EUROPEAN COMMISSION
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REFIT Platform

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**STAKEHOLDER SUGGESTIONS**

# - INTERNAL MARKET, INDUSTRY, ENTREPRENEURSHIP AND SMEs -

**DISCLAIMER**

This document contains suggestions from stakeholders (for example citizens, NGOs, companies) or Member State authorities communicated to the Commission and submitted to the REFIT Platform in a particular policy area.

It is provided by the secretariat to the REFIT Platform members to support their deliberations on the relevant submissions by stakeholders and Member States authorities.

The Commission services have complemented relevant quotes from each suggestion with a short factual explanation of the state of play of any recent, relevant ongoing or planned work by the EU institutions.

The document does not contain any official positions of the European Commission unless expressly cited.

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## 1. SUMMARY

The briefing includes 15 suggestions in 12 policy areas:

*General aspects of the Single Market:*

- BUSINESSEUROPE asks for enhanced efforts to collect precise and comparable sector-specific data without increasing administrative burdens to business. The Commission is currently developing the "Single Market Information Tool" (SMIT) and the Framework Regulation Integrating Business Statistics (FRIBS)

*The Internal Market Information system:*

- BUSINESSEUROPE stresses that public authorities in Member States should make more use of the Internal Market Information (IMI) in order to alleviate administrative burden on business by comparing information with other Member States. The Commission is currently working with Member States on improving the use of IMI.

*Rights of Establishment:*

- A citizen suggests setting up an internal system incorporating databases on bureaucracy in all EU Member States in order to facilitate a company to establish a new branch in another country. The concept of a branch and the procedure for opening a branch is currently not harmonised at EU level.

*The Services Directive:*

- The Danish Business Forum (DBF) suggests integrating services into the existing Technical Regulation Information System (TRIS) database in order to limit the amount of national technical rules obstructing the internal market for services.

- The Board of Swedish Industry and Commerce (NNR) suggests putting more pressure on Member States failing to comply with agreed provisions under the Services Directive. In relation with notifications, the Commission announced in the recent Communication on the Internal Market Strategy (COM(2015)550 that it will present a legislative proposal for services currently not covered by that Directive. `

- BUSINESSEUROPE proposes the establishment of so-called Single Market Centres in every EU Member State. Some Member States have already done so (e.g. UK and Denmark), and several have grouped together at least some of the relevant functions.

- The Board of Swedish Industry and Commerce (NNR) suggests including health- and elderly care in the provisions of the Services Directive.

*Point of Single Contact under the Services Directive:*

- Two submissions on online business portals have been received, one from the Danish Business Forum (DBF) and one from BUSINESSEUROPE. The Commission has launched a number of initiatives to meet the need for access to clear information on rights, rules and opportunities, such as Your Business Europe and is currently discussing further action under the the Single Digital Gateway concept announced in the Digital Single Market Strategy.

*Single Market Transparency Directive:*

- The Danish Business Forum (DBF) suggests improving the clarity regarding national technical rules by developing additional guidelines which support Member States in justifying the need for new national technical regulations and providing more detailed and accurate assessments of proportionality.

*Postal Service Directive*

- The Finnish Survey on Better Regulation suggests introducing more flexible regulations to create favourable conditions for the use of electronic channels and services. The Commission is monitoring developments very closely, so as to be able to build up a sufficiently robust evidence base for any future requests for review.

*Construction Product Regulation*

- The Danish Business Forum (DBF) proposes to use the same standards for requirements for construction materials and to reduce and combine the different EU policies in this area. The Commission is currently undertaking a Fitness Check on the construction sector which will help to identify possible regulatory overlaps and inconsistencies. The results of the evaluation are planned for the end of 2016.

*EcoDesign*

- The German Chamber of Commerce and Industry (DIHK) is concerned that the EcoDesign Directive could become an instrument used to steer extensive production and technology developments. The Energy Labelling Directive and certain parts of the Eco-design Directive have been recently reviewed.

*Non-Life Insurance*

- The German Insurance Association (GDV) argues that one size fits all" approach would increase insurance costs and bureaucracy. The Commission proposal on general medical devices is currently being discussed with the Council and the European Parliament.

*Fibre Labels*

- The Finnish Survey for better regulation recommends developing a standard on fibre abbreviations.

*Transfer of motor vehicles*

- The Finnish Survey on Better Regulation suggests that the proposal for a regulation simplifying the transfer of motor vehicles registered in another Member State will increase administrative burden. The proposal is currently in inter institutional negotiations.

## 2. GENERAL ASPECTS OF THE SINGLE MARKET

### 2.1. Submission by BUSINESSEUROPE

Refocus data collection and research on the application of single market rules and step up the efforts of EUROSTAT, EU Institutions, academia and researchers to collect more precise and comparable sector-specific data, without increasing administrative costs to business.

### 2.2. Policy Context

As announced by President Juncker, the Single Market needs to be revived and modernised in a way that improves the functioning of the markets for products and services and guarantees appropriate protection for people.

Effective compliance is one of the means to deliver the opportunities and benefits of the Single Market. In the Commission Communication COM(2015) 550 "Upgrading the Single Market: more opportunities for people and business" – a strategy to improve the functioning of the single market the Commission announced its intention to propose a regulatory initiative on a market information tool for the Single Market, enabling it to collect information from selected market players. The rational being that the ability to obtain timely, comprehensive and reliable quantitative and qualitative information from selected market players should improve the Commission's ability to monitor and enforce EU rules in priority areas.

As part of the strategy, the Commission has proposed a regulatory initiative to collect comprehensive, reliable and unbiased information from selected market players to improve the Commission's ability to monitor and enforce EU rules – the Single Market Information Tool (SMIT).

*What is the Single Market Information Tool going to be used for?*

Experience in the competition policy field shows that information collection tools help gather robust information for the Commission to develop more focused and efficient policy and enforcement. Whilst the situation in the Single Market area is different, information tools can be helpful to gather a better understanding of market operators' behaviour, particularly concerning private firms in Single Market areas as for example geo-blocking or cross-border parcel pricing.

*Will the Single Market Information Tool put additional burden on companies?*

The SMIT would only be used when the Commission has grounds to believe that there is a problem it can help solve. It will be used selectively and only in particularly important cases, for example once a proper screening of all available information shows the need to gather input directly from market players.

This tool will not be a blanket right to require information from any firm at any time. First of all, before engaging into such an exercise, the Commission will analyse whether already available data are sufficient to address the issues at stake. Second, information requests will only be addressed to a subset of the most affected firms. Third, the data sought through the SMIT will normally be readily available to the market players concerned, such as questions relating to market behaviour, cross-border trade and business model and will typically cover factual market data (e.g. market size and share, level of imports etc.), company data (e.g. cost structure, profits, volumes, new products, ownership, control, participations in other companies, etc.) and facts-based analysis of the market functioning (e.g. regulatory and entry barriers, entry cost, growth rate of the market, growth perspectives or overcapacity).

Information gathered through the SMIT will be made publicly available in a report once confidentiality issues have been addressed.

For more information see paragraph 4.1.3. Single Market Information Tool (SMIT) – pages 85 and 86 of the SWD(2015) 202 "A Single Market Strategy for Europe - Analysis and Evidence."

2) In the context of this question (but not connected to Single Market Strategy) Eurostat is currently developing a cross-cutting legal framework for the systematic collection, compilation, transmission and dissemination of statistics related to the structure, economic activity, competitiveness, global transactions and performance of the European business sector Framework Regulation Integrating Business Statistics (FRIBS).

The main policy objectives are:

a) to streamline and rationalize the framework for European business statistics, reducing unnecessary statistical burden on respondents, and

b) to define a new architecture for European business statistics instrumental to the compilation of quality and purpose-relevant European business statistics, including the provision of higher quality statistics on services, globalisation and entrepreneurship.

FRIBS' cross-domain approach aims at strengthening sectorial data analyses that require combining harmonised information from various business statistics (trade, investment, employment, ICT, R&D, SME data, etc.). As part of this, FRIBS will establish an enhanced EuroGroupsRegister of European enterprise groups and a network of national business registers for collecting statistical data more consistently and harmonised throughout Europe.

By enabling a wider re-use of existing micro-data sources in the Member States, unnecessary burden on businesses can be avoided and new information demands can be met in a low/no-burden manner. An example of this is the current research of re-using intra-EU exports data for compiling intra-EU imports (SIMSTAT). In order to minimize further the administrative burden on smaller business economies FRIBS reinforces a number of simplifying measures.

It will, however, be up to the Member States how and to what extent they implement these burden-reducing enabling measures of FRIBS. As such FRIBS is primarily output-oriented (focussing on statistical end-products), whereas the collection of the data at the national level is ruled by subsidiarity.

Besides infrastructural improvements, FRIBS will also include several new/renewed statistics to address better today's information needs of policy makers, business

federations, researchers and other users at both national and international level. Future changes in the system of European business statistics will be implemented by FRIBS explicitly taking into account the user needs as well as the need not to increase unnecessary the administrative burden on businesses

## 3. INTERNAL MARKET INFORMATION SYSTEM

### 3.1. Submission by BUSINESSEUROPE

National governments must further develop the still underused Internal Market Information (IMI) system. Public authorities should make better use of IMI in order to alleviate administrative burden on business by checking information through this network directly with other Member States if needed, saving both time and costs.

### 3.2. Policy Context

The Internal Market Information system (IMI) is a secure and multilingual online application that allows national, regional and local authorities to communicate quickly and easily with their counterparts in the EU, Iceland, Liechtenstein and Norway about the practical implementation of EU Internal Market law. It links 7,251 public authorities across the EEA, helping them to overcome practical difficulties related, in particular, to differences in administrative culture, the use of different languages and the identification of partners in other EEA countries. This service, which has been developed by the Commission and is running since 2008, is available in all EU languages, without generating any extra IT costs for the Member States.

**IMI is therefore a horizontal tool supporting 16 administrative cooperation procedures in the following 9 policy areas**:

- **Professional Qualifications:** Information exchange between competent authorities and notifications of automatically recognised professional titles ;
- **Services:** Information exchange between competent authorities; notifications of national requirements; and alert mechanism about activities that could have health, safety or environmental implications;
- **Posting of Workers:** Information exchange between competent authorities;
- **Euro-cash-transportation:** Repository of issued licences;
- **SOLVIT:** cooperation between national SOLVIT centres to handle complaints submitted by citizen and businesses concerning misapplication of EU Single Market rules law by public authorities in cross-border situations;
- **Patient's rights:** Information exchange between competent authorities (IMI module launched end 2013);
- **E-commerce:** Notifications and requests for measures against and on-line service provider(IMI module launched end 2013);
- **Train driving licences:** Information exchange between competent authorities, notification of suspension of licences (IMI module launched end 2014);
- **Public Procurement:** Information exchange between competent authorities, notification of suspension of licences (IMI module launched April 2015);

**The awareness of competent authorities on the different obligations for**

**administrative cooperation is unequal per policy area and per Member State**: while in some areas (i.e., Professional Qualifications and Posting of workers) IMI has become a well-established corporate tool for administrative cooperation between public authorities, some other IMI functionalities are less used.

**The use of the system is still low in the area of Services and in the recently developed IMI module for public procurement procedures**:

- Information exchanges based on the Services Directive are available since 2009: the system usage in this area is still moderate, although efficient exchange of information between Member States clearly facilitates the free movement of service providers, the cross border provision of services and the establishment of service providers in other Member States;
- In April 2015 an administrative cooperation procedure foreseen in the Public Procurement Directive was established in IMI. Competent authorities can now easily and quickly exchange information about foreign bidders who participate in Public Procurement tenders but the use of IMI in this area has been rather low so far.

**A more efficient use of IMI could indirectly facilitate the cross border activities of businesses and service providers**. If competent authorities regularly used IMI to check cross-border service provider, they would easily obtain the necessary information to authorise in a timely manner, e.g., the establishment of a service provider in their territory.

Competent authorities can quickly obtain information from another Member State via IMI. This speeds up the significantly administrative procedures in the currently supported policy areas. In addition, the use of IMI allows them to successfully overcome language barriers, due to the multilingual nature of the tool.

**Current Situation**

The Commission is currently working with Member States on improving the use of IMI.

**The rules for the use of IMI were laid down by the** Regulation (EU) No. 1024/2012 **("the IMI Regulation")[1],** entered into force on 4 December 2012 with the aim to:

- establish a sound legal framework for IMI,
- define roles and responsibilities of the Member States and the Commission,
- create a legal basis for the expansion of IMI to new areas of EU law,
- provide a comprehensive data protection framework by setting out the rules for the processing of personal data in IMI.

According to Article 3, of the IMI Regulation the use of IMI is mandatory for those Union acts listed in the Annex[2].

[1] Regulation (EU) No 1024/2012 of the European Parliament and of the Council of 25 October 2012 on administrative cooperation through the Internal Market Information System and repealing Commission Decision 2008/49/EC (OJ No. L 316 of 14.11.2012, p. 1).

[2] The Annex lists the following Union acts:

1. Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market

2. Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications

3. Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare

## 4. RIGHT OF ESTABLISHMENT

### 4.1. Submission by a citizen

There is discrepancy in all the documentation needed to establish a branch between the EU states which complicates and prolongs the procedure of establishing a new branch.

My suggestion is to form an internal system which would incorporate databases of all the states within the EU regarding bureaucracy and how to faster and easier establish a new branch in other EU state.

### 4.2. Policy Context

Legal background:

- The 11th Company Law Directive – 89/666/EC of 21 December 1989 concerning disclosure requirements in respect of branches opened in a Member State by certain types of company governed by the law of another State.

- Directive 2012/17/EU of the European Parliament and of the Council amending Council Directive 89/666/EEC and Directives 2005/56/EC and 2009/101/EC of the European Parliament and of the Council as regards the interconnection of central, commercial and companies registers.

- Member States have on the basis of Directive 2006/123/EC on services in the internal market the obligation to set up a Point of Single Contact (PSC). The PSCs are online e-government portals that allow service providers to get the information they need and complete administrative procedures online. They have been established in order to facilitate entrepreneurs and business to access information on regulations procedures and deadlines related to the provision of services online and to complete all administrative procedures electronically.

Directive 89/666/EC lays down the rules defining which disclosure requirements apply to branches opened in a Member State by limited liability companies from another Member State. The documents and particulars which need to be compulsorily disclosed will be made publicly available through the system of interconnection of central, commercial and companies registers established by Directive 2012/17/EU and available at the latest by mid-2017. The system is to be composed of the Member States registers, a European central platform and the **European e-Justice Portal**, serving as the European electronic access point through which it will be possible to search for those documents and particulars. Link to the e-Justice portal: https://e-justice.europa.eu/content_business_registers_at_european_level-105-en.do?clang=en.

The central platform and the e-justice portal are operated by the Commission.

The business register interconnection system will provide a system incorporating business

4. Regulation (EU) No 1214/2011 of the European Parliament and of the Council of 16 November 2011 on the professional cross-border transport of euro cash by road between euro-area Member States

5. Commission Recommendation of 7 December 2001 on principles for using 'SOLVIT' — the Internal Market Problem Solving Network

registers of all Member States via the central platform. As this system will however not provide information on how to establish a branch more quickly and easily, further action would be required to implement this suggestion.

## 5. SERVICES DIRECTIVE

### 5.1. Submission by the Danish Business Forum (DBF)

The Technical Regulation Information System (TRIS) database based on the 98/34 notification procedure gives the European Commission and Member States the possibility of reviewing the technical regulation that Member States propose to introduce on goods (in the areas of industry, agriculture and fisheries) and services related to the information society prior to their adoption. The goal is to make sure that national regulation is compatible with EU-legislation and the principles of the internal market.

However, this does not apply to services. As a result, the internal market for services is fragmented and businesses that operate in several Member States are faced with additional burdens.

**Suggestion**

A register similar to the TRIS database should be established. All national rules with potential influence on the internal market for services should be reported to the register with the purpose of consulting stakeholders and getting approval from the European Commission. The goal should be to limit the amount of national technical rules that hinder the internal market for services and cause unnecessary burdens, so only valid justifications are accepted.

If possible, the best solution would be to integrate services in the existing TRIS database. In the long term, a common notification procedure for technical rules on goods and services would be favourable to ensure uniform rules and increased transparency.

### 5.2. Submission by the Board of Swedish Industry and Commerce (NNR)

**Legislation** Services Directive 2006/123/EC

**Burden on business:** The Service Directive has not been fully implemented across the EU. And it still allows European states the ability to maintain far too many restrictions in their services markets. The European Commission has predicted a potential gain of 1.8 % of EU GDP if EU states were to remove all outstanding EU barriers to trade in services. It is also clear that more ought to be done to raise performance on services integration. This becomes even more important at a time when Europe needs to boost competiveness and realize untapped potential for growth: also through free trade agreements with third countries, either within the framework of the WTO (which is currently negotiating a plurilateral services agreement – TiSA) or bilaterally with the US through the Transatlantic Trade and Investment Partnership, TTIP

**Simplification proposal:** The European Commission should ensure the full implementation of the Services Directive across the EU by putting more pressure on Member States failing to comply with agreed provisions.

**Effects of the simplification proposal:** Time-saving, reduced costs**,** increased investments**,** reduced uncertainty

### 5.3. Policy Context

The Services Directive was adopted in 2006 and implemented by all EU Member States in 2009. The objective of the Services Directive is to realise the full potential of services markets in Europe by removing legal and administrative barriers to intra-EU trade

The Services Directive 2006/123/EC[3] established that national rules restricting the right of establishment and the freedom to provide services falling under the directive must be non-discriminatory, proportionate and justified by public interest objectives.

To ensure that all new regulatory measures imposed by Member States fulfil these conditions, the Services Directive introduced a procedure whereby Member States must notify to the Commission new regulatory measures having an effect on services. This should allow the Commission to assess whether such measures are justified and proportionate. Experience with the application of the Directive over past years shows, however, that the existing notification procedure is not working and is not fit for its purpose to avoid introduction of disproportionate restrictions.

Nearly half the Member States have barely notified any national regulations under the procedure, whilst others have notified many national regulations. Currently, there is no sanction for failure to notify new rules. Furthermore, there is no requirement for Member States to notify draft regulations. In practice, the very large majority of measures notified have already been adopted in a Member State. The existing procedure does also not allow third parties to access the contents of the notifications (= contents of national rules, any explanation by a Member State). As a result, service providers do not have the possibility to react and will be confronted with the barriers which they create once they start to

[3] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32006L0123&from=EN

apply.

Today, Member States often provide incomplete and insufficient proportionality assessments when notifying national measures under the Services Directive. There is also no clear outlook on how the Commission can react under the existing regime. The Commission can adopt formal Decisions with regard to notifications of regulations applying to the establishment of service providers, but only provide technical comments with regard to notifications of measures applying to the cross-border provision of services. Differences between the notification obligations regarding establishment (Article 15) and temporary service provision (Article 16 and 39) currently in the Service Directive lead to different legal consequences. On the basis of Article 15(7) the Commission may adopt a decision on establishment requesting the Member State in question to refrain from adopting the notified measures or abolish them. In case of national measures notified on the basis of Articles 16 and 39, i.e. restricting the temporary provision of services, the Commission does not have the same possibility as for measures affecting the right of establishment to adopt a decision in which the Member State in question is requested to refrain from adopting the notified measure or abolish it.

These shortcomings have been reflected in debates on the notification procedure in the Council, which adopted Conclusions on 2 March calling upon the Commission "to increase the effectiveness of the notification procedure under Directive 2006/123/EC, including by investigating the possibility of introducing a 'standstill period', where appropriate, and providing clear guidance as to the notification obligations and as well as making notifications public and transparent as is the case for goods." The Council therefore: "invites the Commission to address this issue and to propose the necessary action in its forthcoming Single Market Strategy".

In the Communication 'Upgrading the Single Market: more opportunities for people and business' the Commission announced a legislative proposal modelled on the successful features of the notification procedure under Directive (EU) 2015/1535 for services currently not covered by that Directive. This will allow for more upstream verification of the justification and proportionality of new national regulations restricting the free movement of services

### 5.4. Submission by BUSINESSEUROPE

Every Member State should put in place one Single Market Centre with authority over national transposition, implementation and enforcement of EU legislation. It would be a focal point for the Commission and a tool to provide tailored assistance to Member States. The centres would be part of a strong network with other Single Market tools such as SOLVIT - to ensure better application of Single Market rules on the ground.

### 5.5. Policy Context

The Commission Recommendation of 29 June 2009 on measures to improve the functioning of the single market (2009/524/EC)[4] invites Member States to assign to a new

[4] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32009H0524

or existing authority within the national administration the responsibility for coordination on Single Market issues.

The Commission Communication of May 2012 "Better Governance for the Single Market" (the "Governance Communication", COM (2012) 259/2) takes this idea further and recommends Member States to follow the good practice developed in several Member States and appoint one instance within the national administration in charge of overseeing and monitoring the functioning of the Single Market at national level ("Single Market centres") in each Member State with the aim to:

• *monitor the timely transposition and effective implementation of Single Market rules (and liaise with relevant national parliamentary bodies on this);*

• *ensure that citizens and businesses are informed of relevant national rules and procedures (in co-operation with existing tools and relevant networks, such as for instance the Enterprise Europe Network and the European Consumer Centres);*

• *provide guidance and promote good practices amongst the relevant administrations;*

• *detect, gather data and evidence on problems and obstacles to an effective functioning of the Single Market in their countries, and*

• *act as a contact point for EU institutions.*

These entities could also be made responsible for offering first-line help where rights are breached.

The Advisory Committee for coordination in the Internal Market field (IMAC) serves as a platform for monitoring the implementation of the recommendations proposed in the 2012 Communication and exchange of best practices in relation to the Single Market Centres.

In its Communication of 28 October 2015 "Upgrading the Single Market: more opportunities for people and business" (the "Single Market Strategy", COM(2015)550 final), the Commission commits to improving awareness among citizens and companies of their rights and the use of national redress mechanisms, including through the Single Digital Gateway. The gateway, designed as a one-stop entry point for firms and individuals to all Single Market related information, assistance, advice and problem solving services (including SOLVIT) as well as to national and the EU-wide procedures (as already announced in the Digital Single Market Strategy) will in practice implement a part of the tasks foreseen by the 2012 Communication

### 5.6. Submission by the Board of Swedish Industry and Commerce (NNR)

**Legislation Services Directive 2006/123/EC**

Burden on business As people increasingly move between EU Member States the demand for well-functioning transnational health and elderly care increases. Companies active in health-and elderly care do not have access to an open European market. This sector was let outside of the provisions of the Services Directive. New health care methods are often seen with suspicion by traditional medicine and officials. Where there are thorough research behind, there should be better possibilities to try new, effective methods for saving pain and hustle for patients and saving resources for governments. Slow authorization administration delays and hampers the movement of nurses cross-border, causes extra costs for the company and its clients — in this case the private and

public hospitals, extending the waiting time for the patients and thereby causes extra costs for society.

**Simplification proposal:** Removal of remaining barriers to establishment, by including health-and elderly care in the provisions of the Services Directive and thereby giving companies working in this sector access to the full European Market. By this proposal, including health and elderly care in the provisions, we do not want to revise the Directive but include the sector in the advantages of the Services Directive in order to promote cross border services and raise the quality and effectiveness. Additionally, simplify administrative requirements.

Effects of the simplification proposal:

- Reduced costs
- Increased investments
- Reduced uncertainty

### 5.7. Policy Context

The European Legislator decided to exclude Healthcare and Social services relating to social housing, childcare and support of families and persons permanently or temporarily in need from the application of the Services Directive (SD). This exclusion is however not complete:

**Healthcare**

The exclusion of healthcare in Article 2(2)(f) covers *"healthcare and pharmaceutical services provided by health professionals to patients to assess, maintain or restore their state of health where those activities are reserved to a regulated health profession in the Member State in which the services are provided"*.

This means that services which are not provided to a patient but to the health professional himself or to a hospital such as accounting services, cleaning services, secretarial and administration services, the provision and maintenance of medical equipment as well as the services of medical research centres, are not covered by this exclusion. Moreover, the exclusion does not cover activities which are not designed to maintain, assess or restore patients' state of health.

For example, activities which are designed to enhance wellness or to provide relaxation, such as sports or fitness clubs, are covered by the Services Directive. Furthermore, the exclusion of health services only covers activities which are reserved to a regulated health profession in the Member State where the service is provided. Services which can be provided without specific professional qualification being required can thus be covered by the Services Directive.

**Social services relating to social housing, childcare and support of families and persons permanently or temporarily in need**

The social services in Article 2(2)(j) are excluded to the extent that they are provided by the State itself, by providers which are mandated by the State and are thus under an obligation to provide such services, or by charities recognised as such by the State. The

notion of “charities recognised as such by the State” includes churches and church organisations which serve charitable and benevolent purposes. On the basis of the wording of this exclusion, and the explanations given in Recital 27 of the SD, it is clear that such services are not excluded if they are provided by other types of providers, for example private operators acting without a mandate from the State.

For instance, childcare which is provided by private nannies or other childcare services (such as summer camps) provided by private operators are not excluded from the scope of application of the SD. Similarly, social services relating to the support of families and persons who are permanently or temporarily in a state of need because of their insufficient family income or total or partial lack of independence and for those who risk being marginalised, such as services concerning care for elderly people or services to the unemployed, are excluded from the scope of application of the SD only to the extent that they are provided by any of the providers mentioned above (i.e. the State itself, providers mandated by the State or charities recognised as such by the State). Thus, for instance, private household support services are services not excluded from the SD.

## 6. POINT OF SINGLE CONTACT UNDER THE SERVICES DIRECTIVE 2006/123/EC

Points of Single Contact are established by the Services directive 2006/123/EC; they can be seen as 'one stop shops' for service providers wishing to provide their services in other Member States. They have been established in order to make life easier for service providers, by allowing them to receive information and administrative requirements that companies need to comply with when they provide their services, and to complete procedures online. The Danish Business Forum (DBF) argues that there is still information lacking and that the limited possibilities for online communication with national authorities hinder cross-border activity. They suggest establishing one fully fledged contact point for all business in each Member States, which describes procedures for both establishment and operation and allows handling permits, certificates, registrations etc. online.

The Commission has worked in recent years with Member States on a voluntary basis to extend the scope of the PSCs, which has, however, not delivered significant improvements. Extending the scope of the Points of Single Contact and turning them into comprehensive business portals could contribute to simplification, savings for public administrations and more a coherent approach in providing information and e-services to businesses. This action is being discussed in the framework of the Internal Market Strategy and covered by a Single Digital Gateway concept, which aims to align EU and national content to be able to easily establish links between the two levels and to allow business (but also citizens) to access both levels seamlessly. The Commission is also committed to further developing and completing Your Europe Business, a portal which gives clear, jargon-free and multilingual information on the applicable EU rules for doing business in another EU Member State.

Two submissions on online business portals have been received, one from the Danish Business Forum (DBF) and one from BUSINESSEUROPE.

### 6.1. Submission by the Danish Business Forum (DBF)

*Challenge*

Much has been done to make relevant information accessible to businesses that wish to engage in cross-border activity. However, there is still a lot of important information that is not covered by the existing portals, websites, etc. The Points of Single Contact (PSC) Charter has already identified information to be included in the PSCs. The lack of information as well as the limited possibility to communicate online with national authorities is a barrier to cross-border activity.

*Suggestion*

A consistent approach should be adopted so that businesses have only one contact point in each Member State if they wish to establish themselves in another country or have problems operating - regardless of sector. The portal should relate to and describe procedures for both establishment and operation (PSC only deals with establishment). The portal should, for example, both contain information on how to establish a shop or a hotel and on how to get the necessary permits to sell food products (in a store or at a hotel). At the same time, permits, certificates, registrations, information about tax and employment and other governmental approvals and reporting obligations could be made here, and the procedures should be fully digitised. Everything should be available in English. The intention is to create a single legal base for contact with authorities and information (one business portal per Member State). Other areas of legislation (the services directive, the VAT directive etc.) could refer to this database instead of establishing separate portals - making it easier and more accessible for businesses. The intention is not to provide advice on specific issues to businesses.

### 6.2. Policy Context

The suggestion refers to the Points of Single Contact established under the Directive 2006/123/EC on services in the internal market. The Points of Single Contact act as 'one stop shops' for service providers wishing to provide their services in other Member States.

They have been established in order to make life easier for service providers by allowing them to receive information and administrative requirements that the companies need to comply with when they provide their services and to allow them to complete procedures online.

A similar approach as the one proposed here has been already pursued by the European Commission by adopting the PSC Charter, which is voluntary commitment of Member States to improve the functioning of the Points of Single Contact and extend their scope in order to make them comprehensive business portals.

However, as showed by the last assessment of the PSCs, 'The Performance of the Points of Single Contact: An Assessment against the PSC Charter'[5], this approach has not delivered desired results. The study showed that no tangible progress has been made by many Member States and that some even fail to fulfil the minimum requirements of the Services Directive. Overall, the performance of the PSCs in the 28 EU Member States is

[5] http://bookshop.europa.eu/en/the-performance-of-the-points-of-single-contact-pbET0215504/

mediocre, with considerable scope for improvement.

***Current situation***

Possible action is currently being discussed in the framework of the Internal Market Strategy and covered by a Single Digital Gateway concept (which was also announced by the Digital Single Market).

The Single Digital Gateway aims to align EU and national content to be able to easily establish links between the two levels and to allow business (but also citizens) to access both levels seamlessly.

### 6.3. Submission by BUSINESSEUROPE

National governments should transform their existing Points of Single Contact (PSC) into true Online Business Portals for goods and services, offering companies all the information and help the need to operate across borders and on the home market, including the completion of administrative procedures entirely online.

### 6.4. Policy Context

The suggestion refers to the Points of Single Contact (PSCs) established under the Directive 2006/123/EC on services in the internal market[6] and to Product Contact Points (PCPs) established under Regulations (EC) No 764/2008[7] and to Product Contact Points for Construction (PCPCs) under Regulation (EU) No 305/2011[8].

The PSCs are online e-government portals that allow service providers to get the information they need and complete administrative procedures online. They have been established in order to facilitate entrepreneurs and business to access information on regulations procedures and deadlines related to the provision of services online and to complete all administrative procedures electronically.

The approach proposed here has already partly been pursued by the European Commission through the agreement between the Member States and the Commission on the PSC Charter - voluntary commitments of Member States to improve the functioning of the (PSCs) and extend their scope in order to make them more comprehensive business portals. However, as showed by the last assessment of the PSCs, "The Performance of the Points of Single Contact: An Assessment against the PSC Charter'[9], this approach has not delivered desired results. Results clearly indicate that the online business portals are still – more than 5 years after the deadline - far from delivering what is expected from them. It

[6] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32006L0123&from=EN

[7] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:218:0021:0029:en:PDF

[8] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011R0305&from=EN

[9] http://bookshop.europa.eu/en/the-performance-of-the-points-of-single-contact-pbET0215504/

can be concluded that the PSC Charter which the Commission developed as a framework for implementation has not had its desired effect.

Information provided is often basic information on general requirements and sector specific information is insufficient. Information is also still structured according to the logic of the administration and not according to the logic of the business user. Also in terms of the availability of administrative procedures for online completion and the extent to which they can be completed online for general requirements many administrative procedures are available for online completion whereas most specific requirements are not. Access for to the PSC by foreign user is poor and there is a need to make the PSCs more user friendly.

Regulation (EC) No 764/2008 ("the Mutual Recognition Regulation") provides in its article 9(1) for Product Contact Points (PCP) to be set up in each Member State.

PCP provide economic operators or a competent authorities of another Member State with the following information:

- The technical rules applicable to a specific type of product in the territory in which those Product Contact Points are established and information as to whether that type of product is subject to a requirement for prior authorisation under the laws of their Member State, together with information concerning the principle of mutual recognition and the application of this Regulation in the territory of that Member State;
- The contact details of the competent authorities within that Member State by means of which they may be contacted directly, including the particulars of the authorities responsible for supervising the implementation of the technical rules in question in the territory of that Member State; and
- The remedies generally available in the territory of that Member State in the event of a dispute between the competent authorities and an economic operator.

Product Contact Points respond free of charge and within 15 working days of receiving the information requests contemplated by the Mutual Recognition Regulation. They are encouraged to provide their services in several languages and to provide personalised advice to users.

A similar mechanism exists under the Construction Products Regulation (CPR) No 305/2011. Under it, EU countries have to inform on their rules and regulations for construction products through the specific national contact points (PCPC).

In both cases there exists lack of administrative cooperation among PCPs, which takes the form of unduly long delays in replying to requests for information or even of mere lack of reaction from the counterpart in another Member State. Three quarters of PCPs report unduly long delays for replies, while two thirds reported the mere lack of reaction from their counterpart in another Member State.

Due to the lack of specific obligations as regards the information to be provided, the quality of the information provided online varies greatly, with just one third of both kinds of CP having webpages at all. Readability, user-friendliness, sheer usefulness and reliability of the offered contact details also vary greatly.

***Current situation***

The ***Your Europe Business*** portal gives clear, jargon-free, multilingual information on

the applicable EU rules for doing business in another EU Member State. Furthermore, it links to existing national business portals, including PSCs, when it comes to national implementation rules and procedures to follow.

Possible other actions are currently being discussed in the framework of the Internal Market Strategy and covered by a Single Digital Gateway concept (which was also announced by the Digital Single Market).

The Single Digital Gateway aims to align EU and national content to be able to easily establish links between the two levels and to allow business (but also citizens) to access both levels seamlessly.

## 7. SINGLE MARKET TRANSPARENCY DIRECTIVE

### 7.1. Submission by the Danish Business Forum (DBF)

Every year Member States notify 600-800 new national rules regarding technical standards and regulations under directive 98/34. These technical rules may cover both harmonized and non-harmonized areas, where the principle of mutual recognition should apply. Directive 98/34 requires that Member States immediately send any draft technical regulation to the European Commission with the justification that it is necessary to introduce such a technical regulation. However, the justifications given are often very general and brief (e.g. protection of persons, animals, the environment, or consumer information) rather than being specific on how conditions might differ from those of other Member States (which could justify the introduction of national regulation).

*Suggestion*

There should be greater clarity regarding national technical rules. This can be achieved through the following steps:

Clarification of documentation requirements: The European Commission should develop additional guidelines with the aim of guiding Member States to justify the need for new national technical regulations in the notification process under e.g. directive 98/34. These guidelines could help Member States to provide more detailed and accurate assessments of proportionality under directive 98/34. Increased transparency in the TRIS database: There should be public access to the comments given regarding notifications on goods under directive 98/34. This access could inform businesses about parts of the national legislation that may constitute an obstacle to the free movement of goods. Evaluation similar to the peer review under the Services Directive: The Commission should launch an evaluation of the notification procedure under directive 98/34 and follow up on the findings.

### 7.2. Policy Context

The Single Market Transparency Directive (EU) 2015/1535 (repealing and replacing Directive 98/34/EC) notification procedure for national technical regulations allows the Commission and the Member States to examine the technical regulations Member States

intend to introduce for goods and for Information Society services.

Lack of respect for this procedure can lead to a Member State technical regulation being ruled inapplicable to an applicant by a national court. It applies in a simplified manner to the European Free Trade Association (EFTA) Member States which are signatories to the Agreement on the European Economic Area (EEA) and to Switzerland and Turkey.

The major benefits of the procedure:

- Notified drafts are available electronically, free of charge and in all the official languages of the EU, thus providing the opportunity for economic operators and other stakeholders to comment on them.
- It allows new barriers to the internal market to be detected before they have any negative effects, thus avoiding long and costly infringement proceedings.
- It allows the detection of protectionist measures which might be drawn up by Member States under exceptional circumstances, such as an economic and financial crisis.
- It allows Member States to ascertain the degree of compatibility of notified drafts with European Union legislation.
- It allows an effective dialogue between Members States and the Commission when assessing notified drafts.
- It is a benchmarking tool allowing Member States to draw on the ideas of their partners in order to solve common problems regarding technical regulations.
- It allows economic operators, including small and medium-sized enterprises (SMEs), to make their voices heard and to adapt their activities in good time to future technical regulations. This right of scrutiny is used extensively by economic operators, helping the Commission and national authorities to detect any barriers to trade.
- It contributes to the application of the subsidiarity principle.
- It is a regulatory instrument which can be used to identify areas where harmonisation is necessary.
- It helps to improve the quality of national and EU regulations in line with the "Better regulation" approach.
- It contributes to improving competitiveness of enterprises in the context of industrial policy.

*Notably, on the use of the procedure within the context of "Better regulation"*

In its Communication "Better regulation for growth and jobs in the EU", the Commission has highlighted that the preventive control mechanism established by the Transparency Directive is crucial for improving national regulations on products and Information Society services.

In the framework of the Commission's action plan to simplify and improve the regulatory environment, Member States have been invited to submit impact studies (or their conclusions) together with notified drafts, where such studies have been carried out internally. The analysis of these impact studies encourages the Member States to reflect in advance on the most appropriate instrument to be used, and allows the Commission to check the necessity and proportionality of the measures proposed.

The cooperation between the Commission and the Member States in the context of the notification procedure helps to improve the clarity and consistency of the notified draft national legislations. This cooperation will be intensified with a view to ensuring a clear

and legible regulatory framework for economic operators while guaranteeing a high level of protection for public health, consumers and the environment.

The national authorities are encouraged to consider the following aspects in particular:

- the wording of drafts: clarity, consistency, transparency and legal certainty in the application of the texts;
- the possibility of accessing all regulations in a given sector through the publication both on paper and on-line of consolidated versions of the texts;
- the identification and avoidance of procedures imposing unnecessarily complex and onerous administrative burdens on economic operators, particularly when placing a product on the market.

*Notably, on the use of the procedure to improve competitiveness*

In the framework of the EU 2020 strategy, a new approach of the industrial policy based on competitiveness analysis of legislation has been proposed.

In this context, in the latest update of the Communication on Industrial Policy of 10 October 2012 - Communication of the Commission to the European Parliament, to the Council, to the European Social and Economic Committee and to the Committee of the Regions - A stronger European industry at the service of economic growth and re-launch - COM (2012)582 final – the Commission underlined that:
"Governance and regulatory obstacles to the Internal Market also arise from policy areas that are regulated by Member States, for example technical rules, refusals to apply mutual recognition and mismatches between the 27 different sets of taxation rules. An upstream analysis of draft technical rules can prevent the emergence of regulatory obstacles. This is precisely the objective of the 98/34 notification procedure, which requires draft legislation containing technical rules on products and information society services to be communicated to the Commission before they are adopted. The preventive nature of this procedure has avoided a large number of contraventions of free movement of goods rules. This notification procedure can also be used, however, to improve national legislation in line with "Better Regulation" principles and through benchmarking. Its potential can be further exploited by recommending that Member States use competitiveness proofing in the context of national impact assessments."

The Communication of the Commission on industrial policy makes an explicit reference to Directive 98/34/EC (currently Directive (EU) 2015/1535) which, beside its role as an instrument for prevention of obstacles to intra-EU trade has the task to encourage Member States to proceed to a competitiveness analysis of national legislation.

This approach was endorsed by the European Parliament in its Report of 18 December 2013 on reindustrialising Europe to promote competitiveness and sustainability ((2013/2006(INI)) where it encouraged further exploitation of the potential of the 98/34 notification procedure and suggested that the Member States introduce competitiveness proofing in impact assessments conducted at the drafting stages of national legislative processes, in the wider framework of the 'Single Market Test' called for in Parliament's resolution of 7 February 2013 with recommendations to the Commission on the governance of the Single Market.

In this context, Member States, as of March 2014, have been invited to prepare on a regular basis a competitiveness analysis of the national legislation notified under the scope of the procedure established by the Single Market Transparency Directive.

## 8. POSTAL SERVICES DIRECTIVE

### 8.1. Submission by the Finnish Survey for better regulation

The postal services directive (1997/67/EC) seeks to ensure access to affordable universal postal services of a specified quality. Article 3 stipulates that this universal service shall be provided on at least five days a week and contains provisions on the products to be included in this service. The importance of traditional postal services has declined while the role of logistics and overall service has grown. The provisions on delivery on five days could be repealed or more flexible regulations introduced to create favourable conditions for the use of electronic channels and services.

### 8.2. Policy Context

The suggestion relates to the Postal Services Directive (1997/67/EC), as last amended through Directive 2008/6/EC.

Through this Directive, the former postal monopoly (i.e. "reserved area") was gradually eliminated, while ensuring the continued provision of basic universal postal services.

On 17/11/2015, the European Commission adopted an Application Report of the Directive (see COM(2015)568), in which it carefully analysed both the implementation of the Directive by the Member States, and the changing nature of Europe's letter and parcel markets. This report concluded inter alia that the sustained provision of universal letter services has indeed come under pressure through e-substitution.

The above-mentioned Application Report also concluded that, together will all stakeholders, it will monitor further developments very closely, so as to be able to build up a sufficiently robust evidence base for any future requests for review.

## 9. CONSTRUCTION PRODUCT REGULATION (EU) NO305/2011

### 9.1. Submission by the Danish Business Forum (DBF)

*Challenge*

Manufacturers of construction materials have to live up to requirements regarding energy performance, environmental impact, safety, health, etc. These requirements stem from various pieces of EU regulation, EU labelling schemes etc. that sometimes overlap (e.g. Eco Design Directive, Directive on the energy performance of buildings, Construction Product Regulation, Directive on energy efficiency, Communication on resource efficiency opportunities in the building sector, and the Product Environmental Footprint).

As a consequence of overlap, manufacturers of construction materials are experiencing two major challenges when trying to comply with the legislation: Manufacture must calculate and document the same characteristics several times using different methods and the sheer amount of regulation is burdensome for businesses. Both challenges lead to unnecessarily high compliance costs.

*Suggestion*

Requirements for construction materials should be based on the same standards and the many different EU policies should be reduced and combined. Future regulation of construction materials should be based on the harmonised product standards and the standard for environmental product declaration (EDP).

The standard for environmental product declaration for construction products (EN 15804) should be the foundation for future environmental product declarations used for CE marking of construction products and the future system should be based on an already developed system.

### 9.2. Policy Context

The Construction Products Regulation (EU) No 305/2011 (the CPR) creates a harmonised framework of construction products in accordance with harmonised technical specifications (either mandatory standards or ad-request European Assessment Documents) and for CE marking these products. It aims to remove technical barriers in the field of construction products and simplify construction product performance assessment procedures.

The harmonised technical specifications developed under the regulation may cover seven requirements for buildings and civil engineering works, including safety, health, environment, sustainability, etc.

The European harmonised standards (hENs) developed under the framework of the regulation are mandatory and define common assessment methods for certain products, based on existing regulatory requirements at EU and national level (including all legislation mentioned above by the Danish Business Forum and more)..

In case the performance of a certain construction products are governed by several mandatory EU legislative measures (for example, under the CPR and the Ecodesign or the Machinery Directives), the relevant hENs include the requirements of the different EU measures. This ensures legal certainty and consistency.

EN 15804 is a voluntary standard, not based on any EU legislation. It defines Product Category Rules (PCRs), which are indicators for environmental performance (e.g.: CO2 emissions, use of primary resources like water) and provides guidance on which technical units (e.g. tonnes, W/m2K) should be used to describe the environmental performance. It is a horizontal approach which has not yet been translated into mandatory standards for particular products. EN 15804 only provides the framework for developing Environmental Product Declarations (EPD) via European harmonised standards for particular products.

There is currently no EU or national legislation which would make EPDs mandatory.

European Product Environmental Footprints (PEFs) is also a voluntary project, not imposing any legal obligations. Current pilot projects for products potentially covered by PEFs have shown weaknesses in EN 15804 in the fields of assessing recycling potential and data quality.

***Current situation***

The Commission is currently assessing the possibility to mandate the European Standardisation bodies to improve the quality of EN 15804. This should allow the future inclusion of relevant elements from EN 15804 into product specific standards under the regulation. Depending on how much the revised standard is covering requirements set in EU policies and laws, and depending if there will be EU or national regulatory requirements for construction products, mandates for harmonised European product standards might be amended to cover EPDs where needed.

The Commission is currently undertaking an evaluation (Fitness Check on the Construction Sector) of different pieces of EU legislation affecting the construction sector. One of the objectives of this evaluation is to identify possible regulatory overlaps and inconsistencies. The results of the evaluation are currently planned for the end of 2016.

## 10. ECODESIGN

### 10.1. Submission by the DIHK (German Chambers of Commerce and Industry)

The eco-design Directive is in danger of itself becoming an instrument used to steer extensive production and technology developments, which curtails a range of products, disenfranchises consumers and inhibits innovation. The reason for this is that the regulations make high product standards mandatory instead of taking "low end" product versions which are no longer contemporary out of the market.

For this reason, the EU legislators should refrain from further expanding the regulations. In view of the ongoing implementation process, such expansion is premature, and is very questionable anyway: the cost to business is not proportionate to the - hoped-for - benefits to the environment and climate.

*Excessive, duplicating and disproportionate regulation.*

A sense of proportion is also required within the current scope of the Directive: new eco-design requirements governing resource efficiency must not lead to regulatory duplication. For electrical and electronic devices, for example, there are already regulations in existence on the use of substances and recycling. Regulations on water taps and shower heads are of concern because saving water in many regions of Europe would be unnecessary or even harmful; due to the population decline in Germany, as well as the careful use of water, many water pipes are no longer sufficiently flushed through too. In the same way, eco-design regulations for windows and insulation material are questionable, as there is already a directive on the total energy performance of buildings.

### 10.2. Policy Context

The Eco-design Directive (Directive 2009/125/EC), in conjunction with the Energy Labelling Directive (Directive 2010/30/EU), provides a framework for setting product-specific requirements through implementing measures, addressing energy efficiency and other environmental aspects.

Art 15 of the Eco-design Directive establishes criteria for product groups that can be addressed under the Directive and for the specific implementing measures. Implementing measures adopted so far do not "make high product standards mandatory" but remove the

worst-performing products from the market, based on a least life cycle cost assessment.

Products to be covered under eco-design and energy labelling are identified following an extensive consultation process including a preparatory study following a specific methodology (for more information see: www.meerp.eu) and discussions with Member States, industry and NGO representatives.

While there are indeed costs to businesses for complying with the different implementing measures, a large part of European industry broadly supports this policy as the directives are seen as a strategic asset for EU competitiveness and providing predictability for investments in innovative solutions. Each implementing measure is accompanied by an impact assessment to ensure that costs for Member States, consumers and industry, including SMEs, are proportionate to the environmental benefits achieved by the proposed requirements. The members of DIHK are encouraged to participate in public consultations organized in the framework of such assessments when appropriate.

Risk of regulatory duplication for each implementing measures with other existing regulations are carefully assessed. For example, the Commission stopped work on eco-design measures for thermal insulation as it was found that the energy efficiency of such products was sufficiently addressed under the implementation of the Energy Performance of Buildings Directive. The product group 'windows' is still under discussion and no decision has been taken whether or not to propose eco-design and/or energy labelling measures. While for electric and electronic products the WEEE and RoHS Directives set requirements for hazardous substance use and recycling. Article 4 of the WEEE Directive specifically refers to the eco-design Directive as a means to establish appropriate measures facilitating re-use and treatment of WEEE.

As regards taps and showers in Ecodesign, this issue has been considered in the Joint Research Council Ecodesign preparatory [study] on taps and showers that was finalized in November 2014. Stakeholders have been fully involved in the process of developing the preparatory study and were able to contribute via the project website, three stake-holder meetings and a number of specific questionnaires. Based on the conclusions of the study, there does not seem to be enough evidence that reduced consumption of water in taps and showers would be critical for the functioning of water distribution and wastewater management networks.

**Current situation**

The Eco-design Directive was evaluated in 2012[10] and again in 2015[11]. On both occasions, the Commission concluded that the Directive was fit for purpose and that those aspects which required more attention (e.g. timely standards, better market surveillance) did not require changes to the legislative text

The Energy Labelling Directive has also been recently reviewed. The Commission concluded that the regulatory framework for Eco-design is fit for purpose and that the one for Energy Labelling needed revision. To this end, the Commission adopted a legislative proposal in July 2015 to convert the Energy Labelling Directive into a Regulation and progressively rescale energy labels to an A to G efficiency scale.

[10] See http://ec.europa.eu/transparency/regdoc/rep/1/2012/EN/1-2012-765-EN-F1-1.Pdf

[11] See http://ec.europa.eu/energy/sites/ener/files/documents/1_EN_ACT_part1_v5.pdf

## 11. NON-LIFE INSURANCE

### 11.1. Submission by the GDV (German Insurance Association)

Mandatory insurance is regularly discussed at a European level, currently in relation to the proposals for regulations on medical devices and in vitro diagnostic medical devices. The introduction of mandatory insurance for medical device manufacturers as demanded by the European Parliament is unnecessary. The large number of insurance policies for claims triggered by medical devices and the lack of added value for patient safety make them unnecessary.

In principle, the consequences of mandatory insurance can be significant and run contrary to consumer interests. When insurance solutions tailored to needs and risks are hindered, the consequence is often inadequate over-insurance for low claims risk. Insurance costs rise through this "one size fits all" approach. Some businesses can be confronted with financial problems as a result. Moreover, mandatory insurance lowers the motivation to prevent risks and raises the danger of "moral hazard". Mandatory insurance also does not prevent or eliminate any bureaucracy. To the contrary, additional bureaucracy has to monitor compliance with requirements, thus costing taxpayers money. Through unnecessarily increased premiums, consumer prices can also increase, without consumers receiving a higher quality product.

Voluntary insurance solutions are thus preferable in the spirit of European competitiveness. This also applies with respect to environmental liability. The Environmental Liability Directive is currently being reviewed within the framework of REFIT in terms of its effectiveness and bureaucratic burdens.

### 11.2. Policy Context

In 2012, the Commission adopted a package of measures on innovation in health. The package consisted of a Communication and two regulation proposals to revise existing legislation on general medical devices (COM(2012)542) and in vitro diagnostic medical devices (COM(2012) 541).

The aim of the revisions was to ensure: (i) a consistently high level of health and safety protection for EU citizens using these products; (ii) the free and fair trade of the products throughout the EU; (iii) that EU legislation is adapted to the significant technological and scientific progress in this sector over the last 20 years.

Revisions included the extending of the scope for legislation; better supervision of independent assessment bodies; clear rights for manufacturers/distributors; and stronger requirements for medical evidence.

The Commission proposal does not contain mandatory insurance requirements for medical devices.

**Current situation**

The Commission proposal on general medical devices is currently being discussed with the Council and the European Parliament. Five informal trialogues took place so far under the LU Presidency in the context of the first reading. Despite good progress, many controversial issues remain to be discussed and/or settled. Compulsory liability insurance for manufacturers covering damages due to defective products is a major issue for the EP. On the other hand, Member States strongly object to setting an EU-wide requirement for

manufacturers and instead consider that each Member State should be free to decide on the system to be put in place.

After some first discussions, the positions between the co-legislators remain divergent.

## 12. FIBRE LABELS

### 12.1. Submission by the Finnish Survey for better regulation

Article 16(3) of the regulation 1007/2011 stipulates that fibre labels shall be provided in the official language of the Member State unless the Member State concerned provides otherwise. In reality, this means market-specific markings and unnecessary costs. A standard should be prepared on fibre abbreviations.

### 12.2. Policy Context

Regulation (EU) No 1007/2011, on fibre names, related labelling and marking of the fibre composition of textile products, aligns laws in all EU countries protecting consumer interests and reducing the risk of fraud. Regulation (EU) No 1007/2011 repealed Directives 73/44/EC, 96/73/EC and 2008/121/EC as of 8 May 2012. It was underpinned by an impact assessment[12].

The current obligations under the Textile Regulation have not significantly changed compared to obligations under the former Directive 2008/121/EC. Further details on the Textile Regulation are available at: http://ec.europa.eu/growth/sectors/fashion/textiles-clothing/index_en.htm. The text of Regulation (EU) No 1007/2011 is available in all EU languages at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:02011R1007-20111221:EN:NOT

## 13. TRANSFER OF MOTOR VEHICLES REGISTERED IN ANOTHER MEMBER STATE

### 13.1. Submission by the Finnish Survey for better regulation

The proposal for a regulation simplifying the transfer of motor vehicles registered in another Member State (COM(2012)0164) is not based on a sufficiently extensive impact assessment in terms of the registration rules, tax laws, motor liability insurance policies and capacity for traffic control and law enforcement. Additionally, the proposal increases the administrative burden, which is at variance with the objectives established for it.

### 13.2. Policy Context

The Commission adopted the Proposal on simplifying the transfer of motor vehicles

[12] See 2009/01/30

http://ec.europa.eu/smart-regulation/impact/ia_carried_out/cia_2009_en.htm#entr

registered in another Member State within the Single Market (COM(2012) 164 final) on 4 April 2012. It aims at tacking the obstacles that citizens face when trying to use or re-register a vehicle already registered in another Member State, entailing problems that are among the "20 mains obstacles in the internal market".

*The proposal is based on 3 main elements:*

1. Establishing common criteria to decide where a vehicle should be registered: the residence of the holder of the registration certificate, natural persons or companies.

2. Limiting the situations in which technical inspections of the vehicle can be requested or registration refused.

3. Establish a system of exchange of information about vehicle registration data among Member States.

***Current situation***

The impact assessment provided by the European Commission in April 2012 (http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52012SC0082) pointed, among other elements, to an important reduction of the administrative burden in Europe, contrary to the statement in the suggestion. The impact assessment states that "no negative impacts could be identified for (the option retained in the draft Regulation that registration is performed in the Member State of the holder of the vehicle and that re-registration is simplified). It would have a neutral impact on motor vehicle taxation, traffic enforcement, road safety and motor vehicle insurance while it would have a positive impact on the other affected groups. The administrative costs would be reduced because this option would eliminate the need for de-registration and would reduce the time and costs needed for re-registration. (…) This option would allow savings estimated at EUR 1,171 million annually".

Furthermore, on 31 January 2014, COREPER requested the Commission to further study the fiscal implications of the draft Regulation following a request by the Member States which had expressed concerns about the possible taxation side effects of the proposal (as referred in the suggestion). The analysis, which was presented by the Commission to the Council Working Party on 16 December 2014, concluded that the fiscal impact would be very limited. The led to the re-opening the debate in the Council.

The Inter-institutional negotiations are currently on-going.