Improving the Common EU Regulatory Environment for all Stakeholders

EU regulation is hugely important for European public and environmental health and for European industry competitiveness and innovation. Every industry sector has an interest not only in applicable sectoral and substance-by-substance regulation but also in the common regulatory environment that crosses all sectors. The European Regulation and Innovation Forum (ERIF) believes that the EU Better Regulation agenda provides an opportunity to improve the common regulatory environment for all stakeholders, and has identified the following horizontal regulatory issues for attention. A cross-industry initial workshop is proposed to confirm the common regulatory challenges facing all sectors and to seek practical improvements building on the Better Regulation agenda.

Key Issues for Consideration

1. **Cost of up-front data acquisition and prioritisation:** EU regulators often request extensive data packages in advance of a legislative initiative or regulatory action. This imposes heavy costs on companies before it is known that a legislative or regulatory action will proceed. Initial data acquisition requirements should consequently be limited to the level necessary for addressing the question: 'is there a robust cost-benefit case for regulatory action?' If a regulatory action does proceed, subsequent data acquisition requirements should be phased in as required for each stage of the regulatory process and not before.

2. **Opportunity costs and diversion of resources:** Complex compliance processes not only cost money but also tie up key personnel and R&D efforts. The same experts who might be developing new products or safer alternatives must instead spend hundreds of hours preparing regulatory dossiers. The opportunity cost in terms of diversion of time and talent, and of innovation delayed or foregone, can be much larger than the direct cost of compliance. Impact assessments must consequently take account of opportunity as well as direct costs, in order to provide a fully-worked up basis for regulatory intervention.

3. **Up-front impact assessment and prioritisation:** Robust up-front impact assessments are a crucial tool for enabling the feasibility and prioritisation of regulatory actions. Not everything can be a priority. Regulatory intervention should focus first on the regulatory actions having the greatest benefits relative to costs (including opportunity costs).

4. **Impact on availability and final costs to users:** Regulations can have knock-on effects on the end consumer. If compliance is costly or bans certain inputs, companies may withdraw products or raise prices. This can reduce the availability of certain goods or services in the EU market and make those that remain more expensive for users. For instance, in highly regulated sectors like medical devices, overly strict rules have in some cases risked the premature withdrawal of essential equipment, which could negatively impact healthcare delivery.

5. **Assessing the balance of hazard and risk:** The public interest is best served when risks are managed in a proportionate manner as called for by the EU Treaties. Regulatory interventions should aim for the most effective means of managing the risks arising from well-defined hazards. Regulatory interventions – including for low-volume, well-controlled uses – should carefully consider in what circumstances and quantities a product or material is used, and ensure that the precautions taken are proportionate to the assessed level of risk.

6. **Over-reliance on the precautionary principle:** Along with proportionality, the precautionary principle is a cornerstone of EU policy, allowing action to prevent harm even when scientific evidence is not 100% certain. However, the precautionary principle is not intended as a justification for inadequate science in regulatory action. A carefully weighed assessment of the risks in the light of best available scientific evidence is crucial to avoid loss of public welfare. ERIF's analysis of the recent European Court judgement on titanium dioxide indicates ways in which unjustified over-precautionary approaches can be avoided.

7. **Regulatory consistency:** Inconsistency in regulation and lack of predictability in regulatory outcomes – both across EU member states and across different EU regulations – increase investor uncertainty and are a significant cause of investment delays and cancellations in Europe. ERIF believes that the Commission, in particular, has an important responsibility to identify and address inconsistent regulation and this should be a high priority. There are good reasons to foresee that the application of AI can be particularly effective in this area.

8. **Consistent standards for use of Weight of Evidence:** Good quality regulation requires all available scientific data to be considered together. Reliance on a single or limited set of studies or datapoints carries a profound risk of imposing political preferences on the evidence (such as when classifying a hazard or approving a product). The EU system has significant challenges in applying a consistent approach. Different committees or agencies weigh studies in different ways, and provide different opportunities for expert involvment. ERIF believes that the responsibility lies firmly with the Commission to standardise how scientific evidence is assessed and presented e.g. to clarify what constitutes relevant and high-quality data, and how to weigh and judge conflicting results. Again ERIF believes that prompt application of AI can provide considerable assistance in this area.

9. **Access to and use of best scientific expertise:** High-quality decisions depend on high-quality science. Regulators need access to top experts and up-to-date research when crafting and implementing regulatory actions. Experts should not be excluded because of their affiliations, provided that interests are fully declared. If expert committees or decision-makers lack specialist knowledge, they will not be well placed to assess the evidence before them. For example, the titanium dioxide classification was annulled by the European Court in 2025, as the initial regulatory decision had not properly accounted for scientific evidence on actual risk.

10. **Scientific appeal:** The pathways available within the EU for challenging the use of science in a regulatory action are effectively limited to a long and costly journey through the European courts. A regulatory system based on science should include a readily accessible means of scientific review short of jumping straight to legal process. Such a mechanism would allow regulators to revisit or refine decisions when new evidence emerges, or when scientific evidence is subjected to reasonable challenge. There are clear benefits for all stakeholders if differences of scientific interpretation can be addressed, and are possible resolved, before entering into full legal process.

11. **Innovation Stress Test:** EU regulators have consistently recognised the importance of not damaging innovation through unintended regulatory impacts. However, the EU has no standard procedure for indentifying and avoiding such negative effects. An "innovation stress test" developed by the EESC, endorsed by the Council and supported by ERIF, provides a systematic tool for evaluating how a proposed regulatory action could impact the development of new technologies, products, or business models. Regulators can then adjust policies to mitigate unintended negative impacts. ERIF strongly recommends embedding an innovation stress test within all EU regulatory processes to ensure a consistent approach to innovation impact.

12. **Internationalisation:** EU regulations have to be seen in a global context. There is a valid argument that the EU does lead by example and can have a first mover effect on regulation in other major jurisdictions. On the other hand, if EU rules are visibly more stringent or complex than those elsewhere, it is a commerical reality that investments will be made elsewhere and operations and employment within Europe will decline. The EU should continue to work towards common global rules and/or mutual recognition, while recognising that it must always calibrate its own regulatory approach against the realities of international competition.

13. **Imports and enforcement:** Even the best-crafted EU rules mean little if they are not properly enforced at the border and in the market. A perennial challenge is ensuring that imported goods comply with the same requirements as EU-made products. Robust enforcement is required to ensure that non-compliant imports do not undercut EU companies or undermine health or environmental objectives. Effective enforcement involves customs checks, market surveillance, and cooperation with trading partners, and should be treated as a core EU regulatory function.

14. **Joined-Up Regulatory Practice**: joined up regulatory practice requires that potentially competing goals of competitiveness, environmental and human health, consumer choice and social welfare, are balanced and resolved within the regulatory process. However, in reality, European regulators are often perceived as focusing on their own area of competence irrespective of the wider impacts of their actions. It is especially important that the Commission, as sole originator of EU legislative and regulatory actions, make clear to all staff that a joined up approach is non-negotiable and expected in all circumstances.

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November 2025