

INNOVATION, ESSENTIALITY AND BETTER REGULATION

HIGHLIGHTS NOTE 19

- The European Green Deal seeks to make the development and use of technologies in the EU conditional on satisfying a test of ‘essentiality’¹. Proponents argue that this requirement will improve the protection of man and nature and stimulate innovation.
- However, the evidence supporting these claims is not robust. The mandatory test of ‘essentiality’ is novel and untried and may create strategic risks and weaken framework conditions, thereby making it less attractive for the private sector to allocate the necessary capital for the green transition in Europe.
- The concept of ‘essential use’ must therefore be subject to a careful review of its underlying assumptions; be clearly and carefully designed; and be accompanied by strong governance. The principles and tools of Better Regulation should be applied to this process.

This Highlights Note forms part of ERIF’s focus on the complex relationship between innovation and the EU’s regulatory framework.

Specifically, the Note examines the potential impacts of the adoption of the Essential Use Concept (‘essentiality’) by the European Commission on future innovation investment by the private sector in the European Union. It makes explicit use of the analysis of factors that underpin the allocation of capital by private sector actors outlined in [ERIF Highlights Note 18 Allocation of Capital, Better Regulation and Delivery of the Green Deal \(2022\)](#). Based on this framework, the Note considers the potential impacts of essentiality on strategic risks, framework conditions and investment economics. Finally, the Note includes recommendations for reforms that build on Better Regulation principles and are designed to limit obstacles to innovation for the Green Deal.

¹ This will occur through implementation of the Chemicals Sustainability Strategy as part of the Green Deal.

INNOVATION, PROSPERITY AND THE GREEN DEAL

Innovation is a defining characteristic of the modern economy. It delivers new ideas; it creates new technologies; and it leads to new and improved products, services and operating methods. Whilst some new ideas lead to radical change, most incrementally improve the efficacy, effectiveness, and efficiency of existing investments, leading to higher productivity and greater value added.

Indeed, in mature economies, innovation is the primary driver of prosperity, economic dynamism, greater choice, more jobs and enhanced prosperity. It is mostly undertaken by the private sector, particularly large-scale firms, although the State plays an important role, both through direct investment and by limiting strategic risks and creating favourable framework conditions, including the regulatory framework. Equally, however, poorly designed interventions by the State can create strategic risks or weaken framework conditions, eroding incentives to allocate capital and to invest in innovation.

The recently adopted European Innovation Agenda recognises the pivotal role that innovation plays in achieving the EU’s social, economic and political objectives. It also highlights the positive contribution that a well-designed regulatory framework can make to fostering innovation.

Indeed, recovery from Covid, greater social cohesion, and enhanced strategic resilience in the face of external challenges, depend upon the economies of the EU becoming more prosperous. This, in turn, is possible thanks to investments in innovation to drive up output and productivity.

In addition, **delivery of the Green Deal depends fundamentally upon investments by the private sector in innovation on an unprecedented scale.** The policy objectives are radical and envisage explicitly the discontinuation of the ‘status quo’ (‘negative’ decisions)

followed by the application of new technologies, the fruits of investment in innovation ('positive' decisions).

However, positive investment decisions do not follow deterministically from negative ones, many of which are likely to involve curtailing the exploitation of existing assets before their capacity to create economic benefits is exhausted. Value will be destroyed, creating obstacles to the allocation of capital. At the same time, many of the new technologies needed either do not yet exist or a long way from commercial viability and material scale (See [ERIF Highlights Note 13 The European Green Deal and Better Regulation 2020](#)).

The impact of the Essential Use Concept on incentives to invest in innovation must be examined within this challenging context.

ESSENTIALITY – MANAGEMENT OF USE AND DEVELOPMENT OF TECHNOLOGIES

The Essential Use Concept ('essentiality'), set out in the Chemicals Sustainability Strategy, forms part of the EU's Green Deal. It is designed to restrict the development, availability and use of existing and new technologies. It has two manifestations: the 'narrow' form proposed within the Green Deal; and the 'wide' form that defines the overall rationale for the concept. In both forms it departs explicitly from scientific assessment as the starting point for managing possible harm to society. (See [ERIF Highlights Note 16 'Essentiality', Better Regulation, and Management of Risk from Technologies 2021](#)).

The 'narrow' form of essentiality seeks to ban all applications of a particular metallic or chemical technology on the basis of intrinsic properties alone. After applications have been banned, users may seek to retain individual uses if they can demonstrate the 'essentiality' of such uses. Such a right may be granted through a temporary derogation by the EU regulator – a fundamentally weak property right. Yet 'essential use' is a concept that is difficult to define or predict, and is based on perceptions of 'need' as determined by officials, rather than 'safety' based on likelihood of harm derived from high quality scientific assessments.

In its 'narrow' form, the application of the essentiality concept challenges the traditional risk management policy used throughout the OECD area:

- There is no attention to safety, safe enjoyment of benefits or specific exposures;
- Toxicological science is marginalised;
- Administrative discretion will create uncertainty and regulatory unpredictability;
- Derogations do not provide strong property rights for further investment. They are temporary and may be removed by the regulator;
- Rights to property are eroded and may potentially be withdrawn without due process; and

- Government interventions are not technologically neutral and proportionate, and applications of technologies may be lost without understanding of potential benefits.

This form of 'essentiality' therefore poses structural challenges to prosperity and to the delivery of the Green Deal. Its application may, moreover, lead progressively to the concept of essentiality becoming part of the regulatory culture of the European Union, thereby mutating from its 'narrow' to the 'wide' form. A similar process has occurred with the concept of precaution since the introduction of the Commission's Communication on the Precautionary Principle in 2000.

In its 'wide' form, the concept of essentiality becomes a test of necessity: by default, applications are assessed, before safety or intrinsic properties are considered, on the basis of their contribution to social betterment. Applications are, therefore, banned unless they demonstrate that their use will be consistent with the values of specific social groups. Perceptions of social acceptability become the primary test of market access. This is the intellectual origin of the overall essentiality concept.

The application of the concept of essentiality in its wide form fundamentally sets out to establish a new economic model: the commercial society is to be replaced with a new approach based on the decisions of officials rather than customers. If applied, this approach will create systemic uncertainty, regulatory unpredictability, loss of property rights and limitation of individual choice.

ESSENTIALITY – STIMULUS FOR INNOVATION

Supporters of the concept of essentiality argue that it is necessary because of the scale and urgency of the health and environmental challenges facing the EU's citizens and environment, as a result of involuntary exposure to unregulated hazardous substances and the inadequacies and slowness of the existing regulatory framework. It will, supporters argue, speed up the transition to a "toxic-free world".

These arguments are disputed. Senior scientists at the BfR (German Federal Risk Assessment Institute) have challenged the evidence used to underpin the application of essentiality and other initiatives within the Chemicals Sustainability Strategy. They point out that the EU's existing regulatory framework is of very high quality and that there is a lack of credible science to support assertions of material unregulated or unmitigated threats.²

Supporters of the essentiality concept also argue that it will trigger innovation. This will occur, they

² See Herzler, M. et al (2021), "The 'EU chemicals strategy for sustainability' questions regulatory toxicology as we know it: is it all rooted in sound scientific evidence?", in *Archives of Toxicology*, <https://doi.org/10.1007/s00204-021-03091-3>.

claim, for three reasons: market-based substitution of 'unsafe' with 'safe' technologies; mandatory anticipation of 'green' demand, thereby creating so-called first-mover advantages for EU-based firms; and improved customer confidence in technologies. Specifically,

(1) Substitution – it is argued that mandatory bans or restrictions, based on the implementation of the essentiality concept, will trigger a market response whereby companies will compete to replace old 'unsafe' technologies with new 'safe' ones.

This claim, based on untested assumptions about the future economy-wide behaviour of private sector actors, lacks demonstrable evidence. In contrast, empirical evidence, based on a review of the use by nation states of mandatory substitution, suggests that investment in new ideas is not triggered. Instead, potentially major risk-risk outcomes emerge because (i) replacement technologies are less well-known and may therefore be less safe; (ii) spending has shifted towards Defensive R&D under increased regulatory pressure; and (iii) major companies delocalise activities in response to value destruction and non-availability of substitute technologies.³

(2) Green Demand – it is argued that governments, rather than the private sector and markets, are better placed and more able to identify the successful technologies of the future and to anticipate the emergence of 'green' demand. As a result, companies should be forced through regulation to adopt these new technologies, thereby creating competitive, first-mover advantages in global markets.

These arguments suggest that markets are functioning poorly and that EU regulators can better determine global investment and technology trends and related decisions. However, there is little empirical evidence of companies failing to understand and respond to the changing purchasing preferences of their customers, or failing to seek technological advances to open up new market opportunities.

In general, governments lack the capability to forecast changes in consumer demand or to understand complex and rapidly evolving technological pathways, whereas companies have powerful incentives to do so. Recent work by the OECD supports this conclusion and suggests, moreover, that there is **no significant empirical evidence to support the theory that stringent national or regional regulation creates first-mover advantages in global markets.**⁴

(3) Consumer Confidence – a third argument claims that incentives to innovate are eroded because consumers lack confidence in new ideas, as a result of

³ See for instance Lofstedt, R. (2013), "The substitution principle in chemical regulation: a constructive critique", in *Journal of Risk Research*, DOI: 10.1080/13669877.2013.841733.

⁴ See OECD (2022), *Are industrial policy instruments effective? A review of the evidence in OECD countries*, STI Policy Papers nr.128.

the presence in markets of technologies that may present potential or hypothetically harmful intrinsic properties.

However, poorly designed or implemented risk management laws may also weaken consumer confidence. Work by ERIF has highlighted areas of concern in the implementation of the existing framework of EU risk management legislation. (See [ERIF Monograph *Risk Management and the EU's Administrative State. Implementing Law through Science, Regulation and Guidance* 2019](#)).

Furthermore, the assessment of the BfR is that there are no significant harmful intrinsic properties that are not being effectively managed by the EU. On the contrary, the application of the essentiality concept, targeting all applications of technology regardless of exposure, safety or likelihood of harm, is likely to create social amplification of risk, thereby increasing risk aversion and eroding consumer trust not only in innovation but also in the public risk management system.

Each of the arguments above lacks strong empirical evidence, while implementation of the essentiality concept may also create strategic risks, weakening incentives to allocate capital to the EU.

ESSENTIALITY AND STRATEGIC RISKS

When allocating corporate resources, private firms and investors take into account differences in the types of risk that investments face in different regional economies. Of particular concern tend to be risks to property rights (including intellectual property), legal certainty and the rule-of-law; regulatory predictability; lack of monetary and fiscal stability; regulatory restrictions on market access or the use of critical technologies; and diversion of investment resources away from innovation and competitiveness enhancement. Taken together, these are considered to be 'strategic risks'.

Within this framework of strategic risk assessment by private sector firms, the EU must compete with other economic blocs globally for the allocation of private capital.

Implementation of the essentiality concept by the EU will create strategic risks:

- **Loss or erosion of property rights** – future creation of value may be found to depend on derogations (a weak property right), and to be combined with destruction of existing investments because of their general intrinsic properties, rather than specific exposures and likelihood of harm in individual applications;
- **Loss of access to markets and critical upstream technologies** – bans on all or critical applications will limit access to technologies;
- **Threats to the rule-of-law and legal certainty** – this will occur because of the subordination of fundamental principles of EU law to poorly defined concepts of 'essentiality' and 'necessity';

- **Major regulatory uncertainties** – this will be the result of the expansion of administrative discretion and reliance on social value judgements in place of science, emphasis on non-toxic harms rather than safety, and complex implementation of novel and untried regulatory philosophies. These problems are likely to be amplified by difficult, partial or no access to administrative or judicial redress mechanisms for investors, producers and users;
- **Inadequate capacity of the EU Administrative State to implement the scale of the ambition of the new approach** – this structural weakness will be exposed because of complicated implementation of novel and untried regulatory philosophies with economy-wide impacts, longer decision-making due to the number of likely applications for derogations and lack of expertise and technical capacity; and
- **Restructuring of the market economy** – this will occur because decisions by officials on the basis of private political values replace choices by customers from a range of safe products supplied by competing firms. Competitive intensity is likely to be reduced, weakening one of the most powerful drivers of investment in innovation.

Overall, there is the potential for the large-scale destruction of business value. Bans and restrictions will curtail earnings generated by existing investments in technologies, whilst obstacles to innovation will make it more difficult to invest in new ideas to create additional competitive advantage.

Finally, alternative markets and production locations to the EU are readily accessible, large in scale, and may offer stronger framework conditions, less strategic risk, stronger property rights (and rule of law) and a more traditional market economy model.

For these reasons, the implementation of the essentiality concept, as a means to manage the development and use of technologies, is likely to create significant obstacles to the future allocation of capital to the EU.

ESSENTIALITY AND FRAMEWORK CONDITIONS

Framework conditions play a major role in creating incentives for firms to invest, particularly in innovation. Public policy plays a leading role in shaping this crucial dimension of the business environment, both by creating incentives and by eliminating obstacles. At the same time, regulatory factors, including policy design, law-making and implementation of legislation, can distort framework conditions, inhibiting private sector investment in innovation.

Recent work by the OECD and research by ERIF suggests that **the framework conditions for investment in innovation reflect three groups of factors** (see [ERIF Highlights Note 07 Risk Regulation and Innovation 2016](#)):

(1) Social attitudes – particularly towards new ideas, risk-taking, precaution and new technologies;

(2) Demand – including access to markets, consumer confidence, use of competitive strategies, market size and adoption of new ideas and technologies; and

(3) Availability of critical inputs – particularly ideas (including access to upstream and other ‘platform’ technologies) as well as financial capital, human capital and digital infrastructure amongst other factors.

The application of the essentiality concept to manage the development and use of technologies is likely to weaken the framework conditions for investment in innovation in the EU.

A major unintended consequence is that competitive intensity is likely to be reduced. Competitive intensity is the capacity of firms in a given market to exert pressure on one another. As such, it is a critical determinant of incentives for private firms to invest in innovation. Essentiality cuts down consumer choice and creates incentives to seek rents based on derogations and administrative discretion, rather than fighting for profits from the development of superior offerings for consumers.

Demand factors are also likely to be weakened:

- Widespread bans create **social amplification of risk**, stigmatising metallic, chemical and other technologies, including those critical for the delivery of the Green Deal;
- Bans and restrictions **reduce market opportunities based on incremental innovation**, where exploitation of known properties of technologies provides a critical innovation pathway;
- **Barriers to market access** are created due to administrative discretion, uncertainty and regulatory unpredictability;
- **Loss of existing markets**, creating uncertainty for future innovation, destroying value and loss of related opportunities in other sectors;
- **Erosion of efficacy due to loss of access to technologies**, thereby reducing product performance, customer satisfaction and value added; and
- **Less differentiation, competition and user choice**, due to restrictions on applications (unless deemed ‘essential’) and loss of efficacy.

Within this context, SMEs could suffer particular damage. Legal uncertainty, regulatory uncertainty, barriers to the use of existing technologies, loss of existing products (and associated profits) and diversion of resources to seek derogations, will all constitute significant barriers to continued market participation.

Access to critical inputs is likely to be restricted:

- **Loss of access to ideas** – upstream and platform technologies that are banned can no longer be exploited by downstream sectors, a major source

of innovative ideas throughout the EU economy. Such restrictions will also disrupt existing innovation pathways, further inhibiting investment in new ideas.

- **Loss of access to capital** – widespread bans of applications of technologies will destroy existing margins and revenues. Retained earnings, derived from existing technologies and assets, are the most important source of finance for investment in new ideas for all firms and for SMEs in particular, because they lack access to public capital markets.

At the same time, firms will have an incentive to divert resources to **Defensive R&D**, to keep old products on the market by incurring expenditure to obtain derogations. However, these weak property rights are unlikely to provide an attractive basis for continuing innovative product development and investment.

Taken together, these impacts are likely to erode incentives to invest in innovation because they materially weaken framework conditions.

ERIF OBSERVATIONS

The concept of 'essential use' is set out in the European Commission's Chemical Sustainability Strategy. It is not, however, considered or clarified in the Commission's Industrial Policy or New Innovation Agenda. The contribution that 'essentiality' is expected to make in fostering innovation remains, therefore, vague, incomplete and poorly explored.

Without reform, including careful design and strong governance of its application, the essentiality concept in either of its forms generates significant obstacles to innovation and few offsetting benefits. Indeed, the concept's potential benefits for innovation are based on theories, ideals or weak evidence rather than strong empirical experience.

There are also weaknesses in the intervention logic that has been developed to support the application of this new and untried regulatory concept. Evidence of regulatory failure of the traditional risk management philosophy based on likelihood of harm is weak, while assessments of specific potential benefits that may result from the implementation of the essentiality concept are inadequate.

Application of the concept of essentiality to manage the development and use of technologies in the EU, is likely to pose a significant threat to the delivery of the Green Deal and to improving prosperity.

The delivery of the Green Deal will face additional obstacles. Negative decisions will be triggered by regulators, leading to the loss of assets and technologies but without the emergence of compensating new investments. Greater strategic risk for private firms and investors will affect the allocation of capital to the EU. Technologies, some of which have complex intrinsic properties but are critical to wider Green Deal objectives, may be lost. Removal of existing

technologies, because of their intrinsic properties, will also make it more difficult for SMEs to innovate, inhibiting the "entrepreneurial renaissance" that it is hoped will form part of the EU's new, green economy.

Creating a more prosperous economy, the foundation of strategic resilience and social equity, will also be more difficult. Application of the essentiality concept will lead to the destruction of value for companies, whilst also inhibiting investment in new ideas to create additional sources of competitive advantage. These potential impacts, combined with increased strategic risk and disruption of value chains, are likely to weaken incentives to allocate capital to the EU to replace, upgrade and expand productive capacity, as well as for innovation.

One of the principal reasons why these potential problems have emerged, has been the failure of decision-makers to adequately distinguish between political goals (the 'ends' of interventions) and the 'means' by which the goals are implemented. As a result, the principles and tools of Better Regulation have not been applied to policy development, which is one of the 'means' by which political 'ends' are delivered. In the light of this, the intervention logic, costs and benefits supporting the implementation of the essentiality concept have not been examined rigorously. There is also a lack of understanding amongst regulators of the potential dynamic impacts of proposed interventions. As a result of these failures of governance, decision-makers have not been able to make fully informed choices.

There is an urgent need to identify ways in which the potential negative impacts of the concept of essentiality on innovation, and hence on delivery of the Green Deal and stimulation of greater prosperity, can be ameliorated. This will require the development of an appropriate governance framework.

RECOMMENDATIONS

To meet these challenges, a number of actions are recommended:

(1) Innovation Principle – the impacts of EU policies on incentives to innovate are not considered in a coherent, co-ordinated and strategic manner. EU decision-makers should make extensive and transparent use of the Innovation Principle and apply it to all proposed policy, legislative and implementing measures. New guidance should be drawn up to ensure that the Innovation Principle is used to highlight incentives and obstacles to investment in innovation and to the allocation of capital to the EU.

(2) Commitment to applying Better Regulation Principles and Tools to policy development – the EU institutions should formally reaffirm the centrality of Better Regulation as the core foundation of decision-making. These commitments should require the application of Better Regulation principles and tools conceptually, methodically and rigorously to all stages of the Green Deal policy and implementation cycle,

including the 'upstream' phase of policy development. Requirements to focus on coherence and proportionality in policy-making should be strengthened.

(3) Better Regulation Guidelines and Impact Assessments – the requirements and methodological guidance for assessing and understanding the dynamic impacts of proposed policy, legislative and implementing measures should be strengthened, particularly with respect to risk-risk tradeoffs; incentives to innovate, including framework conditions and investment economics; obstacles to capital allocation, including strategic risks; adjustment costs; health-health outcomes; and distributional outcomes.

(4) Better Regulation Guidelines and Consultation – informed consultation and interaction with parties affected by proposed measures should be promoted further by, for instance, greater use of public hearings. New guidance should be issued to include identification, by parties affected by proposed measures, of potential dynamic impacts and to allow external assessment of evidence used to support the adoption of new or untried regulatory philosophies or tools. Guidance should encompass all stages of the policy cycle.

(5) Viable Implementation and Innovation – the implementation of the concept of essentiality should aim to minimise its negative consequences:

- The test of 'essentiality', its scope and its implementation framework, should be established under the full EU legislative procedure to ensure full democratic scrutiny and legitimacy. The legal basis for such legislation should be clearly identified.
- Tests of 'essentiality' should only be applied at the end of application-specific risk analysis processes, if at all. They should not precede scientific assessments of the likelihood of harm posed by specific applications of technologies. This is consistent with the established approach for allowing applications to remain on the market, when there are concerns about the level of risk but no viable alternatives and continued use delivers important benefits to users. In these circumstances the use of 'essentiality' should form part of the assessment of risk management options for specific applications, most likely within the assessment of socio-economic factors.
- A definition of 'essentiality' needs to be developed that recognises the complexity of user ecosystems. It should recognise the importance of benefits that form part of the way of life of citizens. This

definition should be reviewed rigorously using Better Regulation principles and guidelines.

- A clear process for determining 'essentiality' must be defined, including provision for appropriate appeal and redress mechanisms.
- The criteria for issuing derogations must be set out clearly, along with the legal basis for and degree of legal certainty provided by such decisions.
- The implementation framework should recognise explicitly the impact of the proposals on the demands made of the EU Administrative State and the resources needed to implement, including impacts on the work of the EU risk assessment agencies.
- The overall legislative proposal for the introduction of the essential use concept into the EU legal framework, including its implementation mechanisms, should be preceded by a comprehensive ex post evaluation of the EU's existing innovation policy framework and its performance. It should also be assessed using Better Regulation concepts to determine the impact on consumer choice, the functioning of markets, incentives to innovate, technical progress, value chain implications, trade barriers and achievement of wider EU political goals. Each of these assessments should include extensive public consultation.

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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