



IMPACT OF EU REGULATION ON INNOVATION

REPOSITORY OF INDUSTRY CASES



**Impact of EU regulation on innovation
Repository of industry cases examples**

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Introduction

Innovation is critical to maintaining competitiveness as it provides a growth engine for the European economy. Regulation is required to set a level playing field for innovation, ensuring it does not harm human health or the environment. However, regulation can influence innovation priorities of companies and their willingness to devote substantial resources in research and development.

While well-drafted legislation can stimulate innovation, poorly designed legislation can stifle it. Regulation highly focused on precaution concentrates on risk avoidance but risks to fail in considering potential benefits, stifling investments in innovation and jeopardising future competitiveness.

The following repository gathers not exhaustive but illustrative cases of regulations that impact on innovation across a wide range of industrial sectors. Each concrete example aims to introduce an additional criteria policymakers should account when assessing the impact of regulation on innovation. This will imply systematic adoption of the Innovation Principle which states that “*whenever a regulation is under consideration, its impact on innovation should be assessed and addressed*”.

This document therefore sets out to draw attention to the need for a more innovation friendly regulatory policy environment and to promote an informed dialogue between industry, policymakers and other stakeholders. The table of contents will help the reader navigate through the document, within the different cases collected and the criteria derived from them.

This document intends to provide a basis for further discussion on innovation with all relevant stakeholders.

“The present repository gathers contributions, anonymised for the purpose of publication, provided by individual companies, members of BusinessEurope, the European Roundtable of Industrialists and the European Risk Forum. The opinions expressed represent the point of view of the authors and not the official positions of the three Organisations”.

Regulation stimulating innovation

CRITERIA → Based on robust scientific evidences (2)

Science-based decision-making provides a predictable and objective framework for investments in new products and services. All impact assessments need to have a sufficiently robust scientific background, no matter of their origin.

Sector	Case in synthesis
Food	<p data-bbox="1016 509 1944 572"><u>Innovation clause on food for specific groups of population</u> Regulation on Food for Specific Groups 609/2013/EU (FSG Regulation)</p> <p data-bbox="1016 612 2011 676">The EU Commission updated delegated acts, consulting interested parties in relation to innovative products and gathering scientific evidence.</p>
<p data-bbox="188 753 1120 817"><u>Legislation/regulation</u> Regulation on Food for Specific Groups 609/2013/EU (FSG Regulation)</p> <p data-bbox="188 852 2045 979"><u>Context</u> Article 11(2) of the FSG Regulation empowers the EU Commission to update delegated acts on Food for Specific Groups by “taking into account relevant technical and scientific progress, including data provided by interested parties in relation to innovative products”, for instance with respect to the legal requirements of their composition.</p> <p data-bbox="188 1023 2045 1118"><u>Impact on innovation</u> The above provision has the potential to play an important role in encouraging the development of innovative products that target the specific groups in the scope of the FSG Regulation.</p> <p data-bbox="188 1161 2045 1257"><u>Path forward</u> Based on the above article in the FSG regulation, the EU Commission should adopt provisions in the delegated acts allowing new optional ingredients and the requirements of their use when there is enough scientific evidence that they are suitable for the envisaged target group.</p>	

Sector	Case in synthesis
Passengers car	<u>Sustainable mobility</u>
<p><u>Legislation / regulation</u></p> <ul style="list-style-type: none"> · Commission Regulation (EC) No 692/2008 of 18 July 2008 implementing and amending Regulation (EC) No 715/2007 of the European Parliament and of the Council on type-approval of motor vehicles with respect to emissions from light passenger and commercial vehicles (Euro 5 and Euro 6) and on access to vehicle repair and maintenance information. · Commission Regulation (EU) 2016/646 of 20 April 2016 amending Regulation (EC) No 692/2008 as regards emissions from light passenger and commercial vehicles (Euro 6) · Regulation (EC) No 443/2009 of the European Parliament and of the Council of 23 April 2009 setting emission performance standards for new passenger cars as part of the Community's integrated approach to reduce CO2 emissions from light-duty vehicles (consolidated version including Commission Regulation (EU) No 397/2013 and Regulation (EU) No 333/2014). <p><u>Context</u></p> <p>European emission standards define the acceptable limits for exhaust emissions (Nitrogen oxides, hydrocarbons, carbon monoxide, particulate matter) of new vehicles sold in the EU and EEA member states, staging progressive introduction of increasingly stringent standards based on the 1970 Directive, from Euro 1 (new vehicles introduced from 1993) to Euro 6 (new vehicles introduced from 2014). In parallel, the EU has also put a range of policies in place aimed at lowering CO2 emissions from road transport - the main greenhouse gas contributor within the transport sector.</p> <p><u>Impact</u></p> <p>Regulations governing exhaust emissions and standards for passenger cars in the EU have spurred the development of many new innovative technologies for the catalytic treatment of the exhaust gases of internal combustion engines impressive improvements in the performance of many other powertrain components. This has ultimately resulted in the establishment in Europe of three of the most important manufacturers of catalytic emission control devices being EU based companies contributing to a “positive” global footprint. Additionally, the gradual decrease of CO2 emission limits has resulted in further remarkable improvements in the design of gasoline powered internal combustion engines, for which the EU is still at the forefront in worldwide technology.</p> <p><u>Path forward</u></p> <p>Implementation of the regulation; in-field and in-use compliance; durability; certification process; Cop21.</p> <p>There is no doubt that the application of catalytic emission control technologies for passenger cars in the EU over the past thirty years has contributed to cleaner air. Nevertheless, we are still behind in meeting the ambitious targets of the Clean Air regulation. Recent analysis of the root causes for this delay shows that several aspects of the implementation of the existing legislation need to be revised and upgraded. The</p>	

required improvements include better management of the vehicle certification process, and the implementation of real driving emission testing in addition to laboratory testing procedures (where an upgrade is also needed). Along the same lines, more measures need to be taken to improve the in-use compliance of existing regulation. The requirements of the COP21 agreement will lead to a further substantial reduction in CO2 emissions. This will again guide further changes in the conception of the vehicle powertrain, ultimately leading to various degrees of electrification.

CRITERIA → Engaging Stakeholders (1)

Early engagement of stakeholders, including industry, helps to avoid unforeseen negative consequences by providing informed feedback. This goes for new legislative processes as well as for revisions to existing laws.

Sector	Case in synthesis
Circular Economy	<u>Waste policies</u>
<p><u>Legislation / regulation</u></p> <ul style="list-style-type: none"> · Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives · Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE) · Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC · COM (2015) 614 final: Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee of the Regions – Closing the loop – An EU action plan for the Circular Economy · Proposal for a Directive of the European Parliament and of the Council amending Directive 2008/98/EC on waste. <p><u>Context</u></p> <p>Human health and the environment were severely impacted due to poor handling of waste and the uncontrolled transboundary movement of waste within the EU and also into third countries in the 1970's and 1980's. As a result, Member States began taking national measures to control the handling of waste. This then led to wider EU waste policies and strategies. Improved management of waste, and in particular the promotion of recycling, re-use and energy recovery from the disposal of waste was a major step forward. There were certain waste streams with a particularly high environmental impact that proved difficult to organise both financially and logistically, in spite of there being clear environmental benefits. Therefore, dedicated separate legislation for certain waste streams were adopted, such as waste electrical and</p>	

electronic equipment (WEEE) and waste batteries - including collection targets, minimum depollution criteria, recycling and recovery targets. Today, waste is seen more and more as a resource and in addition to the environmental benefits, sound recycling has been recognized as an important contributor to secure EU's raw material needs. Consequently, the Circular Economy package aims to minimise waste, boost recycling and keep the value of products, materials and resources as long as possible in the economy.

Impact on innovation

For certain problematic and complex waste streams, legislation has been necessary to incentivize their collection and proper recycling and treatment. Without it these streams would not have been dealt with properly under free market conditions. Legal certainty and stability has allowed recycling industries to strategize and manage investments in further refining/recycling services for “new” markets (WEEE/waste rechargeable batteries), in the knowledge that there would be a definite demand for recycling services. The extended producer responsibility and polluter pays principles have also helped by providing minimum criteria of treatment responsibilities and a stable source of financing to balance the cost of recycling versus energy recovery and landfill (the latter options being the very last resort of the waste hierarchy). The existing and widespread separate collection systems and targets have also helped avoiding certain waste streams, especially end of life products, to enter municipal solid waste streams for disposal. Beyond this creation of a new market, waste legislation has also led to significant technology innovation in physical pre-processing of waste (e.g. shredding, material recognition, sorting) and environmentally sound extractive metallurgy for secondary raw materials. Moreover, legislation triggered a better understanding of waste flows and fostered the consideration of lifecycle aspects of products.

Path forward

Policy and legislation play key roles as without it waste would probably still go directly to landfills or to incineration, and innovation in recycling technology would have been much slower. However, there is still room for improvement, and proper adoption and implementation across all Member States is still a challenge, as is reaching collection and recycling targets. The current developments of the circular economy package offer a window of opportunity to improve existing waste legislation and create the necessary framework conditions to guarantee high-quality recycling treatment processes, level playing field conditions and material recovery. A global level playing field is necessary for recycling activities to support Europe's competitiveness in the field. Depollution performance, safety levels, health and environmental measures, control procedures, as well as the range and yields of raw materials recycled differ considerably not only globally but also within the EU. In addition, there's a challenging trade-off between the cost-effective recovery of large volume materials on the one hand, and a gradual recovery of critical and valuable materials present in small quantities on the other. Legislation should not only take into account quantity mass-based recycling targets but also recycling of quality valuable materials. The involvement of stakeholders from industry and science in the further shaping of legislation for waste and the circular economy will continue to be crucial for to ensure its success.

Regulation hampering innovation

CRITERIA → Legal uncertainty due to incomplete standard procedure (6)

The lack of a regulatory framework can represent substantial risk for new innovative projects, and may impede the development of an innovative product.

Sector	Case in synthesis
Food	<p data-bbox="1016 509 1827 572"><u>Missing nutrient profiles</u> Nutrition and Health Claims Regulation 1924/2006/EC (NHCR)</p> <p data-bbox="1016 612 2045 708">The lack of science-based nutrient profiles affects companies and hampers the improvement of the composition of those products which have an impact on the so-called non-communicable diseases (e.g. obesity)</p>
<p data-bbox="192 751 1003 812"><u>Legislation/regulation</u> Nutrition and Health Claims Regulation 1924/2006/EC (NHCR)</p> <p data-bbox="192 852 2045 1118"><u>Context</u> The NHCR foresaw in Article 4 that by 19 January 2009 the Commission should establish specific nutrient profiles. Despite the increasing importance of the issue of non-communicable diseases (e.g. obesity) this important element is still missing in the Regulation. In this context it is questionable whether it makes sense to undertake a REFIT fitness check on this element of the legislation – as it has now been initiated by the EU Commission – although these nutrient profiles have not yet been proposed and thus not yet been applied. However, one option would be the establishment of science-based nutrient profiles for nutrition and health claims across the EU and the food sector would welcome a proposal from the EU Commission with achievable criteria that encourage product innovation and provide a level playing field but take into account the technological, legal and organoleptic limitations of reformulations distinguishing a range of clearly defined food categories.</p> <p data-bbox="192 1158 2045 1286"><u>Impact on innovation</u> The setting of nutrient profiles in the above mentioned way would encourage food business operators to reformulate their food products or to even develop new innovative food products in order to fulfil the requirements of the nutrient profiles and thus to be able to make nutrition and health claims on them.</p> <p data-bbox="192 1326 2045 1386"><u>Path forward</u> The EU Commission should present a proposal according to Article 4 of the NHCR with nutrient profiles to be developed in the above-</p>	

mentioned way. In addition this proposal should be embedded into a harmonized EU nutrition policy framework in order to create a level playing field, allowing companies to compete using the nutritional qualities of their products on top of taste or price. Product benchmarks to guide healthier recipes through voluntary food product reformulation would provide this framework and bring the long-term predictability needed to support investments in health-related innovation across the entire food industry.

Sector	Case in synthesis
Renewable fuels	<p><u>Fuel Quality Directives (FQD) and Renewable Energy Directives (RED)</u> The lack of a level playing field for renewable fuels - including those from industrial residues - impedes synergies and the possibility to exploit the full potential of industry to reduce greenhouse gas emissions.</p>

Legislation/regulation
 Fuel Quality Directives (FQD) and Renewable Energy Directives (RED)

Context
 There is a need for an EU regulatory framework that creates a level playing field for all renewable fuels, including those from industrial residues. Such a framework would boost synergies between different industries. Regulatory, market and legislative barriers are the main reason for not tapping the full potential of industry to reduce greenhouse gas emissions.

Impact on innovation
 A proper regulatory, market and legislative framework should incentivize and promote the untapped potential of both existing and emerging technologies. In particular the use of alternative fuels and feed stocks derived from industrial process gases may contribute considerably to achieve the EU objectives for environment protection, competitiveness and job creation.

Path forward
 Policy makers could take the following actions:

- Acknowledge the full potential of alternative fuels and feed stocks derived from industrial process gases as a key enabler of the energy and climate targets in Europe, while maintaining the competitiveness of energy intensive industries and enhancing the energy security of the EU economy;
- Develop a strategic action plan to assess the economic potential of alternative fuels and feed stocks derived from industrial process gases, and provide a recommendation for how to tap the full potential by 2030 (or 2050);
- Propose EU legislation ensuring that alternative fuels and feed stocks from industrial process gases, including the multiple use of carbon, will get the same benefits foreseen under the Renewable Fuels Status;
- Amend existing Directives, in particular the Fuel Quality Directives (FQD) and the Renewable Energy Directives (RED), in order to

assure that fuels and feed stocks from industrial process gases are treated on an equal level as traditional bio-fuels in the market. Hence the creation of a new category next to traditional bio-fuels is welcome. Fuels or feed stock from process gases should qualify for this category;

- Support the subsequent use or recycling of residual gases like CO₂, CO, or H₂ in EU legislation. This could be achieved through the creation of new fuel categories (“multiple use of carbon” or “recyclable carbon” etc.) to allow these low-carbon technologies to enjoy the same advantageous treatment as the traditional bio-based counterparts;
- Amend the ETS Monitoring and Reporting Regulation by deleting the reference to energy from renewable sources, in order to promote the subsequent use of CO₂ or CO as a low-carbon practice.

Sector	Case in synthesis
Nano-technology	<p><u>Legislative framework for Nano-technology and nanomaterials</u> The lack of clear and uniform EU standards (under REACH legislation) leaves room for manoeuvre at national level, with Members States introducing their own requirements to classify a nano-material which – in the end – has no common definition.</p>
<p><u>Legislation/Regulation</u> Legislative framework for Nano-technology and nanomaterials.</p> <p><u>Context</u> Nanotechnology has been identified by the EU as one of six key enabling technologies. Nanotechnology is a cross-sectional technology and a promoter of innovations in a huge number of sectors such as health, automotive, electronics, cosmetics, aerospace and construction. It contributes to sustainable development by enabling novel materials with enhanced efficiency and performance. The regulation of Nano-technology has been addressed at national and at European level. In the last three years France, Belgium and Denmark introduced specific reporting requirements for nanomaterials and for Nano-products. These requirements have been introduced, even though there is scientific consensus that nanomaterials give no particular cause for concern and that REACH is the appropriate legal framework to address safety of nanomaterials.</p> <p><u>Impact on innovation</u> A recent study by the German Chemical Industry Association VCI, “Paving the Way for Innovation” confirmed that 46% of the surveyed companies identified REACH compliance as a strong or moderately strong obstacle to innovation, while nanotechnology regulations were identified by 26% of the companies.</p> <p>Nanomaterial inventories are not harmonized and impose high bureaucratic requirements on companies. More important, the existence of nano-specific inventories can signal that these materials are of specific concern and provide incentives for the development of nano-free product alternatives.</p>	

Registration of nanomaterials under REACH is still under discussion, and increasing evaluation under the Community Rolling Action Plan (CoRAP) adds uncertainty for registrants. Single consortia have already appealed against the European Chemicals Agency ECHA decisions, demonstrating the lack of legal clarity in this context.

Regulation on nanomaterials in the European Union remains unclear. The concern that nanomaterials will need to fulfil much stricter safety requirements than other chemicals and the lack of predictability about how these could change during a long and costly innovation project are the biggest obstacle for innovation in this technology field.

Path forward

There is a need to clarify regulatory requirements for nanomaterials under REACH, to improve legal certainty for existing materials and predictability for innovative projects. When nanomaterials are properly addressed under REACH, there should be no need for national nanomaterial inventories. National rules and inventories create confusion, and they risk creating unnecessary stigmatisation and double regulation.

Sector	Case in synthesis
Medical	<p><u>Clinical samples for research purpose</u> The recently approved General Data Protection Regulation (GDPR) offers greater flexibility for organizations involved in the processing of personal data for scientific research and public health purposes. Such flexibility is subject to having certain privacy-enhancing measures in place. Measures may include pseudonymisation and anonymisation. Nevertheless, at the moment the standards according to which data is considered anonymous or pseudonymous are not uniform and this creates legal uncertainty.</p> <p>In addition, there are concerns about how to conduct scientific research using health data in compliance with legal requirements and the data protection principles of the GDPR; in particular, regarding the implementation of the principle of data minimisation.</p>

Legislation/Regulation

EU legislation on the use of clinical samples for research purposes.

Context

It is hard to determine whether, under the GDPR, it will be possible to benefit from the greater flexibility afforded to anonymous and

pseudonymous data.

The principle of data minimisation makes certain scientific research projects useless or less valuable, since often it is initially unclear what insights can be gleaned from a certain dataset. If the amount of data collected is limited this may result in missed research opportunities, because the added value of collecting data for scientific research may reside in the potential to uncover new correlations/results for new potential uses once the data have been collected.

Impact on innovation

The conditions described above make research less efficient and effective by not facilitating the use of data. Excellent research opportunities can be lost and it ultimately limits the improvement of many sectors, including healthcare.

Path forward

There should be EU agreement, possibly in the form of guidelines, on how anonymisation and pseudonymisation should be conducted in a reliable and safe way. National Data Protection Authorities should follow such EU guidelines instead of establishing their own standards on anonymisation and pseudonymisation. This would facilitate common understanding and harmonization.

Regarding scientific research, the principle of data minimization should not necessarily apply because data protection risks must be balanced against broader potential benefits for individuals and society as a whole.

Sector	Case in synthesis
GMO	<u>Directive 2001/18 and Regulation (EC) No 1829/2003 on EU authorization system for genetically modified crops</u> The EU authorisation process is dysfunctional as almost 35 GM products are currently being assessed by European Food Safety Authority (EFSA). The timeline to complete the assessments has tripled in the past few years. The data requirements are ever-changing and increasingly prescriptive without scientific rationale.

Legislation/Regulation

Directive 2001/18 and Regulation (EC) No 1829/2003 on EU authorization system for genetically modified crops.

Context

The above-mentioned legislation set out the EU authorization system both for cultivation of GMO seeds for farmers in the EU, and for imports

of commodities derived from GM crops grown by farmers outside the EU. It foresees a scientific safety assessment by the European Food Safety Authority (EFSA), followed by a Commission authorization proposal which is then voted on by EU Member States - just like other EU comitology systems for pre-market product approvals.

There is a large backlog of around 35 GM products whose assessment is currently pending with EFSA. The timeline to complete the assessment of any one GMO has tripled in the past few years to over five years. In view of the fact that not one single GMO has been found to be less safe than conventional crops, it is surprising that assessments for GMO safety are now taking much longer than similar assessments for other products. One of the major reasons is that the data requirements are constantly changing and are becoming increasingly prescriptive without any scientific rationale. Since 2006, 19 guidance documents were issued and up to 8 additional ones are expected by the end of 2017¹. Guidance documents are being applied nearly as a letter of law, leaving no room for a case-by-case approach². In addition, There is a lack of dialogue between EFSA and applicants. All EFSA regulated industries have [jointly identified the need of achieving greater efficiencies](#) in the EFSA evaluation procedures, and a better communication with applicants, as well as concrete proposals for solutions.

The legal provisions mentioned above are mostly workable in theory. But unlike other EU systems for pre market product authorization, the one for GMOs has never been correctly implemented. Therefore, the GMO authorisation system has been dysfunctional: permanently dysfunctional in the case of GMO cultivation, and partly dysfunctional for imports.

While Member States are allowed to vote against the science, the European Commission is legally obliged to put authorisation proposals forward to vote. GM crops have been regularly found to be as safe as conventionally bred crops, notably by EFSA (which provides GMO safety assessment for the EU authorization procedure),

- However, the Commission has been systemically delaying the processing of dossiers without a reasonable justification and in breach of the existing legal requirements. In January 2016, the European Ombudsman [recognised](#) that these constitute maladministration on the part of the Commission. In the case of imports, the risk of trade disruptions worth billions of Euros has been recognized by the Commission. This is well documented – most recently by the European Ombudsman - and the EC admitted it on the record.
- In the case of cultivation dossiers, in most cases the Commission never puts products to vote, as a result of which EU farmers are largely forbidden to choose safe GM seeds. The European Court of Justice ruled in 2013 that the “*Commission has failed to fulfil its obligations*” for a cultivation dossier which had been pending in the system since 2001. The Commission then finally put the product to the Council vote in February 2014, following which the Commission “shall approve”, but more than two years on, the approval decision by the Commission is still outstanding.

Impact on innovation

An EU authorisation for a GMO was estimated some years ago to cost seven to ten million Euros. No matter how much time or money is invested or how many times the product is confirmed to be safe, authorisation of these safe products for cultivation in the EU never

¹ For 2016-2017, 2 GMO specific Guidances are expected and 6 horizontal ones which also impact on GMO assessment.

² This is a basic risk assessment principle: Annex II Cartagena Protocol, “*Risk assessment should be carried out on a case-by-case basis. The required information may vary in nature and level of detail from case to case, depending on the living modified organism concerned, its intended use and the likely potential receiving environment*”.

materialises, despite more than ten years of failed attempts. As a result, EU farmers are largely prevented from using this safe technology. This ideologically motivated in-compliance with EU law by public institutions has removed any possibility to recoup the huge R&D and regulatory investments. The plant science industry has withdrawn the vast majority of cultivation applications, dramatically reduced its R&D investments in products for the EU market, and relocated highly qualified jobs to other parts of the world. In the few remaining private agricultural biotech research facilities located in the EU, the research is focused on crops for other continents.

As far as maladministration and undue delays for imports are concerned, at the time of writing (May 2016), the Commission’s delay in granting final approval to 3 soybean products, in clear contradiction with a decision by the Ombudsman from January 2016, has effectively prevented North American farmers from buying innovative seeds for their soybean growing season.

A system which does not enable the commercialisation of safe products is dysfunctional, discriminatory, and drives innovation and investments out of the EU. In the case of GMOs, it also distorts trade.

Path forward

Pragmatic, proportionate and efficient risk assessment is essential to allow for innovation. Predictability in safety assessment should be ensured by increasing process transparency and by not developing new requirements, and by avoiding re-interpretation until the approvals from the Commission. It is simply necessary to apply and implement the existing EU legislation on GMOs properly and improve legal certainty.

Sector	Case in synthesis
GMO	<p><u>New Plant Breeding Techniques</u> Directive 2001/18 (“GMO cultivation directive”)</p> <p>It is unclear if any of these New Plant Breeding techniques may be conserved under EU law to lead to genetically modified organisms (GMOs). The EC has significantly delayed its plans to provide clarity on the legal status of NBTs by way of a legal guidance/interpretative document.</p>

Legislation/regulation

Directive 2001/18 (“GMO cultivation directive”).

Context

A range of New Plant Breeding Techniques (NBTs), including gene-editing techniques, have been developed by scientists after the “cultivation directive”, with its definitions of GMOs, came into force in 2001. However, it is unclear if any of these techniques may be conserved under EU law if they lead to genetically modified organisms (GMOs). The EC has significantly delayed its plans to provide clarity on the legal status of NBTs by way of a legal guidance/interpretative document, and has even failed to publish the findings of a Member States Experts’ report which it had convened in 2007 and which finalized its [report](#) in early 2012.

Impact on innovation

In case NBTs would need to undergo the (partly) dysfunctional EU authorization system for GMOs, this would extend the current stop sign for innovation in genetic engineering to a much wider part of modern plant breeding (see other entries in this list for more detail on the innovation impact around GMOs).

Path forward

The EU Commission must provide clear and science-based legal guidance: the Member States' experts and the authorities of many Member States, as well as most scientists agree that most of the NBTs do not lead to GMOs.

CRITERIA → Inconsistency with coexisting regulatory requirements (3)

The conflicting objectives and targets of a parallel regulatory approach generate barriers to innovation and a loss of confidence in the regulatory process, especially for projects and investments with higher risk

Sector	Case in synthesis
Food	<p><u>Conflicting requirements in the food sector</u></p> <ul style="list-style-type: none">- Nutrition and Health Claims Regulation 1924/2006/EC (NHCR)- Food Information to Consumers Regulation 1169/2011/EU (FIC Regulation)- Directive on Natural Mineral Waters 2009/54/EC (NMW Directive) <p>Conflicting requirements occur between national and EU level, e.g. some Member States currently develop rules on the Country of Origin Labelling (of food) although this area is regulated on an EU basis in the FIC Regulation.</p>
<p><u>Legislation/regulation</u></p> <ul style="list-style-type: none">- Nutrition and Health Claims Regulation 1924/2006/EC (NHCR)- Food Information to Consumers Regulation 1169/2011/EU (FIC Regulation)- Directive on Natural Mineral Waters 2009/54/EC (NMW Directive)	

Context

Conflicting requirements occur at the level of EU legislation, e.g. the NHCR is to some extent not perfectly aligned with the FIC Regulation or with the NMW Directive.

In addition, between EU regulations and national regulations of Member States conflicting requirements exist, e.g. some Member States currently develop rules on the Country of Origin Labelling (of food) although this area is regulated on EU basis in the FIC Regulation.

Impact on innovation

Unclear and inconsistent legislative frameworks create legal uncertainty. This can impede innovation.

Path forward

Consistency between different legislative measures at EU level should be created by amending the existing rules.

As regards the relationship between EU and national regulations of Member States it should be ensured that the legislative competencies are separated in a clear way and followed accordingly. The EU Commission should also make use of the notification process by member states to encourage consistency.

Sector	Case in synthesis
Telecommunication	<p><u>Lack of consistency in terms of consumer protection for digital services</u></p> <ul style="list-style-type: none">- Telecom Package and all the sector-specific rules for services derived from it- EU Consumer law – under REFIT- Draft directive on contracts for the supply of digital content- GDPR and ongoing review of the ePrivacy Directive <p>Rules on consumer protection are becoming obsolete due to market evolution. Moreover, EU legislation has generated an arbitrary distinction between operators' services and other digital services, to the detriment of consumer protection, fair competition and public authorities' enforcement tools. Operators are indeed subject to specific and stringent obligations when providing their services to the final customers. On the other side, Internet service providers offering similar services are not subject to the same rules.</p> <p>Consumer protection that relies on so many different frameworks becomes complex to understand not only for consumers but also for operators.</p>

Legislation/Regulation

- Telecom Package and all the sector-specific rules for services derived from it
- EU Consumer law – under REFIT
- Draft directive on contracts for the supply of digital content
- GDPR and ongoing review of the ePrivacy Directive

Context

The current telecommunications regulatory framework includes sector-specific consumer protection rules, applicable only for services provided by telecom operators. When the framework was conceived in 2002 telecom operators were the only market players able to deliver voice or sms services. However, telecom markets have evolved rapidly and new players emerged (so-called Over the Top players), changing the way of providing services dramatically. With all these changes several sector-specific consumer rules became obsolete.

The current sector specific regulation anchored in an outdated definition of electronic communication services leads to an arbitrary distinction between telecom services and other digital services, to detriment of consumer protection, fair competition and public authorities' enforcement tools. Telecom operators are subject to specific and stringent obligations when providing services to end-users while OTTs offering similar services are not subject to the same or equivalent rules. In the digital area, this unlevelled playing field is not justified and needs to be tackled in the new framework. Beyond regulatory asymmetries, services are increasingly bundled in single offerings. This convergence and bundling can only be governed by horizontal consumer rules applying to all services in the digital value chain equally, ensuring a consistent and proportionate level of protection that consumers can rely on.

However, the current initiatives from the European Commission seem to keep that distinction or even create more fragmentation (e.g.: new service category of digital content), making the situation even more complex.

Impact on innovation

Consumer protection relying on so many different frameworks is complex for both consumers and operators.

Sector specific regulation impacts telecom operators' capacity to compete with OTTs as it hampers or delays innovation due to long and complex regulatory compliance procedures - including negotiation with regulators or even their prior approval, less flexibility to introduce new business models due to more restrictions, and higher compliance costs caused by more obligations. All this has a huge impact on innovation, costs and time-to-market for new services. Many telecom services that would have been launched in the absence of regulation were only launched with considerable delay or even not launched at all, impacting the competitiveness of the involved undertaking (e.g. telecom companies prevented from reacting swiftly to their competitors' offers). Many business opportunities are never realized, because of expected regulatory interventions.

Path forward

New regulatory framework should ensure a level playing field between operators providing similar services. Beyond substitutable services, services provided in the digital market should be based on the same standards. Considering the pace of innovation, efficient and future-proof service regulation need to be light touch and based on principles. This implies that sector specific regulation should be minimal, i.e. reduced to

what is indeed specific to the sector and indispensable from the end-users' perspective. Based on this assessment, selected specific rules with regard to internet access, communications services interoperability and ensured quality may remain. The other obligations currently enshrined in the telecom framework should be re-assessed in light of the digital needs of end users, leading either to their deletion for obsolescence or redundancy with current horizontal laws, or to their removal from horizontal laws when justified. The EU Commission should also ensure better consistency in the various ongoing initiatives concerning consumer protection, for e.g. the current review of the ePrivacy directive whose timing is rather questionable, - started after the adoption of the General Data Protection Regulation (GDPR) and not at the same time as the telecom framework review – or with the initiative on digital contracts, where complexity and lack of consistency are already obvious.

Sector	Case in synthesis
Telecommunication	<p><u>Favouring 5G innovation in telecom networks</u> Sector specific regulation should support telecom operators' innovation in new networks and services.</p>
<p><u>Legislation/regulation</u></p> <ul style="list-style-type: none"> - Telecom Package, notably spectrum aspects - all the sector-specific rules derived from it such as open internet rules <p><u>Context</u></p> <p>5G will provide a new architecture for a seamless end-to-end connectivity - the basis for a networked society. 5G will not only be about radio access and mobile networks, but will bring new unique network and service capabilities and will represent an important step in terms of convergence between fixed and mobile networks. 5G will clearly facilitate the digitalisation of industry and society. It will, in addition to enhanced broadband, serve a variety of new demands, e.g. from sensors, control of critical remote devices, smart vehicles, smart infrastructures and monitoring of wide-ranging control systems, media produced and consumed everywhere, or the provision of educational, societal and governmental services.</p> <p>Europe is in a challenging position, but there is still a good opportunity on the supply side for the timely provisioning of 5G. Nevertheless, appropriate regulatory conditions should appear in the market to fully exploit 5G economic and social potential. In addition, the demand side needs to materialize and engage now in order to be able to cater to the requirements of the networked society in a timely manner. Europe should raise its ambitions in relation to other regions of the world that are pushing ahead with 5G. Given that 5G communication networks, services and applications are expected to significantly change industries, it is crucial to provide guidance and political support for enhanced collaboration between the vertical domains and the 5G industry, across entire value chains.</p> <p>5G will without doubt be a global communication system, but it will only be able to serve consumers and society fully with the appropriate amount of new spectrum allocations. Spectrum is indeed a scarce resource; therefore any new allocation should be better coordinated and harmonized in Europe. It is also key to ensure that the regulatory framework is sufficiently innovation-supportive and flexible in order to support investment and allow a smooth deployment of 5G.</p>	

Impact on innovation

5G is currently a work-in-progress. Its roll-out will require substantial investment in both fixed and mobile networks and the various services it will allow are today largely unknown. It is therefore essential to ensure that the regulatory framework becomes more investment-friendly and future proof in the way it is defined and interpreted.

Sector specific regulation should not prevent telecom operators from innovating in new networks and services. As far as 5G is concerned, it means allowing operators to deploy those new networks as efficiently as possible by granting relevant spectrum resources, based on individual licenses in a timely manner and under reasonable conditions, as well as easing microcells use. It also means ensuring that such network evolutions are not hampered by too restrictive an interpretation of the Open Internet Regulation.

Path forward

The EU regulatory framework should be reformed to have as a primary objective a requirement for regulators to secure long-term benefits to consumers and European economic development by incentivising investments in connectivity by all players and promoting innovation, in contrast with the past focus on short term cheaper prices. The policy and regulatory environment must provide more favourable conditions for the development of the required telecommunications infrastructure to satisfy the connectivity needs of the digitised European industry.

The review of the telecom framework is an opportunity to foster an investment-friendly environment for 5G deployment and use. This requires notably that

- sufficient spectrum should be licensed in time and at reasonable, more harmonized, conditions to encourage investments in mobile technologies; individual licenses should remain the default regime and micro cells usage should also be simplified;
- Open Internet Regulation should be enforced to allow innovation and quality of services throughout the value chain, and in particular:
 - Regulators should allow for quality-differentiated services in particular IoT services (e-Health, connected cars, etc) that are based on specific commercial agreements and Quality-of-Service levels;
 - Operators will need to be free to offer dedicated network functions to different verticals through innovative solutions. The implementation of new technologies on a pan-European basis - such as Software Defined Networking (SDN), Network Functions Virtualization (NFV) and small cell technologies in order to achieve the required performance, scalability and agility - should not be hindered by regulation or its interpretation by regulators.
- The EU Commission should stimulate telecom vendors and Telecom and Internet Service Providers to work closely together with the stakeholders (including with their regulators) in various vertical industries to jointly develop meaningful applications that benefit from 5G connectivity. Without these applications and governance, 5G connectivity is meaningless.

CRITERIA → Too technology prescriptive (2)

The narrow top-down approach limits the technological range.

Sector	Case in synthesis
Resource efficiency	<p><u>Europe 2020 strategy initiative for a resource-efficient Europe</u></p> <p>Product design is at the centre of innovation. Efficiency requirements can promote innovation, prescriptive rules on resource efficiency would actually hinder innovation. The Eco-design directive has a big impact in this sense.</p>
<p><u>Legislation/regulation</u> Europe 2020 strategy initiative for a resource-efficient Europe</p> <p><u>Context</u> The European Commission discusses if and how resource efficiency criteria can be implemented in the EU regulatory framework. Criteria such as manual disassembly, recycled content, recyclability and reparability are discussed for inclusion into the EU Ecodesign Directive.</p> <p><u>Impact on innovation</u> Product design is at the centre of innovation. Each product design is determined after careful evaluation of trade-offs of a variety of parameters, including safety, usability, energy efficiency, resource efficiency, costs. While we are convinced efficiency requirements can promote innovation, prescriptive rules on resource efficiency would actually hinder innovation:</p> <ul style="list-style-type: none"> - Integrating the material efficiency requirements in the Ecodesign Directive implementing measures would have substantial impact on innovative solutions, leading to additional economic, social and environmental impacts. - Untapped implementation opportunities for material efficiency, e.g. designing for circularity, recyclability benefit rates, recycled content, lifetime etc. of energy related products. - Applying design solutions (like the use of more durable parts, or the reduction of product weight) for a restricted set of existing products (microwaves, LCD televisions, washing machines, tumble dryers, laptops, and refrigerators) could lead to Greenhouse Gas savings and product material savings. 	

Sector	Case in synthesis
Electricity	<p><u>Vehicle to Grid (V2G)</u> Power Grid stability requires the supply of ancillary services in order to ensure that voltage and frequency levels are maintained at standards compliant with the power quality. The current ancillary services regulation is, in most EU countries, focused on large generation units. As a consequence, the decentralized V2G technology is unable to participate in the procurement procedure organized by the grid operator.</p>
<p><u>Legislation/regulation</u> Power Grid stability requires the supply of ancillary services in order to ensure that voltage and frequency levels are maintained at standards compliant with the power quality. These services are procured either in a regulated or a competitive way. European trend versus larger competition has led to centralized and standardized auctions organized by the Transmission system operator (TSO). In most countries, the service is supplied only by large generating units that book part of their active and reactive power to adjust, in different lead times, to the variations of voltage and frequency.</p> <p><u>Context</u> New technologies allow other actors to participate in maintaining grid stability. Among them, V2G (vehicle to grid) represents a very promising solution that allows the use of electric cars, when at home or in a parking lot, to make their batteries available to charge and discharge accordingly to the needs of the grid in a very flexible way, storing potential excess of renewable energy, and maximizing its use. Additional profits for this service can also help to the kick-off of e-mobility.</p> <p><u>Impact on innovation</u> The current ancillary services regulation is, in most of the countries, focused on large generation units. As a consequence, the decentralized V2G technology results are unable to participate in the procurement procedure organized by the grid operator.</p> <p><u>Path forward</u> Danish and UK regulators have recently allowed the participation of V2G in the ancillary services procurement. In Denmark a V2G hub will help stabilize the national electric grid by providing power capacity services to grid operator Energinet.dk. In the UK, owners of electric cars that agree to take part in the scheme will be paid to allow National Grid to access their cars through their home charging points.</p>	

CRITERIA → Burdensome national requirements (3)

Additional requirements at national level can add regulatory burden.

Sector	Case in synthesis
Food	<p><u>Lacking maximum levels for vitamins and minerals in food</u></p> <ul style="list-style-type: none"> - Regulation on the addition of vitamins and minerals and of certain other substances to foods 1925/2006/EC (Fortification Reg.) - Directive on food supplements 2002/46/EC (FS Directive) <p>Current regulations foresee an EU legislative framework on fortified food and food supplements including the setting of harmonized maximum limits for vitamins and minerals. However, Member States have developed different national rules with widely diverging requirements.</p> <p>As a result consumer choice is limited and the marketing of innovative products is impeded.</p>
<p><u>Legislation/regulation</u></p> <ul style="list-style-type: none"> - Regulation on the addition of vitamins and minerals and of certain other substances to foods 1925/2006/EC (Fortification Reg.) - Directive on food supplements 2002/46/EC (FS Directive) <p><u>Context</u></p> <p>Both the Fortification Reg. and the FS Directive foresee an EU legislative framework on fortified food and food supplements including the setting of harmonized maximum limits for vitamins and minerals. However, although these legal acts have existed for 10 and 14 years respectively, the limits still have not been set.</p> <p>As a result, Member States have developed different national rules with widely diverging requirements. Some countries have banned food fortification in most foods and they outlaw the import of fortified foods and food supplements which have been legally manufactured in other EU Member States, thereby ignoring the application of the Mutual Recognition Principle.</p> <p>In many cases this forces manufacturers to develop specific recipes for individual Member States that exclude certain vitamins and minerals. This pushes up the price for consumers in that country. And in other cases manufacturers decide not to launch the food in that country at all if</p>	

the market there is deemed too small to justify the additional complexity in terms of manufacturing and logistics.

Impact on innovation

As a result of the situation described above consumer choice is limited and the marketing of innovative products impeded.

Path forward

The EU Commission should present proposals setting harmonised maximum limits for vitamins and minerals across the EU This would create a level playing field across the Internal Market and spur the development and marketing of such innovative products on a larger scale.

Sector	Case in synthesis
Chemical	<u>Classification, Labelling and Packaging</u>

Legislation/Regulation
Classification, Labelling and Packaging (CLP) regulation

Context

Member States' competent authorities interpret CLP differently. In some countries authorities do not take into account that the decision tree for classification has been changed under CLP compared to Parcel Packaging and Labelling DPD, i.e. test data on mixtures/similar mixtures have now prevalence before the additivity approach. Furthermore, experience from inspections shows that the application of Bridging Principles and Weight of Evidence determinations including expert judgement as well as data from certain in vivo and in vitro tests are not accepted every in the same way leading to stricter classification in some Member States than in others.

Impact

Lack of harmonisation results in a fragmented approach towards classification and labelling of the same product type. This leads to disruptions in the free movement of goods. In addition, higher costs for businesses occur when selling the same product type in various Member States.

Path forward

Agreement between member states on one approach could easily solve the problem. If such an agreement cannot be reached (e.g. in the CARACAL framework) the EU Commission needs to solve the problem as part of its ongoing REFIT Chemicals Legislation.

Sector	Case in synthesis
All	<p><u>Dual Use Regulation limits exports with respect to human rights requirements</u> The EU is about to revise the current Dual Use Regulation. According to a leaked draft of a proposal by the EU Commission, some of the proposed changes may have an impact on European businesses. One important change concerns an attempt to promote human rights. The export of goods, software and services (items) shall be subject to prior approvals by the export control authorities if the items may be used in violation of human rights.</p>
<p><u>Legislation/regulation</u> Revision of Regulation 428/2009/EC.</p> <p><u>Context</u> The European Commission initiated an export control policy review in 2011. The resulting proposal for a revised Dual Use Regulation (“EC Proposal”) shall be submitted to the European Council and the European Parliament within the next few weeks and thereby the legislative process be initiated. At the time this repository was published the EU Commission’s proposal had not yet been published. The concerns within industry are therefore prompted by recent leaks in the press, which are considered reliable enough to warrant comment.</p> <p><u>Impact on innovation</u> The export of items to non-EU customers will be subject to prior approvals by the export control authorities if those items may be used in violation of human rights. For E.g.: software and Cloud computing software that can analyse social media to identify bloggers and other market influencers. If the same software or Cloud service could also be used by foreign governments to identify and pursue dissidents this would represent a dual use of the software. This control requirement is unique and may put EU based businesses at a disadvantage compared to businesses located in other jurisdictions that make the same software.</p> <p><u>Path forward</u> A revision of the Dual Use Regulation that levels the playing field for EU companies, instead of putting them at a disadvantage to competitors from the US and elsewhere would be welcome. The burden to identify potential human rights violations should not be placed on individual businesses.</p>	

CRITERIA → Compliance time constrains and costs (1)

Unreasonable duration of the compliance period and related costs limit the innovative potential.

Sector	Case in synthesis
Chemical	<p><u>Registration of Chromates under REACH in the aerospace sector</u></p> <p>REACH can significantly impact the innovation process if the EU does not take into account the long investment cycles and the complex supply chain of the aerospace sector.</p> <p>Industry and the legislator (in this case the Executive Chemical Agency (ECHA) in Helsinki) have to communicate at a very early stage about future plans to phase out certain substances of very high concern. In the case of Chromates compliance time constrains and costs could generate a safety problem and an innovation problem since there is currently no alternative for all Chromate substances.</p>
<p><u>Legislation/Regulation</u> Registration of Chromates under REACH in the aerospace sector.</p> <p><u>Context</u> An important and striking example is the obligatory registration of <i>Chromates</i> under the existing REACH legislation (Registration, Evaluation, Authorization and Restriction of Chemicals). Chromates are just one of many examples of <i>Substances of Very High Concern (SVHC's)</i> which the European Union wants to control and eventually replace by other 'healthier and sustainable' substances.</p> <p>The general goal of the REACH legislation is supported by industry, but companies should be informed in time. If companies are informed in time and can act early REACH could even be a 'driver' for innovation, because it could give companies incentives to look for other (often more sustainable and healthier) substances as a replacement of the more dangerous substances. However, this takes <i>time and money</i> and sometimes there is no replacement substance available at all.</p> <p><u>Impact on innovation</u> The aerospace sector is a very good example of a complex industry with very long investment cycles and a complex supply chain (probably</p>	

one of the most complex one's).

Therefore, REACH can be very damaging to the innovation process if the EU does not take these long investment and innovation cycles into account. This means that the industry and the legislator (in this case the Executive Chemical Agency (ECHA) in Helsinki) have to communicate at a very early stage about future plans to phase out certain substances of very high concern.

The example of Chromates is an important one, because it is *in certain forms* an essential substance for the aerospace industry. The problem in this case is twofold: 1) a safety problem 2) an innovation problem since there is currently no alternative for all Chromate substances.

Path forward

It would be important to think about how a company can decide to invest in a new product when it can be confronted with a ban or phasing out of a specific substance at all times and with little time to find and qualify a replacement substance.

CRITERIA → Biased Regulation (1)

Politically-driven regulation that isn't based on scientific risk assessment undermines confidence in the rationality of regulatory systems.

Sector	Case in synthesis
Chemical	<u>Multiple use of substances treated as pesticide residues</u> The application of scientifically unjustified restrictions on substances treated as pesticide residues that are unlikely ever to be ingested by humans represents an impediment to innovation.
<u>Legislation/regulation</u> Regulation on maximum residue levels (MRLs) of pesticides in or on food and feed of plant and animal origin 396/2005/EC.	
<u>Context</u> Regulation 396/2005/EC has laid down harmonized MRLs for pesticide residues in food and feed in the European Union. In the absence of specific MRLs Article 18(1)b) of this Regulation stipulates a very low default MRL of 0,01 mg/kg. The definition of "pesticide residues" in its Article 3 covers "residues including active substances, metabolites and/or breakdown or reaction products of active substances currently or formerly used in plant protection products [...] including in particular those which may arise as a result of use in plant protection, in veterinary medicine and as a biocide". Based on this broad definition several problems have arisen, or may yet arise, with substances that may have more than one source:	

- Substances which are currently used or were formerly used in plant protection products but can also be found as contaminants and/or are naturally occurring (e.g. mercury, nicotine, copper and bromide)
- Substances which are used in plant protection products and in veterinary medicines (e.g. cypermethrin), including those not listed in Regulation (EU) No 37/2010 on pharmacologically active substances
- Substances which are or formerly were used in plant protection products and are currently used as biocides and are found in food and feed (e.g. Sanitizers/disinfectants) used responsibly by the food industry under Good Manufacturing Practice (GMP) to clean food contact surfaces and equipment, e.g. residues of chlorate, being a by-product of chlorine building agents, that are in addition also used by the municipal water supply
- Substances intentionally used in, or otherwise migrating from, for example, food contact materials (e.g. biphenyl, ortho-phenylphenole and diphenylamine), including substances listed in Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food
- Substances to which the default value of 0,01 mg/kg applies but which are used as ingredients including additives according to Regulation (EC) No 1333/2008 and flavourings according to Regulation (EC) No 1334/2008 (e.g. olive oil, sodium chloride, lecithin and eugenol). If traces of such multiple use substances (e.g. Chlorates) in foods are treated as pesticide residues applying the very low default MRL according to Article 18(1)b) of Regulation 396/2005/EC this will create unjustified compliance issues if those substances have not been used as plant protection products but for one of the other justified purposes mentioned above. This is because the default MRL has been set at the lower level of analytical determination and not for reasons of food safety and consumer protection.

Impact on innovation

Applying scientifically unjustified requirements on substances not used as plant protection products but for other recognized purposes is an impediment to the marketing of food products if this is not necessary for food safety reasons.

Path forward

The default pesticide MRL should be applied only to substances used as plant protection products, according to good agricultural practices. Residues resulting from other recognized purposes should not fall under the default MRL rule applied to plant protection products. The setting of a maximum level should be envisaged by the EU Commission when an active substance, listed as plant protection product, is used also for the other recognized purposes such as a disinfectant, e.g. in the Biocide Regulation 528/2012/EU.

CRITERIA → Conflicting interests (2)

Supposed conflicts of interest obstruct collaboration between industry and experienced scientists.

Sector	Case in synthesis
Horizontal issue	<p><u>Research Integrity</u> Industry was not involved in the definition of the European Code of Conduct for Research integrity, which was developed in 2011 by and for academia.</p> <p>Its application and the consequent adaptation of the art. 34 of H2020 Model Grant Agreement might hamper industry participation in H2020 and the collaboration with science.</p>
<p><u>Legislation/regulation</u> Mandatory compliance by all beneficiaries of Horizon 2020 to the European Code of Conduct for Research Integrity³ developed in 2011 by the European Science Foundation (ESF) and All European Academies (ALLEA).</p> <p><u>Context</u> Acting with integrity is a core value in the business sector. It is a key element of the business principles of many companies. Therefore, in principle, the current political attention to research integrity can only be welcomed. Nevertheless, we are concerned about the Council Resolution on Research Integrity adopted on 1 December 2015, in particular about the general applicability of some of the principles listed in the "European Code of Conduct for Research Integrity" developed in 2011 by the European Science Foundation (ESF) and All European Academies (ALLEA). The Council called for the consistent application of the aforementioned Code in EU-funded research. For this purpose the European Commission has already adapted article 34 of the Model Grant Agreement (MGA) for Horizon 2020. The Code of Conduct of ESF and ALLEA has been developed by and for academia, and might well be very appropriate for the scientific part (e.g. the European Research Council) of Horizon 2020. However, Horizon 2020 is not only about scientific research, but also about applied research, industrial R&D and innovation. H2020 beneficiaries involved in the latter activities will now be confronted with MGA provisions derived from a Code of Conduct on which they have not been consulted. Nevertheless, the Code of Conduct of ESF and ALLEA applies not only to universities and institutes, but also to "all others who employ researchers", and similarly the MGA applies to all H2020 beneficiaries.</p> <p>Furthermore, some parts of this Code of Conduct are impossible to comply with for actors in applied research, industrial R&D and innovation. For example, they cannot provide their researchers with the prescribed academic freedoms, including the right to communicate freely. These</p>	

³ See http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf

and possibly also other provisions would need to be adapted. As another example, the required “independence from commissioning or interested parties” is not really applicable for companies and applied research institutes.

Impact on innovation

1. Mandatory adherence to the European Code of Conduct for Research Integrity will hamper participation of actors in applied research, industrial R&D and innovation in Horizon 2020.
2. Furthermore it will prevent collaboration between industry and science: for fear of endangering their integrity, researchers in universities and research institutes may be reluctant to engage in contract research for or collaborative research with industry.

Path forward

1. Involve industry in the forthcoming revision of the European Code of Conduct for Research Integrity.
2. Revise article 34 of the MGA so that it does not go any further than stipulated in the Rules for Participation. Article 18(5) thereof merely states that the “grant agreement shall, where appropriate and to the extent possible reflectprinciples of research integrity ”. It is neither appropriate nor possible to demand that rules of integrity stemming from academic research equally apply to all applied research, industrial R&D and innovation.

Sector	Case in synthesis
Horizontal issue	<u>Research Fund for Coal and Steel</u>

Legislation/regulation

Review of Council Decision (legal basis) for the Research Fund for Coal and Steel (2008/376/EC) bringing it in line with Horizon 2020

Context

The most important features of the RFCS programme rely on the specificities of the so-called Advisory Groups and Technical Groups. The Advisory Groups have a broader responsibility in comparison with the standard Commission experts groups within Horizon 2020, as they have to advise the Commission on the evaluation of the proposals and the priority to be given for funding. The Advisory Groups need to have the freedom to perform their tasks efficiently, according to the legal basis, by receiving all the necessary information and by being able to control the evaluation process, whilst respecting adapted confidentiality and conflict of interest rules.

As an example, the strict application of confidentiality rules prevented the Steel Advisory Group (SAG) members from receiving the evaluation of the proposals from the Commission services - as had always been the case in the past. This effectively denied the SAG the ability to give any advice, which is their key mission.

Furthermore, the strict application of conflict of interest rules excludes from the meeting room all SAG members whose company is involved in at least one proposal. As the RFCS is an industrial programme with a strong industrial participation, most of the SAG members are therefore excluded (+/- 25); the only people allowed to remain for the discussion (without having received the evaluation of the proposals) are a few representatives of associations including the unions (6-7).

Impact on innovation

Since the efficiency of the RFCS programme relies mainly on the specificities of the so-called Advisory Groups and Technical Groups, ideally they should not be impacted by a review the RFCS legal basis.

Path forward

The Commission will provide the Advisory Group members with the ranking list, as well as with a summary of the proposals, the composition of the consortia and the quotations (global and by criteria) for the Advisory Group annual meeting before the COSCO [WHAT IS COSCO??] meeting. After the official decision on the selected projects, the Commission will communicate the full evaluation reports to the Advisory Group members. The Technical Group members will be eligible as experts in the evaluation of proposals.

CRITERIA → Excessive precaution (5)

Regulation based too heavily on risk avoidance creates barriers to ideas and innovative solutions even at the early stage.

Sector	Case in synthesis
Mobility	<p><u>EU Standards and regulation for radio-frequency identification</u></p> <p>Complex and burdensome administration today creates problems for free movement of vehicles within the EU. Because of a number of uncertainties both from a legal point of view and from a consumer acceptance point of view, the adoption of new technologies including those based on radio-frequency identification (RFID) is rather slow. As a result vehicles stick to pseudo-compliant technologies such as camera control. This hinders innovation.</p>
<p><u>Legislation/Regulation</u> EU Standards and regulation for radio-frequency identification</p>	

Context

Legislation for RFID technologies had been proposed in order to improve cross-border mobility. However there are concerns that the new technology might compromise privacy. Thus sticking with pseudo-compliant technologies such as camera control is the norm. This hinders innovation.

The complex and burdensome administration today creates problems for free movement of vehicles within the EU. Therefore there is a need to reduce the formalities and to recognize documents & roadworthiness tests issues in other Member States – in other words create a “uniform registration certificate”. Furthermore, there is a need to facilitate cross-border mobility when travelling in Europe. eLicense plates (license plates with an integrated RFID chip) and/or windshield tags are innovative solutions towards the recognition of cars. Encryption features on the chip also contribute to advanced security and privacy protection including protection against unauthorized tracking. Furthermore, it makes counterfeiting and fraudulent swapping of license plates between cars much more difficult. The chips can be read at a distance of up to 20 m and at speeds above 200km/h. eLicense plates have many uses: speed checks, red light checks, to check whether a car registration has expired, or whether the vehicle has a valid technical inspection document, if road tolls have been paid etc. Even the parallel use of the eLicense plates by fleet management organizations is possible, at the same time that authorities use them for the sorts of checks mentioned above.

Impact on innovation

Because of a number of uncertainties both from a legal point of view and from a consumer acceptance point of view, the uptake of these new technologies is rather slow. Nevertheless, they can put Europe in the lead in technology terms and they offer consumers considerable advantages. Hence there is a need for a joint innovation and marketing initiative in order to get the new technology introduced in society instead of using older proven technologies such as camera-based recognition.

The alternative to RFID technologies is the less innovative solution we have now, based on the optical recognition of license plates with cameras. While RFID and windshield tags have immediate results in identifying fraud (stolen or non-registered vehicles), the camera-based approach requires old-fashioned sharing of the picture with a central database in order to see whether car and license plate belong to each other. When a license plate is linked to the driver instead of to the car, it cannot be considered as a valuable alternative solution. Furthermore, camera-based solutions cost significantly more than electronic identification and they don't offer the possibility to implement additional features (such as paid parking, etc). They can't tell whether the license plate is authentic or not and they offer no additional benefits in terms of privacy protection.

Path forward

Field tests and innovation pilots should be further promoted. At least discovery-oriented research should include testing of innovations in particular for emerging ecosystems/markets like Smart Mobility Solutions.

Sector	Case in synthesis
Medical	<p><u>EU Medical Devices Directive</u></p> <p>Due to an approach focused on risk avoidance, the EU Commission refuses to publish the latest versions of dozens of medical devices standards. This gives a mismatch with the requirements in other legislation, fails to recognize the state of the art, creates legal uncertainty and does not in practice make any medical device any safer. Public healthcare suffers, vendors suffer and market authorities lack clarity on acceptance criteria.</p> <p>The endless debate about this (7+ years now) uses up substantial resources (money and scarce expertise) and makes investment in innovation for the EU market very uncertain.</p>
<p><u>Legislation/regulation</u> EU Medical Devices Directive</p> <p><u>Context</u></p> <p>For mainly legalistic reasons, the EU Commission refuses to publish the latest versions of dozens of medical devices standards in the Official Journal of the European Union. This creates a mismatch with the requirements laid out in other legislation,, fails to recognize the state of the art, creates legal uncertainty and does not in practice make medical devices any safer. A true dialogue on the content matter is impossible as the EU Commission takes a formal stance and appears to be uninterested in resolving any real issues. Public healthcare suffers, vendors suffer and market authorities lack clarity on acceptance criteria.</p> <p>Market access rules for Medical Devices (MDs) in the EU become ever harder to meet by device vendors. There is no evidence that existing rules cannot ensure MD's on the market are safe. The Commission points to the PIP (Poly Implant Prothese) scandal, but that resulted from abuse and insufficient enforcement of existing rules.</p> <p>Unlike all other legislators who require risk of MD's to be As Low As Reasonably Practicable (ALARP), the Commission requires that the risk be As Low As Possible (ALAP). This is in fact impossible to realize. Risk can never be reduced to zero, but any non-zero risk can be further reduced, even far beyond rational risk management.</p> <p><u>Impact on innovation</u></p> <p>The endless debate about this (7+ years now) uses up substantial resources (money and scarce expertise) and makes investment in innovation in the EU market very uncertain. Vendors must make specific adjustment in MD designs and documentation solely to accommodate EU-specific requirements. All this will inevitably slow down innovation and make MD's more expensive, increasing the mounting challenges for public healthcare. There is no attempt to grasp innovative opportunities for delivering healthcare and not even for rational risk management. The focus is on risk avoidance in general and on applying laws, in the most literal sense.</p>	

Path forward

As recommended by the Joint Initiative on Standardisation developed by the Commission with many standardisation stakeholders under leadership of the DG GROW Unit *Standards for Growth*, there should be an in-depth discussion on what is really at stake, what are the real issues that need to be addressed, and how to resolve them in an efficient, realistic and effective manner. Facts and rational arguments should prevail, and independent expertise should be involved.

Sector

Hot surfaces

Case in synthesis

EU Low Voltage Directive

With no evidence-based risk analysis, national market surveillance authorities are defining their own maximum surface temperature.

Legislation/regulation

EU Low Voltage Directive

Context

Consumer appliances must meet the essential requirements in the EU Low Voltage Directive. Compliance with standards published in the Official Journal of the EU in this context gives the presumption of conformity.

However, market authority officers of some member states postulate risks for certain product categories in a different manner, and make formal objections against the standards that presume conformity, without providing any rational analysis or evidence base. This way they can make additional requirements, which do not exist legally in the EU or are interpreted in different way among member states.

In the so-called case of the maximum surface temperature (of products like toasters and table grills) the risk of a first degree finger-tip burn is deemed unacceptable, while a risk analysis according to the accepted EU method demonstrates there is only a small risk, and is categorized as acceptable.

Market authorities in some Member States take ever more freedom to create soft law by using delegated act powers in the EU. There is no political discussion, nor is there a built-in mechanism to prioritise the most serious risks. Instead, imaginary risks are raised at random for products that are used on a daily basis by consumers without any problems occurring.

Impact on innovation

In-depth analysis into the risks from hot surfaces concludes that European industry should re-invest €100 million in new product designs and manufacturing tools to address this risk. Another €50 million should be spent annually in additional materials use. Bear in mind that this is a market which is only worth in total €860 million. Another example is kitchen blenders. The risk of someone putting their hand deep enough into a blender to cut their finger has to be mitigated, even though no one actually would intentionally to put their hand into a rotating blender. This drain on resources, the legal uncertainty for investment in novel products for the EU market, and the necessity to adjust designs for specific, often exaggerated EU requirements will inevitably come at the expense of innovation.

Path forward

There should be an in-depth discussion about what is really at stake, what are the real issues that need to be addressed if any, and how to resolve them in an efficient, realistic and effective manner. Facts and rational arguments should prevail over too excessive and unjustifiable ones, and as always, independent expertise should be involved. These discussions should take place under the auspices of the Joint Initiative on Standardisation developed by the EU Commission, which brings together many standardisation stakeholders under the leadership of the DG GROW Unit *Standards for Growth*

Sector

Next Generation Access

Case in synthesis

Framework/Access Directives of the Telecom Package

The deployment in Europe of Next Generation Access has a limited scope for innovation and differentiation of products/services as regulation is still hesitant in moving towards an infrastructure-based competition model.

Legislation/Regulation

Framework / Access Directives of the Telecom Package and all the rules derived from it.

Context

As a result of the current regulation, operators deemed by national regulators as having significant market power are subject to an extensive set of wholesale obligations. The situation is such that, under the current framework, the Significant Market Power operators have to offer a wide range of regulated wholesale access products along the value chain to cater for any business model, whether it is sustainable or not, to their competitors on the retail market.

Impact on innovation

Under the current regulatory framework, the scope for innovation and differentiation is very limited. An essential investment incentive is the ability to differentiate from competitors. If an investor has to make the differentiating factor fully available to other competitors by way of wholesale access products along the entire value chain, then the investment incentive disappears for both the investor and competitors (access seekers). Access seekers prefer to wait and rely on SMP operators' wholesale services rather than undertaking risky investments. The result of EU telecommunications regulation is an investment gap in new networks (in order to fulfil the objectives of the Digital Agenda) and, consequently, in the development of new innovative services.

Path forward

The upcoming review of the telecommunications regulatory framework is the right opportunity to encourage private investment in NGA networks and innovation for all players. Hence, the new regulatory framework should move from a service-based to an Infrastructure-based

competition model. It should be fully recognized that competitive dynamics created by infrastructure competition (investment, innovation and differentiated offers) is much superior for end-users in the long run than the ones generated by a service-competition model. A cost-benefit analysis of regulation (focused on innovation and impact on investment) should be made mandatory for National Regulatory Authorities in future regulatory decisions. Regulation of wholesale products, when deemed necessary, should only apply to the relevant key network input and be focused on favouring efficient competition. Strict controls of wholesale prices like cost orientation should be abandoned, as these drastically limit the value of the networks and discourage investment and innovation. The application of the full set of wholesale products following the ladder of investment approach should be explicitly excluded as a possibility.

Sector	Case in synthesis
Data Protection	<u>General Data Protection Regulation and the ePrivacy Directive</u> <ul style="list-style-type: none"> - ePrivacy Directive - General Data Protection Regulation

Regulation/legislation

ePrivacy Directive and General Data Protection Regulation.

Context

A political agreement on the General Data Protection Regulation (GDPR) was reached in December 2015. The goal of the regulation was to enhance data protection rights of individuals and to update data protection legislation in light of new technologies driving the data economy.. There should not be a contradiction between the protection of customers' privacy and the development of new products and services, in this context, all privacy issues should be carefully assessed when launching new data centric products and services. A harmonized Data Protection Regulation should provide a trusted framework for the EU to realize its Digital Single Market, providing a balance between protecting the data rights of citizens, and allowing for more data innovation.

Differences in approach to data protection between Member States heavily impact companies processing special categories of personal data such as health data. In view of the right of Member States to decide on matters of public health in their own jurisdiction, fragmentation and lack of harmonization regarding the processing of health data will continue.

Impact on innovation

The overall objective of the Regulation was to fully harmonise a fractured set of laws in an effort provide legal certainty for companies and lower their costs. While it still is a Regulation, the final text includes numerous carve outs and exemptions for Member States which allows for a high margin of manoeuvre. For example rules on the further processing of data (Art.6) may differ in different Member States. This is far from providing harmonisation and legal certainty. The Regulation failed to address the question of data processing within the modern context. It took an approach to data processing which is not well suited to the Big Data and Analytics era. This will lead to higher compliance costs and may

even lead to companies deciding that it is simply not worth doing their R&D product development in Europe.

When it comes to the e-privacy directive, telecom operators have been hampered in their ability to enter into new business models based on data by the existence of an additional specific set of rules on the processing of personal data in the electronic communications sector, including rules on traffic and location data, as well as data breach notification. Both the processing of personal location & traffic data are, however, already covered by the GDPR. A need to maintain the strict consent requirements in Art. 6 and 9 of the ePrivacy Directive would only be justified if stronger protection of such data would be needed to protect user privacy. That may have been the case under the previous data protection directive, but with the GDPR it is no longer needed, since the regulation provides for a significantly higher level of protection for data processing than the former directive. It equips consumers with improved rights and imposes obligations on data controllers and processors to carefully evaluate the risks for individuals when processing personal data. At the same time, the GDPR increases user privacy by introducing new safeguards like pseudonymisation & encryption. The e-privacy directive should not replicate any specific provisions or any extra security requirements set out in the GDPR. This could hamper the creation of innovative data-based services in the telecom sector.

Path forward

The entire area of electronic communications has undergone significant changes. It is now converging and is no longer exclusively reserved for telecom providers. A range of new telecom-like services (such as Internet-based OTT services) are not subject to the ePrivacy directive. The review of the Directive is therefore necessary in order to create a level playing field so that telecom and OTT services can compete on an equal footing in these innovative spaces. The GDPR creates a comprehensive set of horizontal rules that will apply equally to all market players, irrespective of sector and underlying technology. A future, sector specific ePrivacy instrument would thus hamper this achieved level playing field and should therefore be repealed.

For the GDPR

Throughout the implementation phase of the GDPR, the work of transposing and interpreting the GDPR will be essential. It will be very important throughout this phase to engage with experts. This could be in the format of frequent and ongoing consultation with industry and privacy professionals to help bridge the gap between policy and technology. Additionally, formal and informal consultation and fact gathering processes can help make sure that policies reflect technology use cases across all sectors. The GDPR's mandate for consultation with the European Data Protection Board (EDPB) and the Commission should find a formal channel through an Industry Advisory Board, authorised to represent every industry sector. Its initial goals should include ensuring a transparent implementation phase at the EU level, securing industry and economic input to the EDPB and the Commission, and more broadly across the EU, and assessing and monitoring the economic impact of the GDPR, in both the public and private sectors.

CRITERIA → Harmonization failure (2)

Regulation failing to harmonize a set of different existing laws containing numerous exceptions.

Sector	Case in synthesis
Medical	<p><u>Definition of Medical Nutrition</u> Innovative nutritional approaches focus on the pathophysiology of a disease rather than traditional nutrient deficiencies and the acceptance of this approach by policy makers and regulators is a prerequisite to foster innovation. Current EU regulation promotes a narrow interpretation of the definition of Food for Special Medical Purposes and Member States can still dispute how to define and classify this status.</p>
<p><u>Legislation/Regulation</u> Medical nutrition⁴is regulated through new EU legislation for Food for Specific Groups (FSG) applying as of July 2016. This legislation also covers Food for Special Medical Purposes (FSMP) which can be administered via enteral tubes or oral supplementation for the dietary management of a disease or medical disorder.</p> <p><u>Context</u> In particular in association with demographic and lifestyle changes, medical nutrition offers manifold solutions to address unmet needs from both an individual patient's and a societal perspective. New diagnostic tools to explore the "(gen~, prote~, metagen~, metabol~-)omics" have advanced the understanding of links between food, health and disease. It also emphasizes the complexity of this relationship, making the evaluation of the impact sometimes challenging. These tools will allow for earlier detection of disease or its risk factors. Preventing or treatment of disease is considered the legally defined domain of medicines. Yet new tools will provide questions on where health ends and disease starts. Typically safer for its usage than medicines, nutrition is considered by healthcare professionals (HCPs) sometimes as the most appropriate and safest 'therapy' (e.g. pediatric Crohn's disease). Further examples for nutrition and disease management include severe cow's milk allergy, or inborn errors of metabolism (e.g. PKU), yet the term prevention or therapy is not permitted. Likewise, discoveries concerning the interactions of the microbiome, diet and health will create new possibilities, as well as new areas of uncertainty.</p> <p><u>Impact on innovation</u> Innovation in medical nutrition - often complementing drug research - is a vital tool to address unmet medical needs and should not be held</p>	

⁴ *Medical Nutrition also includes parenteral nutrition which is regulated as medicinal (drug) products.

back by regulatory barriers. Medical nutrition offers potential benefits that drugs cannot match and this must be recognized by regulators. Data requirements should therefore not mimic those for drugs. Innovative nutritional approaches focus on the pathophysiology of a disease rather than on traditional nutrient deficiencies and the acceptance of this approach by policy makers and regulators is a prerequisite to foster innovation.

Furthermore, innovation in medical nutrition must not be hampered by a narrow interpretation of the legal definition of FSGs in the European Union. There is a paragraph in the new regulations (i.e. Article 3) which allows Member States to dispute the FSMP status of a product at the European level. If this process is used to enforce a narrow interpretation of the definition of an FSMP this will discourage advances in nutritional research and the development of innovative FSMP products.

Path forward

1. Interpret new FSG regulations bearing the benefit to patients in mind, including shifting part of the decision-making to the post-marketing “Phase IV”, defining the process to strengthen evidence «certainty» and allow for earlier access of solutions for patients.
2. Refine legal interpretation in the Food Medicine Continuum, i.e. Nutrition & Disease prevention (primary, secondary, tertiary), management and therapy; personalized (also called targeted or stratified) nutrition, and the new frontier microbiome. This includes removing technical development barriers for nutrients when switching between food and medicine categories (i.e. quality/safety, rather than health or disease-based).
3. Given the high product development costs, accelerate policy making to foster incentives & investments for developing healthcare solutions, and strive for global convergence of regulations as well as more flexibility in their interpretation.

Sector	Case in synthesis
Data protection	<p><u>General Data Protection Regulation</u> After four years of negotiations, the EU Regulation has not yet achieved the proper balance between the fundamental right to privacy, and the safeguarding of other fundamental rights such as the ability for people and businesses to ensure job creation and growth, and creating the right environment for innovation and investment in the Data Protection sector. The legislative text includes numerous carve outs/exemptions for Member States which allows for a high margin of manoeuvre. This is far from providing harmonization and legal certainty.</p>

Legislation/Regulation

General Data Protection Regulation

Context

The EU was keen to establish a new set of rules that reflected the current reality of data usage and in response to calls that the Data Protection laws were out of date (The current directive was from 1995). In January 2012, the European Commission made a proposal for a single harmonized General Data protection regulation across the EU.

The political mood when developing the proposal for these rules was that of mistrust of how business currently handles data privacy. The data protection proposal has been highly contentious and has been subject to intense debate within the European institutions.

After four years of intense negotiations a political agreement on the General Data Protection Regulation was finally reached in December 2015. This was formally adopted into European law in May 2016. Companies now have two years to implement and conform to the new regulation which will enter into force in 2018. Although called a regulation with numerous provisions left open to Member States, it is more 'Directive-like' and has failed to be a harmonized regulation. For example, rules on the further processing of data could end up very different in different EU Member States of the EU.

Impact on Innovation

During the four years of negotiations, the positions of the European Commission and the European Parliament have failed to take into account the importance of striking the right balance between the fundamental right to privacy, and the safeguarding of other fundamental rights such as the ability for people and businesses to ensure job creation and growth, and creating the right environment for innovation and investment. The GDPR has not met its objective in 3 fundamental ways:

Harmonization: The overall objective of the Regulation was to fully harmonize a fractured set of laws in an effort provide legal certainty for companies and lower their costs. While it still is a Regulation, the final text includes numerous carve outs/exemptions for Member States which allows for a high margin of interpretation. This is far from the initial goal of providing harmonization and legal certainty.

As result, many sectors and companies will be seriously affected. For example, in the healthcare field, a patchwork of diverging provisions to process health data will create difficulties for achieving wider interoperability of eHealth services. The lack of such interoperability will be detrimental to providing European citizens with better and cheaper and better health services.

Assessment: The impact assessment was flawed. British and Dutch governments both came out with their own impact assessment where they showed the negative impact that the Regulation will bring to the European economy. The UK Government study estimated an unbalanced Regulation would result in UK companies alone facing up to £360m net compliance costs per year.⁽⁵⁾ A study in May 2013 for the Dutch

⁵ UK Ministry of Justice Impact Assessment on Proposal for an EU Data Protection Regulation –22 November 2012

Government estimated a €1.1bn additional cost for Dutch businesses.⁽⁶⁾ The impact assessment of the Commission did not balance different interests and the normative framework (fundamental right to privacy) took precedence over market economy considerations (for example, there is no market failure to justify joint liability between the Data Controller and Data Processor). There will also be a compliance burden on SMEs and additional jurisprudence.

Context: The Regulation failed to address the question of data processing within the modern context. It took an approach to data processing which is not fit for the Big Data and Analytics era. This will lead to higher compliance costs and companies may decide that it is not worth doing their R&D product development in Europe.

Way Forward

Throughout the next two years of the GDPR implementation process, the work of transposing and interpreting the GDPR will be just as important as the development of the text itself for industry in Europe.

Engage with experts: Frequent and ongoing consultation with industry, privacy professionals and experts can help bridge the gap between policy and technology. Additionally, formal and informal consultation and fact gathering processes can help make sure that policies reflect technology use cases across all sectors. The GDPR's mandate for consultation with the European Data Protection Board (EDPB) and the Commission should find a formal channel through an Industry Advisory Board, constituted to represent every sector. Its initial goals should include ensuring a transparent implementation phase at the EU level, securing industry and economic input to the EDPB and the Commission, and more broadly across the EU, and assessing and monitoring the economic impact of the GDPR, in both the public and private sectors.

Engage the public: European citizens have made it clear that data protection and technology policy issues matter to them. EDPB opinions should be informed by their views via a clear and public consultation that is open to all stakeholders. The GDPR also gives data protection authorities more responsibility than ever. To equip them to discharge their statutory role, more attention is needed to create conditions for development of business insight, technical understanding, and consistent judgment among DPA staff. This is critical not only for a consistent interpretation, but for oversight and substantively fair enforcement. DPA's should focus on guidance with respect to best practices, guidelines and methodologies that can be adapted to evolving contexts rather than all-inclusive checklists on matters like high-risk processing.

⁶ CRC/CPR 13-14a Toetsing Europese Dataprotectieverordening – 31 May 2013

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