‘ESSENTIALITY’, BETTER REGULATION, AND MANAGEMENT OF RISK FROM TECHNOLOGIES

HIGHLIGHTS NOTE 16

- **A major issue of principle has been raised about the way in which the EU manages the risks posed by the use of existing technologies and the development of new ones. Various tests of ‘essentiality’ based on intrinsic properties are being proposed to progressively supplement or replace application-specific assessments of the likelihood of harm.**
- **This is a new, largely untried regulatory concept that challenges the proven benefits of basing risk management policy on the harm principle. Such a fundamental shift is legitimated exclusively by the hazard of the intrinsic properties of substances, and not the actual risks from exposure. It has occurred without any substantive review of feasibility or potential impacts, including the potential negative consequences for the EU’s ability to deliver its current major goals of Recovery, Resilience and the Green Deal.**
- **Changes of this type and magnitude should, moreover, only be made after public debate and using full legislative powers. This is vital to protect the rule of law.**

This ERF Highlights Note briefly examines the concept of ‘essential use’ when managing technologies. It highlights issues of concern and draw lessons from historic experience. It concludes with a list of key considerations for this important public debate.

‘ESSENTIALITY’ AND RISK MANAGEMENT

‘Essentiality’ is a concept, for restricting the availability (and use) of existing technologies and the development of new ones. Its systematic application is untested. Without any formal assessment of its feasibility, benefits, impacts, or consequences for other policy objectives, such as those set out in the EU Green Deal, ‘essentiality’ is being progressively proposed at EU-level as a new regulatory principle.

It has two different manifestations: the ‘narrow’ and ‘wide’ strands.

“NARROW ESSENTIALITY”

From a narrow perspective, this new approach to regulating technology application and development forms part of the EU Chemicals Sustainability Strategy. It targets all applications of groups of chemicals. Its explicit objective is to phase out and ban all applications apart from those deemed to be ‘essential’. It is proposed to use the Montreal Protocol definition of ‘essential’ to guide regulators. Implementation will be undertaken by the EU Administrative State, resting on grouped scientific assessments, wide definitions of hazard, and generic scientific evidence.

Traditional risk analysis, based on high quality science and application-specific risk assessment, is considered to be too slow and inefficient for the challenges facing the EU. Accordingly, this new approach is proposed in order to (a) speed up the review of hazardous substances; (b) accelerate the process of substitution, remedying the shortcomings of REACH; and (c) act as a spur to innovation.

Application of the ‘essentiality’ concept poses a series of major ‘horizontal’ issues for the EU:

(1) Scale of impacts – restrictions based on this approach will affect most value chains of materials technologies, encompassing metals and chemicals. There could be significant disruption of the functioning of large parts of the EU economy, including relations with global trading partners, which is impossible to anticipate in its entirety or to manage.

(2) Feasibility and unpredictability – the application of a largely untested regulatory approach, using a concept that cannot easily be defined and that must be applied by regulators on a case-by-case basis across large parts of the EU’s manufacturing sector, has the potential to exceed the capacity of the EU’s Administrative State and to create widespread regulatory unpredictability. This would erode incentives to innovate.

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(3) Risk-risk outcomes – efforts to promote widespread substitution, without rigorous assessment of alternatives, increases the likelihood of risk-risk tradeoffs, whereby net risk is increased. This is a form of regulatory failure.

(4) Impact on 'Recovery' goals – it could be significantly more difficult to overcome the economic impacts of COVID, if the application of the 'essentiality' concept undermines incentives to invest in the EU because of potential threats to property rights, markets, and technologies.

(5) Impact on 'Resilience' goals – the EU's aim of increasing strategic autonomy could be undermined if the use of the 'essentiality' concept restricts demand or access to upstream technologies, triggering reductions in activity throughout major value chains (such as processing or formulator industries), in turn, leading to delocalisation and to substitution through importation.

(6) Impact on Green Deal goals – the delivery of the EU's Green Deal could become more difficult. An 'essentiality' test may lead to the loss of key technologies if value chains are undermined. Moreover, pre-determining what is essential and what is not may well prove to be a barrier to innovation. The application of tests of 'essentiality' may also direct even more investment towards Defensive R&D and the retention of old technologies, rather than innovation. And regulatory unpredictability, combined with the loss of markets and technologies, may weaken the investment climate for allocation of capital to the EU.

"WIDE ESSENTIALITY"

The origins of this new approach lie in arguments developed in some policy circles to regulate the application of technologies not on the basis of safety, using traditional risk analysis, but rather on the basis of the social purpose of uses reflecting values and moral criteria. Applications that are non-essential or "nice-to-have" should be banned, it is argued, because they do not contribute to the betterment of society or may not contribute to a particular moral perspective. This is, in effect, a non-essential or 'necessity' test. Based on value judgements, it moves beyond the "harm principle", sets aside traditional risk management, and provides a new basis to legitimate State intervention, and to organise society and the economy.

This wider understanding of 'essentiality' is already being applied in a limited number of policy areas such as product design guidelines, eco-labels and standards, responsible research and innovation initiatives, R&D support, and eligibility for State Aid programmes.

Supporters of this approach to the management of technologies argue that it is necessary for three reasons. First, we are facing pressing health and environmental crises: traditional approaches are no longer appropriate, and action is imperative. Second, markets have failed to deliver the social and environmental goals desired by political leaders (although this is questionable in view of the enormous contribution that market economies have made to prosperity and the quality of human life.) Finally, consumers are unable to make informed choices through a lack of moral autonomy. Hence, officials must set out and enforce value standards.

This wider interpretation of 'essentiality' is problematic. In addition to the 'horizontal' challenges described earlier, it poses a number of additional issues:

(1) Functioning of the economy – this concept changes the way our market economy functions. Officials rather than markets would decide product choices: availability of goods and services would be determined on the basis of their contribution to 'betterment' of society rather than safety or the needs of citizens. The scale of State intervention in private choices will be extended. Producers of goods and services face systemic uncertainty, regulatory unpredictability, and loss of property rights.

(2) Understanding the dynamic nature of 'essentiality' – the idea that it is possible to attribute 'essentiality' status to a technology on the basis of current value judgements of official and technical current knowledge, implies the capacity by regulators to both fully anticipate or to exclude future potential uses. It is, moreover, a static and deterministic vision of society, that fails to recognise how innovation is stimulated and unfolds over time. 'Essentiality' is dynamic. Use of value judgements, rather than likelihood of harm, also questions fundamentally the role of evidence, particularly science, in protecting man and nature.

(3) Legitimacy – value judgements made by officials (and, ultimately, by the State) would, using this regulatory concept, replace systemically the autonomous decisions and agency of individuals, posing potential problems of consent, legitimacy, and freedom of choice.

ISSUES OF CONCERN

Decisions by officials and regulators to implement this new approach to the regulation of technologies, in both its 'narrow' and 'wide' manifestations, raise a number of wider issues of concern, including:

(1) Lack of informed debate – there has been no adequate or rigorous public assessment of the costs and benefits of the use of this new concept and, as yet, no impact assessment of the overall strategy for management of chemicals or of the progressive introduction of the "non-essential" test to guide a wide range of policy choices. Furthermore, no assessment appears to have been made of the feasibility of applying this concept, including the capacity of the EU Administrative State to implement it. Similarly, no structured ex post evaluation of other forms of the essential use concept has been carried out. There appears to be a lack of awareness of the use of the 'essentiality' concept, its importance, and its implications for the EU. Indeed, there have been suggestions to

introduce use of the concept through comitology and guidance, despite the obvious importance and the scale of its potential impacts. The legal base in the EU Lisbon Treaty for the 'essentiality' concept should be clearly identified and such changes should only be introduced using the appropriate legislative procedures.

(2) Failure to examine fundamental assumptions – these assumptions include:

- **The progressive and systematic phasing out of hazardous substances will deliver higher levels of health, safety, and environmental protection.** Recognising the difference between hazard and risk, and noting the possibility to mitigate the likelihood of harm, what evidence is there of the systematic and credible net benefits that primarily hazard-based approaches have delivered to Europe? Moreover, can citizens be reassured that replacements will be safer or more sustainable and is there a need to clearly demonstrate the necessity of a necessity test?
- **Bans, substitution or State direction will trigger significant investment in innovation by private companies.** Is there sufficient evidence that this is systemically the case?
- **Incentives to allocate capital to the EU for investment and innovation will be strengthened.** Despite potential reductions in demand, loss of technologies, higher fixed costs and increased regulatory uncertainty, (because 'essentiality' cannot be easily defined and will be subject to administrative discretion) incentives to allocate capital to the EU will be strengthened. How likely is this to occur when other markets offer different opportunities?
- **The EU will not be affected by reciprocal actions, despite the possibility that these new concepts may create barriers to trade, because of its importance as a global trading partner.** How important is the EU within the global economy, and have the potential impacts of reciprocal non-tariff barriers been fully evaluated?
- **The EU Administrative State has the capacity and expertise to implement this new conceptual approach to managing technologies without the possibility of regulatory failure.** In view of the scale of application and the difficulty of defining the meaning and scope of the 'essentiality' test, is this credible? Because of its reliance on administrative discretion, how will this new approach avoid creating systemic regulatory risk and unpredictability?

(3) Value chain disruption – in its 'narrow' manifestation, the 'essentiality' concept could have very significant implications for the future scale and shape of important materials value chains. In processing industries with high capital intensity and high fixed costs, the loss of non-essential applications and threats to property rights may trigger significant restructuring. Similarly, the application of the wider form of 'essentiality', based on banning 'non-essential' applications that meet emotional needs, could adversely affect consumer goods sectors, undermining brand equity, plant efficiency, technology availability, consumer choice, retail employment, as well as diverting resources into Defensive R&D.

(4) Functioning of a new economic model – the adoption of the essentiality concept, in all of its forms, challenges many of the assumptions, such as property rights, legal certainty, autonomy, and private choice, on which the market economy rests. A new "moral economy", based on consumption and production for the betterment of society, may emerge, where government decisions dominate. The consequences of this do not yet appear to have been rigorously examined but comparison with previous experience in planned economies may be instructive. Does this new approach provide incentives for the private sector to allocate capital and to innovate, or is this threatened by lack of property rights, loss of technologies, and regulatory uncertainty? Finally, there are questions to ask about the durability of this new approach. Moral choices made by officials, the new basis of technology management, may be challenged by citizens, posing issues of consent, and may change over time.

(5) Impact on wider political goals – there is, as yet, no adequate assessment of the impact of the progressive adoption of the 'essentiality' concept on the ability of the EU to achieve wider social goals, most notably the Green Deal. Movement to a low carbon, more sustainable future may be threatened if the application of tests of 'essentiality' leads to a loss of key technologies (needed for Farm-to-Fork, Circular Economy, or Movement strategies, for example), or a failure to invest in innovation, or to allocate capital to re-quip production processes with low carbon technologies. **There is, so far, no workable definition of the concept of 'essentiality' beyond that used in the highly focused Montreal Declaration. Moreover, 'essentiality is likely to evolve over time; it is not binary. It is also a process and not an event. Applications and technologies that may not appear to be for the betterment of society today, judged by a particular set of moral values, may be indispensable for solving the challenges of the future.**

LESSONS FROM HISTORY

Looking at these issues, it is possible that lessons can be learned from other recent policy experiences.

(1) Widespread substitution, innovation, and risk-risk – recent academic research suggests that in the small number of cases in EU Member States where the substitution principle has been applied widely there has been no evidence of significant benefits. There is no evidence that bans and substitution promote large-scale investment in innovation. Resources were instead allocated to Defensive R&D, older technologies were adopted to replace newer ones subject to restrictions, and there were risk-risk tradeoffs because the risks posed by replacement technologies were less well understood.

(2) Derogations and incentives to invest – in a number of risk domains, such as crop protection products, and substances used in electrical and electronic equipment, EU risk management laws allow the Commission to keep substances on the market, despite the presence of risks, because there are no alternatives, and the application is 'essential'. European Court of Justice rulings and case law supports the use of this risk management option. There is, in other words, an existing 'essentiality' already present in EU risk management practices. Derogations are, however, temporary and confer only weak property rights. They are not a characteristic of a high-quality regulatory framework and have not proved to provide a basis for innovation. These new forms of 'essentiality' seek, in turn, to base economic activity on derogations that may be rescinded.

Derogations, moreover, do little to provide the property rights needed for the allocation of capital in applications where technologies that are changing rapidly, such as batteries or medical sciences. Investors would face the threat of losing their weak property rights as soon as other but less proven technological approaches become available. Economic and social progress, however, may benefit from the competition between multiple technologies.

(3) 'Fourth Hurdle' and access to medical technologies - towards the end of the 1990s, EU regulators examined the possibility of increasing the tests that pharmaceutical technologies had to satisfy before they could be placed on the market. It was proposed to add 'Need', a test of essentiality, to the traditional requirements of Safety, Quality, and Efficacy. After considerable public debate, this 'fourth hurdle' was dropped. Regulators accepted that its application failed to recognise the complexity of human biology and patients' needs and wants, and would create rents for incumbents, reduce competitive intensity, increase prices, and limit incremental innovation. (Whilst an EU-level test of 'Need' was not adopted, similar tests continue to be used by some Member States.)

(4) Montreal Protocol – this international treaty for managing the risks posed by ozone-depleting substances is often used to illustrate the merits of the 'essentiality' concept. A close examination suggests that it has been successful because of a number of clearly defined and widely accepted factors. The focus of the policy was limited. There was widespread acceptance of the science-based intervention logic. Alternative technologies were already available. Finally, the test of 'essentiality' was applied when alternatives when not available and it recognised intellectual and cultural factors, as well other socio-economic needs. These are important lessons.

(5) EU Administrative State – recent research by ERIF (see *Monograph 'Risk Management and the EU's Administrative State' 2019*) identified major failings of governance and a mismatch between resources and the scope of responsibilities entrusted to the EU's Administrative State. These contribute to a significant risk of implementation decisions failing to meet global standards of regulatory quality. Indeed, the ERIF report concluded that in too many cases, decisions are disproportionate or unduly precautionary or unpredictable, or take too long, or impose unjustified costs. These weaknesses, and their outcomes, are a structural impediment to the effective implementation of an untested and potentially far-reaching regulatory concept such as 'essentiality'.

ERIF OBSERVATIONS

The EU faces major challenges as it seeks to meet the expectations of its citizens for a more resilient, healthier, prosperous, and greener future. All new policy ideas should support the fulfilment of these goals.

In this context, new, untried concepts for the management of the use and development of technologies should be subject, prior to introduction, to extensive and informed debate. So far, however, there is lack of adequate awareness of the scale of potential change and the potential impacts that could emerge if 'essentiality' replaces safety, based on application-specific risk analysis, as the basis for regulating the use and development of technologies.

Better regulation concepts provide the most relevant framework for examining the costs and benefits of new ideas for the management of technologies. They ensure that assessments are dynamic and holistic. They examine feasibility, articulate outcomes (positive and negative), and set out the balance of benefits and costs. They are designed to enable policy-makers to recognise and understand trade-offs (such as risk-risk), unintended outcomes, regulatory failures and human consequences, including impacts on fundamental rights, living standards, mortality, and morbidity. They focus on evidence rather than academic theories or idealistic plans. Finally, Better Regulation processes used to undertake assessments, ensure that citizens and affected parties are consulted and that proposals recognise the success or failure of historic initiatives.

A further strength of Better Regulation is its capacity to encompass, within its overall conceptual approach, new concerns. In this instance, it is of critical importance to ensure that the introduction of untried and controversial concepts for the management of technologies, do not undermine the attractiveness of the EU for the allocation of capital, or trigger the loss of technologies needed to meet future challenges, or erode incentives to innovate. Delivering the EU's Green Deal depends, for example, on access to capital, technologies, and the innovative potential of businesses of all sizes.

Finally, the rule of law must be respected. Fundamental changes in the way in which the use of existing technologies and the development of new ones is managed, using untried ideas and affecting most of the EU's manufacturing sectors, should only be made through duly enacted legislation. They should be subject to full legislative scrutiny. They should not be introduced using implementing mechanisms.

To meet these challenges, a number of actions are needed. Specifically:

(1) Public debate – a structured and informed society-wide debate should be launched. It should encompass:

- An assessment of the socio-economic benefits of using 'safety', 'risk', and 'sustainability', rather than 'essentiality', to regulate the use and development of technologies. This will provide a better understanding of the context within which new, untested ideas are being proposed;
- A detailed review, using Better Regulation concepts and tools, of all forms of 'essentiality' used by the EU institutions, as well as proposals set out in the Chemicals Sustainability Strategy. It should include all of the areas of concern identified within this ERIF Highlights Note;
- A critical examination of the evidence and rationale that supports the assumptions used to promote the widespread use of 'essentiality'. This ERIF Highlights Note identifies the most important assumptions;
- A review of the relevant historical evidence;
- A clarification of the rationale and limits, of hazard-based approaches to managing technologies, as well as an examination of the purpose and role of precaution in risk management decisions. (Any review should recognise that the EU's approach to precaution, set out in the 2000 Communication, places precaution unequivocally within the traditional application-specific model of risk analysis.)

(2) Chemicals Strategy – the EU Chemicals Sustainability Strategy, its specific proposals, and the assumptions on which it rests, should be subject to an extensive and rigorous Better Regulation scrutiny.

(3) Rule of law – all new proposals that seek to implement tests of 'essentiality', non-essentiality', 'necessity' or equivalent concepts for the management of technologies, should be made using formal legislative procedures. They should not be introduced through executive powers, by means of comitology decisions, or substantive guidance.

(4) Better Regulation guidelines – these should be revised to provide officials with the specific tools needed to assess new proposals for the management of technologies, including focus on property rights, policy trade-offs, risk-risk outcomes, allocation of capital, incentives to innovate, value chain impacts, other dynamic impacts, and identification of the ultimate benefits of proposals for humans and nature.

(5) Viable Implementation and Risk Management – in the event that a test of 'essentiality' is adopted as a tool for managing the risks posed by technologies, then its implementation should aim to minimise negative consequences including regulatory uncertainty; to strengthen incentives to innovate and to allocate capital to the EU; and to support the achievement of wider EU policy goals, including the EU Green Deal. Specifically:

- The test of 'essentiality' and its implementation framework should be established using full legislative procedure. This should clearly identify the appropriate legal basis for such legislation.
- Tests of 'essentiality' should only be applied at the end of application-specific risk analysis processes. They should not precede scientific assessments of the likelihood of harm posed by specific applications of technologies. This reflects their historic use as a rationale 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, probably within the assessment of socio-economic factors.
- A definition of 'essentiality' must be developed that recognises the complexity of user needs. This definition should be reviewed rigorously using Better Regulation principles and guidelines.
- A clear process for determining 'essentiality' must be defined, including providing appropriate appeals and redress mechanisms.
- The criteria for issuing derogations must be set out clearly, along with the legal basis for and legal certainty provided by such decisions.
- The implementation framework must recognise explicitly the impact of the proposals on the capacity of the EU Administrative State, including impacts on the work of EU risk assessment agencies.
- The overall legislative proposal, including the implementation framework, should be reviewed 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.

European Regulation and Innovation Forum
May 2021

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