Better regulation for science and innovation: the new game changer for Europe

Questions for the debate:
1. Could you share your views and experiences on how to overcome the regulatory barriers for research and innovation?
2. Would you consider Innovation Deals a proper tool and way forward to accelerate market uptake of innovations at European and national level?
3. Would you be willing to support the use of an innovation principle in the regulatory process and explore further steps together?

Introduction: why regulation matters
If we want to pave the way to sustainable growth, it is necessary to boost private and public investment in research and innovation. Europe needs to be able to attract and maintain the best talents, innovative businesses and investors. To that end, we need to be able to capitalise on our research results and create a vibrant, innovation-friendly ecosystem. This cannot be done unless the European regulatory environment is research and innovation-friendly too.

Today the pace of innovation is faster than ever. The process of developing legislation does however not necessarily match the rate of technological and digital change. Take the introduction of LED street lighting. The EU legislation for street lighting was based on traditional technology, from which LED lighting technology diverted. It took more than two years to make the necessary legislative improvements allowing for the commercial introduction of this energy-efficient alternative. This is just one example of many, leading to the heart of this debate: How well is Europe doing in offering a regulatory framework which is fit for (future) research and innovation? Considering that Europe risks falling behind as a location for world-class science and innovative businesses: what can be done to improve this state of affairs?

In Europe we are faced with an ever-increasing rate of technological and societal changes which will challenge the existing order. It will change our lives and our perspective on the world we live in. The enclosed Commission document quotes a recent CEPS study which indicates that regulation matters in all stages of the innovation process, from science, R&D to commercialisation. We need to be able to anticipate new developments, incorporate these into our systems and introduce sustainable regulatory reform in a timely manner. Doing nothing may increasingly impede our innovative capabilities. The focus is therefore not so much on ‘more or less regulation’, but rather on ‘better and smarter’ regulation. In short: regulation which is ‘fit’ to deal with (future) research and innovation. As such the debate in this Council and possible measures could contribute to the Better Regulation agenda and REFIT programme of the Commission and possibly Member States. Below follows a brief explanation for each question:

1. The problem: regulatory barriers to research and innovation
The enclosed Commission Staff Working Document identifies the following regulatory barriers:
- **Legislative barriers which hinder innovation**: one could think of legislation, such as the LED case, which is too technically prescriptive and therefore discourages new solutions and new entrants.
- **Regulatory frameworks which are not innovation-friendly**: the health technology assessments, for example, analyse such things as the medical and economic implications of medicines, medical devices and surgical procedures. Each country carries out these assessments individually, under different legal frameworks. This causes duplication of work and delays in market access which vary significantly across Europe.
- **Implementation problems**: these problems arise when legislation is not uniformly or appropriately implemented across Member States or when EU and national legislation overlap. Take, for example, the issue of electrified vehicles. Innovation in this field is hindered by market segmentation and Europe is already lagging behind in the deployment of electrified road transport as a result.
• **Gaps in legislation:** These occur when no EU legislation exists in a given field. As a result, barriers may arise in the internal market, causing uncertainty that could hinder investment and innovation. Examples of this are drones and road vehicle automation.

2. **A possible way forward: Innovation Deals**

The Innovation Deals could be considered as a non-legislative, pragmatic and transparent approach to address existing barriers to innovation in EU regulation. The objective of the deals is to improve legal certainty, facilitate innovative solutions and enable investments in innovation.

Innovation Deals are voluntary agreements between the Commission, investors/stakeholders and relevant public authorities. The deals will address concrete cases - brought forward by private or public stakeholders - of potential innovation barriers from the existing EU implementation. The Netherlands has some experience with this approach, which started in the energy domain and which is called the ‘Green Deals’. From the Green Deals experience it emerges that most of the perceived regulatory barriers can be resolved through explanation and clearer interpretation by public authorities of the regulations concerned.

The Innovation Deals will support stakeholders to find solutions within the boundaries of existing legislation. For instance by clarifying legislation, providing enhanced guidance or demonstrating innovative solutions. If the existence of regulatory barriers however is confirmed, the Commission may consider legislative amendments, subject to further evaluation. As such the Innovation Deals would not only complement the REFIT programme of the Commission, but could also feed into it. A pilot for Innovation Deals has been proposed in the area of the Circular Economy. If it is successful, the deals could be extended to other areas.

3. **A possible way forward: the Innovation Principle**

As mentioned in the introduction, Europe is facing many societal challenges, such as an ageing population and climate change. These environmental and societal challenges have one thing in common: they will not be resolved if nothing changes. This is a key feature of innovation: it does not fit within the existing order. It does not always fit the current processes and structures of our institutions. It most likely needs to go beyond our current solutions and vision of our ‘day-to-day world’. Innovation by definition deviates from the ‘usual way of doing things’. This means that we need not only to look into current legislation and its problems, but also find ways to accommodate future innovations and new business models which could help us address these challenges. This approach respects the risk assessment requirement established by the precautionary principle (Article 191 TFEU).

The Better Regulation Guidelines of the Commission provide a ‘Research and Innovation tool’ which offers guidance on how to evaluate the innovation implications of new EU legislation. A step forward would be to improve our laws and regulations by means of an Innovation Principle. This principle would require an assessment, by default, of the impact on innovation in the legislative process, without increasing the administrative burden unnecessarily. This could apply to new legislation and to the revision of existing regulation as well as to policy decisions, and it would be a step forward towards a research and innovation-friendly regulatory framework.

**Structure of the debate**

The debate will start with key notes of speakers who will share their experiences in Europe in view of the fast pace of innovation and the European regulatory framework, including challenges for investment in research and innovation. One of the speakers will highlight regulatory barriers in the context of Open Science/Open Access. Ministers are invited to contribute in an interactive questions and answers session, based on the aforementioned questions and issues. There will be no traditional *tour de table*.