholder groups, including determination of functional unit(s), selection of relevant impact categories and preferred weight space constraints (Wender et al., 2014). The mechanism by which these might be elicited in LCA is anything but methodical. Typically, a diverse set of stakeholders are convened in a workshop setting that includes academics, LCA analysts, and technology developers to facilitate conversations that build the capacity for representing multiple perspectives. Regardless of elicitation methods, anticipatory LCA suggests exploring uncertainty in stakeholder-driven parameters. For example, Ganesan & Valderrama (2022) used an online survey to elicit impact category weights in an anticipatory LCA evaluating end-of-life technologies for silicon PV. In exploring the sensitivity of the resulting rank-ordering of preferred technologies, they discovered that preference rankings were sensitive to weightings. While they identified this sensitivity as an “important limitation” of anticipatory LCA, from the perspective of a technology developer or research funding agencies, revealing this sensitivity may also be perceived as a strength.

Product vs priorities
The single most important distinction between anticipatory and other methods of prospective LCA is the insistence of anticipatory approaches on exploring uncertainty in interpretation. For example, *ex-ante* LCA emphasises the environmental characterization of pre-market products, whereas anticipatory LCA focuses on identifying research priorities.

5.

Application of anticipatory LCA

Anticipatory approaches to LCA were designed in concert with technology developers and researchers seeking to incorporate environmental considerations into new technology development. Engagement with technology developers, even before stakeholders, is essential. Table 3 guides LCA analysts in dialog with developers by identifying analogs in LCA that correspond to questions that developers working in a lean/agile model must confront. Developers might be able to guide analysts toward answers for some of these questions, such as competing or incumbent alternatives or thermodynamic process models. However, proposed functional units are more likely to emerge in dialog with developers, while in some categories (e.g., environmental risk modeling), knowledge that is likely outside the technology developers’ expertise will be required.

Specific aspects

(in reference to ISO guidelines, cf. table 2)

Inventory building
Like other methods of LCA, anticipatory LCA requires constructing a mathematical model representing the thermodynamic (material & energy) process conversions at relevant stages of the life cycle, and the exchanges with the environment at each stage, including resource extractions & emissions. These steps are not novel to anticipatory LCA.

Characterization
Considerable uncertainty exists in the characterization of novel materials released to the environment. Rather than expect to improve risk-analytic models of fate, exposure and effect, anticipatory LCA allows the estimation

Table 3 | Guiding questions

Lean/agile	Anticipatory LCA
What problem is the technology solution attempting to solve?	What functional unit represents the effectiveness of the technology? What boundaries of analysis correlate to that unit?
Who has this problem?	Which stakeholders should be engaged?
What alternatives, competitors or incumbents offer solutions?	What alternatives shall be included in a comparative analysis?
What are they willing to pay for the solution?	What environmental values (e.g., impact categories & weights) represent stakeholder concerns?
What is the lifetime value of customers to the business enterprise?	What environmental liabilities (e.g., end of life) might be hidden from technology developers?
How is the product or technology created & delivered?	What are the thermodynamic (material & energy) requirements of the technology at each life cycle stage? How shall environmental risk assessment models/parameters be modeled for novel materials?
What is the set of minimum viable features to incorporate into the next product release? What is the next set of experiments necessary to develop those features?	To what processes or parameters is environmental assessment most sensitive?

of characterization as probability distributions that could hypothetically span several orders of magnitude. For example, in the case of nanomaterials, the exceptional heterogeneity of available variables makes characterization with confidence an extraordinarily laborious research task. However, allowing the analysis to proceed based on a uniform, log normal, or another probability distribution of risk parameters allows the analyst to explore the sensitivity of results to these risk-based uncertainties. In one case, the environmental impacts of nanomaterials manufacturing so dominated life cycle analysis that uncertainties in the fate and toxicological risk of novel nanomaterials were irrelevant to technology assessment (Eckelman et al., 2012). Thus, proceeding with the LCA analysis on the basis of estimates can reprioritize research resources towards uncertainties with the greatest impact or potential for improvement.

Normalization & weighting

Although optional under ISO guidelines, normalization is essential for anticipatory LCA. In particular, internal normalization techniques developed in multi-criteria decision analysis are applicable. For example, early efforts in anticipatory LCA were predicated on stochastic multi-attribute analysis (Prado-Lopez et al., 2014) that use pair-wise comparison for internal normalization and stochastic exploration of constrained weight spaces. However, other multi-criteria methods are also applicable. The advantages of internal normalization, compared to external, are principally two: (1) normalization relative to alternatives simplifies data requirements by obviating the need for selection of external normalization references, and (2) by avoiding bias and masking effects associated with external normalization, internal normalization is a better approach for elucidating the environmental tradeoffs that pertain to both stakeholder values and development decisions. The advantage of stochastic exploration of weight spaces is that it avoids privileging any default position. The disadvantage is that it requires additional computational effort. Existing commercial software packages in LCA do not automate internal normalization or stochastic weight exploration, which presents a barrier to pursuing anticipatory LCA approaches.

Sensitivity & uncertainty exploration

Where sensitivity analysis is conducted at all in LCA, it typically proceeds by identifying the sensitivity of environmental outcomes to variables that are (in the analyst's judgment) worthy of exploration. In addition to this approach, anticipatory LCA suggests global sensitivity analysis to identify those parameters that contribute the most to the uncertainty of outcomes. For example, Spearman rank ordering coefficients calculated in the anticipatory LCA of emerging PV technologies revealed counter-intuitive results regarding metals depletion and marine eutrophication that analysts may have otherwise overlooked (Ravikumar et al., 2018). Sensitivity results are sometimes presented as a tornado diagram that rank-orders the parameters that contribute most to uncertainties. This allows investigation of hypothetical experimental programs that might improve certainty (i.e., reduce uncertainty) to test comparative confidence. Those parameters that improve confidence in comparative technology assessment can be identified as high priorities for research.

6.

Recommendations and conclusions

Scholars of LCA for emerging technologies typically emphasize both the strength of the ISO guidelines and the necessity of departing from them (e.g., Bergerson et al., 2020). Recognizing that there are at least two models of innovation – TRL/stage-gate and lean/agile – will assist LCA analysts in matching a method of analysis that serves the needs of the development project. In general, TRL/stage-gate is found in large, well-funded organizations operating in mature markets like those for which ISO guidelines were originally developed. In contrast, lean/agile is found in start-up organizations and in large corporations seeking breakthrough innovations for markets that may not yet exist. Additionally, hybrid models of innovation are becoming increasingly common, especially as updated descriptions of stage-gate incorporate more recursive and flexible aspects of agile innovation.

Despite the applicability of anticipatory approaches to lean/agile models of innovation, the lack of automated computational tools in existing LCA software programs is a significant impediment to adopting and improving the methods. Incorporating internal normalization tools, stochastic exploration of constrained weight spaces, and global sensitivity analysis into available software packages would overcome the increased computational obstacles of anticipatory LCA, and likely lead to improved identification of environmental research priorities.

Anticipatory LCA outcomes can be used in a decision-making process where funding agencies, technology investors in industry or grantmaking organizations, or regulators are confronted with the question of having to decide on enabling, funding or authorizing an emerging technology development. This analysis suggests that continuing to explore and develop anticipatory LCA will be valuable to help identify and conduct an early assessment of possible environmental risks and threats to environmental sustainability embedded into emerging technologies.

However, it is too early to recommend that funding agencies and investors suggest or mandate the use of anticipatory LCA by technology developers. Nevertheless, from their perspective, formulating the guiding questions that would be asked during an anticipatory LCA process could help reveal the uncertainties embedded in the vision of the emerging technology design and possible outcomes. Anticipatory LCA offers funding agencies and other investors a basis for identifying those environmentally relevant hypotheses or research questions that are immediate, compared to those questions that are curiosity-based (e.g., at TRL 1) or made necessary by TRL/stage-gate criteria that may have little environmental relevance to the agile/lean innovation process that characterizes today's technology world.

Box 1: Development of the TRL model of innovation

The TRL model of innovation is consistent with the linear understanding of technological progress that has dominated research & development since the end of World War II. It is based on principles described by Vannevar Bush in his seminal research policy report to the President of the United States (Bush, 1945; Wender et al., 2012). In it, Bush advocated for government sponsorship of basic research, and cited disease and national security as motivating examples of the benefits that will accrue to society.

Bush argued that "Basic research is performed without thought of practical ends. It results in general knowledge and an understanding of nature and its laws."

He wrote:

> "Today, it is truer than ever that basic research is the pacemaker of technological progress. In the nineteenth century, Yankee mechanical ingenuity, building largely upon the basic discoveries of European scientists, could greatly advance the technical arts. Now the situation is different.
> A nation which depends upon others for its new basic scientific knowledge will be slow in its industrial progress and weak in its competitive position in world trade, regardless of its mechanical skill."

In other words, Bush argued for federal government investments in scientific curiosity, with the understanding that new knowledge created without concern for its application would provide an intellectual foundation for improvements in the "technical arts" that naturally followed later. As federal government funding for basic research expanded, American Universities underwent a gradual restructuring away from education in either the classics, or the practical arts (agricultural and mechanical) and towards government-sponsored basic science.

Examples of curiosity-driven, or even accidental, discoveries that later found ground-breaking practical applications, such as the laser, reinforced Bush's view. However, some of the most important technological advances of the 20th century did not develop along this path. For example, the invention of the solid-state transistor at Bell Labs was problem-driven. The creation of the first atomic bomb, and the moon landing, were organized around practical challenges, not scientific curiosity. In these cases, it can be said that basic science followed the need for practical application, rather than preceded it.

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Paper 11

Liability’s role in managing potential risks of environmental impacts of emerging technologies

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Introduction

This paper has been prepared in the context of EPFL International Risk Governance Center's (IRGC) project on ensuring the environmental sustainability of emerging technology outcomes. It discusses whether liability (or rather expanded liability regimes) could, and under which conditions, complement a portfolio of strategies, such as regulation, to manage emerging risks of emerging technologies and novel, innovative products. Could liability law take on a larger role than it currently has in managing these risks? For liability law to do so, it would have to generate adequate *ex-ante* incentives for good governance of innovation. However, liability laws are currently not designed to generate adequate *ex-ante* incentives in such cases. The paper thus focuses on the extent to which liability systems could be tuned to generate *ex-ante* incentives for good governance of innovation, and what the implications for technology developers and industry of such liability systems would be.

In this respect, a key issue is the generation of data before and after the introduction of new technologies and innovative products. Under civil liability law, this is the duty to investigate possible risks and disadvantages of new technologies. In theory, a technology developer or industry could be exposed to liability if (1) data is generated and (2) no data is generated, and it is hard to identify in a specific case whether the risk of liability exposure is larger with respect to the first or the second. From a theoretical perspective, it might be possible to identify an optimal point for data generation from the viewpoint of the liable entity, but, given that there is liability exposure associated with generating data, there is no reason to believe that this point will also be the optimal point from a public policy perspective.

The analysis presented in this paper is based on a rational, realistic approach to liability law and the likely response of potential liable entities to the incentives arising from liability exposure. The paper discusses both the possibilities and the limits of liability regimes in creating incentives for better management of the environmental sustainability of emerging technologies and innovative products, as well as possible approaches to mitigating the limitations of liability law and the pros and cons of such approaches. To illustrate the issues, a recent court judgment involving climate change is reviewed. The analysis suggests that liability law, given the self-interest of potentially liable entities and the epistemic and normative limitations of courts of law, is an inherently limited instrument in managing emerging risks of emerging technologies and novel, innovative products. Effective ways to eliminate (some of) the barriers to expanding liability exposure are likely to impose significant costs that need to be weighed carefully against their benefits.

1.

The issue

Invention, new technologies and innovation are critical to sustaining an increasing world population with ever growing demands. New technologies often provide substantial benefits to mankind, and enable human development, economic growth and prosperity. New technologies, however, also create uncertainty, because the experience with them is limited. In some cases, technologies turned out to have unforeseen adverse effects, in particular on human health and the environment. The issue discussed in this paper is what role civil liability can play in managing and controlling the risks of environmental impacts of emerging technologies.

The analysis presented here reflects common features of civil liability law in Europe. There is no uniform Europe-wide liability law, so liability systems and rules differ between countries. There are also commonalities, however, and the issues arising in the application of the rules tend to be similar. A broad distinction can be made between common law jurisdictions, such as the United Kingdom and the United States of America, and civil law jurisdictions, such as those of continental Europe.[2] This distinction is not relevant, however, to many of the issues discussed in this paper. A potentially more relevant factor is that liability systems evolve over time, and that the rate of evolution differs between jurisdictions. Despite (temporary) divergence on some issues, a discussion of common features and trends is useful to illustrate the issues arising

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[2] For a discussion of differences between European and US civil liability litigation, see Bergkamp, L., & Hunter, R. (1996). Product liability litigation in the US and Europe: Diverging procedure and damage awards. Maastricht Journal of International and Comparative Law, 3, 399–418.

in relation to emerging technologies. The focus in this paper is chiefly on continental European liability systems. Liability of the legislature, executive government and regulators is not covered in this paper.

1.1 Regulation in general

To control the risks associated with emerging technologies, governments have adopted regulatory regimes. These regulatory regimes are typically specific to groups of products or sectors, and deal with technology outcomes such as genetically modified organisms, pesticides and other chemical substances. The instruments employed in these regimes typically involve duties imposed on the producer to investigate and test for potential hazards and risks, reporting obligation, permitting obligations, monitoring obligations, and notification obligations. In general terms, the objectives of these regulatory regimes are to identify and manage risks associated with emerging technologies, while allowing their deployment under certain conditions.

It has been recognized that regulatory approaches to controlling the risks of emerging technologies can have various disadvantages. These kinds of regulations generally require deep knowledge of the industries, and technologies involved. This knowledge is present within the industry to be regulated, but not necessarily in the regulatory agency. Agencies, to a not insignificant extent, may have to depend on industry representatives to obtain the information that enables them to regulate effectively and intelligently. This presents a risk of “regulatory capture,” and a regulatory agency that is created to act in the public interest ends up advancing the commercial interest of an industry or sector the agency is charged with regulating.

Another disadvantage of regulatory approaches is their inherent “one size fits all” approach. Although regulations can be drafted to allow for flexibility and even adaptation, they typically impose a relatively rigid set of generic rules. These rules may work well for some cases, but in other cases they do not produce good results. Furthermore, the scope of regulations is an important preliminary consideration — if emerging technologies fall outside the scope of existing regulatory regimes, they may not be subject to regulation.

1.2 Regulatory duty to test

These kinds of regulations typically impose a duty to investigate or test for hazards or risks belonging to categories that have been defined in regulations. The producer is not required to examine whether a new product poses any new hazards or risks that do not belong to any of these categories or are not picked up by the test methods prescribed by regulations. In relation to testing, the same issue as discussed above arises: the regulations may work well for some products or technologies, but may be inadequate for other technologies. For instance, the testing of chemicals under the EU Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulation was deemed to be inadequate for chemicals in nano-form, and the rules have been amended to address nano-substances specifically.

Regulatory duties to investigate and test not only involve generalizations necessary for a regulation to apply to a broad category of products, they also necessarily involve a trade-off between, on the one hand, the interest in the upfront identification and control of hazards and risks, and, on the other hand, the interest in allowing the introduction of new technologies so that their benefit can be reaped.

Due, in part, to the issues discussed above and the trade-offs involved in any regulatory regime, the question arises whether regulations for products of emerging technologies lead to an optimal or even an adequate upfront risk prevention or control. In some cases, the regulations may be deemed to be inadequate in managing risks of specific techniques or applications. In these cases, other regimes may be deemed necessary to provide for further incentives for risk management. Liability is such a regime.

1.3 Liability in general

There are three types of liability: administrative liability, criminal liability and civil liability. Administrative liability means that regulated entities may be exposed to administrative sanctions, such as fines or loss of a right, if they violate their regulatory obligations. Criminal liability involves criminal fines or imprisonment that may be imposed if corporations violate specific criminal statutes in relation to the endangerment of human health or the environment. The threshold for criminal liability is typically higher than for administrative liability.

Civil liability, which is the focus of this report, is a corporation's exposure to an obligation to pay compensation (or to do some act or refrain from doing some act), where the corporation breaches a duty of care under civil law, i.e., the law that governs the relations between private parties. Civil liability can be imposed if another private party brings (or threatens to bring) a lawsuit against the corporation concerned. The most common type of liability requires that the claimant establish that (1) it suffered a harm, (2) the corporation breached a duty of care, and (3) there is a causal link between this breach and the harm suffered by the claimant. In short, liability requires damage, negligence and a causal link. In relation to all three requirements, complex issues can arise, particularly in relation to products derived from emerging technologies.

Liability can be viewed as a remedy or sanction for non-compliance with regulations. Where it serves in that role, liability is another sanction for non-compliance imposed through the civil law system. A modern concept of civil liability, however, often goes beyond administrative violations. In this conception of liability, it functions as a system for filling in the gaps in the regulations and for supplementing regulations where they do not extend far enough. It might even be viewed as a system for correcting regulations where they are inadequate.

It is important to understand that regulation is an *ex-ante* approach that may also impose some *ex-post* obligations (e.g., an obligation to report if harm is caused), while civil liability is an *ex-post* approach (it kicks in only after there is harm or imminent harm) that ideally generates *ex-ante* incentives. Because liability threatens to hold companies that cause harm liable, companies have incentives to reduce the risk of harm, at least up to the point where the marginal costs of doing so is lower than the marginal cost associated with compensating the harms caused.

1.4 Could liability take on a larger role as a risk management tool?

As discussed above, in addition to regulation, liability law can play a role in managing the risks of emerging technologies and novel, innovative products. For liability law to do so, it must generate adequate *ex-ante* incentives for good governance of innovative technologies. Currently, due to issues such as evidentiary obstacles, liability laws are not designed to generate adequate *ex-ante* incentives in all cases; the question is whether tinkering with liability law to achieve an optimal incentive structure would be possible or desirable.

The analysis presented in this report focuses on three main questions:

1. What are the reasons as to why liability does not necessarily generate adequate *ex-ante* incentives for risk management? Barriers to liability's proper functioning.
2. How can liability systems be tuned to generate *ex-ante* incentives for good governance of innovative technologies? Possible remedies to liability barriers.
3. What are the implications of such liability systems for technology developers and policymakers? Implications of possible remedies.

The discussion of these questions is illustrated with considerations and examples that are specific to environmental effects of the products of emerging technologies. This combination raises a level of complexity that poses challenges to civil liability systems.

The generation and availability of data before and after the introduction of new technologies and innovative products is a key issue in relation to the questions. A company that introduces products derived from emerging technologies will have to comply with applicable regulatory requirements and generate the environmental safety data required by such regulations. Increasingly, product regulations require pre-authorization based on the provision of environmental safety data. Under civil liability law, the generic duty to investigate possible risks and disadvantages of new technologies may or may not result in the *ex-ante* generation of data not required by applicable regulations in specific cases. In theory, a company that places an innovative technology or product on the market could be exposed to liability (1) if no data is generated beyond regulatory requirements, but also (2) if data is generated where there is no regulatory requirement. In a specific case, it is hard to assess whether the risk of (1) is larger or smaller than the risk of (2). From the perspective of coherence of the law, ideally, there should be an optimal point at which one should be able to say that the data generated are sufficient, but not excessive. Given that there is liability exposure associated with generating data, however, the optimal point for a potentially liable entity is unlikely to coincide with the optimal point from a public policy perspective.

In this study, elements of liability law that impact this balance are identified and discussed. Adjustments to these elements to augment the incentives to generate data are proposed. This study then places the possible remedies in perspective and introduces the concept of balance. It also considers the public/private good (negative versus positive externality) distinction. Based on this broad analysis, the study discusses what liability systems can mean for the management of risks arising from emerging technologies from the perspective of technology developers and policymakers. The focus is on the challenge of damage to the environment (or, to use a somewhat vague term, "environmental sustainability"). Innovative products derived from emerging technologies may pose uncertain risks to the environment that manifest themselves only in the long-term or after addition or accumulation. There may be a lack of data and tools to perform comprehensive technology and risk assessment at the time when the technology is being developed, and even during early deployment. Could liability help to ensure that new technologies do not cause or contribute to environmental harms, and thus help to ensure long-term "environmental sustainability"?

2.

Barriers to liability's proper functioning

There are several reasons as to why liability does not necessarily generate adequate incentives to generate data *ex-ante*. Some of these reasons are generic and relate to the structure of the corporate law and liability systems, and some are specific to features of the current liability system. Below, we will review the most common barriers to liability's proper functioning as a system for creating data generation incentives.

2.1 Limited liability

Limited liability implies that the shareholders of a company, subject to limited exceptions, are not liable for the company's debts. Put differently, the assets available to a company's creditors are limited to those of the company, to the exclusion of the assets of its owners. Limited liability presents a problem for liability's proper functioning, because the incentives arising from the obligation to compensate harms caused will not have any effect on the company's conduct to the extent that the obligation exceeds the company's assets.

This problem is known as the "judgment-proof" problem, which arises also in parent-subsidiary relationships, as each legal entity, in principle, benefits from limited liability. In the context of emerging technologies, by establishing separate companies that commercialize the technology, corporate groups can shield their other assets. There are various solutions to this problem that are discussed in section 3, below.

2.2 Cost of lawsuits and small harms

On the side of the victim, called the "plaintiff" in liability law, there are incentives to sue a company that has caused harm, because the plaintiff could receive compensation. There are also disincentives, however, to initiating litigation, including attorney fees, court fees, possible counterclaims, and stress. If the harm, and thus, the amount that can be recovered through a law suit is small, the cost of a law suit weighs more heavily. This may be true even if a company in the aggregate has caused substantial harm. If many victims each suffer a small harm, none of them individually would have an incentive to sue. This is known as the rational disinterest phenomenon: when harm is wide-spread and individuals have a very small stake, they have no incentive to sue. The solutions to this problem are discussed in section 3, below.

2.3 Harm to the commons

A comparable problem arises if a company causes harm to common goods. If a company causes harm to the unowned environment, e.g., to public land or to wild animals, no one may have a claim on the company. Even if it is possible to assert claims, no one may have an incentive to sue because no one has suffered a compensable harm. In some jurisdictions, governments or their agencies may have claims against companies that damage public goods. Other solutions to this problem are discussed in section 3, below. Examples of products derived from emerging technologies that may cause harm to the commons include new hazardous chemical substances using advanced materials that could cause environmental harm if critical thresholds are exceeded, and products whose manufacturing process releases greenhouse gases that have adverse effects on the climate system.

2.4 Negligence

The dominant concept of liability is fault liability or negligence. Implicit in this type of liability is the concept of the duty of care. Under fault liability or negligence, it is not sufficient that a company caused harm – the company must also have breached a duty of care applicable to it. The flipside is that a plaintiff must prove that a company had a duty of care and breached it. This requirement serves as a barrier to holding companies liable, because it is hard to prove negligence and a plaintiff may fail.

The counterpart of fault liability is strict liability, also known as no-fault liability. Strict liability is imposed only in specific areas of liability law; fault liability is the generic regime by default. Needless to say, strict liability lowers the barriers to holding companies liable, because it eliminates the requirement that a company has breached a duty of care; it is sufficient that a company's conduct caused the harm.

2.5 Causation

Under both fault and no-fault liability, a plaintiff must prove that the company caused the harm that the plaintiff wishes to have compensated. The legal test for causation differs; a common test is the necessary condition test, or *conditio sine qua non*. Causation may be straight forward, where, for instance, a company has introduced an innovative product that turned out to be unsafe and caused a unique "signature" harm in victims. Generalized causation asks the question "does this kind of product (e.g., an innovative pesticide) cause this kind of adverse effect (e.g., abnormal level of death in fisheries)", while individualized causation asks "did the defendant's product (e.g., some innovative pesticide) cause the adverse effect suffered by the plaintiff (e.g., actual dead fish)".

There are several complications that may arise in determining causal links between technologies or products and harms. Many of these situations involve several or many causes and several or many victims, and they often arise in cases of environmental harm (or harm to environmental sustainability), including harm due to products derived from emerging technologies. These are common types of causal complications:

- **Overdetermined causation (preemptive causation and duplicative causation).** In some cases, there are multiple causes for which multiple defendants are responsible. A textbook example is the firing squad — a man is hit by seven bullets simultaneously, and each of the bullets would have been sufficient to cause the man's death. An example in the area of environmental damage may be the long-term consequences of the use of chemicals such as plant protection products (or pesticides) in agriculture over a long period of time, which might result in diffuse, but widespread pollution of aquifers above non-observable effect levels for groups of chemicals in a large geographical area. In this case, the cumulative effect of only some of the chemicals might be sufficient to cause the harm, so some of the pollution is redundant from a causation viewpoint.
- **Indeterminate defendants**. Several or many companies have each marketed the same technology or product that is known to have caused injury. Victims, however, cannot tell which of these companies has caused the injury in their specific case because the technologies or products sold by the companies cannot be distinguished. In the agricultural pollution example set forth above, it may be impossible to determine which farm or farmer used the products that resulted in the contamination, so it may not be possible to hold any farmer liable.
- **Indeterminate plaintiffs**. A single company may have marketed a technology or product that is known to have caused injury to victims, but these victims are indistinguishable from other people suffering from the same injury caused by natural causes. An example is a product that causes an increased incidence of leukemia, which also occurs spontaneously in the population. Some asbestos-related cancers fall into this category (but not mesothelioma, which is most often caused by asbestos exposure and is therefore called a "signature harm").

For each of these problems there is one or more solutions, which are discussed in section 3, below.

A particularly difficult issue is deep causal uncertainty. In these kinds of cases, there is some evidence of an association between a putative cause and a potential adverse effect, but the evidence is not sufficiently strong. The *conditio sine qua non* test is not met. The causal link between neonicotinoids and harm to bee populations discussed in Sach's paper[3] is a case in point: there are several causes of harm to bee populations which act in combination, biological mechanisms are complex, scientific studies and risk assessments were biased, data and advice diverged, and decision-making was politicized.

2.6 Liability for harms caused by others

As a general rule, a legal entity is liable only for the harms that it caused, not for the harms caused by other persons. There are exceptions to this rule, however. An important exception is the doctrine of joint and several liability. This doctrine may apply where several companies engage in unlawful conduct that causes one indivisible harm. For instance, each of them marketed a chemical substance that has contaminated the environment, and each of them is liable for the entire harm caused. In the agricultural pollution example discussed above, if joint and several liability applies because the pesticide usage was unlawful (e.g., due to a higher dosage than permitted, or use outside the permitted season), each of the farmers that can be shown to have used the relevant pesticides could be held liable for all of the aquifer pollution.

Companies are generally liable for harms caused by their employees, subject to limited exceptions, and, in some instances, also for harms caused by independent contractors performing a specific task for the company. In general, companies are not liable for harms caused by their business partners, even if they have superior risk management knowledge and could have used their influence to prevent the harm. Novel concepts of liability extend the liability of multinational enterprises to the harms caused by persons that use their products or by business partners within their supply chain (see further section 3, below).

2.7 Burden of proof

Under liability law, the plaintiff typically bears the burden of proof. The burden of proof is to be distinguished from the standard of proof, which is the standard by which a court determines whether the burden of proof is met, and the burden of production, which relates to the obligation to make information available (known as "discovery" under US law). The burden of proof effectively implies the burden of persuasion.

Proving negligence and causation can be very challenging if the plaintiff does not have the necessary information and expertise. These are two separate issues, and require different kinds of solutions. In section 3, below, possible solutions are discussed.

2.8 Liability due to data generation

As noted above, there may also be liability associated with the generation of data. For instance, if a company conducts testing of a technology or product not required by regulation, and generates additional data on the technology or product, this data may result in the company being able to improve the technology or product or its use and application. However, it may also not enable the company to take any measures to reduce or mitigate the hazards or risks associated with the technology or products.

In these cases, the additional data could become a ground for claims in a later phase. For instance, if the additional data show that there is a hazard or risk associated with the technology or product, it could be argued that consumers or users should have been warned, but even if they were warned, it could be argued that the technology or product was defectively designed and should not have been placed on the market. If there is a regulatory obligation to disclose or report any such additional data the disincentives to generate the data may even be stronger, because it would imply that the data would be available to government agencies or even the general public. This issue may be particularly relevant in the context of ensuring environmental sustainability of emerging technologies, since it would tend to counsel against generating environmental safety data that is not required by regulation.

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[3] See the paper written for the ESET project by Rainer Sachs, "Risk governance of emerging technologies: Learning from the past" (2022).

2.9 Claim expiration and long tail damage

Liability laws typically impose time limitations within which claims must be brought. If these limits are not respected, claims will lapse and can no longer be pursued. There are two types of such limitations: time limits triggered by the plaintiff's knowledge (i.e, of the injury and the defendant's identity), and time limits triggered by the lapse of time (e.g., all claims expire 30 years after the event that caused the harm). Complications arise if the relevant event extended over a long period of time and caused harm continually, or if it is not clear what the relevant event is (e.g., the product has been spilled into the soil but not yet migrated into the groundwater, which may be the harm at issue). There are ways to address such complications (see section 3, below).

In some instances, a long time may elapse between the exposure to some technology or product and the injury caused thereby becoming apparent. This is the problem of "long tail" harm. An example is cancer caused by exposure to a new chemical substance; it may take years and years before the cancer will manifest itself. In the case of emerging technologies, the issues posed by "long tail" damage are acute if it takes decades before both the environmental harm and the association with the technology become apparent. The potential adverse effect on the ozone layer of chlorofluorocarbons (CFCs), which had been in commercial use since the 1930s, was not discovered until 1985, as Sach's paper[4] discusses.

3.

Possible remedies to liability barriers

Section 2 discussed barriers to liability's proper functioning. Due to these barriers, liability cannot or does not fully play its useful role in generating incentives for optimal or adequate risk management of emerging technologies and innovative products. Many of these barriers are common to the main legal systems of European nations. To improve liability's role in risk management, these barriers should be addressed. There is also a flipside to the possible solutions, however, since all of them have their pros and cons.

In this section, the focus is on possible solutions for the barriers identified in section 2. This discussion does not attempt to identify and evaluate possible negative side effects of each option, such as the negative consequences for incentives to innovate. In section 4 below, however, some comments are made on this problem, as there often is a balance to be struck between competing interests.

3.1 Solutions to the "judgment-proof" problem

An obvious solution to the problems posed by limited liability is abolishing limited liability. Unlimited liability would imply that the shareholders of the company would be liable for the company's debts, so there would be more assets available to satisfy the claims of the victims of the company's harmful conduct. Shareholder liability could be either joint and several liability or proportional to the percentage of each shareholder.

Abolishing limited liability, however, has broader implications for the economy and in particular for innovation. Put in simple terms, it would discourage risk-taking in innovation because it would shift more of the cost to the owners of the technologies and products. To mitigate this potential adverse effect on innovation, it has been proposed to abolish limited liability only in the context of corporate groups, which is known as "enterprise liability" and is similar to the theory of "economic unity" employed in competition law. Under this approach, natural persons that are shareholders would not be exposed to liability.

3.2 Cost recovery and collective claims

To eliminate the disincentives arising from the cost of bringing lawsuits, legal aid can be provided. A more appropriate way to address this issue, however, is to allow a successful victim to recover its cost from the defendant. In Europe, the rules regarding

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[4] See the paper written for the ESET project by Rainer Sachs, "Risk governance of emerging technologies: Learning from the past" (2022).

cost recovery often provide for only limited, partial recovery. A more generous approach that covers the full, actual cost would improve the current situation.

Small claims could be handled in separate, low-cost procedures before specialized “small claims” courts. Where many small claims are against the same defendants and are related to the same technology or product, a collective claim procedure can be used to create economies of scale. In many countries, such procedures now exist.

3.3 Public interest litigation

To create incentives to initiate law suits against companies that have harmed the commons, regimes of public interest litigation have been established. In Europe, the right to sue is often granted only to legal entities specifically established for the purpose of protecting consumers or the environment. Citizens are often not able to bring such law suits, since they are not granted standing or are deemed not to have legally protectable interests.

3.4 Strict liability

Compared to fault liability (negligence), strict liability lowers the barriers to prosecution, because it eliminates one key hurdle towards recovery – it does not require a showing of a duty of care, nor of breach of any such duty. Consequently, liability is more likely to generate proper incentives for data generation, as it now is up to the company concerned to decide whether further data are in the interest of risk management and the company will be exposed to the consequences of its decision. Thus, in the case of emerging technologies, a shift from fault to strict liability would help to ensure their environmental sustainability, assuming the disincentives arising from regulatory disclosure and reporting obligations do not override the incentives arising from this shift.

Quasi-strict liability is fault liability under which the duty of care is so onerous that it is virtually impossible to meet it. For instance, if a court finds that a company has a duty to investigate extensively all possible hazards and risks of a technology or product prior to placing it on the market, in practice,

Examples of risks of products that were not known at the time the product was first introduced

- Risks for human health associated with smoking were not generally known when cigarettes were first produced at an industrial scale. Regulations did not require that these risks be investigated, but, once these risks became known, regulations required disclosure through labeling and notices in ads. Despite these more stringent regulations, tobacco companies were not necessarily deemed liable for health damage. In these cases, the defense of “risk assumption” and the question of the (intentionally enhanced) addictive nature of cigarettes were issues.
- The risks associated with inhalation of asbestos (mesothelioma, lung cancer) were not known when workers were exposed to asbestos in the workplace. When regulations imposed risk management measures, both asbestos producers and companies that exposed their workers to asbestos were held liable based on the theory that they knew or should have known of the risks prior to the regulations being amended.
- A group of chemicals known as per- and polyfluoroalkyl substances (PFAS), which were the outcome of emerging technology at the time, was used widely in non-stick cookware, water-repellent clothing, firefighting foams, food packaging, and other products that resist grease, water and oil. Most PFAS are non-biodegradable and persistent in the environment. Due to these properties, they have been regulated, including under the Stockholm Convention. In high concentrations, PFAS are associated with human carcinogenic and teratogenic effects. Under EU law, perfluorooctanoic acid (PFOA), for instance, has been classified as suspected to be carcinogenic, toxic to reproduction, persistent, bioaccumulative and toxic, and a persistent organic pollutant. At low levels of exposure, uncertainties about the effects of PFOA remain.

this duty cannot be met and fault liability is turned into something that resembles strict liability. For instance, assuming neonicotinoids cause harm to bees, if a court were to rule that the producers of neonicotinoids had an obligation to investigate this effect of their products (even though it was unforeseeable), producers would effectively be exposed to strict liability. As noted above, in the case of emerging technologies, a strict liability rule may be beneficial in terms of controlling the risk (or ensuring "environmental sustainability").

As liability shifts from fault to no fault, however, there may also be shifts in the causal requirements. For instance, under strict liability, there may be a tendency to apply stricter causal requirements, so that some of the harm will be deemed not to have been caused by it.

3.5 NESS and proportional liability

The problem of overdetermined causation can be solved by applying a causal test that asks whether the specific cause under review is a necessary element of a sufficient set (NESS). If, for instance, five units of a chemical were necessary and sufficient for the injury and each of seven defendants discharged one unit of the chemical, each defendant's one unit was neither necessary nor independently sufficient for the injury. However, each defendant's unit was necessary for the sufficiency of a set of actual antecedent conditions that included only four of the other units, and the sufficiency of this particular set of actual antecedent conditions was not affected by the existence of two additional duplicative units.

Problems of indeterminate plaintiffs and defendants can be resolved by concepts of proportional liability. Under these concepts, liability is not treated as an all or nothing decision, but as a matter of degree. The concept of relative risk can be used here – if the defendant's act increased a background risk by 25%, the defendant is responsible for 25% of the harm if it materialized. In cases involving indeterminate defendants, the market shares of the companies concerned can be used as a proxy for proportional causation – each company is liable for a portion of the injury that corresponds to its market share (e.g., if a company had a 25% market share, it is liable for 25% of the damage).

These solutions can be directly relevant to environmental harms caused by products derived from emerging technologies. In the case of multiple sources of pesticide pollution resulting in diffuse, widespread environmental contamination, for instance, theories of proportional liability can be employed to determine the share of the damage that should be imputed to each pesticide user. Each user's percentage of the total usage of the pertinent pesticides could be a rational basis for allocating liability.

3.6 Expanded joint liability, liability for other companies, and director liability

Under the theory of joint liability, a company can be held liable for a single indivisible loss for which it is only partially responsible and which has been co-caused by a possibly large number of other parties. A company that bears a small share of the responsibility for a plaintiff's injury can be compelled to pay all of the damages. Joint liability enables plaintiffs to seek out defendants with large resources ("deep pockets"). Note that joint liability goes a step further than proportional liability and is more favorable to victims. Joint liability could be expanded by relaxing the conditions applicable to finding a single injury. For instance, if the aggregate loss suffered by all victims jointly is considered an indivisible harm, joint liability would apply.

Joint liability only covers single indivisible harms to which the defendant contributes, and does not extend to harms caused entirely by other entities. Under novel liability concepts, however, damage caused by other entities may entail the liability of, typically, a large multinational company (also known as a "deep pocket"). These other entities may be direct or indirect customers for the company's products or other business partners within their supply chain. Concepts such as corporate social responsibility, product stewardship, extended producer responsibility and supply chain responsibility provide a basis for such novel liability theories. Under the theory of supply chain liability, a multinational corporation is liable for harms caused by the business partners up and down its supply chain, typically based on the doctrine of negligence (but the standards may be demanding so that it effectively becomes quasi-strict liability). The idea is that large multinational corporations have a duty to take measures to prevent harms caused by other entities over which they have some level of control; if they fail to meet this duty and harm arises, they are exposed to liability.

Expanded director liability would result in directors having individualized incentives to ensure that the company takes adequate measures to prevent and manage hazards and risks. Director liability could be triggered on the basis of the same standards that apply to the company's liability. In theory, this kind of liability could alleviate the problem that directors are inclined to allow a company to take too much risk, e.g., because it increases profits and thus their own compensation.

3.7 Alleviating the plaintiff's burden of proof

There are several ways in which the law can assist a plaintiff in meeting its burden of proof. First, the defendant can be ordered to produce information relevant to the plaintiff's claim. This is particularly relevant in cases in which the defendant controls the relevant information. Second, once the plaintiff has made a *prima facie* case that its claim has merit, the court may shift the burden of proof to the defendant. Third, the court may lower the standard of proof in complex cases and, for instance, allow the plaintiff to proceed on the basis of the "weight of the evidence" approach.

The precautionary principle also provides a way to alleviate a plaintiff's burden of proof. Where there is scientific uncertainty about the pertinent causal relation and the plaintiff has been able to demonstrate some sufficient association, a court could decide to shift the burden of proof to the defendant. If the defendant is unable to disprove a causal link, they will be liable. In cases involving genuine deep causal uncertainty, such a reversal of the burden of proof would invariably result in defendants being held liable for harms they may not have caused.

3.8 Exoneration from liability

To counter the disincentives arising from the generation of additional data, a company could be shielded from additional liability exposure arising from such data. For instance, a company could be exonerated from additional liability if it has demonstrated to the regulatory authorities that it made responsible risk management decisions based on the additional data.

3.9 No expiration

There is also a possible solution to the problem of long tail damage. If a company knew of the risks posed by its technology or product, but failed to take appropriate action, the law could provide that the claims plaintiffs may have in relation to such risks will never expire.

3.10 Human rights

Recently, courts in The Netherlands have based civil liability on human rights, instead of conventional civil liability theories. In many ways, resorting to human rights represents the "nuclear option," because it upsets the concepts and rules that otherwise apply. First, the Dutch Supreme Court confirmed the ruling in Urgenda's case against the state of The Netherlands. Based on an imminent breach of the human right to life, the state was ordered to increase its emission reduction target from 20% to 25% by the end of 2020 (relative to 1990 levels).

Then, the The Hague District Court ruled in favor of Friends of the Earth in a case against Shell. Shell was ordered to ensure that by 2030 its group-wide and world-wide carbon dioxide (CO_2) emissions are reduced by at least 45% relative to 2009. This obligation applies to Shell, all of its subsidiaries, all of its suppliers, and all of its customers (thus, scope 1, 2 and 3 emissions). This judgment is currently being appealed. The Hague Court of Appeal has full authority to confirm or overrule the judgment in first instance. In either case, it is likely that the case will go to the Dutch Supreme Court, which may review only issues of law.

Climate judgment against Shell

The climate judgment against Shell was revolutionary, even after the Dutch Supreme Court's ruling in the Urgenda case. The reasons as to why it was revolutionary become clear once we compare this judgment to conventional liability rules.

- In Shell, the legal basis for liability was not negligence, but a court-invented "social duty of care" which boiled down to the obligation to respect the human right to life. To this end, the court construed this right to encompass a "right to a safe climate." Consequently, no complex analysis of the benefits and costs of taking preventive measures against climate change, which would ordinarily occupy the court, had to be done.
- The court found that CO_2 emissions cause "dangerous climate change" and violate the right to a safe climate. A safe climate was defined with reference to the Paris Agreement's target of limiting the temperature increase to 1.5 °C. It found that Shell would encroach on the right to a safe climate in the future. To compute how much Shell's emissions should be cut back the court applied the concept of the carbon budget, imposed a pro rata reduction obligation on the basis of equality, and used a linear reduction pathway. Again, in this way, all complexities could be avoided that are typically associated with arriving at individualized obligations for future harms to the commons.
- Having found a right to a safe climate, the court did not have to worry about the question as to what the harm is. Friends of the Earth did not have to demonstrate any harm or threatened harm; a mere reference to the Intergovernmental Panel on Climate Change (IPCC) and other reports on the possible consequences of global warming were deemed sufficient to establish a relevant possible future injury to the right to a safe climate. The precautionary principle played a role in the court's reasoning as well.
- As a result of the court's rights-based reasoning, the question of the causal link between the emissions for which Shell is deemed responsible and the (future) damage to the climate became moot. It was no defense that Shell's emissions are not a *conditio sine qua non* for the threatened harm, nor that global emissions are not projected to decrease to the level necessary for reaching the 1.5 °C limit. Shell was held to bear a partial responsibility for reducing its emissions and the causal analysis was limited only to Shell's portion of the currently foreseeable harm to be prevented by it.

In short, by shifting the legal basis to the human right to a safe climate, the liability regime changed fundamentally and many of the complicated issues disappeared. Because of this fundamental change of civil liability law, the court has been criticized for overstepping its authority, ignoring the separation of powers, acting as an unauthorized substitute-legislature, breaching the rule of law, and setting aside democracy. These issues will be debated before the The Hague Court of Appeals in the fall of 2022.

4.

Implications of possible remedies

In theory, if all of the remedies discussed in section 3, above, were implemented, liability could provide stronger incentives for innovative companies to anticipate possible hazards and risks of their products. Indeed, liability could play a stronger role in managing the risks of emerging technologies and innovative products by increasing the extent of responsibility to be borne by the company if harm arises.

The implications for policymakers would appear to be clear — they should implement the remedies discussed in section 3, above, to give liability a stronger risk management role. However, the analysis provided in this report is incomplete and has not considered the possible adverse effects associated with the remedies. In other words, comparative and marginal cost-benefit analysis would have to be done to determine which possible liability reforms are attractive. A generic problem with all possible remedies is that they may have a chilling effect on inventers, innovators and technology developers — the fear of exposure to potentially large claims may deter them from engaging in invention and innovation. This chilling effect is undesirable from a public interest perspective because it would deprive society of the benefits of innovative technologies and products. At the same time, the preservation of the environment and the pursuit of environmental sustainability are also major public interests that are protected by laws and that many governments have stated they wish to prioritize above economic interests, albeit not at any cost.

Unavoidably, there are countervailing considerations. For liability to play a role in ensuring the environmental sustainability of emerging technologies, the judiciary should be both normatively and epistemically legitimized in expanding its mission. This implies that the judiciary should have been granted the authority to apply liability regimes to the issues raised by environmental sustainability of emerging technologies. It means also that the judiciary should have access to all necessary information, data and analysis, understand everything that was provided, and be able to make sound decisions on that basis. Needless to say, this is a tall order. Judicial resort to human rights (also called "humanrightsization") in the Dutch climate cases has been controversial precisely because it raises issues of judicial authority (may a court expand the undefined right to life to include a specific right to a safe climate) and the epistemic capabilities of judges (can judges understand the relevant science and climate policies, and make sound, informed, balanced and science-based decisions).

The task for policymakers may not be to revolutionize the liability system, but rather to adjust the rules in an iterative, adaptive manner, based on the effects on both compensation of harms (in this context, harms to the environment or "environmental sustainability") and the rate and nature of innovation. Some, but probably not all of the features discussed in section 3, above, could be included in such a programme.

For companies developing innovative technologies the challenge would be to distil clues or signals from the abstract, general set of liability rules. If a company is to be encouraged to generate additional data beyond regulatory requirements, it needs to be able to determine whether data generation will avoid liability in the future. Such assessments are hard due to the imprecision of liability standards. Nevertheless, two general rules of thumb for technology developers might be derived from liability law:

- Make sure you are on top of the science, monitor new scientific publications relevant to your technology and products, and analyze their implications; and
- If there are gaps in the data on the technology or product, consider generating additional data.

This guidance is particularly relevant with respect to ensuring the environmental sustainability of emerging technologies because there tends to be more uncertainty around environmental impacts in these kinds of situations, particularly with regards to long-term impacts.

A liability system that is well adapted to addressing harms caused by outcomes of emerging technologies (such as harm to the environment or environmental sustainability) should be balanced, reasonable and predictable. Below, each of these concepts is discussed in more detail. Before doing so, a few comments on public goods are in order.

4.1 Public goods

A private good is characterized by rivalry and excludability. A public good, on the other hand, is characterized by non-rivalry and non-excludability, with semi-public goods having only one of these characteristics. Information, by definition, is a semi-public good, because there is no rivalry in its use; excludability determines the value of data to a private entity. If a company generates data on its technology, such data may be a private good owned and controlled by the company that paid for it; competitors may not be able to benefit from the company's efforts.

The trouble with data on a technology's or product's environmental and health effects, however, is that the information may have to be disclosed either to be effectively deployed or as a matter of law. Where that is so, the data becomes a public good available to all. This creates a "free rider" problem, as only one company paid for the data and all other entities can use it for free. The free rider problem generates a disincentive for data generation by a single private entity.

Despite the free rider problem, data may still be generated by companies (but not necessarily shared with others) if they perceive there to be a net benefit, for instance, on one of the following grounds:

- The company is a market leader and can reap other benefits from data generation, such as increasing its opportunities in the marketplace, using the data to shape industry standards that benefit the company itself, or building its reputation as a responsible corporate citizen.
- The company that generates the data has a significant timing advantage, because it will have access to the data earlier than its competitors and, thus, can make adjustments before they can, which gives the company a competitive edge.
- The data generation is funded by a group of companies, so that the cost can be spread over a number of entities.
- Under the applicable law, the company that generated the data is entitled to require that other entities using the data pay a cost share.

The lesson to be learned is that, if the liability system is to generate incentives for the creation of data by private companies, and such data are a public good, additional legal or regulatory regimes may be necessary to ensure that data are effectively created and made available to all those that need access. It is one thing for a company to generate additional data in its own self-interest but quite another thing for a company to generate data in the public interest. This notion may have implications for data generation for the purpose of ensuring the environmental sustainability of emerging technology outcomes.

4.2 Balanced and reasonable

If all of the amendments discussed in section 3, above, were made, the liability system would provide significant incentives to manage the risks associated with emerging technologies or products, including incentives to generate additional data beyond the data required by regulatory requirements. Probably, such a novel, expansive liability regime would serve the purpose of ensuring environmental sustainability of emerging technologies. However, these amendments would also have broader effects on companies and particularly on their inclination to develop and market innovative technologies and products.

In general terms, increased liability exposure may imply disincentives to innovate and place innovative technologies and products on the market. Whether the improved incentives to invest in risk management of innovative technologies and products outweigh the disincentives to innovate and place innovative products on the market, is an empirical question that goes beyond the scope of this report. Given that both innovation and risks management are critical to society, the incentives and disincentives should be in balance. This challenge, of course, is not unique to liability systems; regulatory regimes struggle with the same issues. Take the EU Chemicals Strategy for Sustainability – it is aimed at ensuring an as of yet undefined "toxic-free environment" in Europe, but it is unclear how the additional regulatory requirements will impact technology development and the industry's innovation potential.

The requirement that the liability rules be reasonable implies that liability rules should meet the basic demands of justice, both where companies escape liability in violation of the demands of justice, and where they are held liable in violation of the demands of justice.

4.3 Predictability

For an improved liability system to generate specific incentives to generate data beyond regulatory requirements, it needs to be not only balanced and reasonable, but also predictable. If technology developers are unable to predict whether liability will be imposed in a specific case, they will not be able to take liability exposure into account in their decision-making. In other words, ideally, technology developers should be able to tell whether a specific action or measure they could take will in fact reduce the company's future liability exposure.

Case law does not necessarily guarantee predictability – the Dutch climate cases are the prime example. Courts can base their judgments on novel theories not previously entertained and on some issues, they issue inconsistent judgments. Thus, one of the main issues with liability law is that it tends to be relatively unpredictable in terms of outcomes in specific cases, in part, because liability rules are often applied *ex-post* by judges with no prior scientific training, which creates the risk of hindsight bias. Technology developers need information on liability exposure *ex-ante*, i.e., before any problems occur and in many cases years before products even reach the marketplace. Liability laws are not written in terms that are sufficiently specific for technology developers to predict liability exposure in the future. Given that liability is applied by the courts only after the fact (*ex-post*) when a case is brought and there is either harm or threatened harm, sufficiently precise decision rules that technology developers need to make decisions, will often not be available.

A key question, thus, is whether the predictability of liability exposure in the future can be improved. In other words, what could be done to make liability exposure so predictable and specific that it can be translated into specific requirements for technology developers in terms of the design, applications and use instructions of specific innovative technologies and products? This would appear to be an enormous challenge, given liability's stop-gap function and mode of operation. And if it can be done, the argument will be made that it is more appropriate to enact a regulation imposing these requirements.

To improve the predictability of liability exposure, the general liability rules could be supplemented with specific exonerations or with specific conditions for liability in relation to specific innovative technologies and products. An example of a possible exoneration rule was discussed in section 3, above: if a company generates additional data beyond regulatory requirements and on the basis of such data adjusts its risk management practices, it could seek regulatory approval, which, if granted, would grant exoneration from liability on the basis of the additional data. Further, more generally, the liability rules could be adjusted to accommodate the specificities that are relevant to an innovative technology or product; a company's entire risk management programme could be subjected to review and approval, with approval functioning as exoneration from liability. This combination of *ex-post* liability rules and *ex-ante* regulatory conditions is unusual. There is some precedent for similar arrangements in connection with the so-called regulatory compliance defense or permit defense in liability cases.

4.4 Implications for stakeholders

To a significant degree, liability's role as an instrument to manage the environmental risks of emerging technologies is a function of one's view on law as such. There is the idealist's view and the realist's view. In the idealist's view, liability law is a flexible instrument that is able to respond to new challenges, including those posed by the risks associated with emerging technologies. The realist, however, pays attention to how liability works in the real world. While the idealist asks, "how can liability respond to emerging risks," the realist asks "how does the liability system, in fact, respond to such risks." To the realist, the key question is "what will a judge rule" in a particular case, not "what should a judge rule." In other words, in the realist perspective, liability's actual limits take center stage.

In a realist perspective, liability's implications for stakeholders are a function of the incentives that are actually generated by the system. Liability is an exogenous (as opposed to an endogenous) factor in the decision-making of a person that is actually was exposed to the consequences of liability. Liability law does not protect all interests, and targets only some groups of potentially liable parties. As discussed above, liability law is characterized by a series of institutional, procedural and substantive limitations, which distort the incentives that liability can generate for damage prevention, even where risks are foreseeable. This explains also why the guidance that can be provided to technology developers, research funders, financial investors and industry is fairly general and abstract, and chiefly related to investigating possible causal links between the technology under development and environmental risks. Generating information, however, can itself increase, rather than reduce, liability exposure and related legal risks. Guidance to policymakers can be more specific, as discussed, but improvements of the liability system unavoidably involve trade-offs and value judgments.

5.

Conclusions

The analysis has come full circle. Based on the assumption that regulations are not necessarily sufficient to generate adequate incentives for the proper management of the risks of innovative technologies and products, we set out to determine how the liability system could be improved to better supplement the regulatory regimes in managing the risks of emerging technologies. We analysed what role liability law could play in supplementing the regulatory incentives and encouraging companies to generate additional data beyond regulatory requirements. The analysis resulted in the conclusion that liability law would have to be adjusted to assume the role of supplemental incentive generator.

Expanding this line of thought, multi-faceted analysis suggested that liability should also have a regulatory component to improve its functioning. A conundrum presents itself, since we would have to conclude that liability law must be supplemented with regulatory requirements in order for liability to supplement regulations and, thus, to generate sufficiently specific incentives to encourage technology developers to generate additional data on specific innovative technologies and products. But maybe this is not that much of a problem, and maybe there are other approaches to the problem.

The limits inherent to the civil liability system should also be taken into account. Since liability is administered through civil litigation between private parties before courts of law, institutional and procedural limitations come into play. Courts of law have only limited authority and fact-finding is limited to what the parties to a dispute want to expose. The liability system cannot and may not usurp the role of the legislature or regulators in setting standards for economic activities. Courts of law may apply or "find" the relevant law, they may not make it. Certain conditions must be met for liability (specifically, the most common form of liability based on negligence) to work well as a system for creating *ex-ante* incentives for prevention. These conditions include that (1) the risk must be foreseeable (i.e., the causal link must be clear), (2) there must be a reasonably available option to protect against the risk (other than not engaging in the activity at all), (3) the damage that results from the activity must be unambiguous, not inherently tied to economic and social benefits, and constitute injury to legally protected interests, (4) the standard of care requiring preventive measures must be knowable (i.e., identifiable) beforehand, and (5) the question presented to the court must not be a politically charged issue with which the legislature occupies itself. In the case of asbestos-related harms to human health, these conditions were met and liability worked well, although it certainly did not prevent all asbestos-related harm. In the case of climate change and mitigation obligations, however, not all conditions are met, and liability is unlikely to generate incentives for prevention.

Risks to the environment (or environmental sustainability) present two related issues with which the liability system will have great difficulty — uncertainty and timing. If liability is supposed to prevent environmental risks that will arise only in the future, the liability system must be able to identify such risks and distinguish them from spurious risks to the environment. It is doubtful whether courts composed exclusively of lawyers, even if they have formal authority to do so, are able to sort real risks of future environmental harm from false risks and impose liability only with respect to the first. Unforeseeable risks of damage to the environment will not magically become foreseeable in civil litigation. The more remote the risks (i.e., how far into the future a possible risk will materialize), the harder it will be for the court to identify real risks, as causal links may be complex due to fundamental uncertainty, threshold issues, bioaccumulation, synergistic effects, etc. So-called "long tail" damage, which is characterized by a long time gap between the time of introduction of a technology and the manifestation of consequences, presents serious challenges to the liability system as well. If progress in risk assessment techniques results in reliable early information about future adverse consequences of emerging technology applications, it is conceivable that this information could be used successfully to expand liability's role in managing potential risks of environmental impacts of emerging technologies regimes.

In the context of ensuring the environmental sustainability of emerging technologies, the key issue may well be the foreseeability of long-term risks to the environment. These issues tend to be scientifically complex, there often is deep uncertainty about causal relations, data may be ambiguous, values come into play, and there invariably are conflicting interests, including, but not limited to, economic and environmental interests and short-term and long-term interests. For the judiciary, wading into this minefield poses normative and epistemic challenges — are the courts authorized to weigh the conflicting interests involved, is the necessary data available, and are courts able to digest it? In the ideal world, courts would be able to incentivize companies to generate data that provide the necessary insights into the long-term impacts and consequences of emerging technologies on the environment, without discouraging incentives and imposing undue burdens on society. In the real world, courts are made up of judges that are fallible.

If no harm has arisen at the time a court is asked to impose liability, the only remedy that is able to address this possible harm is an injunction or similar court order. Before a court of law may impose an injunction, however, it must ascertain that (1) there is a causal link between the activity at issue and the threatened harm, and (2) the injunction or order sought will prevent the harm. Where causal links are inherently uncertain, ambiguous, and value-laden (e.g., because there are several, different ways to control the risk), courts lack the political accountability to make the necessary value judgments.

The key to ameliorating the problem may be to develop better risk management regulations (perhaps through the use of planned adaptive regulation) and better liability rules and systems. In particular, the interaction between the regulations and liability should be improved, not to create the perfect system, but to address shortcomings and make some improvements. Predictability is an important element of a liability regime, and it can be improved in a number of ways, including better training of judges in the sciences. Moreover, as we have seen, there are other elements of liability law that can be adjusted and improved to provide for better incentives to generate data and manage risks of emerging technologies. Legislature can create additional strict liability regimes, which eliminate the requirement to demonstrate fault on the part of the defendant. Because liability creates incentives and disincentives, however, it is important that a balance is kept, the rules are reasonable, and their application in specific cases is as predictable as feasible.

There is no holy grail. The liability system can be adjusted to improve the management of the risks of emerging technologies, while not discouraging desirable innovation. The balance is delicate, however, and adjustments are best made carefully, iteratively, and one by one, while learning from their effects and adapting the system as we go along. Legislatures, not courts, are best placed to take the lead and make the incremental changes to better equip the liability system to manage the risks of environmental impacts of emerging technologies.

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Paper 12

Ensuring environmental sustainability of emerging technologies – the case for applying the IRGC emerging and systemic risk governance guidelines

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Introduction

Risks from emerging technologies can have new characteristics. When they are radically new, there is a general lack of data and risk assessment methods. Risks may even be systemic, i.e., they arise from the complexity of the technology itself and/or their interaction with the environment.

In this paper, we propose a set of risk governance strategies selected from the EPFL International Risk Governance Center (IRGC) "Guidelines for the governance of emerging risks" (IRGC, 2015) and "Guidelines for the governance of systemic risks" (IRGC, 2018). The selection is based on insights from the IRGC project "Ensuring the environmental sustainability of emerging technologies" (ESET) (IRGC, 2022) and an analysis of past examples[2]. The paper aims to provide a bridge for the transfer of generic concepts and principles into practical recommendations for ensuring the environmental sustainability of emerging technology outcomes. We start by summarising the defining properties of emerging and systemic risks, motivating the relevance of the two corresponding guidelines in the ESET context (section 1) and reviewing certain governance strategies for ESET (section 2). We use several examples of how some risks involving novel technologies or products were handled in the past, e.g., the use of chlorofluorocarbons (CFCs), and emerging technologies, such as for carbon dioxide removal (CDR) and sequestration, gene drives, and operations in outer space, to illustrate the application of the selected strategies in the case of each technology and their operationalisation.

1.

Background and context

Emerging technologies are developed for a purpose, including but not limited to improving sustainability. Ensuring the environmental sustainability of emerging technologies is the core objective of the IRGC project ESET. Environmental sustainability is at risk if either the target benefits of the technology are not realised as intended, or negative side-effects (ancillary risks) are not sufficiently mitigated and reduce the target benefit.

Emerging technologies within this project are defined by the following set of criteria (Rotolo et al., 2015): radical novelty, prominent impact, fast growth, ambiguity, and uncertainty. Complexity and transformative power are not strictly part of this definition. However, the combination of defining features of emerging technologies and analysis of past emerging technologies lead to the conclusion that the risk governance of emerging technologies needs to address complexity and transition risks as well. For example, rapid digitalisation has changed and is still changing society's entire way of living and working.

We can reasonably assume that emerging technologies can lead to both emerging and systemic risks. These types of non-classical risks require novel approaches in risk management. IRGC has developed conceptual frameworks for these risks[3]: the "Guidelines for emerging risk governance" (IRGC, 2015) and the "Guidelines for the governance of systemic risks" (IRGC, 2018). In this paper, we are mainly interested in the applicability of these guidelines to specific emerging technology use cases. We do not provide a comprehensive overview of the guidelines here, beyond a brief summary of the basic concepts and necessary terminology.

1.1 Emerging risks

Emerging risks are often associated with new technologies. They are either new risks, or known risks that become apparent in new, unfamiliar, or changing context conditions. The smartphone provides a classic example of existing technology (computers) applied in new contexts (mobile use). The different use patterns changed how we access digital information and revolutionised social interaction, thereby impacting existing economic and societal structures, data privacy and security.

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[2] See also the paper written for the ESET project by Rainer Sachs, "Risk governance of emerging technologies: Learning from the past" (2022).

[3] See www.epfl.ch/research/domains/irgc/concepts-and-frameworks/emerging-risks and www.epfl.ch/research/domains/irgc/concepts-and-frameworks/systemic-risks

Emerging risks are characterised by uncertainty regarding their potential consequences and/or probabilities of occurrence, i.e., these properties cannot be quantified. Quite often, emerging risks are unanticipated and manifest as surprises. There is typically a lack of knowledge about causal or functional relationships between the sources of emerging risks and their environment. Emerging risks are not restricted to the domain where the technology is applied but can occur in seemingly unrelated fields.

1.2 Systemic risks

Emerging technologies are applied in a world characterised by an increasing interconnectedness within and between systems. We follow the IRGC definition of the term “system” as being a “regularly interacting or interdependent group of items forming a unified whole” (IRGC, 2018).

Due to the interconnectedness and complexity of systems, conventional risk governance approaches reach their limits. Risk management by fragmentation of risks into individual categories and of the environment into isolated systems has been successful in the past. In the first step of such an approach, individual risks are identified, modelled, and mitigated separately. Only in the second step their possible connections and dependencies are considered, and individual risk models are aggregated. However, for complex systems, the fragmentation approach is too reductionist and limited in scope. The key to identifying and managing risks in complex systems is understanding and modelling the dependency structure first. The vital information is in this structure, not in the individual system nodes. Defining properties of complex systems like emergence and adaptation arise from the interaction of system nodes.

Systemic risks typically evolve in interconnected systems. They are characterised by contagion and proliferation processes (ripple effects), frequently on the basis of a network structure. A seemingly harmless event, e.g., individual failure, disruption or accident, poses a threat to the entire system and can even cause a complete collapse (Lucas et al., 2018). Systemic risks are stochastic and often appear seemingly out of the blue.

The application of current and future emerging technologies can be expected to cause systemic risks. Emerging technologies can diffuse across system borders, and so will the associated risks. Isolated islands will be scarce in interconnected system landscapes, and the conventional containment approach of risk management will not be effective anymore.

2.

Risk governance for ESET

In this section, we provide a selection of elements from the emerging risk and systemic risk governance guidelines (IRGC, 2015, 2018) to the risk governance objectives of ESET. The selection is based on examples from the technology domains of the ESET workshop (IRGC, 2022) and the lessons learned from past examples.

This paper thus suggests elements for consideration towards the sustainability governance of emerging technologies by reflecting specifically their non-conventional emerging and systemic risks to the environment. The objective of this paper is to recommend risk governance strategies and offer ideas for their operationalisation for specific applications with a focus on environmental sustainability. We illustrate these strategies with examples from specific technological applications and products.

There is no one-size-fits-all solution for the environmental risk governance of emerging technologies, which each has its specific challenges, such as uncertainty and the need to prepare for surprises or complexity. Moreover, there may or may not be a responsible organisation (risk owner) for the risk aspects of that specific emerging technology. Hence, ensuring the environmental sustainability for a particular emerging technology will require several elements, different for each emerging technology. The whole set of elements provides a preliminary collection of risk governance strategies for consideration, and the applicability of each element can be checked.

2.1 Implement strategies to resolve uncertainty

Emerging technologies are characterised by significant uncertainty. Uncertainty denotes a cognitive state of incomplete knowledge resulting from a lack of information and/or disagreement about what is known or even knowable. In conventional risk framing, for instance, an event is regarded as uncertain when the probabilities or outcomes are not precisely known. The lack of knowledge can, however, also pertain to the type of consequences, the severity of the consequences, or the time or location where and when these consequences may occur (IRGC, 2017).

In the context of environmental sustainability, only a limited subset of unexpected consequences of emerging technologies can be assessed quantitatively. Most consequences can be assessed only with qualitative methods, if at all. It is often challenging to imagine what has never happened before; the context (environment) is often difficult to describe and frame. Scientific unknowns, whether tractable or intractable, contribute to risks being unanticipated, unnoticed, and over- or underestimated.

In order to resolve uncertainty in a systematic manner, it is useful to distinguish between different types of uncertainty. Kunreuther et al. (2014) provide a classification of the term in the context of environmental and climate risks, which is briefly summarised here:

- **Paradigmatic uncertainty** results from the absence of prior agreement on the framing of problems, the methods for scientifically investigating them, and the difficulty of how to combine knowledge from disparate research traditions.
- **Epistemic uncertainty** results from a lack of information or knowledge for characterising phenomena.
- **Ambiguity** implies that there are vague, but usually differing beliefs about the likelihood of events occurring. If people are not able to form any beliefs about probabilities, this particular case is termed complete ignorance.
- **Translational uncertainty** results from scientific findings that are incomplete or conflicting, so that they can be invoked to support divergent policy positions.

The following strategies for emerging risk governance are particularly useful for addressing and resolving different types of uncertainty related to emerging technologies:

- In the case of epistemic uncertainty about an emerging technology outcome, more **research and monitoring** are necessary. Knowledge gaps must be identified and can possibly be filled through fundamental research and the transfer/application of existing related knowledge.
- What remains unknown or even, in principle, unknowable, must be clearly articulated and explicitly made transparent. Knowing the **limits in understanding and modelling** is the prerequisite for improving risk governance of emerging technologies.
- When little is and can be known about a technology that potentially has severe negative consequences, "wait-and-see" strategies must be avoided. Instead, **precaution-based and resilience-focused strategies** should be considered. They are particularly relevant where the ratio of knowledge to ignorance is low, as with emerging technologies. They can ensure the reversibility of critical decisions (e.g., about the deployment of emerging technology in the environment) and increase the environment's coping capacity so it can withstand shocks or adapt to new conditions.

Particular attention to address cognitive biases is needed. There is a tendency to underestimate surprises systematically, assume that lessons have been learned from the past, or overestimate the ability to make judgments under unpredictable circumstances. Problems of collective judgment, such as group biases towards cautious or risky shifts, are frequent in situations of ambiguity. Organisations may show inertia and reluctance to change because of vested economic or political interests.

> **Exemplification**: The failure of risk governance of neonicotinoids and CFCs in the past can clearly be attributed to two reasons: First, the ubiquitous lack of knowledge and understanding pertains not only to the (arguably unintended) adverse consequences of emerging technologies, but also to the methods required for risk assessment (epistemic and paradigmatic uncertainty). The second reason is that vested interests may lead to wilful ignorance of early warning signals or research outcomes. Another example is the failure to act upon the outcomes of scientific research on the consequences of greenhouse gas (GHG) emissions.

Therefore, it appears wise to ask the following questions, even before beginning the risk assessment of radically new technologies, and find meaningful answers to them:

- How suitable are the existing risk assessment methods, and how should they be modified or re-developed from scratch? For example, Cucurachi & Blanco[4] show this for life cycle assessment (LCA), when both the technology and the context of its application change from the current situation.

- How can the concept of "environmental sustainability" be meaningfully operationalised? What exactly does "environment" mean, and which parts are included or intentionally excluded in the assessment?
- How do we define, articulate, and set the risk appetite, i.e., the tolerances of stakeholders towards potential harm to the environment?
- How can we improve responsible decision-making, e.g., by the design of structures and processes to reduce the impact of cognitive and organisational biases?
- What is needed to avoid wilful blindness and the tendency to interpret harmful consequences as unforeseeable surprises? Unfortunately, it appears more acceptable to the public if decision-makers are caught by surprise (or pretend to be) than if they knew in advance and their decisions turned out to be wrong, for whatever reason.

The concept of post normal science (PNS) approach (Funtowicz & Ravetz, 1994) explicitly includes a greater spectrum of **values and beliefs** in risk assessments. PNS involves the consultation of extended peer and stakeholder communities (beyond scientific researchers) to understand and interpret the limits of knowledge and their influence on policy decision-making. Such discourse-based approaches are also recommended by IRGC (2017) for risk situations characterised by ambiguity, where stakeholders have different beliefs about the benefits and risks of a particular technology. Such strategies aim to create tolerance and mutual understanding of conflicting views and eventually find ways to resolve the conflicts.

> **Exemplification**: Gene drives technology is an emerging technology that can lead to significant and permanent changes in entire populations' genetic information, with possible long-term and far-reaching impacts on the whole ecosystem.[5] Adopting a PNS approach is suggested when uncertainty is considerable, and impacts on the environment can be drastic.

2.2 Overcoming obstacles to the systematic consideration of early warning signals

Concerns about long-term environmental sustainability require attention to early warning signals and preparation for unexpected events. Hence, proactive governance of emerging technology aims to enhance anticipation and forward-looking capabilities.

Early warning aims to make sense of weak signals indicating whether the deployment of an emerging technology might positively or adversely impact the environment. Making sense of weak signals is much easier if they are actively sought, and if the search strategy is based on scenarios, which must already be part of the technology development process.

Risk mitigation options are available throughout the process (figure 1). Early in the process, options may be more abundant and broader, especially as precautionary and preventative approaches may be considered. However, early mitigation may conflict with innovation, which it may stifle. Late mitigations come at higher costs in case environmental damage has already occurred but may be more targeted

> **Exemplification**: The detection of the ozone hole was the result of long-term systematic monitoring (Farman, 2001). CFCs were not expected to deplete the ozone layer in the remote stratosphere to such an extent, even if their potential to break down ozone molecules had already been known for over a decade.

Explorative scenarios aim to find answers to "what if?" questions and acknowledge the possibility that context conditions could differ from today. Divergent futures may result from known or unknown trends and events for which a probability distribution does not exist. Explorative scenarios look into alternative views of the future and create plausible stories from them. For example, one could ask how the environment — even in the distant future and distant geographically from the intended application of the emerging technology — will develop and could be adversely impacted.

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[4] See also the paper written for the ESET project by Stefano Cucurachi and Carlos F. Blanco, "Practical solutions for *ex-ante* LCA illustrated by emerging PV technologies" (2022).

[5] See also the paper written for the ESET project by Jennifer Kuzma "Gene drives: Environmental impacts, sustainability, and governance" (2022).

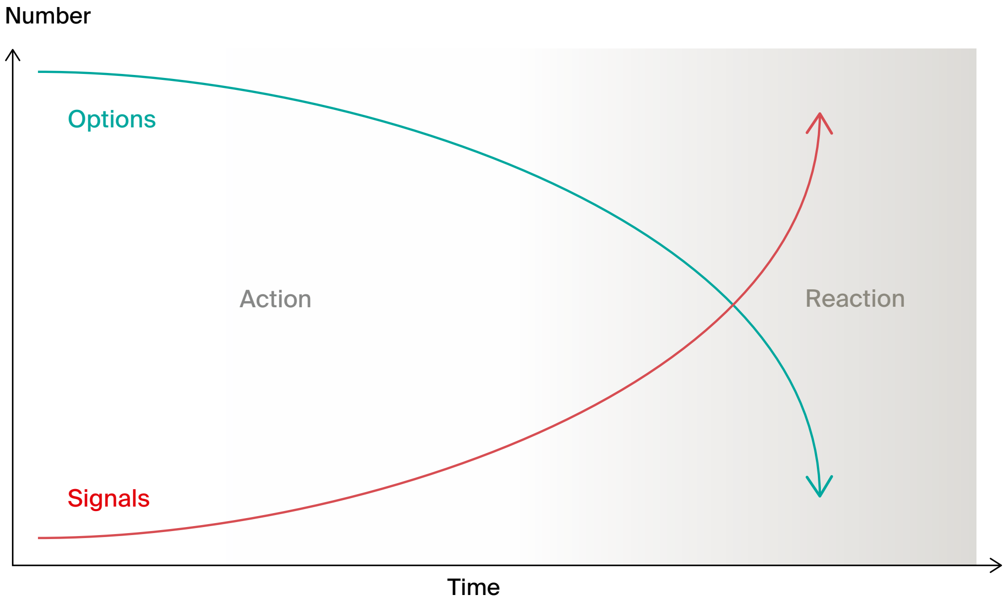

Figure 1 | Indication of damage (signals) increases over time, but risk mitigation options decrease in parallel. Eventually, the decision space changes from "action" to "reaction"

In other words, these scenarios contain possible development paths for both the emerging technology and the environment, whether or not those changes would be attributable to the technology. In particular, the environment needs to be observed for potential precursors of major changes and transitions that might affect the applications of emerging technologies.

Vulnerabilities and potential impacts of emerging technology on the ecosystem need to be identified and included in scenarios and early warnings.

> **Exemplification**: Carbon dioxide removal (CDR) includes a set of technologies necessary to meet emissions targets in our attempts to combat climate change. In broad terms, CDR proposals can be grouped into engineering-based methods (e.g., direct air carbon capture and storage) or nature-based solutions (e.g., forestation).
>
> While nature-based solutions appear easier to sell to the public, these approaches are typically more complex and their environmental carbon cycles are less understood. Societal preferences may be due to biased perceptions of risks and benefits, especially in environmental matters where "nature" is trusted more than "technology." In other words, there may be some doubts regarding the ability of technology to fix problems that were caused by technology in the first place.
>
> To avoid mistakes made with the early development of large-scale liquid biofuel production case in the 2010s, CDR **scenarios** should pay special attention to the following aspects regarding nature-based solutions:
>
> - What are the economic, social, and political impacts of changing land use? How are the conflicts with agriculture for food production resolved (Harvey, 2021)?
> - What is the anticipated change of the environment due to climate change, independent from but also directly and indirectly impacted by large-scale deployment of CDR (feedback loops)?
> - Biodiversity and local ecosystems will most likely be adversely affected (increasing monoculture). How is this risk-risk trade-off managed?
> - How can we assure there is a net reduction of CO_2 by converting arable land or carbon sinks (e.g., wetland, peatland) for, say, forestation, possibly requiring artificial irrigation and energy (what would be their source?) that could subsequently not be used for other purposes?
> - How to ensure that CDR does not aggravate climate change? The permanency of CO_2 storage needs to be ensured, and sequestration must not be reversible (Alcalde et al., 2018).

Scenarios can help decision-makers **structure and organise the many uncertainties** arising from an emerging technology, as well as from the complex character of their political, social, and natural environment. However, they are not meant or constructed to predict the future. Even with the most sophisticated analysis of future developments, unexpected events will occur.

2.3 Strategies to prepare for unexpected events

Preparation is required for sudden events with adverse consequences (crises, disruptions, accidents), which may also prevent the effective deployment of technology and mitigation strategies. Therefore, the risk governance process must contain specific measures to **build resilience** to prepare for uncertain and unknown shocks and stresses.

Unanticipated barriers (occurring in the technology and/or the environment) that may come up during the process must be addressed, sometimes requiring drastic **revision of decisions and swift adaptation**. Governing risks in a systems approach requires engaging in deliberative exercises to identify and overcome barriers and obstacles before they grow (figure 1 above).

> **Exemplification**: CFCs were utilised for many decades without concern about adverse impacts on the environment. This is because the compounds of CFCs are chemically inert in the lower atmosphere and essentially nontoxic. However, there is a risk-risk trade-off in this specific safety design that was largely ignored at the time: because of their inertia, CFCs have extremely long persistence times (40–150 years) and can reach remote areas far away from their original deployment region. While CFCs do not react easily with other chemicals in the lower atmosphere, they become highly reactive as they move into the stratosphere where UV radiation can break up CFC molecules.
>
> Scientific evidence of environmental harm had been available for more than a decade before action was taken. Only a sense of urgency created by media exposure and public attention to the ozone hole, and the availability of alternative substances (substitutes) led to a relatively fast decision to phase out CFCs.
>
> **Exemplification**: The adaptation of the EU biofuels regulations in several waves between 2003 and 2018 illustrates a policy response to a better understanding of the environmental and societal impacts caused by the growth of biofuel crops, which were threatening one of the initial targets of improving the economic situation of local farmers (cf. also next section).

2.4 Understand and embrace complexity

Complexity could lead emerging technologies to adversely impact the long-term sustainability of the environment or the climate. Low predictability, limited modelling capabilities and emergence are prominent features of connected complex systems. Emergence means that the overall behaviour of a system, composed of interacting elements, can be qualitatively different from the simple aggregation or extrapolation of the behaviour of individual elements.

Complex adaptive systems can also exhibit feedback mechanisms that amplify change or perturbation that affects them. Positive feedback tends to be destabilising and can thus amplify the likelihood or consequences of risks from emerging technologies. For example, burning fossil fuels impacts the Earth's climate system and triggers positive feedback: GHG emissions causing the melting of permafrost, leading to more GHG emissions, or reduced ice cover on glaciers and the arctic reducing the surface albedo leading to more energy from the sun being absorbed on Earth.

It is important to realise that feedback is not necessarily a process within a single system node, e.g., the natural environment, but it can involve multiple nodes across different system boundaries: from technology to society to politics to environment. This makes identification and assessment a challenging task that can only be accomplished by strict adherence to the system approach combined with active transdisciplinary collaboration and, for example, adaptive regulation.

> **Exemplification**: The increased growth of biofuel crops not only triggered the obvious food vs fuel debate (direct consequence), but also caused unexpected harm in the societal domain (changing land ownership and local structures as indirect consequences). The target benefit remains questionable: previously unused land (forests, peat) serving as a GHG sink is converted into agricultural land, thus threatening the emissions reduction targets (Hunsberger, 2015).

This is typical for a systemic risk situation, where risk mitigations may backfire: the attempt to address the risks of climate change by increasing biofuel production at a scale that would disrupt ecosystems caused harm in other connected systems. Adapting regulations in the EU in several waves from 2003 to 2018 has been a largely successful response to complexity.

Systemic risk governance strategies aim to improve the system's capacity to absorb and recover from shocks and stresses and adapt to new context conditions. Rather than avoiding complexity and working against it, one should use the inherent tendency of complex systems to self-organise and thereby create a stable, ordered state or controllable transition. For example, the design of the emerging technology could contain features of negative feedback to diminish the potential for adverse environmental impact. The concept of Safe and Sustainable by Design (SSbD) aims explicitly at developing and implementing such aspects right from the initial development process. We refer to a recent report from the Joint Research Centre (2022) for a comprehensive review of SSbD.

Exemplification: Smart materials (SMs) are adaptive substances that can change certain critical properties during use.[6] Because of their changing properties, SMs pose crucial challenges from a risk perspective: one cannot predict with sufficient certainty the behaviour of the materials and their possible adverse effects after release into the environment. SMs could therefore be designed with very specific and limited adaptive features or finite lifetimes.

Risk governance should adopt a system approach whereby the environment in which SMs are intended to be deployed is scrutinised:

- What are the possibilities to strengthen the environment's robustness and resilience by introducing coping mechanisms if the SM behaviour is outside its intended regime?
- Reverse stress tests could be conducted: starting from the assumption that an essential part of a system would collapse or that critical ecosystem services would be disrupted, what could be the possible causes (individual or combined), and what role could SMs play in such an event?
- Which design of SMs can help to avoid system damage?

Exemplification: Similar considerations are recommended for deploying **gene drives technologies**[7] where, in contrast to natural (Mendelian) inheritance where only 50% of the genes are passed to the offspring, the modified genetic information is passed dominantly to future generations – possibly up to 100%. In theory, releasing just a few modified organisms could permanently change entire populations. As a safety measure, gene drive systems can also be designed to be limited in geography or spread, or to be reversible. As of today, laboratory experiments have been conducted, but no gene drives have been released into the environment.

As has also been observed in the case of liquid biofuels[8] the solution to narrowly defined problems will typically cause the problem to move to adjacent systems. This is very relevant for the planned applications of gene drives, e.g., the eradication of invasive species or disease vectors, and illustrates again the risk-risk trade-off that often occurs in risk governance (Wiener, 1998): the mitigation of a particular risk can create countervailing risks with possibly even greater harm. In the case of gene drives, this translates to the fact that removing a species (whether native or invasive) "could produce unintended cascades that may represent a greater net threat than that of the target species" (Webber et al., 2015).

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[6] See also the paper written for the ESET project by Steffen F. Hansen, Freja Paulsen and Xenia Trier, "Smart materials and safe and sustainable-by-design – a feasibility and policy analysis" (2022).

[7] See also the paper written for the ESET project by Jennifer Kuzma, "Gene drives: Environmental impacts, sustainability, and governance" (2022).

[8] See also the paper written for the ESET project by Rainer Sachs, "Risk governance of emerging technologies: Learning from the past" (2022).

2.5 Implement ways to assign accountability despite a lack of risk ownership

Effective risk governance needs adequate structures and resources. Learning from past examples shows that there is a general lack of resources for the assessment and management of risks from new technologies. This may be caused by an unbalanced prioritisation of the preferred scenario where target benefits would be achieved without collateral damage. Resources and competencies required for the identification, prioritisation and development of alternative scenarios are often profoundly underestimated. Few organisations are willing to invest sufficiently in this expensive and time-consuming task and in forward-looking risk assessment processes, methods and competencies.

> **Exemplification:** The case of **neonicotinoids** provides the perfect example for the consequences of low priorities on understanding the risks: the focus was (and still is) on the benefits of pesticide use. There were insufficient resources and funding in the development phase for a scientifically sound and fair risk governance process (Maxim & van der Sluijs, 2013). There were no functional organisational structures in place to manage the risk governance process and assign responsibilities to the stakeholders. Ultimately, after a long and highly political debate, major stakeholders with conflicting interests could not arrive at a mutually agreeable solution.

IRGC (2015, 2018) emphasises the need for a risk governance facilitator and defines the roles of a "navigator" for systemic risks and a "conductor" for emerging risks. The facilitator's role combines elements from both "navigator" and "conductor", coordinates and leads the internal and external stakeholders involved in the assessment, management and communication of risk issues. The question of ownership and oversight is crucial in structures of distributed responsibility if risks are or may be systemic: everyone is responsible for some part of the system, but no one has the responsibility to act on the entire system.

The facilitator does not need to be the "subject matter expert" for the specific technology. They should be competent in risk governance topics, however. Their responsibility is to facilitate the risk management process. For example, the European Food Safety Authority (EFSA) partially functions as a facilitator in questions related to food security in the EU. The Office of Technology Assessment at the German Bundestag (TAB) has a similar role in Germany.

The core tasks of the facilitator are the following:

- Managing and enabling interaction among stakeholders for collaboration, networking, learning and experimentation;
- Bringing new knowledge to the process and familiarising stakeholders with multi-disciplinary work;
- Organising capacity- and competence-building of stakeholders (e.g., behaviours, attitudes, culture);
- Working to break silos of whatever form (disciplines, sectors, stakeholder groups);
- Validating and legitimising the technical methods and approaches used and developed during the process;
- Ensuring that scientific concepts are translated into understandable concepts for effective risk management and policy; and
- Reporting, reviewing, and monitoring results and performances to demonstrate their relevance.

Emerging technologies, as they are defined in the context of this paper, are potentially pervasive and can diffuse across system boundaries with possibly global reach. Some emerging technologies are designed explicitly for global application, e.g., CDR or space technologies. Such a global technology requires global risk governance and regulation, and the responsibility needs to either sit within an internationally legitimised organisation or be orchestrated within a cooperative network of stakeholders. In any case, there needs to be a dedicated facilitator for the risk governance process.

> **Exemplification**: The paper on space technology[9] demonstrates that risk regulation for access to and use of outer space is still in its infancy. International treaties were adopted before space activities had any significant impact on the

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[9] See also the paper written for the ESET project by Romain Buchs, "Ensuring the environmental sustainability of emerging space technologies" (2022).

space environment and before environmental sustainability became a concern. This may partly be attributable to the political and military interests in space technology. The increase in private space activities will change the picture. In general, risk governance and regulation appear to trail behind technological development.

If regulation is insufficient to manage ET's environmental risks, **liability regimes** (i.e., attributing responsibility in case of harm and compensating damage) could be used as additional policy instruments.[10] Liability regimes complement regulation and can address gaps in regulation, but there are limitations. The typical challenges of protecting the commons, e.g., unowned land or space, via liability instruments are (1) the lack of claimants and (2) undefined or undefinable compensable harm. If a private firm causes harm to the environment, there may be no one to make a claim, or there may be no one who has suffered compensable harm or can quantify the harm. With no cost for externalities, there is no direct incentive for private actors to not only avoid damage to the commons, but also to contribute positively to environmental sustainability.

As one partial solution, regimes of public interest litigation have been established in the EU. They create incentives for public and private organisations to initiate lawsuits against companies that have harmed public goods, thus indirectly increasing the company's interest in avoiding harm.

Risk governance for protecting the commons should, therefore, not just focus on identifying, assessing, and mitigating adverse outcomes from emerging technologies, but also on the issues of responsibility and the design of incentives to avoid harm to the environment. As pointed out by Albrecht & Parker (2019), one of the critical success features of the Montreal Protocol was the promotion of compliance and management of non-compliance.

2.6 Strive for clear communication and broad framing of risks and opportunities

The framing of a potential threat from an emerging technology as a risk to the environment may have significant strategic consequences. The target benefits of the technology are usually the primary focus. Social dynamics (political, societal, media interest), counter incentives, and inappropriate or insufficient incentives may deter stakeholders (decision-makers, technology experts and scientists) from recognising, reporting, and addressing new risks or even framing certain issues as risks. However, a too strong focus on the risks of the technology, although they undoubtedly exist, could be misinterpreted as an undue obstacle to achieving the benefits expected from the emerging technology.

Collins et al. (2021) highlighted this tension in the context of the transition to a low-carbon society and economy. Ignoring or not paying sufficient attention to the risks upfront could cause the failure of the technological deployment. Risks that may materialise later in the process could turn out to be insurmountable. Identifying and assessing obstacles and barriers is ultimately required for successful applications.

> **Exemplification**: The Montreal Protocol to ban CFCs is a landmark example of a collaborative multi-stakeholder decision and regulation of environmental risks. By carefully attributing responsibilities and providing opportunities for innovation, the process contributed to the success of the Protocol.

Trust, mutual understanding and appreciation are key ingredients for an efficient and effective risk culture and must be fostered. Successful risk governance requests that stakeholders can communicate and collaborate on seemingly conflicting perspectives: minimising risks and achieving benefits simultaneously. This has always been challenging and could become even more so. Currently, there appears to be a tendency towards a zero-risk appetite in the public discourse and a concentration on precaution and avoiding all risks. But if technological innovation is possible and appears economically feasible, there will be someone doing it and ignoring the risks.

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[10] See also the paper written for the ESET project by Lucas Bergkamp, "Liability's role in managing potential risks of environmental impacts of emerging technologies" (2022).

For some emerging technologies, the concept of essentiality might offer a way to define risk appetite and possibly agree on a mutually acceptable level. For example, in the case of CDR, there appears to be a global consensus that the technology is urgently needed to combat climate change. However, there is insufficient scientific and public understanding of risks and benefits, and societies seem unwilling to bear at least some of the risks.

Risks from emerging technologies are likely to require a broader framing of the issue. This is due to their potential systemic properties. The key is a willingness to explore and communicate one's exposure and vulnerability to risks across system boundaries and different time horizons. Opportunities to take action eventually need to be identified.

The perceived or actual need to develop and implement emerging technologies is an important obstacle to broader framing and comprehensive risk governance. This is because short-term benefits are typically prioritised over the burden of possible long-term costs. Like in many other domains, short- and long-term negative externalities are not internalised in calculating actual costs.

However, it is not a matter of different time horizons only. The case of CDR illustrates the tension between risk and benefit, which are both long-term. The urgency to address climate change requires deploying CDR on a large scale and as soon as possible. But at the same time, there are identified and potential adverse side effects (countervailing risks), and target benefits remain uncertain. It is important to realise and openly address the influence of urgency on the perception of long-term risks and benefits. Urgency must not lead to wilful blindness or conscious neglect of possible systemic properties and hamper the appropriate framing and analysis.

3.

Recommendations and conclusions

The specific properties of emerging technologies, i.e., radical novelty, uncertainty, ambiguity, fast growth and prominent impact, make a plausible case for applying the IRGC guidelines for emerging and systemic risks governance. In this paper, we analysed how the generic concepts from the guidelines can be applied to ensure the environmental sustainability of emerging technologies.

Table 1 | Recommended risk governance strategies and their possible operationalisation for ensuring the environmental sustainability of emerging technologies

Understanding and embracing complexity	• Accept low predictability, limited modelling capabilities and emergence • Beware of feedback mechanisms that can lead to amplification • Expect risk mitigations to backfire • Support and strengthen the ability of the system to self-organise and self-control • Improve the system's capacity to absorb and recover from shocks and stresses
Implementing strategies to resolve uncertainty	• Enable and conduct more risk-related research and monitoring • Identify and know the limits in understanding and modelling • Consider precaution-based and resilience-focused strategies • Address cognitive biases
Overcoming obstacles to the systematic consideration of early warning signals	• Enhance anticipation and forward-looking capabilities • Actively search for early warning signals, vulnerabilities, and potential adverse impact • Develop explorative scenarios for both the technology and the environment (system perspective) • Imagine divergent futures to structure and organise a broad spectrum of possible development paths
Implementing strategies to prepare for unexpected events	• Build resilience to prepare for uncertain and unknown shocks and stresses • Allow for revision of decisions and swift adaptation

Past and current examples of emerging technologies are analysed in the ESET project. We selected specific elements from the IRGC frameworks based on these case studies. We suggest the following strategies and their operationalisation for risk governance, presented in table 1 below.

In addition, governing risks in complex situations demands careful attention to the execution of strategies: "how" policy decisions are taken is equally important than "what" is decided (Kupers, 2020). The risk governance strategies in table 1 above belongs predominantly to the "what" class. Table 2 below presents some key conditions of success for implementing strategies: accountability communication and framing relate mainly to the "how".

With these strategies and their operationalisation, we link the guidelines for emerging and systemic risk governance and their application in concrete cases of past and current emerging technologies. While there is no perfect solution and no rigorously defined emerging technology risk governance framework (yet), we believe the examples demonstrate how the proven principles from IRGC guidelines for emerging and systemic risk governance can be utilised in specific cases of emerging technologies.

Table 2 | Selected conditions of success for implementing risk governance strategies

Implementing ways to assign accountability for risk governance despite lack of risk ownership	• Balance the attention between target benefits and potential adverse risks • Estimate the required resources and competences adequately • Implement a dedicated owner for risk governance ("facilitator") • Avoid structures of distributed responsibility in systemic risk situations
Implementing strategies to resolve uncertainty	• Looking for risk may be seen as an obstacle to innovation, but ignoring risks upfront can cause the failure of technology • Risks from emerging technologies are likely to require a broader framing of the issue (system view) • It is important to understand social dynamics and risk perception

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About IRGC

The EPFL International Risk Governance Center (IRGC) is an interdisciplinary unit dedicated to extending knowledge about the increasingly complex, uncertain and ambiguous risks that impact human health and safety, the environment, the economy and society at large. IRGC's mission includes developing risk governance concepts and providing risk governance policy advice to decision-makers in the private and public sectors on key emerging or neglected issues. It emphasises the role of risk governance and the need for appropriate policy and regulatory environments for new technologies where risk issues may be important.

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