



DEFENSIVE R&D AND INNOVATION

HIGHLIGHTS NOTE 08

When scarce resources are diverted, for regulatory reasons, into the defence of existing products rather than into investment in new ideas, incentives to innovate are blunted. Known as “Defensive R&D”, this process is one of the most important unintended consequences of the way in which the EU chooses to manage risks to human health, public safety, and the environment.

This ERF Highlights Note examines this ‘hidden’ regulatory impact. It explains its nature and rationale. It comments on its importance for citizens and for innovation. Finally, it identifies a small number of reforms that could, if implemented fully, help limit the negative effects of Defensive R&D (research & development).

DEFENSIVE R&D – DEFINITION

For Europe’s citizens, jobs, wealth, and their quality of life depend on innovation – the main ‘engine’ of enhanced productivity and economic growth, and the principal means of achieving Europe’s social and environmental goals. Growth results primarily from risk-taking by investors, managers, and entrepreneurs. It is a form of investment decision and flourishes when societies create strong incentives for businesses to take risks and to allocate capital to new opportunities.

Investments in research and development (R&D) are critical for innovation – they ‘fuel’ its growth through the employment of scientific and technical resources to develop new knowledge for competitive advantage.

Too often, however, R&D resources are diverted away from this process, in order to fulfil regulatory requirements. Instead of fuelling innovation, they are used to keep ‘old’ products or substances on the market. Moreover, this process of complying with

regulatory requirements rarely triggers the release of additional capital from investors. There is no compensatory flow of scarce capital. Expenditures on R&D are, in general, determined by global norms set by capital markets and, as such, do not take account of national or regional regulatory requirements. In consequence, there are major opportunity and financial costs, and, through the response of affected businesses to such costs, the availability of ideas elsewhere in the economy is restricted. Innovation is restricted and distorted, and citizens face higher prices, less choice, and greater risks.

In its narrowest sense, Defensive R&D occurs when new regulatory requirements are applied to existing products, substances, or technologies. In turn, this requires the diversion of expenditures on science and technology, so as to ensure compliance. Examples include new or enhanced product safety standards; different process or product performance requirements, including environmental outcomes; and the introduction of new testing methods, such as restrictions on animal testing, for establishing existing safety, quality, or efficacy standards.

A wider definition of Defensive R&D focuses, instead, on the diversion of all forms of scarce innovation resources away from the exploitation of market opportunities and towards compliance with regulatory goals. This recognises differences in the innovation models utilised by different sectors. Regulators should focus on this.

DEFENSIVE R&D – RATIONALE

Defensive R&D is not a new phenomenon. It is an inherent characteristic of traditional risk management mechanisms. From its beginnings in the 19th Century, public management of risks posed by technologies to citizens and the environment has required businesses to

up-date protections as knowledge and technology has progressed. Meeting these requirements has been one of the mandatory costs of undertaking economic activity in developed markets.

When well designed, such requirements are predictable and targeted; based on high quality scientific evidence and a robust understanding of real world exposures; and, informed by extensive knowledge of costs and benefits. Traditionally, businesses have been able to absorb such requirements without major distortions in the allocation of capital for innovation.

Things have changed, however, over the last two decades. Instead of requirements being targeted and based on risk, they are increasingly applied to entire categories of substances or products or applications. REACH, for example, applies new hazard-based safety requirements to all existing substance-use combinations of chemicals, regardless of evidence of risk. Other risk management laws take a similar approach. Such increases in the scope of application of new requirements to existing technologies have triggered a major growth in the scale of Defensive R&D. In the chemicals sector, for example, this has been on an enormous scale, absorbing a significant percentage of R&D and costing billions of Euro.

Changes of this nature reflect shifts in underlying social attitudes in the EU. Risk acceptance has declined amongst certain groups and trust in regulators and business has been eroded by regulatory failures (such as contaminated food and BSE). Moral values have changed too, leading to restrictions on using animals for product testing. More transparency, shifts in the burden of proof, and less willingness to accept a lack of knowledge as evidence of lack of harm are the results.

Whilst these changes have created a new context within which risk management laws are developed and implemented at EU-level, the costs and benefits of the resulting growth in Defensive R&D are little understood.

DEFENSIVE R&D – IMPACTS

Mandatory application of new requirements to existing products, substances, or technologies has negative and positive impacts on incentives to innovate.

Positive Impacts – when measures are well designed and are based on high quality scientific evidence and realistic assessments of risk, market confidence can be strengthened, underpinning demand. This occurs through two mechanisms: reductions in potential harms, and greater user knowledge and transparency.

Such gains are lost, however, if the process of applying new requirements provides the basis for social amplification and stigmatisation.

Negative Impacts – disproportionate levels of Defensive R&D have significant wider impacts on the scale and nature of innovation, and on citizens. Specifically:

- **Loss of access to established technologies because of regulatory-induced decisions** - In many sectors, companies rely on access to a 'palate' of proven technologies, many of which are embedded in substances purchased from suppliers. This is particularly the case for SMEs operating in the downstream parts of the EU's value chains.

Risk management decisions can affect the availability and attractiveness well-established technologies, limiting the diffusion of ideas and innovation. If the mandatory costs of ensuring that existing substances and their uses meet new standards of safety (or quality or efficacy) exceed the capitalised future margin of a substance then, in general, they will be voluntarily delisted. Downstream users will lose access to them, along with all of their embedded technologies.

Indeed, a key issue facing risk managers in most OECD countries is how to develop high quality risk management frameworks for the myriad uses of very large numbers of substances in heterogeneous applications throughout complex value chains. To date, the EU has struggled to achieve this, and in too many instances, decisions have been of poor quality. This has created major threats to the continued availability of proven technologies. Categories of products or specific applications have been restricted without conclusive scientific evidence of harm, as has occurred with food ingredients, polycarbonates, metallic chemicals, phthalates, and brominated flame retardants: in other instances, the disproportionate cost of demonstrating safety or quality or efficacy of well-established materials has triggered voluntary withdrawal of substances, most notably in biocides, crop protection, and animal health.

Taken together, this loss of existing substances (and the knowledge embedded within them) distorts innovatory activity and inhibits the development of new products and operating processes, especially incremental innovations by smaller companies operating close to end users. It also reduces the availability of retained earnings for future investment in innovation, a problem of particular importance for SMEs with their lack of access to public capital markets.

- **Diversion of resources away from new ideas because of the cost of "Defensive R&D"** – Loss of existing ideas is not the only problem triggered by the growth of Defensive R&D requirements in the EU. **Mandatory expenditures to demonstrate the safety or efficacy or quality of existing substances, even when there is no evidence of harms, diverts scarce resources away from investment in new ideas. Companies when faced by this requirement do not, in general, allocate additional resources to**

innovation. In the light of this, innovation resources in the EU are used, all too frequently, to “prop up” old technologies rather than to develop new ones or to support incremental improvements. This slows down the pace of productivity growth, limiting increases in employment and wages.

Emerging evidence from the initial evaluation of the EU’s REACH programme for the management of risks posed by chemical usage highlights the problem. Other sectors have experienced similar problems, most notably animal health, biocides, agricultural machinery, and crop protection.

- **Reduced attractiveness of the EU for capital allocation** – High and disproportionate levels of Defensive R&D create market structures that are unattractive for innovative businesses. Product availability is reduced, making it difficult to compete on the basis of variety and choice. Old technologies are favoured, limiting opportunities to create value through the development and application of new ideas. There are barriers to entry as well, because of the cost of applying new requirements to old products. In this context, investors are likely to focus more upon reducing costs through mergers and acquisitions or divestments than on investing in innovation. Evidence of this is already apparent in a number of high technology sectors, most notably biotechnology and biocides.

- **Economic losses for citizens** – In a context of less innovation, reduced product availability, and a focus on older technologies, citizens lose out. Productivity growth is lower, reducing wealth, taxes and employment. Product choice is reduced, limiting consumer satisfaction and surplus. Prices are, moreover, likely to be higher. Less competitive intensity, high barriers to entry, and limited incentives to innovate tend to create ‘rents’ for existing competitors.

- **Increased risks for citizens** – reduced availability of substances and products because of Defensive R&D leads to the loss of existing product benefits. In some cases, this has triggered ‘risk-risk’ outcomes, whereby new harms have been created or existing ones exacerbated. Examples include veterinary medicines and loss of availability of treatments for minor uses or species; reduction in biocides creating health risks in the personal and household care sectors; and the impact of the reduced arsenal of crop protection products on the environmental impacts of agriculture.

When societies choose to manage risks by diverting resources away from investment in new ideas, then such decisions should be taken cautiously and with a full understanding of benefits and costs. This should include a rigorous assessment of potential increases in harms due to risk-risk.

ERF OBSERVATIONS

In a growing number of sectors, Defensive R&D has become a significant problem at EU-level. Instead of building user confidence and reducing harms, it has eroded incentives to innovate, slowed down productivity growth, reduced the attractiveness of the EU for investment, and created additional risks for citizens. Action is now needed to overcome these problems.

A small number of reforms, if implemented together, would begin the process of improvement:

- *Embed the Innovation Principle in legislative and regulatory decision-making* – the EU institutions should build on the decision of the recent EU Competitiveness Council and promote behavioural change throughout the regulatory process;

- *Undertake institutional reform to ensure greater focus on innovation* – to begin with there is a need for the European Commission to establish a revised institutional structure to provide an “innovation champion” in the legislative and regulatory process; to disseminate the horizontal lessons of REFIT; to seek out stakeholder insights, thereby ensuring that wider negative impacts are not overlooked; and to balance political momentum and single issue concerns during the process of law-making;

- *Carry out a major horizontal evaluation of the impacts of risk management laws on innovation* – this should include working with stakeholders to highlight the scale, nature and impacts of Defensive R&D;

- *Revise and expand the ‘innovation’ tool kit within the new Better Regulation integrated guidelines* – this should describe Defensive R&D in detail, provide examples of when it has occurred and its impacts, and set out guidance for minimising its impacts. It should also require regulators to consider the sector-wide and value chain requirements of substances and technologies;

- *Develop design guidelines for future risk management laws* – to limit future Defensive R&D these should require regulators to target specific concerns rather than entire product categories or processes, wherever possible; to avoid untargeted, disproportionate mandatory requirements; to base requirements on risk assessments using the best available science and real world exposures; and to avoid hypothetical, hazard-based analyses of risk.

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Richard Meads, the European Risk Forum’s Rapporteur, wrote this Highlights Note. However, the views and opinions expressed in this paper do not necessarily reflect or state those of the European Risk Forum or its members