SCIENTIFIC INTEGRITY, NOVEL REGULATORY PHILOSOPHIES AND BETTER REGULATION

HIGHLIGHTS NOTE 23

- **This Highlights Note forms part of the ERIF contribution to the new Commission's Better Regulation Agenda.[1] It focuses on scientific integrity and its importance for allocation of capital, incentives to innovate and, most importantly, protection of man and nature.**

- **Structural weaknesses in the EU's existing governance processes undermine scientific integrity, creating major problems for predictability and possibly increasing net risk. These weaknesses will be exacerbated if the EU adopts Novel Regulatory Philosophies (NRPs) for the management of risk. Better Regulation, properly used, provides a means of designing and implementing an effective programme of reform.**

BACKGROUND

Science is fundamental to prosperity and well-being. Confidence in scientific integrity in the design of policy, and its implementation through legislation and regulation, is a pre-condition both of general public consent and for the allocation of capital to the EU, and hence the delivery of its ambitious socio-economic goals of greater strategic resilience, a greener economy and prosperity.

Scientific integrity is one of the foundations of evidence-based government. It determines the nature of scientific evidence used to inform and shape decisions. It is based on the scientific method. It is defined by systemic adherence to a well-accepted set of principles, standards and guidance for the collection, validation, dissemination and assessment of scientific evidence used in the policy-making cycle.

Scientific integrity encompasses four critical processes that are undertaken to draw up assessments used to inform regulatory decisions. These are:

- Study quality;
- Assessment of studies and development of opinions;
- Reporting of findings to risk managers and other decision-makers; and
- The selection of scientific experts to carry out assessments.

The principles and guidelines that define these processes are widely understood and respected globally. (*ERIF Communication 20 Principles and Guidelines for Scientific Integrity in Regulatory Studies 2021*).

Scientific integrity is of particular importance during the process of implementation of legislation. It underpins scientific assessments: the expert processes whereby eminent and relevant experts provide decision-makers with predictable, high quality and impartial advice based upon the best available science.

Management of risk, and hence the development and use of technology, rests upon countless implementation decisions made by the executive function of government, mostly based on expert opinions derived from scientific assessment processes.

SCIENTIFIC INTEGRITY – BENEFITS

If applied systematically to the regulatory framework and its implementation, scientific integrity delivers six critical benefits for societies:

- **Safety** – basing assessments of safety of technologies on the principles and guidelines for scientific integrity, helps deliver high standards of protection for man and nature. It ensures that assessments focus on exposures and likelihood of harm, and helps regulators deliver measurable improvements in protection.

[1] See *ERIF Communication 23 Better Regulation, Prosperity, Transition and Resilience – Ideas for the New Commission, 2023.*

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- **Market Confidence** – customers have confidence in the quality of assessments of the safety of products, encouraging use and application.
- **Trust** – this is the basis of commercial society and is strengthened when regulatory interventions are evidence-based and there is confidence in the way in which governments assess the safety and approve the use of materials and products.
- **Safe Use** – scientific integrity, when applied to decisions about risk and safety, makes use of established toxicological and associated knowledge. As such, it focuses on exposures and likelihood of harm, determining safe use of materials. Access to technologies is critical to achieving ambitious socio-economic goals.
- **Legitimacy** – basing regulatory decisions on evidence, particularly science, demonstrates rationality and causality, justifies the use of the powers of the State and supports public consent. Retaining the support of citizens is essential if radical policy objectives are to be delivered.
- **Predictability** – scientific integrity ensures that regulatory decisions are predictable, reducing uncertainty and limiting strategic risks for companies and investors. In contrast, if it is undermined, then greater systemic uncertainty makes it more difficult to justify the allocation of capital.

EXISTING REGULATORY CHALLENGES

The EU recognises the importance of basing legislation, and its implementation, on high quality evidence, including science. This is reflected in the guiding principles of the European Commission's Better Regulation agenda. It has also shaped the institutional structure of the EU, specifically the creation of risk assessment agencies (for chemicals, medicines and food), independent scientific committees and the Scientific Advice Mechanism (SAM). It has stimulated the development of a number of good practices by some of these bodies, such as the peer review of scientific opinions by the European Medicines Agency and the adoption of world-leading Rules of Procedure by the independent Scientific Committee for Consumer Safety.

Research by ERIF suggests that, despite these reforms, too many policy interventions, laws and implementation decisions at EU-level fail to meet accepted standards of scientific integrity. (See *ERIF Monograph 'Fostering Innovation: Better Management of Risk' 2016*; and *ERIF Monograph Risk Management and the EU's Administrative State. Implementing Law through Science, Regulation and Guidance 2019*.)

Scientific assessments at EU-level are unable, in an increasing number of instances to meet world-class standards of impartiality and excellence. The quality of scientific assessments used in implementing rule-making is, moreover, inconsistent. These failings are due to a number of systemic factors, including:

- Low quality studies, that fail to meet the standards of the scientific method, unduly influence scientific opinions;
- Assessments reflect hypothetical exposures or novel and untested theories;
- Experts, who undertake assessments, lack relevant knowledge or are inappropriately influenced by beliefs, ideals, ideologies or political commitments, whilst scientists with relevant knowledge are excluded because of links to commercial society;
- There is widespread inappropriate application of the Precautionary Principle within scientific studies;
- Assessments fail to respect accepted standards of scientific integrity, particularly the need to base opinions on the weight-of-evidence; and
- The EU has been slow to adopt the most advanced scientific methods.

As a result, EU risk management measures tend to be less predictable (creating uncertainty) and disproportionate (leading to the loss of technologies). Decision-making processes also suffer from unjustified delays in assessment and approval and extended testing costs and time (extending time-to-market and increasing capitalised costs of development). Outcomes may also increase net risk, limiting protection of man and nature.

Weaknesses of governance are one of the most important underlying causes of these outcomes. As yet, there is no mechanism at EU-level whereby significant scientific assessments can be independently reviewed and appealed and reviewed, against failure to respect agreed procedural requirements or for manifest errors by other scientific assessment bodies. There are, moreover, no binding principles and guidelines for scientific integrity and no institutional body responsible for drawing up such standards and for enforcing their application.

A further underlying cause is that, in too many cases, expert groups undertaking scientific assessments lack relevant and eminent expertise. This is a consequence of failing to ensure that eminence and relevance are the primary criteria for the selection of scientific experts.

There are number of dimensions to this problem. First, there is increasing use by the European Commission of 'generic' scientific committees (associated with 'horizontal' risk regulation, for example), to develop opinions for which highly specialised expertise is required. Second, the Technical Working Group model, a significant implementation mechanism, does not reflect the major differences in scientific and technical expertise that may exist between Member States. Finally, conflict of interest policies place undue emphasis on financial conflicts. This approach overlooks predetermination and other non-financial factors, yet excludes many of the most eminent and expert scientists due to their links with business. (See *ERF Monograph Risk Management and Scientific Assessments – Understanding Conflicts of Interest and Managing Bias for Scientific Excellence and Impartiality 2020*.)

These existing failings are likely to be exacerbated by the adoption by the EU of Novel Regulatory Philosophies (NRPs) for the management of risk.

NOVEL REGULATORY PHILOSOPHIES

Technological evolution is central to the process of achieving greater economic competitiveness and hence delivering the EU's ambitious socio-economic objectives. There are complex links between the regulatory framework and incentives to innovate, allocate capital, operate efficiently or adjust to new opportunities. Research by ERIF over more than twenty-five years has identified many of these links. (See *ERF Monograph Fostering Innovation: Better Management of Risk 2015*; *ERF Highlight Note 07 Risk Regulation and Innovation 2016*; and *ERIF Highlights Note 18 Allocation of Capital, Better Regulation and the Delivery of the Green Deal 2022*.)

The ERIF Novel Regulatory Philosophies study (NRP), completed in 2023, builds on this work and highlights new, major concerns. Based on an extensive research programme, including more than 150 depth interviews, it examined the evolution in the way in which the EU manages risk and hence the development and application of technologies. (See *ERIF Monograph Novel Regulatory Philosophies in the European Union: Directions, Implications and the Role of Better Regulation 2023*.)

The NRP study revealed a major shift in the management of risk, away from likelihood of harm, safety and safe use, grounded in expert understanding of exposures and mitigated by proportionate measures. A new and largely untested, approach is instead emerging across many policy domains, based on intrinsic properties, precaution, widespread restrictions, unscientific grouping and new tests of market access, specifically essentiality, non-toxic persistence and sustainability.

Looked at in greater detail, this new approach (Novel Regulatory Philosophies) has a number of defined characteristics. Specifically:

- **Limited focus on the core principles of Better Regulation**, including evidence-based decision-making and impact assessment. Restrictions are proposed even though there is no adequate and specific evidence underpinning them, with weak intervention logic and an inadequate assessment of costs and benefits.
- **New ways of assessing and managing potential harms**, particularly precaution, intrinsic properties, groupings, non-toxic criteria, perceived risk and social concern. Toxicological and associated scientific knowledge is marginalised and existing vertical and expert risk assessment is lost, thereby undermining scientific integrity.
- **Use of widespread restrictions and bans** on uses of substances and technologies, based on intrinsic properties, with economy-wide impacts and continued use of specific applications based on time limited derogations and after satisfying subjective tests of social betterment.
- **New subjective, non-toxic and social criteria, most notably essentiality, as primary tests of market access.** Safety and safe use of technologies, based on likelihood of harm, are secondary considerations.
- **Interventions focus on prescription, inputs and processes** rather than outcomes and incentives. Regulation seeks to drive technological development rather than ensuring safety, facilitating safe use and enabling innovation.

These radical changes to the way in which the EU manages the development and dissemination of technologies, are being implemented without a full or widespread debate.

Moreover, this new approach to risk management (NRPs) is largely untested and hence the claimed benefits remain highly uncertain and are not supported by robust evidence of causality or empirical experience. In contrast, the costs are expected to be significant and include systemic uncertainty, resource diversion (away from safer and more sustainable activities), loss of critical technologies, major damage to SMEs and complex value chains, reduced economic dynamism, diminished incentives to innovate and value destruction.

Adoption by the EU of NRPs for the management of risk will also have significant negative impacts on scientific integrity.

SCIENTIFIC INTEGRITY AND NOVEL REGULATORY PHILOSOPHIES

Without reform, the approach proposed by the EU for the future management of technology and materials poses a number of major problems for scientific integrity. These include:

- **Marginalisation of toxicology** – regulatory decisions will be based increasingly on intrinsic properties, social concerns and non-toxic harms, rather than toxicology and associated scientific knowledge.
- **Disharmonised hazard classifications** – EU-specific hazard classifications based on scientific theories not supported by major trading partners.
- **Horizontal scientific assessments** – loss of vertical (industry, application, activity or technology-specific) risk assessment knowledge and bodies, such as the world-leading Scientific Committee for Consumer Safety (SCCS), diminishing the understanding of applications, exposures and proportionate mitigation measures.
- **Erosion of governance** – loss of 'independent' scientific committees because of integration into other bodies, undermining a highly successful institutional approach to ensuring high quality and

impartial assessments that contribute to trust and confidence.

- **Unscientific groupings of materials** – used to support widespread restrictions not based on evidence of likelihood of harm and undermining due process standards.
- **Mandatory adjustments applied to scientific assessments** – arbitrary distortion of the findings of scientific assessments without justification or recognition of assessment methods.
- **Lack of workability of scientific assessment processes** – adoption of widespread restrictions, based on groupings and intrinsic properties, leading to extensive requests for derogations. The scope of such measures is likely to be beyond the technical or administrative capacity of the EU's Administrative State, potentially facilitating extensive administrative discretion and weaker standards of scientific assessments.
- **Focus on precaution** – the emphasis within the regulatory process is intended to become more precautionary, limiting the application of scientific integrity and the use of proportionality.

The challenge facing the EU is to strengthen scientific integrity, including establishing it as one of the most important pre-conditions for delivering its ambitious socio-economic goals. Achieving this will require significant reform, exploiting fully the European Commission's Better Regulation agenda.

BETTER REGULATION AND SCIENTIFIC INTEGRITY – REFORMS

These reforms focus on strengthening political commitment to basing decisions on the best available science, and on putting in place the organisational and institutional structures to achieve that objective.

- The Council of EU Ministers should adopt dedicated Conclusions calling for the application of **common principles, standards and guidance for Scientific Integrity in regulatory decision-making**.
- The EU Legislature should establish a new **Non-Food Consumer Safety Agency**. This will support the existing independent scientific committees and provide, initially, the implementation mechanisms for legislation, for instance, regulating cosmetics and detergents. The agency will provide part of the structure of governance needed to ensure consumer safety. Over time, the agency could expand its activities to support the implementation of other risk management laws that seek primarily to ensure consumer safety for sectors not covered by the existing agencies for medicines (EMA), chemicals (ECHA) and food (EFSA).[2]
- The European Commission should adopt a Commission Decision establishing a new **Office for Scientific Standards in Regulatory Decision-Making**. The Office, drawn from officials of the European Commission and independent eminent expert scientists, should report to the Vice-President with responsibility for Better Regulation.

  Its role will be to oversee and support the functioning of the new Independent Appeals Board, and to draw up and enforce the new horizontal policy for Principles and Guidance for Scientific Integrity in Regulatory Decision-making.
- The European Commission should adopt a Commission Decision establishing a new **Independent Appeals Board for Scientific Assessments**. The Board, which shall be overseen by the new Office for Scientific Standards in Regulatory Decision-Making, will comprise expert and eminent independent scientists.

  Its task will be to review significant scientific assessments (including hazard assessments, risk assessments and groupings) where there has been evident failure to respect agreed procedural requirements, or evident substantive failings by other scientific assessment bodies in the preparation of EU risk assessment and risk management decisions. Registrants may file appeals. The Board will have the power to reverse previous scientific opinions, where substantive new scientific evidence has become available.
- The European Commission should adopt a Commission Decision establishing a new **network of standing independent scientific committees**.

  These committees should comprise independent eminent scientists. Their governance will be based on the Commission Decisions and Rules of Procedure that currently underpin the functioning of the Scientific Committee for Consumer Safety. The new committees will be structured to focus on highly specific issues such as exposures (emissions or occupational exposures), different hazard classes, groupings and inorganic substances. ECHA Secretariat will support the new independent committees.
- The European Commission should adopt a Commission Decision setting out **principles and guidelines for Scientific Integrity in regulatory decision-making**.

  These should be based on global best practices. They will be mandatory and 'horizontal' in application. They will set a minimum standard. The new Office of Scientific Standards in Regulatory Decision-Making will oversee their development, implementation and enforcement. They will cover minimum standards for study quality, assessment,

[2] See *ERIF Monograph Scientific Excellence in Consumer Safety – Insights for the Better Regulation Agenda 2022*; *ERIF Policy Note 34 Consumer Safety, Good Governance and Scientific Excellence 2022*; and Berry, C. (2020), "Frameworks for evaluation and integration of data in regulatory evaluations. The need for excellence in regulatory toxicology", in *Toxicology Research and Application*, Vol.4.

communication to risk managers of opinions and selection of eminent and relevant experts.[3]

- The European Commission should set out, for instance, in a new Decision, the **key principles for the selection of scientific experts and for the operation of scientific committees**. It should seek to deliver the twin goals of excellence and impartiality in scientific assessments, by combining revised selection procedures for individual experts, with new processes and procedures for the functioning of scientific committees and the management of conflicts of interest.
- These should be minimum standards and should apply to all agencies and directorates, and all forms of scientific committee including Technical Working Groups.[4]

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Richard Meads, the Rapporteur of 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 member

[3] See *ERIF Communication 20 Principles and Guidelines for Scientific Integrity in Regulatory Studies 2021*; and Berry, C. (2020), "Frameworks for evaluation and integration of data in regulatory evaluations. The need for excellence in regulatory toxicology", in *Toxicology Research and Application*, Vol.4.

[4] See *ERF Monograph Risk Management and Scientific Assessments – Understanding Conflicts of Interest and Managing Bias for Scientific Excellence and Impartiality 2020*.)