

INCEPTION IMPACT ASSESSMENT			
TITLE OF THE INITIATIVE	Internal Market for Goods – Enforcement and Compliance		
LEAD DG – RESPONSIBLE UNIT	GROW/B/1 2017/GROW/007	DATE OF INCEPTION IMPACT ASSESSMENT	13/05/2016
LIKELY TYPE OF INITIATIVE	Legislative/Non-legislative		
INDICATIVE PLANNING	See regularly updated 'List of planned Commission initiatives' <a href="http://ec.europa.eu/atwork/key-documents/index_en.htm">http://ec.europa.eu/atwork/key-documents/index_en.htm</a>		
ADDITIONAL INFORMATION	<a href="http://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/index_en.htm">http://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/index_en.htm</a>		
<b>This Inception Impact Assessment is provided for information purposes only and can be subject to change. It does not prejudice the final decision of the Commission on whether this initiative will be pursued or on its final content and structure.</b>			

## A. Context, Subsidiarity Check and Objectives

Context
<p>This initiative is announced in the <b>Single Market Strategy</b>, <i>Upgrading the Single Market: more opportunities for people and business</i>, adopted by the Commission on 28 October 2015<sup>1</sup> and should be set in the context of the fourth priority policy areas to be tackled under President Juncker's Agenda for Jobs, Growth, Fairness and Democratic Change, i.e. a <b>deeper and fairer internal market</b> with a strengthened industrial base.</p> <p>The regulatory regime for goods broadly consists of rules for agricultural and food products on the one hand, and non-food products on the other. This document concerns <b>non-food products</b> (which hereinafter are also referred to as 'industrial products')<sup>2</sup> subject to EU legislation based on Art. 114 TFEU. In this area the Single Market rests on two planks. One is the existence of product requirements (notably, but not exclusively, in relation to human health and safety) harmonised at EU level. The second is that compliant products can then circulate anywhere across the EU and to the countries of the European Economic Area or EEA).</p> <p>The Single Market can only function well and be <b>fair for people and businesses if all market players play by the rules</b>. Most of these rules are set out in EU legislation, the main aim of which is to protect European citizens from health, safety, environmental and other risks and to improve the competitiveness of businesses by eliminating unjustified barriers to trade.</p> <p>EU harmonised legislation covers the great majority of industrial products such as machinery, radio equipment, electrical and electronic devices, toys and many others. It is therefore essential that such EU legislation is correctly implemented by everyone on the ground to maintain the highest level of protection and to safeguard the competitiveness of businesses across the EU.</p> <p>Compliance with EU legislation on non-food products is checked during <b>market surveillance activities</b>, the general principles of which are laid down in Regulation (EC) No 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products. In addition, most of Union harmonised legislation on non-food products and Directive 2001/95/EC contain market surveillance provisions.</p> <p>The Commission therefore carried out an evaluation of EU law in the area of industrial products to assess the regulatory framework's overall coherence and 'fitness for purpose' and to develop an evidence base on the cumulative regulatory effects from an industry perspective. In parallel, the Commission organised a public consultation of stakeholders. The results of the evaluation are set out in the Commission Communication COM(2014)25 and the accompanying Staff Working Document SWD(2014)23.</p> <p>In order to streamline and improve the effectiveness of the rules on market surveillance the Commission adopted already in February 2013 the Product Safety and Market Surveillance Package COM(2013)78 and COM(2013)75. However, the proposed rules on market surveillance have not been adopted by the Council and</p>

<sup>1</sup> Communication from Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, *Upgrading the Single Market: more opportunities for people and business*, COM 2015 550/2

<sup>2</sup> i.e. substances, preparations or goods produced through a manufacturing process other than food, feed, living plants and animals, products of human origin and products of plants and animals relating directly to their future reproduction

the European Parliament.

Against this background, the Commission launched an evaluation of the currently applicable market surveillance provisions, notably those of Regulation (EC) No 765/2008, the results of which should be available during the third quarter of 2016.

#### Issue

**The Single Market has been a frontrunner in EU economic integration.** The most important legislative obstacles have been eliminated through EU harmonisation legislation. The objective of this legislation is twofold, first ensuring that industrial products placed on the European market guarantee high levels of protection for health and safety and the environment and secondly, ensuring the free movement of industrial products by replacing national rules with a single harmonised set of conditions for placing these products on the market.

Although non-compliance often passes unnoticed and the exact share of non-compliant products on the market cannot be quantified, **there are still many products on the EU market that do not comply with the rules on industrial products.** For example, in a public consultation organised by the European Commission in 2010<sup>3</sup>, 92% of businesses considered that their sector is affected by non-compliance. Moreover, in 2014 and 2015 respectively a total of 2 435 and 2 123 notifications of dangerous and/or non-compliant products were submitted by Member States in 2014 through the European rapid alert system for dangerous products 'RAPEX'. Almost 90% of all notifications concerned products which posed a serious risk to consumers. In the field of radio equipment, the impact assessment of the proposed Radio Equipment Directive<sup>4</sup> cited evidence from Market Surveillance Authorities that products fully compliant with the essential requirements ranged between 28% and 56% of the total found on the market. Administrative compliance has been estimated at an even lower level by market surveillance authorities at about 20%. During a campaign to verify the compliance of LED lighting equipment with the directive on electromagnetic compatibility, 168 products were checked by 18 market surveillance authorities. They found that 76.8% of the products complied with CE marking requirements while only 39.9% complied with the Declaration of Conformity requirements<sup>5</sup>. Only 17.3% of the assessed LED lighting equipment was fully compliant.

**Non-compliant products cause harm to consumers and law-abiding businesses alike.** In practice, non-compliance means that citizens are exposed to potentially dangerous products or that the environment is put at risk. Furthermore, non-compliance means that businesses selling compliant products face distorted competition from those traders who cut corners or deliberately flout the rules to gain a competitive edge. For example, the total estimated annual costs of compliance of EU legislation on industrial products across eight harmonised product cases (electric motors, laptops, domestic refrigerators/freezers, lifts, gardening equipment, petrol pumps, air conditioners and integrated circuits) have been estimated<sup>6</sup> at €342 million. Operators who distribute non-compliant products do not incur these costs and thus enjoy significant savings that will be reflected in the final price of their products, hence distorting competition.

Non-compliance often passes unnoticed; the exact share of non-compliant products on the market can therefore not be quantified. On the basis of data reported by Member States in the period 2010-2013 non-compliance was found on average in 32 % of inspections conducted in the field of toys, 55 % in the field of construction products, 30 % in the field of low voltage equipment, 30 % in the field of electromagnetic equipment, 53 % in the field of radio equipment and 40 % in the field of personal protective equipment.<sup>7</sup> In the case of the Ecodesign Directive dealing with products such as electric equipment, air-conditioning systems, machines tools etc., non-compliance was estimated to be 10 % - 20 %<sup>8</sup>. In other areas (e.g. gas appliances, personal protective equipment), existing studies indicate non-compliance levels of 5 % - 10%<sup>9</sup>. During a campaign to verify the compliance of LED

<sup>3</sup> Commission Staff Working Paper 'Impact Assessment 10 Proposals To Align Product Harmonisation Directives To Decision No 768/2008/EC'

<sup>4</sup> Commission Staff Working Document 'Executive Summary of the Impact Assessment, Proposal for a Directive of the European Parliament and of the Council on the harmonisation of laws of the Member States to the making available on the market of radio equipment SWD(2012) 329

<sup>5</sup> Much EU harmonisation legislation requires manufacturers to place a CE mark on the product to demonstrate its compliance with the applicable product laws to market surveillance authorities. A Declaration of Conformity is a document attesting to the compliance of a product with applicable legislation.

<sup>6</sup> Commission Staff Working Document SWD(2014)23.

<sup>7</sup> According to data provided by 16 Member States on number of inspections carried out and on number of findings of non-compliance in the context of national reviews and assessment of market surveillance activities according to Article 18(6) of Regulation (EC) No 765/2008. This figure represents the weighting average of percentages at national level.

<sup>8</sup> European Commission, 'Evaluation of the Ecodesign Directive (2009/125/EC) - Final Report', 2009.

<sup>9</sup> European Commission, 'Impact Assessment study on the review of the Gas Appliances Directive (2009/142/EC)- Final Report', 2009.

lighting equipment with the Directive on electromagnetic compatibility, 168 products were checked by 18 market surveillance authorities<sup>10</sup>, 76.8 % of the products complied with CE marking requirements while only 39.9 % complied with the Declaration of Conformity requirements. The technical assessment indicated that 61.5 % complied with the emissions assessment while 91.3 % passed the immunity assessment. Only 17.3 % of the assessed LED lighting equipment was fully compliant. In the field of radio equipment, the impact assessment on the proposed Radio Equipment Directive cited evidence from market surveillance authorities that products fully compliant with the essential requirements ranged between 28 % and 56 %. Administrative compliance has been estimated at an even lower level by market surveillance authorities at about 20 %<sup>11</sup>.

The **problem of non-compliant products** within the Single Market is driven by many factors<sup>12</sup> which can be categorised into two main categories:

- *Lack of familiarity with product legislation based on EU harmonised rules*<sup>13</sup>. The first condition for regulatory compliance is that businesses have to be aware and understand their obligations under applicable legislation. Unawareness or misunderstanding of requirements may bring about unintentional non-compliance;
- *Low incentives for businesses to comply with the rules*. The second condition for regulatory compliance is that businesses have to be willing to comply. Economic incentives can motivate compliance. A strong enforcement programme and a considerable risk of detection of infringements can discourage non-compliant behaviour;

The existing regulatory framework and these conditions constitute the framework in which the following **drivers** of non-compliance will be examined:

### 1) Lack of regulatory knowledge or comprehension

**Familiarisation with EU legislation on non-food products is an important and on-going task for all businesses that supply those goods.** They typically obtain information about product legislation based on EU harmonised rules, the accompanying technical standards and administrative requirements from a variety of sources (e.g. EC webpages, governments and market surveillance authorities, manufacturers, industry and trade associations, etc). However, there are indications that the level of knowledge among SMEs and especially micro businesses about harmonised rules applicable to industrial products is not always very high<sup>14</sup>. Furthermore, **e-commerce presents serious compliance challenges for suppliers**, partly due to ignorance or ambiguity over responsibilities for importing products or placing products on the market in the case of e-commerce<sup>15</sup>.

**Compliance information:** The exchange of information between businesses that supply products to the EU market and the authorities responsible for checking those products is often laborious and beset with delays. As industrial products become more and more complex and incorporate various different technologies and while product cycles become ever shorter, the traditional paper-based procedures for demonstrating and controlling product compliance are less and less convenient for businesses (especially SMEs), conformity assessment bodies and national authorities.

### 2) Low incentives to comply with the rules

Currently, enforcement mechanisms consist of two distinct elements: market surveillance and deterrence. Effective enforcement actions by market surveillance authorities will have the effect not only of detecting and punishing the placing on the market of non-compliant products but will also have a deterrent effect on other suppliers tempted to cut corners when placing products on the market. By doing so it provides businesses with stronger incentive to comply. Vice-versa ineffective enforcement lowers businesses' willingness to comply with the rules and discriminates businesses that abide to the rules against those who do not.

- a. **Market surveillance:** Market surveillance is a crucial tool to protect consumers and other users from unsafe and non-compliant products, by ensuring that all economic actors stick to the rules. However,

<sup>10</sup> Bundesnetzagentur, 'Market surveillance statistics 2011', 2012.

<sup>11</sup> European Commission, 'Executive summary of the impact assessment accompanying the proposal for a Directive of the European Parliament and the Council on the harmonisation of laws of the Member States to the making available on the market of radio equipment', SWD (2012) 300.

<sup>12</sup> <http://www.oecd.org/regreform/regulatory-policy/1910833.pdf>

<sup>13</sup> Depending on the sector legal product requirements can be contained in EU legislative acts that are directly applicable or in national legislation having transposed EU harmonisation legislation.

<sup>14</sup> See Commission Staff Working document SWD(2015)202.

<sup>15</sup> Ibidem.

enforcement of EU harmonisation legislation must rely on efficient and effective controls carried out by market surveillance authorities operating in the different Member States. Unfortunately, market surveillance does not operate as effectively as it should in the European Union because:

- Market surveillance is fragmented in the Single Market. Coordination among market surveillance authorities in different Member States is fairly weak and the functioning of EU procedures for exchange of information on risky products needs to be improved.
  - Businesses often supply products from outside the jurisdiction of the market surveillance authority where the end customer is located, hence the risk that market surveillance authorities in the latter country might experience difficulties in communicating with the supplier of the products and/or the market surveillance authorities in the supplier's country.
  - It is often difficult for competent authorities to effectively sanction businesses established outside the EU who sell non-compliant products directly to consumers or users in the EU. Market surveillance authorities face significant practical problems to trace and intercept non-compliant products imported from outside the EU, for example via e-commerce, and to identify the responsible business within their jurisdiction. As a result, the risk of being caught and effectively punished for non-compliance is sometimes too low to be an effective deterrent to supplying non-compliant products to the EU market.
  - The amount of resources allocated for market surveillance appears overall to be fairly limited with respect to the size of the Single Market.
- b. **Deterrence failure:** enforcement mechanisms help creating a level playing field for businesses selling products in the EU. Many businesses breaking the rules have high rewards and low probabilities of detection. For example, penalties for non-compliance may not be high enough to offset the profits potentially available from selling non-compliant products. Yet, a fine large enough to deter may bankrupt the business or at least deplete the liquid assets of the business that employees will lose their jobs. In some Member States, market surveillance authorities are entitled to impose fines on businesses selling non-compliant products while in other Member States, sanctions can only be imposed by courts. Some stakeholders argue that a disaggregated, scattered system of economic sanctions results in non-compliance with EU law. Additionally, because of limited market surveillance resources or inconsistency/inefficiency in monitoring and enforcement, non-compliance may have a low probability of being detected and punished, and thus there will be a lack of deterrent effect.

### Subsidiarity check

The Single Market for goods is a key achievement of the European Union. Yet, the elimination of national barriers for products has offered plenty of opportunities for less scrupulous traders who do not comply with EU product legislation. The EU has therefore the right to act on the basis of Article 114 TFEU, in order to ensure the proper functioning of the single market for industrial products.

The proper implementation of the principle of subsidiarity requires that despite the existence of the EU Single Market, the enforcement of product requirements (related to safety or other public interests) via market surveillance is the responsibility of Member States.

Trade in goods between EU Member States (intra-EU trade) was valued — in terms of dispatches — at EUR 2935 billion in 2014. Intra EU-28 trade — again measured by dispatches — increased by 3.3 % across the EU-28 between 2013 and 2014; this was the fifth consecutive rise since 2009. Therefore, one can reasonably expect that the problem would worsen if no action were taken. In a single market in which products circulate freely throughout 28 territories, market surveillance and actions against non-compliance need to be highly coordinated and capable of reacting rapidly over a vast area. The increase in intra-EU trade means that more and more products are manufactured / imported in one Member State, but then supplied in another Member States. This also suggests that products are often made available at the same time in different national markets.

Therefore, while the procedures and actions against businesses continue to be carried out by Member States, enforcement of product legislation based on EU harmonised rules requires market surveillance effort is uniform across the EU. If market surveillance is lacking or 'softer' in some parts of the Single Market than others, weak spots are created where non-compliant products can be supplied which threaten the public interest and create unfair trading conditions. Furthermore, much of the risk presented by products to the various public interests that EU legislation tries to protect derives from products entering the EU from non-EU countries. There must therefore be effective controls of products at the EU's external borders.

Furthermore, cross-national coordination of efforts is necessary to ensure that once non-compliant goods are found their marketing is restricted in any place of the Single Market where they have been made available for sale. Due to the removal of the internal borders within the Single Market, the fact that non-compliance is addressed in one Member State does not automatically solve the problem of non-compliance in other Member States where the same product is also being made available.

The impact assessment will examine if the issues dealt with here have cross-border aspects which cannot be dealt with satisfactorily by Member States alone. It will also examine if action at EU level would produce clear benefits over and above that at the level of Member States in terms both of scale and effectiveness.

### Main policy objectives

The **general objective** of this initiative is to improve the functioning of the Single Market and to achieve a higher level of consumer protection through **the reduction of the number of non-compliant products on the EU Single Market**. In a single market where goods move freely, EU legislation should be correctly applied by all businesses as a tool to avoid harm to consumers, to protect the environment and to give honest traders a chance to compete on equal terms.

The **specific objectives** of this initiative are:

1. **Facilitating compliance** on the single EU market for products, in particular by helping businesses to comply with EU legislation on non-food products and exploiting digital technologies. This objective focuses to a large extent on prevention of non-compliance.
2. **Detecting and taking action against non-compliant products**, in particular by allowing market surveillance authorities to more effectively detect and punish non-compliance by those businesses unwilling to abide by the rules, to deter businesses from evading the rules, and hence to establish a level playing field and fair competition between economic operators.

## B. Option Mapping

Besides the baseline-option (no policy change), the following options have been identified so far for each of the two problem drivers:

### 1) Facilitating compliance with EU legislation on goods by economic operators:

- **Option 1.1: Compliance assistance**, i.e. instruments **available at EU level** to educate and assist businesses, particularly SMEs, to help them to comply with EU legislation on industrial products. This action could aim for example at providing comprehensive information on the requirements applicable to them. The issue of familiarisation of businesses with legislation on industrial products will also be tackled through another Commission initiative, i.e. the "Single Digital Gateway".
- **Option 1.2: Compliance assistance**, i.e. instruments **available in the Member States** to educate and assist businesses, particularly SMEs, to help them to comply with EU legislation on industrial products for instance via the extension of **Product Contact Points** established by Regulation (EC) 764/2008 to the entire internal market for industrial products or via a **voluntary compliance assistance** programme in which businesses form a partnership with a market surveillance authority (e.g. UK Primary Authority model). The possibility of providing assistance also in major exporting countries will be assessed.
- **Option 1.3:** Action to **make it easier for businesses to demonstrate that their products are compliant**. This could be done for example through a (either voluntary or compulsory) 'Digital Compliance' system allowing manufacturers or importers to make the relevant information available in digital form or through e-labelling (e.g. using radio frequency identification tags or barcodes linked to websites providing further legally required product information) to the benefit of both consumers and market surveillance authorities.

### 2) Ensuring that non-compliant products are detected and that action is taken against them by market surveillance authorities (complementary options):

- **Option 2.1:** More effective market surveillance **vis-à-vis products imported from third countries (including on line sales) to ensure that products entering the Union are compliant**, for instance by facilitating action taken by authorities when businesses do not have any presence in the EU, increasing coordination between market surveillance and customs authorities or through cooperation arrangements with third countries. Specific coordination arrangements could be considered to target products sold online.
- **Option 2.2:** More effective market surveillance on industrial products **across national borders to ensure that non-compliant products do not circulate within the market**, by facilitating and

promoting administrative cooperation (for example developing a specific mutual assistance procedure or appointing a lead authority) and by facilitating the applicability of national decisions throughout the internal market (e.g. by ensuring the recognition and enforcement of other Member States' decisions with respect to non-compliant products or their direct applicability or the adoption of joint enforcement actions against non-compliant products). In cases of widespread infringements with significant impact on a large part of the EU territory, the EU Commission could also be vested with explicit powers either to coordinate the enforcement activities of the Member States or carry out investigations.

- **Option 2.3: More deterrent enforcement of applicable rules** to discourage businesses from selling non-compliant products **by increasing the market surveillance authorities' capabilities** (resources, expertise, powers) to carry out checks and sanction wrongdoers. This could be done for instance through recovery of costs of controls via administrative fees or EU financial support to national authorities or more efficient use of existing resources (e.g. via structured coordination, pooling of market 'intelligence'), widening of authorities toolbox (e.g. to include explicitly powers to seize products, impose provisional measures pending investigations), specification of existing common criteria for sanctions (e.g. proportionality, deterrence) and/or approximation of the types of infringements and non-criminal sanctions, minimum rules for the definition of criminal offences and criminal sanctions, sanctions imposed by the Commission.

The options are likely to be complementary. The impact assessment will look into such complementarities.

#### **Baseline scenario – no EU policy change**

The market for non-food consumer products has changed over the last decades. One of the main characteristics of the new environment is the dynamic presence on the EU market of products manufactured in third countries. More developing countries are expected to join the market as producers, while trans-national cooperation will steadily grow, offering a great variety of products. E-commerce will further facilitate cross-border transactions. Consequently, many products marketed in European countries will continue to be manufactured in third countries and then imported in the EU. Customs and market surveillance authorities will gradually develop cooperation on the basis of the existing provisions of Regulation (EC) No. 765/2008. To respond to the developments of globalisation and e-commerce, market surveillance authorities have an increasingly challenging role to play in the field of product safety. New production technologies demand efficient and updated testing methods. On-the-spot checks at business premises require substantial funds and usually yield lower returns on investment, the more so, the further down the supply chain these checks are carried out. The lack of resources for market surveillance authorities at Member State level has a negative impact on the efficiency of market surveillance activities carried out by national authorities.

Except for certain minimum coordination requirements introduced by Regulation (EC) No 765/2008 for the area of harmonised products, Member States undertake pro-active and reactive market surveillance mostly along national lines. Besides the various legal instruments which partly regulate market surveillance for products, the Commission contributes to market surveillance activities through various activities which are summarised in the Multi-Annual Action Plan on Market Surveillance [COM(2013)76], which are mostly informal coordination activities or some co-funding of joint actions.

#### **Options of improving implementation and enforcement of existing legislation or doing less/simplifying existing legislation**

1) Facilitating compliance:

There is no EU legislation in this field.

2) Detecting and taking action against non-compliant products by improving businesses' willingness to comply:

A simplification of the market surveillance provisions in EU legislation, notably in Regulation (EC) No 765/2008, will be envisaged in the impact assessment. Other options here consist in, on the one hand, simplifying existing legislation applicable to the products themselves and, on the other, improving its implementation. The simplification of the regulation of products that can be carried out on existing EU legislation is limited by the fact that, in many cases, the products concerned are highly complex, hence why a layered structure has evolved from EU directives and regulations that define general 'essential requirements' to detailed technical standards harmonised at EU level.

As regards improving the implementation of existing EU legislation, technology can play a role in facilitating communication between businesses supplying products to the EU market and responsible authorities through the use of so-called 'digital compliance schemes'.

<b>Alternative policy approaches</b>
N/A.
<b>Alternative policy instruments</b>
<p>The baseline option consists of legislation combined with the "soft law" approaches (e.g. guidance documents based on a general consensus among market surveillance authorities and coordinated by the European Commission). Any policy aiming at greater compliance by businesses in the Single Market would require a mix of policy instruments. Therefore the options above consist of regulatory and non-regulatory options.</p> <p>'Soft law' will be considered for all options, except for the discarded ones. Market-based instruments (and in particular charges, fees, fines and penalties) will also be considered, especially for improving the willingness to comply (detecting and taking action against non-compliant products).</p>
<b>Alternative/differentiated scope</b>
<p>A differentiated treatment of SME (including micro-enterprises) in respect of the compliance with applicable EU product requirements would result in undesirable negative consequences for the SMEs themselves and the Single Market. Unless the substantive rules make provision for an exemption of SMEs or a 'lighter regime' for them, the enforcement of the rules needs to be ensured with regard to all businesses. If not, the public interests pursued by the EU product rules (e.g. consumer safety, protection of the environment, health and safety of workers etc.) would be put in danger. Exceptions to product legislation for small businesses would in principle lead to distortions in the EU Single Market that the examined policy options are aiming to prevent.</p> <p>Also for practical reasons, it would not be possible to apply a differentiated regime to products as authorities could not identify whether or not their producer, importer, or distributor is a SME.</p> <p>Finally, exempting SMEs (including micro-enterprises) from the enforcement of essential health and safety or environmental protection requirements would be detrimental for their reputation as consumers could consider them as 'unsafe', lose confidence in buying products from SMEs and redirect their purchasing to products produced or sold by large companies.</p> <p>Therefore, an alternative or differentiated scope for the options to improve the regulatory knowledge or comprehension (facilitating compliance) and the willingness to comply (detecting and taking action against non-compliant products) would not make sense. However, actions to help businesses comply with EU legislation could indeed be focussed in the first place on SMEs.</p> <p>Regarding Digital Compliance schemes (facilitating demonstration of compliance), any exclusion of micro enterprises would be detrimental first of all for the micro enterprises themselves: Digital Compliance aims to reduce administrative costs for demonstrating product compliance and targets all enterprises; including SMEs and micro enterprises that due to their size are more sensitive to administrative costs.</p>
<b>Options that take account of new technological developments</b>
New technological developments will be key considerations in all options.
<b>Preliminary proportionality check</b>
In accordance with the principle of proportionality, the proposed modifications should not go beyond what is necessary to achieve the objectives set. Any modifications to be introduced through a possible legislative initiative should not impose unnecessary burdens or costs on industry, having particular regard to small and medium-sized enterprises, or administrations. Modifications to the existing legislative framework should improve its clarity and/or workability. Where a modification would have an impact on burdens or costs, the impact assessment will examine whether it actually represents the most proportionate response to the problem identified.
<b>C. Data Collection and Better Regulation Instruments</b>
<b>Data collection</b>
<p>A public consultation open to key stakeholders will be launched in the second quarter of 2016 (open for 12 weeks).</p> <p>Significant data is already available and was mainly gathered through:</p> <ul style="list-style-type: none"> <li>• Impact assessment Product Safety and Market Surveillance package [SWD(2013)33 final]</li> <li>• Evaluation of the Internal Market Legislation for Industrial Products - Accompanying the document the Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee - A vision for the internal market for products Parts 1 and 2 [SWD (2014) 23]</li> <li>• Impact Assessment - Accompanying document to the 10 Proposals to align Product Harmonisation Directives to Decision No 768/2008/EC [SEC(2011) 1376]</li> </ul>

<p>Additional data will be gathered through an open consultation, in order to confirm the magnitude of the problem, costs associated with certain options, as well as their potential economic impacts.</p> <p>An ex-post evaluation of the applicable market surveillance provisions, notably those provided in the Regulation (EC) No 765/2008, is being conducted in order to assess how the current EU framework for market surveillance is performing, in terms of effectiveness, efficiency, coherence, relevance and EU added value.</p>
<p><b>Consultation approach</b></p> <p>The consultation strategy will consist of a mix of open consultation and targeted meetings. The open online stakeholder consultation related to this initiative will be launched before summer 2016. The questionnaire will be published on the 'Your voice in Europe' portal: <a href="http://ec.europa.eu/yourvoice/consultations/index_en.htm">http://ec.europa.eu/yourvoice/consultations/index_en.htm</a></p> <p>The consultation (questionnaires) will be tailor made for businesses (including their umbrella organisations), relevant civil society stakeholders such as consumer organisations and national authorities. Business organisations, chamber of commerce and business networks such as Europe Enterprise Network will be used to reach SMEs in a targeted way.</p> <p>The Commission will also consult the Expert Group on Internet Market for products, the Market Surveillance Expert Group, the Consumer Safety Network and the Advisory Committees and Expert Groups responsible for product/vertical legislation. Finally, additional data and facts will be gathered through bilateral ad hoc contacts with key stakeholders and representative business organisations.</p>
<p><b>Will an Implementation plan be established?</b></p> <p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p style="text-align: center;"><b>D. Information on the Impact Assessment Process</b></p>
<p>An impact assessment will be carried out with work starting early 2016.</p> <p>An Inter-Service Steering Group (ISSG) chaired by DG Internal Market, Industry, Entrepreneurship and SMEs (GROWTH) will be established to this purpose. Its members will include representatives of:</p> <ul style="list-style-type: none"> <li>• Secretariat-General</li> <li>• Legal Service of the Commission</li> <li>• DG Climate Action (CLIMA)</li> <li>• DG Economic and Financial Affairs (ECFIN)</li> <li>• DG Employment, Social Affairs and Inclusion (EMPL)</li> <li>• DG Energy (ENER)</li> <li>• DG Environment (ENV)</li> <li>• DG Justice and Consumers (JUST)</li> <li>• DG For Mobility and Transport (MOVE)</li> <li>• DG Health and Food Safety (SANTE)</li> <li>• DG Taxation and Customs Union (TAXUD)</li> <li>• DG Trade (TRADE)</li> </ul> <p>ISSG will meet at least three times over the period necessary to achieve the work.</p>
<p style="text-align: center;"><b>E. Preliminary Assessment of Expected Impacts</b></p>
<p><b>Likely economic impacts</b></p> <p>The levelling of the Single Market for goods by addressing non-compliance is likely to have a positive impact on economic growth and activity within the European Union. Further efforts against non-compliant products in the EU would have a deterrent effect on rogue traders and create a level playing field and fair competition among businesses. In addition, it would lead to less non-compliant products becoming or remaining available on the market. However, it is not yet possible to estimate the economic impacts precisely.</p>
<p><b>Likely social impacts</b></p> <p>The main social impact of improved compliance of industrial products with EU legislation is linked to a safer choice for consumers and safer workplaces. Thus a positive impact on human health and wellbeing is expected. This will lead to lower costs for society caused by unsafe products (e.g. public health expenditure due to treatment of injuries and accidents, productivity losses due to absence from work).</p>
<p><b>Likely environmental impacts</b></p> <p>Reducing the occurrence of some non-compliant products onto the single market is likely to ensure a higher level of protection of the environment, by directly impacting on better enforcement of the related EU legislation with a consequent positive environmental impact.</p>



<p><b>Likely impacts on simplification and/or administrative burden</b></p> <p>The aim of policy in the area of market surveillance is to encourage competent authorities to be more selective in their enforcement actions thus reducing the administrative burden of product compliance checks on businesses acting in good faith. Furthermore compliance assistance and digital compliance are expected to reduce businesses costs linked to search of information on legal requirements and demonstration of compliance. Streamlining and modernising the provisions regarding market surveillance might reduce administrative burden for market surveillance authorities in some areas.</p>
<p><b>Likely impacts on SMEs</b></p> <p>SMEs in particular will likely benefit from improved targeting of enforcement actions by market surveillance authorities as cost savings will be spread over a smaller turnover. SMEs will also be better able to exploit the opportunities offered by the Single Market and in particular the possibilities of electronic commerce if a better level playing field can be created.</p>
<p><b>Likely impacts on competitiveness and innovation</b></p> <p>A reduction in administrative burdens on 'willing businesses' (i.e. those acting in good faith in attempting to comply with EU product legislation) is likely to improve competitiveness <i>vis-à-vis</i> both businesses acting in bad faith (attempting to evade compliance) and those outside the EU Single Market. This is also likely to spur product innovation and creativity in terms of development of new and improvement of existing products.</p>
<p><b>Likely impacts on public administrations</b></p> <p>Market surveillance is first and foremost the task of Member States whose administrations are likely to be impacted by providing appropriate resources to strengthen the administrative capacity of their competent authorities. Increased resources would be needed to implement some of the options with a view to ensure improved prevention, detection and deterrent action against non-compliance in the single market for products.</p> <p>On the other hand, enhanced coordination will lead to more efficient and effective use of scarce resources and allow work- and burden-sharing between Member States.</p>
<p><b>Likely impacts on third countries, international trade or investment</b></p> <p>More effective market surveillance should deter exporters of non-compliant products to bring them to the EU market, which could bring in some reduction of imports in the short-medium term. In the longer term, improved integration of approaches to product legislation with non-EU (EEA) countries is likely to restore trust and thus increase international trade in industrial products, and possibly also concomitant investment. It would also likely have a positive, if marginal, effect on public health and the environment in non-EU partner countries.</p>