REGULATION AND MANAGEMENT OF RISK – LIKELIHOOD OF HARM, SAFETY AND SAFE USE

HIGHLIGHTS NOTE 20

- **The way in which societies choose to manage the risks posed by the development, production and use of technologies has a fundamental impact on safety, prosperity, choice and the capability of embracing a greener future. Traditionally, this has been based on determining likelihood of harm through exposure, focusing on safety and the safe use of technology. It is a proven and highly effective part of the regulatory framework.**
- **At EU-level, new ways of managing these risks are being considered. Their nature and novelty pose major challenges for safety, prosperity and delivering the Green Deal. These changes, and their intervention logic, need to be scrutinised.**

This Highlights Note focuses on 'Likelihood of Harm', the principal regulatory philosophy used to manage technological risks throughout the OECD area. It examines its nature, as well as its social, economic and governance benefits. The note also investigates the emergence of alternative and novel ways of regulating technologies, including intrinsic properties and 'non-toxic' harms. Some of the weaknesses of these ideas are considered and a number of recommendations identified

ORIGINS AND PRINCIPLES

Across the OECD area, 'likelihood of harm' remains the dominant regulatory philosophy for the management of potential risks to humans and nature posed by the development, production and use of technologies. This approach to risk management takes into account intrinsic properties ('hazards') and the probability of adverse effects from specific exposures, focusing on safety for humans and the environment. Its origins date back over more than two centuries and lie in the emerging role of the State as a public risk manager, protecting citizens and workers against involuntary exposures to toxic harms. Initially, interventions focused on occupational exposures before encompassing adulteration of foodstuffs and then mitigating exposures from the production and use of complex material and biological technologies.

Over time, the approach has been applied to mitigating exposure to toxic harms. Risk managers recognise that the removal of all exposures to all harmful properties of technologies is neither based in science nor rational, desirable or practicable.

Reinforced by political commitments, the 'likelihood of harm' philosophy has shaped the design of risk management laws, as well as structuring the policies, guidance and institutional architecture that implement specific regulatory objectives.

In the early 1980s, this approach to managing the regulation of risk using the philosophy of likelihood of harm was codified. The so-called 'Red Books' published in the United States set out a series of stages for the effective management of risk that clearly separated risk assessment from risk management, as well as assigning a clear role for regulators in risk communication.

Risk assessment is to be considered as being of high quality if it rests on access to the best available science, assessment by expert scientists, focus on specific exposures and reliance on toxicological principles and knowledge.

Once the risk assessment phase is complete, then proportionate mitigation measures are developed that ensure that benefits justify costs, after taking into account complex trade-offs (**risk management**).

This codification, distinguishing between assessment and mitigation, has been deployed throughout the OECD area, including the EU (for example in the General Food Law. **A number of core principles** underpin risk management based on likelihood of harm:

- **Safety** – this is the primary objective of risk management policy. In most cases, there are no other objectives, therefore avoiding the possibility of

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undesirable regulatory trade-offs, unpredictability, and failure. 'Safety' focuses on identifying and mitigating specific harms for a particular subset or grouping, leading to measurable improvements in outcomes;

- **Safe use of technologies** – measures recognise the benefits of technologies and accept the importance, for social and economic progress, of making risk-benefit assessments. It is also accepted that "controlled toxicity" is, for certain products, critical for human safety and public health;
- **Likelihood of harm based on specific exposures** – assessments are based on real world activities, exposures and applications, focusing on the probability of adverse impacts. This approach facilitates, moreover, the estimation of risk profiles, helping risk managers make transparent choices between measures to protect humans or nature, for example;
- **Toxic harms** – risk management regulations focus on mitigating harms that present a probable threat to the physical health of humans or damage to the natural world;
- **Tangible benefits for man or nature** – legislative interventions target specific toxic threats that cannot be controlled in other ways, and are justified on the basis of measurable improvements in mortality, morbidity, or environmental quality. This helps legitimate the use of the powers of the State;
- **Toxicological knowledge** – assessments of potential harm reflect fully toxicological principles, most notably they recognise that "the dose makes the poison". They accept that hazards and potentially harmful intrinsic properties are always likely to be present when developing, producing or using technologies, but that the insights from toxicology and related scientific disciplines including pharmacology, help societies manage them safely;
- **Controlled toxicity** – the principles and insights of toxicological knowledge enable societies to use the toxic properties of materials in a highly controlled manner that reflects exposures and impacts. Controlled toxicity is critical for public health, human safety and protection of assets, and for the safe use of technologies that underpin high standards of protection and prosperity;
- **Scientific evidence** – interventions and mitigation measures are based on the best available scientific evidence assessed by eminent scientists with relevant knowledge of specific application and exposures;
- **Separation of assessment from management of risk** – this form of decision-making process, often achieved through institutional design, reinforces transparency and accountability;
- **Proportionality** – mitigation measures are proportionate. They target the specific cause, aim to minimise distortion or cost, and seek to ensure that benefits justify costs. Such measures will be rational, effective and transparent. (*ERIF Highlights Note 12 'Proportionality Principle and the Management of Risk' 2020*);
- **Predictability** – risk assessment and management processes focus on specific applications and exposures, follow due process standards and propose mitigation measures that aim to provide legal certainty. Moreover, basing risk management decisions on scientific evidence and proportionality, creates a high level of regulatory predictability;
- **Transparency** – the overall decision-making cycle, encompassing assessment and management, is transparent and based on science. This helps to create trust in regulators and their decisions.

Taken together, these principles have shaped decision-making processes that **satisfy the four primary requirements of Better Regulation**. Specifically, decisions are **based on evidence; consequences of interventions are recognised and understood; mitigation measures are proportionate; and there is process legitimacy through predictability, certainty, the rule of law and transparency.**

Basing measures to manage potential risks posed by technologies on the likelihood of harm, has contributed significantly to the high levels of protection of human health and nature throughout the OECD area, and to the level of prosperity, choice and quality of life enjoyed by citizens. It is a fundamental part of the regulatory framework, tried, tested, evolved and effective.

Policy measures that undermine, mutate, or replace this approach, should consequently have a clear intervention logic that demonstrates unequivocally why this existing approach is failing and how any new philosophy will deliver greater net benefits for man and nature.

DECISION-MAKING PROCESSES AND SUCCESS FACTORS

Decision-making processes to manage risk based on likelihood of harm, typically feature a number of distinct and common characteristics. Risk management laws, primarily focused on specific risk domains, determine social objectives and the acceptance of risk. Implementation, based on application of specific substances and exposures, is then made using a two-stage process of risk assessment and risk management. Specifically:

(1) Risk management legislation

- In general, this is 'vertical' in nature, focusing on specific risk domains or sectors, such as cosmetics, detergents, veterinary medicine, crop protection or medical technology.
- Legislation is technology-neutral, focusing on the safety of outputs and applications rather than the materials and processes that produce them.
- Intervention logic is based on specific harms, rather than social concerns or worries, and targets specific improvements in measurable outcomes, most notably human health or the environment.

- 'Vertical' laws allow legislators to assess social acceptance of risk on the basis of specific applications of technology and their safety (an outcomes approach), rather than regulating the use of technologies (an inputs approach).
- They also allow law-makers to design risk-specific institutional structures, such as agencies or independent scientific committees, that are mandated to focus their expertise on specific uses and their safety.

(2) Implementation – Risk Assessment

- This is the initial phase of the implementation process and includes understanding and characterising the intrinsic properties of hazards prior to assessing, based on specific exposures, the likelihood of harm. It seeks to identify the probability of an adverse effect in an organism, system, or population caused under specific circumstances by exposure to an agent.
- It respects toxicological knowledge, including new forms of toxicology, such as New Approach Methodologies (NAMs).
- Determining the likelihood of harm is a process of scientific assessment and is undertaken by relevant and independent experts, using the best available science and respecting scientific integrity.
- This process is underpinned by clear guidance that sets out transparently how complex issues such as study quality, weight-of-evidence and scientific uncertainty will be considered.

(3) Implementation – Risk Management

- This is the final phase of the process of managing risks based on likelihood of harm. It is mostly separated from the assessment of risk, thereby facilitating transparency and accountability.
- The potential risk mitigation measures target specific and measurable reductions in potential harms to human health or the environment, enabling decision-makers to assess the costs and benefits of different options.
- Measures are proportionate to the likelihood of harm and target its causes.
- Assessment of possible measures takes into account dynamic impacts, including possible risk-risk tradeoffs, as well as assessing risk-benefit issues.
- Measures are evidence-based and seek to ensure legal certainty.
- Decision-making processes are transparent and judicially reviewable.

Throughout the process, good practice recommends the involvement of regulators in risk communication. This, along with the excellence and transparency of the decision-making process, helps to build trust in the regulatory framework.

BENEFITS AND CHALLENGES

Over time, the management of risk based on likelihood of harm has brought significant social, economic and governance benefits for countries and their citizens throughout the OECD area. It has delivered high levels of safety and strengthened the functioning of markets and investment in new or improved ideas. It has facilitated choice and provided a clear rationale for the use of the powers of the State, thereby strengthening governance. It is consistent with the norms of open societies, respecting consent and choice, facilitating freedoms and respecting the rule of law.

Looking at these important benefits in more detail:

(1) Safety – risk management measures based on likelihood of harm have contributed to the high standard of safety and protection for humans and nature enjoyed in the EU and elsewhere in the OECD area. Harms that pose a threat to safety, after taking into account exposures, have been restricted and, where necessary, banned. Interventions have been targeted and effective. Outcomes have been measurable. Advances in toxicological knowledge have identified new harmful end-points, further toxic impacts and a greater range of potentially harmful properties, facilitating additional protective measures.

(2) Safe Use of Technology and Innovation – technologies based on chemicals, metals, biotechnology and biology form the critical underpinning of the functioning and societal benefits of modern economies. Managing the risks posed by these technologies on the basis of likelihood of harm helps create powerful incentives for innovation:

- Safe use of technology is facilitated, enabling access to palettes of established materials and the progressive evolution of technological pathways for incremental innovation;
- Strong property rights, a pre-condition for investment, emerge from the risk management process;
- The regulatory focus on safety and a high-quality decision-making process creates trust, strengthening consumer confidence. Trust in product safety facilitates competition and acceptance of new ideas; The regulatory process is predictable and proportionate, reducing uncertainty for investors in innovation;
- Access to export markets is enhanced, because of the high quality of domestic risk management decisions; and
- Trade frictions are reduced because risk management decisions respect the principles of WTO-based trade.

(3) Safe Enjoyment of Benefits – by permitting the safe use of technologies and facilitating innovation, risk management measures based on the likelihood of harm contribute to a greater range of consumer choice. Additional competitive intensity between private sector

companies, including highly innovative and dynamic SMEs, drives additional economic activity. This results in greater prosperity.

(4) Flexibility and dynamism – policy-makers have access to a flexible, yet robust, philosophy for managing the potential harms posed by the development, production, and use of technologies. Over time, this approach has accommodated, without distorting its effectiveness or undermining its principles, a number of additional characteristics.

- These include additional risk management objectives of quality and efficacy for human and veterinary medicines and the recognition in EU law of other legitimate factors for determining mitigation measures for food and drink.
- This principles-based approach, anchored in toxicological science and its application, recognises the value of limited, science-based groupings of substances when data gaps need to be closed and the use of safety factors when assessing acceptable likelihood of harm. In these instances, experience from toxicological regulatory science provides relevant insights and guidance.
- At the same time, toxicological knowledge allows the use of "controlled toxicity", a characteristic of some technologies that remains critical for the continued safety of humans and nature. Indeed, it is an essential requirement for the protection of public health, human safety and valued assets.
- Finally, this approach is able to accommodate assessment of 'nuisance', such as noise or smell, as a form of harm, where this can be measured objectively.

(5) Governance and the Use of the Powers of the State – one of the most important benefits of the likelihood of harm regulatory philosophy, is its contribution to good governance. This philosophy of risk management, and the principles that form a part of it, enables regulators to justify clearly and transparently why the powers of the State to compel compliance have been employed. Its use, moreover, helps to limit the risk of regulatory failure. It achieves these governance outcomes for the following reasons:

- Interventions are based on evidence, specifically high-quality science. This demonstrates rationality and meets the wider goal of evidence-based decision-making that is the norm across the OECD area.
- The potential for toxic damage takes into account intrinsic properties, specific exposures and the probability of harm. It is empirical, transparent and practical rather than abstract, hypothetical or arbitrary.
- It targets specific improvements in human health or environmental quality for identified groups, facilitating measurement of tangible outcomes and thus assessments of effectiveness.
- By identifying specific, measurable reductions in harm, it enables risk managers to assess explicitly, and weigh proportionally, the costs, benefits, and risks of specific interventions. The extent to which benefits justify costs can be assessed, and the trade-offs examined, such as risk-risk risk-benefit, and priorities between threats to man or nature rationalised.
- The decision-making process, when used fully, reflects the standards for good regulatory practices set out by the OECD since 1995. It helps to create process legitimacy; an important governance requirement when laws are implemented by governments.

(6) Open and Commercial Societies – the emergence of the likelihood of harm as the dominant regulatory philosophy for the management of risk is, in part, the result of the growth of open, commercial societies. It has been shaped by the norms of such societies, as well as reinforcing them. It achieves this for the following reasons:

- It facilitates choice. Safety, as a regulatory objective, builds confidence amongst consumers, growing markets and encouraging competition. It also facilitates trust, the indispensable foundation of commercial society.
- Safe use of technologies contributes to innovation, offering customers choice. Overall, consumers and users choose from competing safe products, rather than governments making choices for citizens. This allows markets, rather than officials, to respond to emerging needs of customers, such as greater demands for sustainability.
- Finally, the rule of law is strengthened. Restrictions are proportionate, targeted and based on predictable processes. There is also legal certainty and thus strong property rights.

Notwithstanding these benefits, the use of likelihood of harm as the regulatory philosophy for risk management faces a number of acknowledged challenges. These include the time needed to carry out assessments; the scale and quality of data required for good decisions; the level and extent of expertise required to assess exposures; and the recognition that assessments must often make expert judgements about scientific uncertainties.

REGULATION OF RISK AND INTRINSIC PROPERTIES

In response to these challenges, as well as other concerns about health and protection of the environment, along with intellectual scepticism about the value of evidence to inform regulation, the European Union institutions have begun to move towards basing risk management decisions primarily on intrinsic properties in a number of risk domains.
It is, however, important to recognise that regulation of risk based on likelihood of harm does not ignore intrinsic properties. Understanding, classifying, and characterising these properties forms the first part of the scientific assessment that also considers exposures and the probability of adverse effects. In

this initial phase, assessors seek to identify the inherent properties of an agent having the potential to cause adverse effects when an organism, system or population is exposed to that agent. The probability of adverse effect or its impact is not identified.

In some limited instances, however, intrinsic properties may be the primary basis for risk management measures, where this is justified by robust scientific knowledge of potential harms. This is a well-accepted approach to managing risk and forms a complementary dimension of the likelihood of harm philosophy of regulation.

Examples include potential harms when exposure conditions cannot be predicted or when no threshold for adverse effects can be identified. Interventions may also be based primarily on intrinsic properties when the toxicological hazard is acute, such that materials are deemed to be too inherently dangerous. These are a limited number of circumstances.

Whilst justified in a small number of instances, basing risk management decisions primarily on intrinsic properties, as increasingly advocated at EU-level, has significant disadvantages. The rationale for the adoption of this regulatory strategy has a number of strands.

Some proponents argue that the existing approach is too slow, rendering it inappropriate for responding to health and environmental crises. The swift phasing out of all hazardous substances is presented as the solution. Other supporters contend that more rapid restrictions, based on intrinsic properties, would speed up substitution and trigger innovation, thereby stimulating economic growth, better health and delivery of the EU's Green Deal. A post-modernist scepticism can also be detected regarding the value of scientific evidence in resolving the uncertainties inherent in scientific assessments and determination of the likelihood of harm.

All of these claims can be heavily disputed. There is little evidence that basing mitigation decisions on intrinsic properties stimulates widespread beneficial substitution or creates incentives to innovate. A recent academic paper by scientists at the German Federal Risk Assessment Institute (BfR) argued that the EU has one of the most complete and effective risk management frameworks for human health in the world. It also pointed out that there was no evidence of a human health crisis within the EU.

As well as little evidence of economic or social benefits from basing risk management primarily on intrinsic properties, there is a lack of understanding of the potential disadvantages. These include:

- **An intrinsic properties approach does not necessarily improve safety** because **(1)** Hazard is not harm. A harmful adverse effect is present when there is a likelihood of harm due to exposure; **(2)** Loss of substances that provide "controlled toxicity" thereby protecting public health, for example; **(3)** Failure to recognise that 'safe' ingredients when combined together do not necessarily create 'safe' products; **(4)** Loss of benefits from safe use of technologies which create safer production processes or products; **(5)** Failure to recognise potential risk-risk outcomes due to behavioural change; **(6)** Inability to make risk-benefit trade-offs, leading to an irreversible loss of benefits.
- **It damages incentives to innovate** because of **(1)** Loss of valuable technologies essential for prosperity, resilience and the Green transition without justification; **(2)** Reduction in revenues and gross margins, thereby eroding financial resources particularly for SMEs and thereby undermining economic dynamism; **(3)** Diversion of resources away from existing innovation pathways without evidence of likelihood of harm; **(4)** Reduction in consumer confidence and trust due to social amplification of risk by public authorities; **(5)** Stigmatisation of technologies, leading to loss of markets; **(6)** Trade frictions because global trading rules are based primarily on likelihood of harm; **(7)** Loss of public support for new technologies and risk-taking, leading instead to risk aversion and a "zero risk" culture.
- **It undermines policy integration and coherence** because the use of intrinsic properties to regulate risk is likely to make it more difficult for the EU to achieve its wider goals of delivering the Green Deal, strategic resilience and prosperity. For example, the strategies outlined by the European Commission to promote industrial policy, research and innovation are not aligned with this approach to risk management and may be jeopardised by it. Incentives to innovate will be weaker; allocation of capital to the EU will be more difficult to justify; and technologies needed for achieving the green transition will be lost.
- **It undermines legitimacy and governance** because of **(1)** Lack of justification for the use of the powers of the State. No specific harm is identified, hence the benefits of intervention cannot be assessed. Interventions are not targeted or proportionate. There is no demonstrable improvement in safety; **(2)** Rule of law is weakened because interventions are arbitrary, property rights are lost without evidence of harm, and proportionality is not respected; **(3)** Major risk of regulatory failure because protection may be reduced and significant negative unintended consequences may emerge; **(4)** The EU's commitment to evidence-based decision-making is undermined, in particular regarding the science of toxicology.

Overall, the use of intrinsic properties as the principal factor for determining risk management fails to achieve its goals. Safety is not improved and incentives to innovate are weakened. There are also additional negative unintended consequences, most notably a weakening of governance and the creation of obstacles for the attainment of other important policy objectives.

RISK REGULATION – NOVEL REGULATORY PHILOSOPHIES

At EU-level, the greater use of the intrinsic properties approach to manage risk is being complemented by the progressive introduction of novel regulatory philosophies to determine market access (and retention) for technologies.

These philosophies encompass a range of new ideas that are mostly untried, untested and often controversial. **New, non-toxic criteria, including 'essentiality', are being promoted as alternatives to safety as the primary test of market access.** Similar ideas are emerging for tests of sustainability, persistence or necessity. New ways of assessing potential harms are being proposed, including new hazard categories, grouped assessments, and social concerns. Upstream policies designed to restrict innovation processes are also being developed, together with such ideas as "safe-by-design" and "sustainable-by-design".

As a consequence of this new approach, choices by customers from amongst safe alternatives, will be replaced by decisions made by officials based on the extent to which use or consumption contributes to social betterment, personal virtue, or other perceived societal preferences. Choice is to be limited not expanded. The criteria for determining product availability are subjective and lacking definitions in law that can be implemented predictably or proportionately. Evidence of toxic harm may no longer be required; concepts such as likelihood of harm and safe use are to be set aside; and toxicological knowledge is to be marginalised.

The supporters of this approach argue that it will enable the EU to achieve the ideals of a new way of living, producing and consuming. These novel philosophies are designed to be revolutionary and to set the standard for global regulatory action.

ERIF OBSERVATIONS

Management of the risks posed by the development, production and use of technologies is one of the most important functions of governments throughout the OECD area. It encompasses most of the material technologies (metals, chemical, biology, biotechnology) that form the basis of our prosperity, way of life and transition to greater sustainability and resilience. Its nature and application reflect 'horizontal' policy choices and, in turn, determine not just safety but also market access, investment in innovation, allocation of capital and achievement of ambitious social goals.

As a principles-based approach, likelihood of harm as the predominant approach for managing technological risks has proven to be highly effective at using the power of the State to deliver major social, economic and governance benefits. It is also able to accommodate scientific progress, take advantage of developments in toxicological knowledge and to encompass other policy objectives where these can be assessed objectively. It is, moreover, consistent with the norms of open, commercial societies.

New ideas about the best way to manage the risks posed by technologies continue to emerge. Recognising the strengths and effectiveness of the traditional approach, proposals for the adoption of new ideas should by subject to systematic, rigorous scrutiny. Proposals should be supported by a persuasive intervention logic, anchored in credible evidence that demonstrates the failings of the traditional approach in an objective manner, highlights potential unintended consequences from adopting a new regulatory philosophy and identifies the superior net benefits of the proposed new approach. These requirements are difficult to satisfy.

At EU-level, major changes are taking place in the regulatory philosophy for the management of risks posed by technologies. Whilst parts of the regulatory framework continue to be based on the likelihood of harm philosophy, the use of intrinsic properties as the primary justification for interventions has become widespread in policy, laws and regulation, and new proposals will expand this further. These changes have occurred despite the evident weaknesses and disadvantages of basing risk management primarily on intrinsic properties.

In parallel, insufficient progress has been made in strengthening the governance of regulatory science, covering study quality, assessment of studies, communication of opinions and selection of experts. (See *ERIF Communication 20 Principles and Guidelines for Scientific Integrity in Regulatory Studies 2021*)

At the same time, new, novel regulatory philosophies are being introduced at EU-level. Most of these new ideas focus on using tests of non-toxic harms, such as 'essentiality', to determine market access and retention of technologies. They are controversial, untried and untested. Indeed, their adoption may make it significantly more difficult for the EU to achieve its ambitious social and economic objectives, including delivery of the Green Deal. (See *ERIF Highlights Note 16 'Essentiality', Better Regulation, and Management of Risk from Technologies 2021*).

These changes have emerged at EU-level without an extensive policy debate or a systemic review of the supporting intervention logic. Better Regulation principles and tools have yet to be used to examine the greater use of intrinsic properties or the introduction of non-toxic harms to manage the development, production and use of technologies.

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Richard Meads and Lorenzo Allio, the Rapporteur and Senior Policy Analyst, at the European Regulation and Innovation Forum (ERIF), wrote this Highlights Note. However, the views and opinions expressed in this paper do not necessarily reflect or state those of ERIF or its members.