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IMPACT ASSESSMENT

Accompanying the document

**Proposal for a
REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
concerning customs enforcement of intellectual property rights**

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This impact assessment commits only the Commission's services involved in its preparation. The document has been prepared as a basis for comment and does not prejudice the final form of any decision to be taken by the Commission.

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1. INTRODUCTION

1.1. General overview

The Commission's Communication "Europe 2020"¹ underlined the importance of strengthening knowledge and innovation and promoting a more competitive economy as drivers of a smart and sustainable growth. Intellectual Property Rights (IPR) are fundamental to these key priorities. For the benefit of its citizens and companies, the European Union is committed to establishing a high level of protection of intellectual property rights on its territory.

Intellectual property protection is a central public policy on which the knowledge-based economy rests. Rapid changes in product development, technologies, social drivers and policies all underscore its growing importance. IPR provide an increasingly critical element for spurring innovation, for stimulating investments needed to develop and market new innovations, and for diffusing technology and other types of knowledge in socially beneficial ways. Sound and strong framework conditions for IPR are therefore indispensable. The economic importance of IPR is likely to increase further in the future, with growing evidence of ever increasing intellectual property infringements. Economic losses relating to counterfeiting have been estimated at around €500 billion per year through lost business opportunities and tax revenues. In addition, counterfeited products are often substandard and can even be dangerous, posing health and safety risks.

Without effective means of enforcing intellectual property rights, innovation and creativity are discouraged and investment diminished. It is therefore necessary to ensure that the substantive law on intellectual property is applied effectively in the Union. In this respect, the means of enforcing intellectual property rights are of paramount importance.

The World Trade Organisation (WTO) recognised the importance of protecting and enforcing intellectual property rights, as well as the role of customs in the border enforcement of such rights, with the adoption of the Agreement on Trade Related aspects of Intellectual Property Rights (TRIPS) in 1994. This instrument, legally binding on all WTO members, contains specific provisions on the border enforcement of IPR. These obligations have been implemented into EU law, by Council Regulation (EC) No 1383/2003 of 22 July 2003, concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights² (hereafter "the Regulation").³

¹ Communication from the Commission: 'Europe 2020: A strategy for smart, sustainable and inclusive growth' of 3 March 2010, COM (2010)2020.

² *OJ L 196*, 2.8.2003, p. 7–14

³ The predecessors of the Council Regulation (EC) No 1383/2003 are:

- Council Regulation (EC) No 3295/94 of 22 December 1994 laying down measures to prohibit the release for free circulation, export, re-export or entry for a suspensive procedure of counterfeit and pirated goods. (*OJ L 341*, 30.12.1994, p. 8–13)

Extensive information has already been collected within the context of the European Observatory on Counterfeiting and Piracy⁴, concerning the growing phenomenon of counterfeiting and piracy and a number of reports and studies have been drawn up in various fora, on related issues. An OECD study, concerning the magnitude of counterfeit and piracy⁵, responded to the growing concern expressed by a number of countries, with the trade on counterfeit and pirated goods. The report, updated in 2009, concluded that the international trade in such goods has grown steadily over the last decade, from just over USD 100 billion in 2000, to up to USD 250 billion in 2007. It was acknowledged that the collection of data for this study was extremely difficult as the source information was often not comparable, due to different methodologies used for collection, analysis and reporting. However, with globalisation and more and more emerging economies competing with EU products and services, both with low and high value added, trade related IPR infringements are on the rise.

A recent report⁶ by the French Union des Fabricants stated that 27 percent of companies spent more than EUR 1 million per year protecting their rights. In the same report 57 percent of companies recognised the direct impact of counterfeiting on employment, while 54 percent stated that counterfeiting is a barrier to innovation.

These concerns diminish ambition and the potential to develop innovative new products and services, ultimately resulting in lower economic growth and lost jobs⁷. This implication is supported by a study by the Centre for Economics and Business Research (CEBR), which stresses that a reduction in investment could have a negative effect on GDP across the EU, to within a region of EUR 8 billion per year⁸. Losses of this magnitude would clearly lead to subsequent reductions in employment.

A study carried out on behalf of the Commission's Enterprise and Industry Directorate General, in 2007, confirmed that Small and Medium Enterprises (SME) were found to have been affected by lost sales, as a direct result of counterfeiting and piracy⁹. The associated damage has also led to impaired business reputations and subsequent harm through job losses and a general stifling of funds for investment in innovation and research and development.

- Council Regulation (EEC) No 3842/86 of 1 December 1986 laying down measures to prohibit the release for free circulation of counterfeit goods (*OJ L 357, 18.12.1986, p1-4*)

⁴ See Commission Communication: 'Enhancing the Enforcement of Intellectual Property Rights in the Internal Market', of 11 September 2009 (COM(2009) 467)

⁵ OECD, Magnitude of counterfeiting and piracy of tangible products – November 2009 update, http://www.oecd.org/document/23/0,3343,en_2649_34173_44088983_1_1_1_1,00.html.

⁶ Union des Fabricants April 2010 report, available at <http://www.unifab.com/downloads/RAPPORTUNIFABavril2010.pdf>

⁷ Union des Fabricants April 2010 report, available at <http://www.unifab.com/downloads/RAPPORTUNIFABavril2010.pdf>

⁸ CEBR (2000), The Impact of Counterfeiting on Four main sectors in the European Union, Centre for Economic and Business Research, London.

⁹ Technopolis (2007), 'Effects of counterfeiting on EU SMEs and a review of various public and private IPR enforcement initiatives and resources', available at http://ec.europa.eu/enterprise/newsroom/cf/document.cfm?action=display&doc_id=4506&userservice_id=1&request.id=0

The Commission's most recent report on EU customs enforcement of intellectual property rights, concerning 2009¹⁰, noted that while the luxury goods sector was traditionally the sector most affected by IPR infringements, more and more potentially dangerous items, used by European consumers in their daily lives, were now being detained by customs. These included medicines, foodstuffs, beverages, shampoos, toothpastes, toys, household appliances, automotive components, electrical components, chemicals and toiletries. In total, approximately 17 million items, or 18% of the total number of detentions made by EU Customs authorities in 2009, would have placed consumers at growing risk¹¹.

The rise of potentially dangerous counterfeit consumer products was illustrated in May 2010, when a two-year Europol investigation resulted in the seizure of 800 tons of counterfeit electrical products, including fake electricity generators, power drills and chainsaws, which did not comply with any European safety standards¹². The seized products represented a value of EUR 12 million and 60 people were arrested in connection with the seizures.

The United National Interregional Crime and Justice Institute (UNICRI) also confirms that dangerous counterfeits have infiltrated the automotive markets and that the incidence of counterfeit spare parts in the automotive sector could represent a loss to the industry of USD 12 billion per year¹³. In addition, UNICRI reports that according to the Toy Industries of Europe (TIE), one toy out of ten, in Europe, could be a counterfeit¹⁴.

Despite numerous reports on the impacts of IPR infringements on society, there is consensus across the board that the data used in these reports lacks credibility mainly due to the fact that sales of IPR infringing goods are of an illegal nature and the quantity of these illegal sales cannot really be known for certain¹⁵.

1.2. Border enforcement of IPR by customs

The 2009 report on EU Customs Enforcement of IPR included summary figures indicating the growing trend in terms of quantities of suspected IPR infringing goods identified by customs, as well as the number of cases where customs intervened (see table 1 - N.B. in 2004, the Member States of the EU increased to 25 and in 2007 to 27). When taken together with the general acceptance that the trade in IPR infringing goods is increasing, it is clear that the level of trade in IPR infringing goods would not only be maintained, but would indeed be magnified in the absence of remedial action.

¹⁰ EU Commission Report on EU Customs Enforcement of Intellectual Property Rights (Results at the EU border – 2009) can be found at http://ec.europa.eu/taxation_customs/customs/customs_controls/counterfeit_piracy/statistics/index_en.htm

¹¹ DG TAXUD, 'Report on EU customs enforcement of intellectual property rights: Results at the EU border – 2009', available at: http://ec.europa.eu/taxation_customs/resources/documents/customs/customs_controls/counterfeit_piracy/statistics/statistics_2009.pdf

¹² <http://www.europol.europa.eu/index.asp?page=news&news=pr100521.htm>

¹³ UNICRI, 'Counterfeiting: a global spread, a global threat', 2008, <http://counterfeiting.unicri.it/report2008.php>

¹⁴ http://www.unicri.it/news/0712-4_Counterfeiting_PressKit.php

¹⁵ For more explanation on lack of reliable data see point 6.1

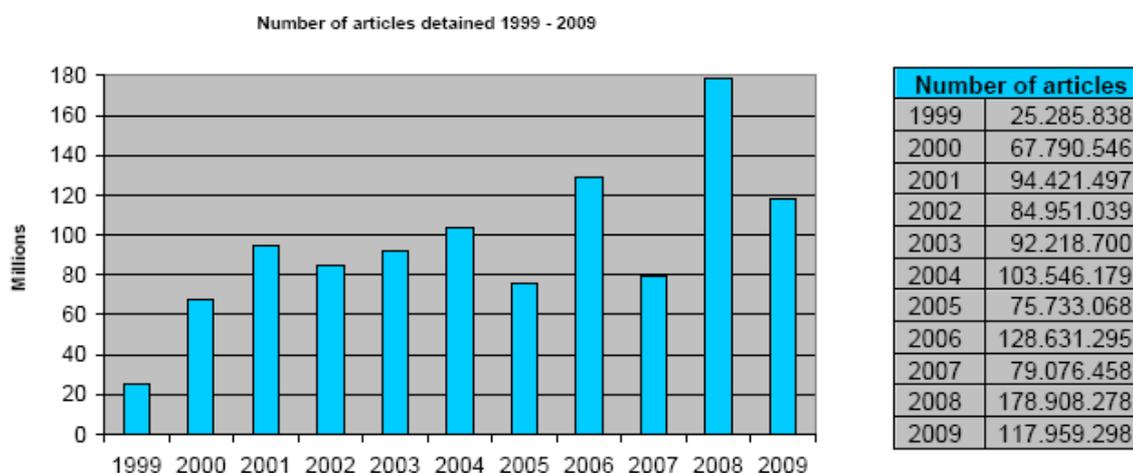
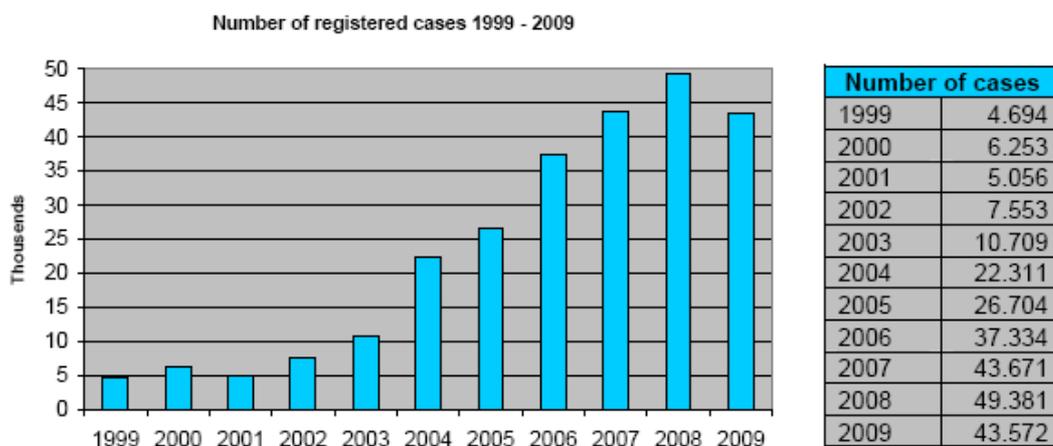


Table 1 - Number of cases and articles detained by customs 1999-2009

Source: EU Commission Report on EU Customs Enforcement of Intellectual Property Rights (Results at the EU Border 2009)

Each case as mentioned in table 1 refers to an interception by customs authorities in the EU. Each case contains a certain amount of individual articles that vary from 1 to several million and can contain articles of different categories and infringing one or more IPR (see table 1 above, and table 2 below).

1.3. Scope of this impact assessment

The TRIPS Agreement requires WTO Members to comply with certain minimum standards for the protection of a range of intellectual property rights listed in the Agreement. Members may choose to implement laws which give more extensive protection than required in the Agreement, as long as the additional protection does not contravene the provisions of the Agreement. The Regulation goes further in terms of border enforcement than the TRIPS requirements, thereby reflecting the EU's commitment towards high levels of IPR protection. Other like-minded jurisdictions, notably the United States, Japan and Switzerland have long considered that the minimal standards provided for by TRIPS did not go far enough in terms of

enforcement and have sought to strengthen international standards, through a new instrument entitled the Anti-Counterfeiting Trade Agreement (ACTA).

The ACTA negotiations involved the participation of 11 parties, including the EU and were concluded at the end of 2010, where the EU sought to raise the level of enforcement required by TRIPS towards the level of EU legislation. Though yet to be ratified, ACTA does raise international standards, including in the area of border enforcement.

Considering that the EU policy to protect and enforce intellectual property rights is clearly established, the baseline for this impact assessment is therefore not to assess whether customs should enforce IPR at the border. In addition to the existing international legal obligations, notably TRIPS, this is already well established as a political priority of the EU.

In September 2008, the Council¹⁶ invited the Commission and the Member States to review Regulation 1383/2003 and evaluate the improvements needed to the legal framework to improve customs action. The Council also invited the Commission to prepare a new Customs Action Plan to combat the trade in IPR infringing goods. This Action Plan¹⁷ was subsequently developed and endorsed by way of a Council Resolution in March 2009. It aims at tackling four main challenges: dangerous counterfeit goods, organised crime, globalisation of counterfeiting and the sale of counterfeits over the internet. The Action Plan included a section concerning the review of the Regulation, which detailed several elements of the Regulation that should be examined. These elements included provisions related to simplified procedures, small consignments, destruction, costs of storage, the provision of additional statistics, the development of an electronic system for applications for action and a database of customs detentions and related statistics and a potential extension of the scope of the Regulation, all of which were examined in the course of the review. The review was carried out by the Commission, in collaboration with the Member States through an expert working group created under the Customs 2013 Programme.

The result of the review was that the Commission and the Member States started to develop a database for the collection of companies' applications for action and statistics of customs detentions. The methodology for collecting statistics was also further refined. As regards the other issues under review, it was considered necessary to amend the Regulation with a view to, inter alia, clarify interpretation, harmonise practises among the Member States or address growing problems such as the rise in internet sales of IPR infringing goods. Recent developments at EU and international levels also influenced the outcome of the review.

From the above, it follows that the impact that is assessed here relates to three main issues. First, the possible additional IPR enforcement activities which customs may

¹⁶ Council Resolution of 25 September 2008 on a comprehensive European anti-counterfeiting and anti-piracy plan (2008/C 253/01)

¹⁷ Council Resolution of 16 March 2009 on the EU Customs Action Plan to combat IPR infringements for the years 2009 to 2012 (2009/C 71/01)

take in the future. Second, the need to make certain procedures less burdensome for customs and right-holders. Third, the need to ensure that all customs provisions remain compatible with developments in EU legislation, notably with regard to the Lisbon Treaty and the Charter on Fundamental Rights, as well as international commitments on for example, access to medicines.

2. PROCEDURAL ISSUES AND CONSULTATION OF INTERESTED PARTIES

2.1. Policy context

As mentioned above, in September 2008 and March 2009 the Council invited the Commission and the Member States to review the Regulation and prepare a proposal to modify the customs legislation, based on a review. Certain instances of detentions by customs authorities of shipments of generic medicines in transit through the EU, which occurred at the end of 2008, have given rise to concerns among certain Members of the WTO, Members of the European Parliament, NGOs and the civil society. It was claimed that such measures could hamper legitimate trade in generic medicines, thus contradicting the EU commitment to facilitating access to medicines in the developing world. On 11 and 12 May 2010 India and Brazil respectively requested consultations with the EU at the WTO in that regard. The concerns raised by India and Brazil during the WTO consultations, as well as the incidents of detentions which have triggered the WTO disputes against the EU, have shown that the relevant EU legislation for intellectual property enforcement by customs authorities could benefit from further clarification to increase legal certainty.

2.2. Internal consultations

The preparation of this Impact Assessment was monitored by an Inter-Service Steering Group, composed of Directorates General TAXUD, MARKT, TRADE, SG, DEV, LS, AGRI, HOME, COMP, JRC, SANCO, OLAF and ENTR. The Steering group met on three occasions. Its last meeting was convened on 29 November 2010.

2.3. Consultation of interested parties

To ensure all stakeholders were given ample opportunity to contribute to the review of the Regulation, the Commission carried out a public consultation through the internet. It presented a consultation paper on 25 March 2010, aiming to identify the possible options to address problems already detected through the experience gained during the years of implementation of Council Regulation 1383/2003. The response to the public consultation included 89 contributions from a wide range of stakeholders¹⁸, including right-holders, providers of services related to international trade (forwarders and carriers), lawyers, academic institutions, NGOs, public authorities and citizens. The consultation, initially envisaged to run until 25 May, was extended to 7 June 2010. An analysis of the outcomes of the public consultation can be found in the Annex.

¹⁸ The consultation paper and the 89 contributions are available at <http://\xxxxxxx>.

One of the main issues that attracted the interest of the respondents to the public consultation was that of costs of storage and destruction of goods (Question 6 of the consultation paper). However, the apportionment of costs is not addressed in this assessment. The intervention of customs usually represents just a first phase in the procedures to enforce IPR; once the alleged infringing goods have been detained by customs authorities, it is up to the right-holder to initiate legal proceedings to enforce his rights. The problem of determining who bears the costs should be handled within the judicial proceedings. The vast majority of the contributions to the public consultation stated that the scope of the provisions on costs in the Regulation should be limited to costs directly incurred by customs.

The Commission maintained regular contacts with the customs authorities of the Member States throughout the review process and there was an active dialogue to identify the main problems and the possible options to address them, notably:

- Under the Customs 2013 Programme, where a Project Group composed of experts from several Customs Administrations was created in order to examine the relevant legislation;
- Through the Customs Code Committee, section Counterfeit goods, composed of Member States' representatives and the Commission.
- Occasional seminars on issues related to the application of the Regulation, where the Customs Authorities of the Member States were invited.

During the course of these contacts, customs experts provided valuable experience of the day-to-day implementation of the current Regulation. Problems and possible weaknesses in the application of the Regulation, measures to strengthen the enforcement capacity of customs and other issues such as the relationship with industry were addressed. As customs experts were ensured confidentiality, it is not possible to present the formal views by Member State. However, in the preparation of this assessment full account was taken of the contributions made, as well as the possible options of the views expressed by the customs experts.

2.4. Impact Assessment Board opinion

A draft Impact Assessment was presented on 26 January 2011 to the Impact Assessment Board. Further to that meeting, the following improvements have been integrated into the document as requested in the opinion of the Board:

- the scope of the Impact Assessment has been clarified in Section 1, through a description of the policy constraints and of the review process.
- more evidence to demonstrate the existence and scale of the problems identified have been included in section 3. As the issues relate to illicit activities, credible data is extremely limited.
- the involvement of the Customs authorities in the review of the Regulation was addressed in Section 2.3 and the option to extend the scope of the Regulation was further refined in section 5.

- where appropriate, further information was included on the possible costs and benefits of extending the scope of the Regulation, though this could not be measured in detail. As indicated already, the lack of available data has placed limitations on the nature of this assessment and though the recently established European Observatory on Counterfeiting and Piracy aims to fill this void, for now, evidence remains anecdotal and is principally limited to examples, opinions of experts, complaints by right-holders.

- with regard to the issue of transit, the WTO Dispute Settlement Procedures are still on-going, though it is acknowledged that further clarification of the customs Regulation, to increase legal certainty would be beneficial and this has been taken into account in Section 3.

In addition, several other minor improvements were made, based on technical comments received from the Board. The Board also suggested that an indication of how the problems identified are likely to be distributed by Member State should also be given. Though it was not felt that a reliable table could be drawn up, the Commission's annual report on customs enforcement of intellectual property rights provides data on the number of cases dealt with by each Member State. Arguably, this table provides an indicator, to the extent that Member States with more cases would tend to encounter more of the difficulties associated with the application of the Regulation.

3. PROBLEM DEFINITION

3.1. Scope of the problems

3.1.1. General description

Customs authorities are able to take action against goods suspected of infringing certain intellectual property rights, which are under customs supervision in the customs territory of the Union. As shown in table 1 above, over the last 10 years, customs interceptions have shown a steady increase. The contribution of customs to IPR enforcement is recognised by public and industry stakeholders.

In the context of the review, three main issues were identified; firstly, some IPR are not enforced by customs at the EU border. The current Regulation provides for the enforcement of a broad range of IPR established under EU or national laws, including trademarks, copyrights, patents, plant variety rights and geographical indications, but the list does not cover all types of IPR. Topographies of semiconductor products for example are not covered. Furthermore, other types of infringements are also currently excluded from the scope of the Regulation, notably with regard to parallel trade and overruns.

Secondly, administrative procedures to enforce IPR are considered to be burdensome to customs and right-holders, especially in relation to small consignments. The procedures provide for the simplified destruction of goods considered to be infringing under certain conditions, without the need to formally establish an infringement in court. The implementation of such simplified procedure is presently not mandatory and consequently it is not implemented in all Member States.

Thirdly, certain general legal principles as developed and interpreted through the jurisprudence of the Court of Justice of the EU are not presently codified in the Regulation for all circumstances where they would apply (e.g. right to be heard, or liability of customs authorities). As a result, there was concern that certain aspects of the administrative procedures contained in the Regulation could lead to an unbalance between, on the one hand, the effectiveness of customs authorities in the fight against international trade in IPR infringing goods and on the other, the facilitation of legitimate trade and business and the right of economic operators to be treated fairly. These concerns were linked to the EU's international obligations in the framework of the WTO, as well as the new legal framework within the EU, following the entry into force of the Lisbon Treaty and in particular the Charter of Fundamental Rights.

3.1.2. The specific problems identified in the application of the current Regulation

3.1.2.1. Problem I: Some IPRs are not enforced by customs at the EU border

IPR enforcement at the EU borders is essential; once IPR infringing goods have been introduced into the internal market, it becomes more difficult to remove them from the market place. This difficulty was also illustrated in a contribution to the Public Consultation which said that despite their clear illegality under trade mark law, due to the inability of customs to seize parallel imports at the border, right-holders' only option was to set up a comprehensive (and complicated) surveillance mechanism scanning internal market sales. Right-holders have to go through hundreds of thousands of stores across the EU to identify such goods and take action on a case by case basis, i.e. for every single small sample found on the market. This ties up enormous resources, both for right-holders and for relevant enforcement authorities/courts; meanwhile, large-scale parallel importers continue to operate, as they know customs will not control them and only some of their customers / resellers will be spotted. The net effect of the current situation is that parallel importation, although illegal in theory, is extremely difficult to curtail in practice.

IPR enforcement by customs has evolved over time, matching the development of protection policies, as well as the growth and increasingly widespread nature of IPR infringements due to the globalisation of production and trade. Council Regulation (EEC) No 3842/86 first gave customs competence on IPR enforcement, which was limited to counterfeit trade mark goods. With Council Regulation 3295/1994, the scope of customs enforcement was extended to pirated copyrights and design rights, whereas the current Council Regulation 1383/2003 further extended the scope of infringements.

The Regulation presently covers counterfeit trade mark goods, pirated copyright and design goods, goods infringing a patent right, goods infringing a supplementary protection certificate for plant protection products or medicinal products, plant variety rights, and protected designation of origin and protected geographical indication for wines, spirits and agricultural farm products and foodstuffs.

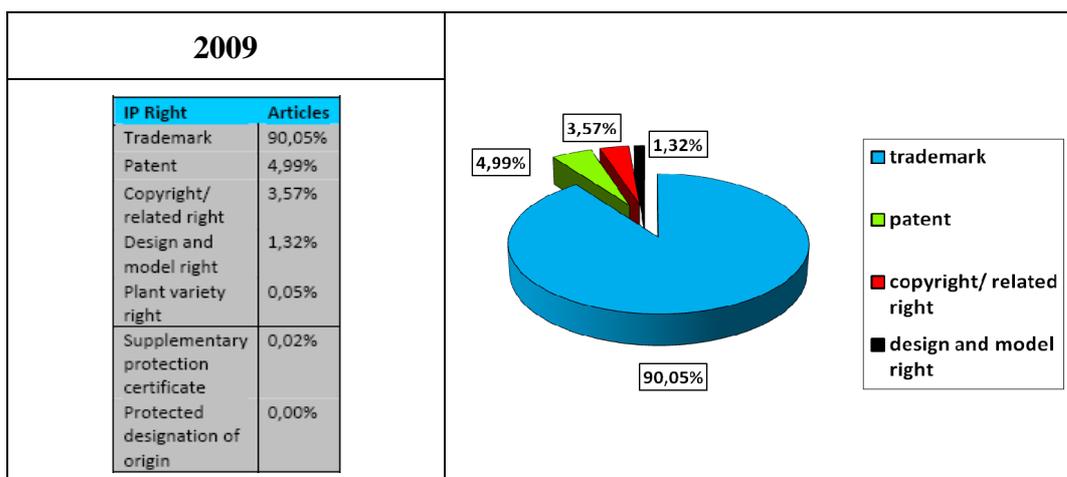


Table 2 - Overview of involved rights in interceptions by customs in 2009

Source: EU Commission Report on EU Customs Enforcement of Intellectual Property Rights (Results at the EU Border 2009)

The concerns expressed by certain stakeholders regarding the broad scope of IPR covered by the current Regulation need to be taken into account. However, any reduction of the scope needs to be seen in the light of existing obligations deriving from international agreements. The TRIPS Agreement obliges WTO Members to provide for border measures only with regards to counterfeit trademarks and pirated copyright goods and only at the time of importation. However, other international agreements¹⁹ do impose a wider scope of border measures, similar to the current Regulation. Subject to ratification, ACTA²⁰ will also provide additional elements covered by TRIPS, notably with regard to import and export shipments, as well as for effective border enforcement of a broader range of IPR.

Nevertheless this document implicitly takes into consideration these concerns by dealing with certain aspects of the administrative procedures that could be interpreted in a manner leading to an unbalanced approach towards interested parties (procedural rights, liability of customs and scope of the simplified procedure). In addition, some options for addressing the problems identified, propose the use of non-legislative

¹⁹ (i) Economic Partnership Agreement with the CARIFORUM States (Council Decision of 15 July 2008, OJ L 289/I/4 of 30.10.2008), Article 163 on border measures refers to goods infringing an intellectual property right: (a) 'counterfeit goods', (b) 'pirated goods', (c) goods which infringe a design or a geographical indication. The EC Party and the Signatory CARIFORUM States agree to collaborate to expand the scope of this definition to cover goods infringing all intellectual property rights.

(ii) EU-Korea FTA, provisionally signed on 6 October 2010. Article 10.67 on border measures refers to goods infringing an intellectual property right: (a) counterfeit goods, (b) pirated copyright goods, or (c) goods which infringe: (i) a patent; (ii) a plant variety right; (iii) a registered design; or (iv) a geographical indication.

²⁰ Final text of ACTA is available at:
http://trade.ec.europa.eu/doclib/docs/2010/december/tradoc_147079.pdf

instruments such as training of customs officers, issuing of guidelines and regular contacts with all stakeholders.

The Regulation does not cover, or expressly excludes from its scope, certain infringements, in particular goods involving an infringement of trade mark rights other than counterfeit trademarks (identical signs for identical type of goods), such as those related to likelihood of confusion (similar sign/similar goods) and well-known trade marks (identical or similar sign and different type of goods); devices to circumvent technological measures designed to prevent or restrict acts which are not authorised by the right-holder (Example: electronic chips that can be fitted into a console so the modified console can be made to play unauthorised copies); goods involving an infringement of design rights other than pirated design right goods; goods involving an infringement of the rights of the creator of the topographies of a semiconductor product (design for electronic function of elements and interconnections of an incorporated circuit in a chip); goods involving an infringement of utility model rights (exclusive protection for an invention with industrial application where the level of inventiveness required is generally lower than that for patents); goods involving an infringement of trade names presented as exclusive property rights in the national law of some Member States; and goods involving infringement of trade secrets (products containing or manufactured using a third parties' undisclosed information, without consent).

The Regulation also excludes from its scope:

- parallel trade;
- goods which have been manufactured or protected by an IPR under conditions other than those agreed with the right-holder;
- non-commercial goods in passengers' baggage within the limits of the duty-free allowance.

The existence and scale of these infringements are difficult to illustrate, and therefore the magnitude of damage to right-holders. There is consensus across the board that there is a lack of credible data in this field. This was underlined in a report²¹ prepared by the United States Government Accountability Office (GAO) in April 2010. The following extract²² expressly refers to the lack of data being a main obstacle to measuring the economic impact of counterfeiting and piracy:

“Quantifying the economic impact of counterfeit and pirated goods on the U.S. economy is challenging primarily because of the lack of available data on the extent and value of counterfeit trade. Counterfeiting and piracy are illicit activities, which makes data on them inherently difficult to obtain. In discussing their own effort to develop a global estimate on the scale of counterfeit trade, OECD officials told us that obtaining reliable data is the most important and difficult part of any attempt to quantify the economic impact of counterfeiting and piracy. OECD’s 2008 report, The

²¹ United States Government Accountability Office – Report to Congressional Committees 'Intellectual Property Observations on efforts to quantify the economic effects of counterfeit and pirated goods' April 2010; GAO-10-423 on <http://www.gao.gov/new.items/d10423.pdf>

²² GAO report, Page 16; opening paragraph of section 'Lack of data is the primary challenge for quantifying economic impacts of counterfeiting and piracy'.

Economic Impact of Counterfeiting and Piracy, further states that available information on the scope and magnitude of counterfeiting and piracy provides only a crude indication of how widespread they may be, and that neither governments nor industry were able to provide solid assessments of their respective situations. The report stated that one of the key problems is that data have not been systematically collected or evaluated and, in many cases, assessments “rely excessively on fragmentary and anecdotal information; where data are lacking, unsubstantiated opinions are often treated as facts”.

Concerns have also been raised in international organisations, such as WIPO, the World Intellectual Property Organisation, that the public debate should not be contaminated by inaccurate and possibly misleading data. At least one member of WIPO has requested that a new and reliable methodology to assess counterfeiting policy be developed.

The main source of information is the Annual report²³ on EU customs enforcement of IPR. The data is provided by EU Member States which forward details of all cases based upon the application of the Regulation, to the Commission on a quarterly basis, in accordance with Article 8 of Commission Regulation (EC) 1891/2004, the implementing regulation for the IPR border enforcement Regulation. These reports provide credible evidence of the work carried out by customs, as well as a useful indicator of the extent of the scale of the trade in IPR infringing goods.

There are two reasons for the lack of data. Firstly, it is very difficult to obtain information on illicit activities. Secondly, the main source to measure external trade in IPR infringing goods usually comes from the statistics of customs interceptions; since the EU customs are not currently competent to intercept goods infringing IPR not covered by the Regulation, this source is not available. There could be alternative methods based on different assumptions, but they would not be reliable and they should be developed for each IPR infringement and sector of products.

With regards to **trademark rights infringements** other than counterfeit goods, 11 submissions to the public consultation suggested broadening the concept of trademark infringement used in the Regulation. According to the right-holders, well known brands are abused for other classes (type of goods) than those registered, such as trade mark signs for beverages that are used for lighters, to confuse the consumer and take unfair profit from the reputation of the well known brand.

Four submissions to the public consultation suggested including **devices to circumvent technological measures** designed to prevent or restrict acts, which are not authorised by the right-holder²⁴. One contribution explained: “*the videogame industry suffers particular damage due to the widespread availability of illegal*

²³ The reports on statistics can be found at http://ec.europa.eu/taxation_customs/customs/customs_controls/counterfeit_piracy/statistics/index_en.htm

²⁴ See Article 7(1)(c) of Directive 2009/24/EC of the European Parliament and of the Council of 23 April 2009 on the legal protection of computer programs (OJ L111, 5.5.2009, p16) and Article 6(2) of Directive 2001/29/EC of the European Parliament and of the Council of 22 May 2001 on the harmonisation of certain aspects of copyright and related rights in the information society (OJ L167, 22.6.2001, p.10).

circumvention devices... the definition of “goods infringing an intellectual property right” in the Regulation should be extended to expressly include illegal circumvention devices, products or components that are designed, produced or adapted to enable or facilitate the circumvention of technological measures”. Another contribution said: “Video game and film producers, inter alia, are facing major difficulties in hindering the circulation of such goods (including, in particular, so-called “game copier devices” and “modchips”) throughout the EU”.

Four submissions to the public consultation expressly mentioned the need to properly enforce **design rights infringements other than pirated goods** (mainly those designs that, without being strictly copies of the protected design right, "does not produce on the informed user a different overall impression"²⁵). One contribution from a textile association said: *“Although the counterfeiting of trade-marks is the infringement the public at large is most familiar with, our textile and clothing industry is also harmed, and perhaps more deeply, by the copying of its designs. This intangible asset is a major trump card for European companies, especially SMEs-SMIs, as it determines to a wide extent the commercial success or failure of a product. Today, we reckon that some 10,000,000 textile designs are created by our companies per year. So far as our sector is concerned, counterfeiting already takes place before the manufacturing and marketing stages of the original design. Indeed, the samples or sketches which are shown either at international fairs or to commission producers or potential customers are immediately reproduced by experienced designers and manufactured even before the original product is manufactured by the owner of the design”.*

Another contribution stated: *“some counterfeit goods are shipped without being marked in their country of manufacture with the third party trade mark under which they would ultimately be disposed of in the country of destination, and that such marking is carried out in the country of destination or an intermediate country. Such behaviour makes seizure by Customs by reference to trade marks, which would otherwise be one of the most straightforward means of identification of counterfeits, difficult if not impossible. Rights holders therefore need to rely on other IPRs such as designs, and may indeed also need to rely on patents”.*

With regard to infringements of the **rights of the creator of the topographies of a semiconductor product**, although the main problem stems from counterfeiting trade marks, right-holders explain that they have experienced the unauthorised reproduction of chip designs.²⁶

As it can be read in the website of the European Space Agency²⁷, *“the topography of an integrated circuit is the result of a huge investment in terms of both finance and know-how. This is also a field in which there is constant need for improvement, such*

²⁵ See art. 10 of Council Regulation (EC) No 6/2002 of 12 December 2001 on Community designs *OJ L 3, 5.1.2002, p. 1–24*

²⁶ See the comments from the Semiconductor Industry Association (SIA) in response to the request from the United States Intellectual Property Enforcement Coordinator for Public Comments on the 2010 US IP Enforcement Joint Strategic Plan in http://www.whitehouse.gov/sites/default/files/omb/IPEC/frn_comments/SemiconductorIndustryAssociation.pdf

²⁷ http://www.esa.int/esaMI/Intellectual_Property_Rights/SEM5JPL26WD_0.html

as reducing the dimensions of integrated circuits. For these reasons, government offices reward these creations of the mind by granting monopoly right of exploitation to the creator. Topographies of semiconductor products also have considerable commercial value as they can be utilised in a wide range of products. A copy of the design could be done easily by photographing the layers of the integrated circuit”.

Six contributions to the public consultation suggested including infringements of **utility model rights**, within the scope of the Regulation. At present, legal protection for inventions by means of utility models is available only at national level. Most EU Member States offer, under various names, utility-model protection. However, their legal systems vary widely. As the WIPO website indicates, “*utility models are considered particularly suited for SMEs that make "minor" improvements to, and adaptations of, existing products. Utility models are primarily used for mechanical innovations*”²⁸.

One contribution asked to include infringements of **trade names** within the scope of the Regulation, where these are presented as exclusive property rights in the national law concerned.

Two contributions suggested including **trade secrets** (products containing or manufactured using a third parties' undisclosed information, without consent), within the scope of the Regulation.

With regard to **illicit parallel trade**, 44 contributions to the public consultation suggested that the derogation in the Regulation be deleted; 5 suggested that the derogation be amended to allow customs authorities to disclose information and 11 suggested that the derogation be maintained. 5 contributions addressed exclusively or principally, the issue of parallel trade; 3 were in favour of withdrawing the derogation and 2 in favour of maintaining the *status quo*.

The European Court of Justice ruled in the Silhouette Case (C-355/96): “*National rules providing for exhaustion of trade-mark rights in respect of products put on the market outside the EEA under that mark by the proprietor or with its consent are contrary to Article 7(1) of First Council Directive 89/104/EEC of 21 December 1988 to approximate the laws of the Member States relating to trade marks, as amended by the Agreement on the European Economic Area of 2 May 1992*”.

There is no credible information on the level of illicit parallel trade. In 1999, a study prepared by NERA at the request of the Commission, was published which examined the economic consequences of the different exhaustion regimes for trade marks²⁹, but it was comparing the economic consequences of the choice of a regime of exhaustion in the area of trademarks assuming that intellectual property was respected. Another report in 1999, “Parallel Imports - Effects of the Silhouette Ruling”³⁰, by the Swedish Competition Authority, investigated and analysed how the Swedish market and Swedish consumers and producers would be affected by the interpretation of the

²⁸ http://www.wipo.int/sme/en/ip_business/utility_models/utility_models.htm

²⁹ The report can be found in http://ec.europa.eu/internal_market/indprop/tm/index_en.htm#docs

³⁰ The report can be found i http://www.konkurrensverket.se/upload/Filer/ENG/Publications/rap_1991-1_eng.pdf

Court in the Silhouette Case, which contrasted with Swedish legal practice. However, the report was based upon the assumption that IPR law was respected.

Situations do arise under the current legislation, where the customs authorities detain a particular shipment suspected of containing counterfeiting goods, and subsequently are informed that the shipment relates to an illicit parallel importation of “genuine” goods. In such cases, the right-holder may not use the information provided by customs to pursue such illicit operations and customs authorities must release the goods. An example of this can be found in the facts giving rise to the proceedings studied in the Opinion of the Advocate General Ruiz-Jarabo Colomer in case C 132/07³¹ (the case was finally removed from the Register of the Court after the parties to the main proceedings resolved the matter amicably).

34 contributions suggested the current derogation concerning **overruns** be deleted, while 8 indicated it should be retained. As one contribution stated, *“there is no justification for treating them differently from goods that have not been licensed at all. In most cases, overruns pose health and safety risks to the consumers since such goods escape from the quality control mechanisms, which the right holders have established for their licensed goods. The lack of quality controls creates the risk that the licensee, which breached a license contracts and produces overruns, which are of a lesser quality and/or of a different composition than the licensed goods, which are subject to quality controls. It is obvious that the interests of the intellectual property rights holder can be seriously affected by overruns, especially if they do not meet the quality requirements of licensed goods, thereby damaging the reputation of the right holder”*.

Goods contained in travelers’ personal baggage, of non-commercial nature and which fall within the limits of the duty-free allowance are excluded from the scope of the Regulation. As the EU report on EU customs enforcement of IPR indicated, the ratio between the number of cases of goods suspected of infringing an IP right found in commercial and passenger traffic is about 84% to 16 %, while as far as the amount of articles detained is concerned, the ratio is about 99% commercial to 1% passenger traffic. Passengers in general will not carry the same amount of goods as are transported in commercial traffic.

Overall, the policy objectives of substantive IPR rules, namely protecting the intellectual property right of a right-holder, are not fully met.

³¹ The Opinion is available in <http://curia.europa.eu/jurisp/cgi-bin/form.pl?lang=en&alljur=alljur&jurcdj=jurcdj&jurtpi=jurtpi&jurtfp=jurtfp&numaff=C-132/07&nomusuel=&docnodecision=docnodecision&allcommjo=allcommjo&affint=affint&affclose=affclose&alldocrec=alldocrec&docor=docor&docav=docav&docsom=docsom&docinf=docinf&alldocnorec=alldocnorec&docnoor=docnoor&docppoag=docppoag&radtypeord=on&newform=newform&docj=docj&docop=docop&docnoj=docnoj&typeord=ALL&domaine=&mots=&resmax=100&Submit=Rechercher>

3.1.2.2. *Problem II: Administrative procedures to enforce IPR are burdensome to customs and right-holders*

Lack of implementation of the simplified procedure in some Member States

The so-called simplified procedure provides for goods to be destroyed in certain circumstances, with the agreement of the right-holder and the owner of the goods and without there being a need to establish the IPR infringement through lengthy and costly legal proceedings. The simplified procedure has proved to be a very useful tool. However, the implementation of the simplified procedure is not mandatory and certain Member States do not provide for it (Bulgaria, France, Italy, Luxembourg and Finland). Some of these are still in the process of introducing national provisions for the implementation of the simplified procedure, whilst others had more substantial problems blocking its introduction. In particular, there were concerns with the compatibility of the simplified procedure with rules governing the fundamental right of property, as well as the fact that criminal procedures applied in some cases, when the right-holder acknowledged a possible infringement of his rights.

Interesting albeit anecdotal evidence concerning the costs involved in pursuing suspected IPR infringements is available from a variety of sources, as shown below. One of the principle aims of the recently established European Observatory on Counterfeit and Piracy is to improve the collection of relevant statistical information, though for now, no substantial credible data is available.

A study called “Damages in Intellectual Property Rights”, prepared by the legal subgroup of the European Observatory on Counterfeiting and Piracy³², underlined the costly nature of infringement proceedings. Right-holders usually have to invest substantial sums to detect an infringement, identify the infringer, investigate and gather evidence of infringement, secure seizure, store and eventually destroy infringing goods. Even small cases could cost over 10,000 € to the right-holder.

Examples of costs related to court proceedings in Germany were provided by Prof. Bornkamm in a document prepared for the World Intellectual Property Organisation (WIPO), entitled “Intellectual Property Litigation under the Civil Law Legal System; experience in Germany”³³, *“the first is a case in which 10.000 € are at stake. The court of first instance hears evidence. The judgment is not appealed against. In this case court costs will amount to c.650 €. Costs for counsel on each side will be about 1.750 €, amounting to total costs of 4.150 €. The second example is a case in which an amount of 100.000 € is in dispute. The second example is a case in which an amount of 100.000 € is in dispute. Again the court of first instance hears evidence, but this time there is an appeal. The Court of Appeal hears and decides the case relying on the evidence heard at first instance. This time court fees for two instances will be about 6.500 €, and the lawyers on each side will charge c.10.300 € bringing the total costs up to 27.200 €. The value of the third case is 1.000.000 €. This time no evidence is heard but the case goes up all the way to and is decided by the Federal Supreme*

³² The study can be found in http://ec.europa.eu/internal_market/iprenforcement/docs/damages_en.pdf

³³ The document can be found in

http://www.wipo.int/edocs/mdocs/enforcement/en/wipo_ace_2/wipo_ace_2_3.pdf

Court. This time court fees amount to c.56.000 €, and the costs for the lawyers on each side will amount to c.42.000 € bringing total costs up to 140.000 €”.

Another example was provided in the Public Consultation. “In Belgium, in case the detention is followed up by a civil procedure the storage and destruction costs have to be advanced by the right-holder and can be claimed back from the infringer. As civil proceedings tend to last for at least one year the costs can pile up. At Antwerp, where entire containers are seized, the storage costs can amount to 500 or even 1.000 € a month. For instance, in December 2009, an amount of 3.850 € has been claimed for the storage and destruction of 2600 infringing trolleys. In March 2010, an amount of 4.750 € was requested for 11.300 kg”.

Sales of IPR infringing goods via the internet

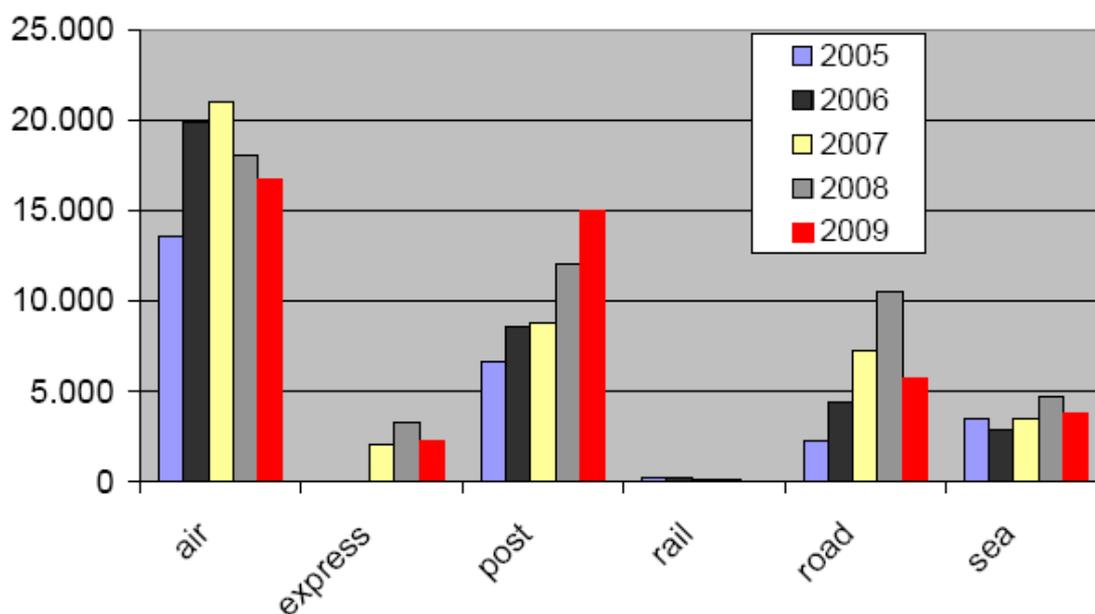
The spectacular rise in online shopping is a recognized phenomenon, which offers new opportunities to consumers in terms of choice and prices, and to companies in terms of market development. Unfortunately, there has been a corresponding rise in the number of cases and quantities of IPR infringing goods identified by customs in small consignments containing goods sold via the internet.

Right-holders perceive an increasing trend towards small consignments of counterfeit or pirated goods, entering the EU through the postal service or via a commercial courier company³⁴. Counterfeiters are now able to send high volumes of parcels, without these items being detected or detained by the customs authorities. This trend is the new supply/traffic channel of choice for counterfeiters and is particularly linked to internet sales.

The 2009 Report on EU Customs Enforcement of IPR shows that there were 17,311 cases of detention of goods (39 % of the total amount of cases) covering only 2,521,976 articles (2 % of the total amount of articles). The trend in the last years indicates that the number of cases of detention of shipments sent by post is growing (see Graph 1 and Table 3 below).

³⁴ The report "Evaluation de l'ampleur de la vente des produits contrefaisants sur Internet" (page 89) states: « Au total, nous pouvons évaluer l'ampleur annuelle de la contrefaçon sur internet en 2006, transitant par la France, à près de 975 000 articles, soit une valeur excédant 83 millions d'euros » ("Evaluation de l'ampleur de la vente des produits contrefaisants sur Internet" *Rapport rédigé sous la direction de Eric SCHMIDT*, Directeur du département Affaires publiques. Compagnie Européenne d'Intelligence Stratégique. Etude commandée par la Direction générale de la Compétitivité, de l'Industrie et des Services. Ministère de l'économie, de l'industrie et de l'emploi de la République Française. The report can be found in http://www.industrie.gouv.fr/enjeux/etude_contref_0209.pdf

Registered cases by means of transport



Graph 1 - Number of cases by means of transport intercepted by customs (2005-2009)

Source: EU Commission Report on EU Customs Enforcement of Intellectual Property Rights (Results at the EU Border 2009)

Cases	2005	%	2006	%	2007	%	2008	%	2009	%
air	13.541	50,71	19.830	53,12	21.041	48,18	18.072	36,60	16.698	38,32
express					2.058	4,71	3.279	6,64	2.308	5,30
post	6.679	25,01	8.613	23,07	8.733	20,00	12.068	24,44	15.003	34,43
rail	222	0,83	190	0,51	136	0,31	102	0,21	57	0,13
road	2.286	8,56	4.400	11,79	7.265	16,64	10.541	21,35	5.714	13,11
sea	3.467	12,98	2.858	7,66	3.483	7,97	4.655	9,43	3.793	8,70
unknown	509	1,91	1.443	3,87	955	2,19	665	1,35	-	-

Table 3 - Number of cases by means of transport intercepted by customs (2005-2009)

Source: EU Commission Report on EU Customs Enforcement of Intellectual Property Rights (Results at the EU Border 2009)

Current procedures involving the implication of the right-holder and the recipient are burdensome. The application of the standard, as well as the simplified procedure, is disproportionate as far as small consignments are concerned. Much of the small shipments, containing suspected IPR infringing goods, are sent by post or courier and

relate to goods being ordered or sold via the internet. These parcels normally contain only a small amount of goods often infringing the rights of several IPR holders (for instance, several T-shirts of different football teams, or several watches bearing different trademarks). The burden for customs to notify each right-holder and for all right-holders to inspect the goods and try to notify the consignee of the parcels in an effort to reach an agreement to destroy the goods is not practical or realistic. As stated before, amounts spent to pursue even the smallest infringers may often run to well over 10,000 Euros. The effect is that the right-holders often do not react to notifications because of the disproportionate and uneconomical burden of cost of storage and judicial procedures, in relation to the amount and value of the infringing goods.

Where the procedures to enforce IPR by customs are disproportionate with regard to the value and amount of alleged infringing goods, both customs and right-holders are discouraged from taking action, thus undermining the effectiveness of the system currently designed in the Regulation.

3.1.2.3. Problem III: Certain aspects of the administrative procedures could be interpreted in a manner leading to an unbalanced approach towards different legitimate stakeholders

Situations in which customs are competent to act might be affecting the smooth transit of medicines across the EU territory towards third countries

The Regulation empowers customs to detain goods suspected of IPR infringements, wherever customs are competent to carry out controls for the performance of their duties. After certain instances of detentions of generic medicines from India in transit through the EU in late 2008, the provisions that determined the scope of customs authority to act has been the basis for concerns that customs could act in a manner that was not compatible with the EU's international obligations in the context of the WTO. These concerns ultimately led to requests by India and Brazil for consultations with the EU, in the framework of the procedures governing the Settlement of Disputes at the World Trade Organisation (WT/DS408³⁵ and WT/DS409³⁶). With a view to an amicable solution of the dispute, the Commission services have explored the possibilities of clarifying the provisions of the Regulation in order to allow for a safe passage of genuine generic medicines through the EU.

Right to be heard

The right of concerned parties to be heard before the decision on the detention of goods is taken is not presently codified in the Regulation. The principle of the right to be heard would be applied on the basis of the ruling given by the European Court of Justice in Case C-349/07 (Sopropé)³⁷. Considering the specific procedures foreseen in the context of IPR enforcement, including time constraints, it is important to establish a practical and harmonised practice for implementing the right to be heard before customs authorities take decisions in this field.

³⁵ http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds408_e.htm

³⁶ http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds409_e.htm

³⁷ See in particular points 33 and 36 to 38 of the ruling.

The principle of right of defence is a well-established legal principle under EU law, which has also been recognised in Article 41 of the Charter of Fundamental Rights of the European Union, dealing with the Right to good administration. This provision establishes that every person has the right to have his or her affairs handled impartially, fairly and within a reasonable time by the institutions, bodies, offices and agencies of the Union and this right includes, amongst others, the right of every person to be heard, before any individual measure, which would affect him or her adversely, is taken.

Liability of customs

Another fundamental legal principle under EU law, which is already well-established in the jurisprudence of the Court of Justice of the EU as well as national courts, is the principle of state responsibility. Its importance has been reaffirmed through the Charter of Fundamental Rights of the European Union, which provides in Article 41 that every person has the right to have the Union make good any damage caused by its institutions or by its servants in the performance of their duties, in accordance with the general principles common to the laws of the Member States. An obligation to provide for liability of public authorities, when they act to enforce IPR at the border on their own initiative, except in situations when they acted in good faith also stems from Article 58 of the TRIPS Agreement.

These principles, while already binding on the EU and its Member States, are not clearly reflected in the current IPR Regulation. Their express codification would therefore be in the interest of greater legal certainty and predictability.

The wording of the provision of Article 19(2) of the Regulation³⁸ may be questioned in the light of national law in the EU Member States, with regard to the non-contractual liability of a public administration concerning any damage caused by it in the performance of its duties. This principle, of course, is not foreign to the EU law and is reflected in Article 41 of the Charter of Fundamental Rights of the European Union and Article 340³⁹, second paragraph, of the Treaty on the Functioning of the European Union, but in that context relates to damages caused by the institutions of the EU.

Simplified procedure: procedure and scope

Article 11 of the Regulation provides for an expeditious procedure for anticipated destruction of the alleged IPR infringing goods detained by customs, where there is an agreement between the right-holder and the declarant, the holder or the owner of the

³⁸ Article 19(2) of the Regulation: “*The exercise by a customs office or by another duly empowered authority of the powers conferred on them in order to fight against goods infringing an intellectual property right shall not render them liable towards the persons involved in the situations referred to in Article 1(1) or the persons affected by the measures provided for in Article 4 for damages suffered by them as a result of the authority's intervention, except where provided for by the law of the Member State in which the application is made or, in the case of an application under Article 5(4), by the law of the Member State in which loss or damage is incurred*”.

³⁹ Article 340 (ex Article 288 TEC) of the Treaty on the Functioning of the European Union (...)

In the case of non-contractual liability, the Union shall, in accordance with the general principles common to the laws of the Member States, make good any damage caused by its institutions or by its servants in the performance of their duties.

goods to abandon the goods for destruction. Such agreement can be explicit or presumed— where the concerned parties do not oppose to destruction after receiving the offer from the right holder. Where there is no agreement or it cannot be presumed, within ten days of receipt of notification of detention of goods, the right holder must initiate the appropriate legal proceedings to determine whether an IPR has been infringed or goods shall be released by customs. Implementation of this simplified procedure is optional for the Member States.

The problems identified with respect to the simplified procedure relate for the most part to the presumption of agreement: “The agreement for destruction shall be presumed to be accepted when the declarant, the holder or the owner of the goods has not specifically opposed destruction within the prescribed period”.

Firstly, the rules stipulating which of the parties (the declarant, the holder, the owner of the goods) should be notified are not sufficiently clear. As a result this can be cause for uncertainty for customs authorities, right-holders and other concerned parties, with regard to the requirements of the procedure.

Secondly, at present, the notification of the proposal of destruction must be done by the right-holders, who subsequently have to prove to customs authorities (i) that they effectively notified the concerned parties and (ii) that the party notified either agreed or – where presumed agreement is sufficient - did not respond to the request from the right holder. The first requirement may be difficult to meet when the concerned party resides in a third country. This requirement also implies a case by case assessment on whether the concerned party was formally and effectively notified or not. The second requirement can be even more difficult to meet, as it requires the right holder to show that he did not receive any reply from the concerned parties. Furthermore, the Regulation does not establish the minimum content of the notification or its form.

Thirdly, the time limits for notifications from the right holder to the concerned parties and for the reply from the concerned parties are not sufficiently defined in the provisions dealing with the simplified procedure. According to article 11 of the Regulation, the concerned parties have to oppose “within the prescribed period”. The “prescribed” period is 10 working days, or three working days in the case of perishable goods, of receipt by the right holder of the notification of detention of goods by customs.

Fourthly, the decision of destruction relies on the initial “suspicion” of IPR infringement by customs authorities that led to the detention on goods, on the lack of reaction from other concerned parties and on the written information from the right holder that “goods concerned by the procedure infringe an intellectual property right”.

In accordance with the Court of Justice jurisprudence on the right to defence, where destruction of goods is based on a presumed agreement, particular attention should be paid to providing sufficient and clear notice to the parties, which rights could be negatively affected, to allow them to make their views effectively known as regards the information on which the authorities intend to base their decision. The latter is a general principle of EU law, which applies where the authorities are minded to adopt a measure, which will adversely affect an individual.

3.2. Who is affected by the identified problems?

The identified problems affect:

- Right-holders, as the proprietors and authorised users of the intellectual property rights and the ones requesting action from customs authorities;
- Carriers and enterprises which offer logistics, freight forwarding and customs services, since the activity of customs on IPR enforcement affects directly their core business;
- Owners and holders of goods internationally traded being the importer, exporter, or consumers of goods and;
- Customs authorities, as the enforcement authority designated under the Regulation.

3.3. How would the problem evolve, all things being equal?

The baseline scenario assumes that the existing Regulation is not modified. The existing legislation does not satisfactorily address the problems or concerns described above. Those problems and concerns, which derive from particular features of the regulatory framework, will persist if the regulatory framework is not modified.

Furthermore, the growing trends of trade in IPR-infringing goods identified in the customs statistics would suggest that the consequences of any weaknesses identified in the current system will also gradually increase in a corresponding manner.

3.4. Right of the EU to act

The European Union has exclusive competence in the area of common commercial policy, as provided for in paragraph (1) of Article 3 of the Treaty on the Functioning of the European Union (TFEU). Article 207⁴⁰ of the TFEU defines common commercial policy and the commercial aspects of intellectual property are expressly included within this definition.

The Regulation concerns the commercial aspects of intellectual property rights in that it deals with measures enabling customs to enforce IPR at the border on goods that are internationally traded. It therefore follows that there is no issue of subsidiarity to be taken into account in this assessment.

⁴⁰ Article 207 (ex Article 133 TEC) of the Treaty on the Functioning of the European Union;
1. The common commercial policy shall be based on uniform principles, particularly with regard to changes in tariff rates, the conclusion of tariff and trade agreements relating to trade in goods and services, and the commercial aspects of intellectual property, foreign direct investment, the achievement of uniformity in measures of liberalisation, export policy and measures to protect trade such as those to be taken in the event of dumping or subsidies. The common commercial policy shall be conducted in the context of the principles and objectives of the Union's external action.

4. OBJECTIVES

The general objective is to ensure that customs measures and procedures concerning border enforcement of IPR are effective and consistent with all relevant legal obligations.

The policy shall in particular pursue the following specific objectives:

- (i) improve IPR enforcement at the border. It is essential that all intellectual property rights can be enforced in an efficient and uniform manner throughout the territory of the Union;
- (ii) limit administrative and economic burdens on customs and right-holders. To make enforcement procedures effective and readily available to all enterprises and especially small and medium-sized enterprises, it is of utmost importance that the procedure for enforcement represents the minimum difficulty to applicants, thereby avoiding unnecessary lengthy procedures.
- (iii) clarify and revisit any provision which may be perceived as imbalances in administrative procedures. All enforcement procedures under the Regulation have to be compatible with the basic principles of EU law and the EU's international obligations.

5. POLICY OPTIONS

5.1. General overview

In considering the different policy options, the baseline scenario is outlined as option A to map out how the situation could be expected to develop if no remedial action was taken. For each problem identified during the course of the review, if appropriate, consideration is also given to resolving the issue through non-legislative means, option B, or through legislative measures, option C.

However, it is not the intention of this assessment to compare the likely merits of options A, B or C, with a view to deciding solely to maintain the baseline scenario, or to introduce non-legislative instruments, or to make a legislative proposal. The aim is to consider the appropriate mix for each specific problem and section 6 of the assessment has therefore been structured around the problems themselves.

5.2. Policy option A – Baseline scenario

The following sections will consider the baseline scenario against all three problems, as well as against the more detailed points within each problem. However, in general terms, on the basis that no proposal was made to amend the provisions of the Regulation and no other measures were taken, the following development of the baseline scenario could be expected:

- the existing rights enforced by customs at the border would continue to be enforced and some IPR infringements would remain outside the scope of competence of customs authorities;

- the current procedures would continue to apply without any possible streamlining, particularly with regard to simplified procedures for destruction and for small consignments;
- no measure would be adopted to address any possible lack of clarity with regard to certain provisions of the Regulation.

5.3. Policy option B – Use of non-legislative instruments

With the implementation of the new customs Action Plan 2009-2012, non-legislative instruments are already being used to a certain extent, to improve the effectiveness of the border measures. The Action Plan includes sections on operational capacity, business and international cooperation, as well as on raising awareness and communication. The Commission will continue to encourage active implementation of the Action Plan, which was accepted by all Member States. It is supported by the Customs 2013 Programme, which can be used to finance certain activities; in the past this has included the elaboration of manuals for right-holders and guidelines for customs on the application of the procedures.

There are further areas where it may be appropriate to consider non-legislative instruments, such as guidance to customs authorities through explanatory notes or guidelines issued by the Commission. These non-legislative instruments could address the interpretation of the Regulation in the light of the WTO law and of the basic principles in the EU law. In addition, further practical cooperation could be envisaged between customs administrations in the Member States to maintain a uniform and effective application of the border measures throughout the EU.

However, problems such as the scope of the competence of customs authorities to enforce IPR could not be addressed by non-legislative instruments; therefore, there would be no change in the scope of the legislation and for example, the rights that customs were competent to enforce.

5.4. Policy option C – Amendment of the Regulation

Under this option, the existing legal framework would be modified. Different options could be available for each of the different identified problems, depending on the outcome of the assessment. Nevertheless, amendments to all or some of the following provisions could be envisaged:

- with regard to problem I (some IPR are not enforced by customs at the EU border), two sub-options could be taken into consideration to extend the scope of the Regulation.

- i. The first sub-option would be to extend the scope of IPR infringements to cover all infringements of the types of IPR already included in the Regulation. Therefore, under this sub-option customs authorities would be competent to take action on goods involving any infringement of trade mark rights (and not only counterfeit goods), of design rights, copyrights and related rights (and not only pirated goods); this would imply also the deletion of the current derogations on parallel trade, overruns and travellers allowance.

- ii. The second sub-option would be to include in addition to the extension proposed in the first sub-option, goods infringing IPRs not already covered by the Regulation. This would cover goods involving an infringement of the rights of the creator of the topographies of a semiconductor product, of utility model rights; of trade names presented as exclusive property rights in the national law of some Member States; and of trade secrets.

- with regard to problem II (administrative procedures to enforce IPR are excessively burdensome), the introduction of a mandatory system for simplified destruction of IPR-infringing goods, subject to clarified conditions and adequate safeguards and the introduction of a specific simplified procedure for small consignments;

- with regard to problem III (rebalancing of certain aspects of the administrative procedures), the introduction of further clarity concerning goods that are merely transiting the EU and not destined for, nor pose a risk of being diverted onto, the EU internal market and the introduction of further clarity in the procedures, to increase legal certainty for all legitimate stakeholders.

Such amendments should not preclude additional support measures, such as training for customs and initiatives to develop further cooperation between customs and stakeholders, including in the area of internet sales.

6. ANALYSIS OF IMPACTS

6.1. Introduction

The absence of data on the volume of EU external trade in goods infringing IPR or of the situation on the internal market renders an assessment of the possible impact of any option difficult. In addition, it is not possible to determine to what extent customs authorities would identify and act upon these infringing goods, as the success of the measures does not solely depend on the decision to modify the legislation. In these circumstances, only a quality assessment is possible.

This document considers a number of technical problems identified in the review of the Regulation that are not necessarily closely interlinked. Therefore, policy options for each separate problem were drawn up and assessed.

6.2. Problem I: Some IPRs are not enforced by customs at the EU border

In order to assess the options for this problem, the following criteria have been considered:

- The level of IPR enforcement within the EU territory, to consider to what extent the possible options could contribute towards better enforcement.
- The cost of enforcing IPR (for right-holders and for enforcement bodies and courts). Where goods have been detained by customs at the border, one legal proceeding will need to be initiated, whereas several separate proceedings will be required for the same level of enforcement for goods found on the market, which have been disaggregated and delivered to retailers.

- Risk of hindering legitimate trade. The measures and procedures to enforce intellectual property rights should not themselves become barriers to legitimate trade.

A - Baseline option

The baseline scenario is that no action is taken. The range of IPR remains within the scope of the Regulation and accordingly, customs authorities would remain competent to take action with regards to goods involving the same intellectual property rights infringements as is currently the case. With this option the number of cases involving customs interventions is not expected to change significantly from the situation portrayed in the latest customs report⁴¹.

The lack of competence of customs with regards to trade in certain IPR infringing goods would mean that:

- The level of IPR enforcement in the EU territory would not be improved at all by maintaining the current scope of the Regulation in terms of IPR infringements covered.
- The cost of enforcing IPR with regards to these infringing goods would remain higher as enforcement could only be done on the market place on the disaggregated consignments.
- The risk of hampering legitimate trade by enforcing IPR at the border would not be increased.

The possible deterrent effect to traders in these infringing goods would be lost; where customs have no competence to take action, there is no need for traders to conceal the shipments at the border.

B – Non-legislative measures option

With regards to the range of IPR covered by the Regulation, non-legislative instruments could not introduce any change as to the scope of competence of customs. Accordingly, the possible impacts concerning the range of IPR covered by the Regulation would be the same as envisaged for the baseline scenario.

Nevertheless, the use of non-legislative instruments to support the extension of the scope of the Regulation to cover new IPR could be considered. These instruments could include training, guidelines and explanatory notes for customs authorities and updating of the manual for right-holders.

⁴¹ Details concerning the last 10 years are available at:
http://ec.europa.eu/taxation_customs/customs/customs_controls/counterfeit_piracy/statistics/index_en.htm

C.1 - Legislative measure sub-option i: extension of the scope to cover goods involving all infringements of the IPR already covered

Concerning the criteria of assessment previously established:

The level of IPR enforcement in the EU territory would be slightly improved by extending the current scope of the Regulation in terms of IPR infringements covered. The main focus for customs control has been on counterfeit products; in 2009, 90% of the articles detained by customs allegedly infringing IPR were counterfeit products. This seems to indicate that customs authorities are mainly finding those IPR infringements, which are more visible and easier to identify. In principle, one would not expect that the simple amendment of the Regulation to include within its scope, goods involving more complex IPR infringements could lead to a radical shift in the type of customs interceptions.

Nevertheless, a relatively significant impact from the introduction of provisions enabling customs to act on confusingly similar trademarks and illicit parallel trade, in particular with regards to trademarks should not be discarded, even though it is not possible to measure the effect in advance. If the volume of trade in these IPR infringing goods was high and the level of effectiveness of customs authorities in targeting it was also high, there would be more enforcement at the border.

However, a deterrent effect on the trade in IPR infringing goods, resulting from an extension of the scope of competences of customs should not be discarded. Where customs are competent to take action concerning a particular IPR infringement, some traders will refrain from trading knowingly in illicit goods. The deterrence effect will not only depend on a modification of the Regulation, but also on the effectiveness of customs in enforcing these IPR.

The deletion of the current derogation in the Regulation concerning goods of a non-commercial nature carried by travellers within their personal baggage should not have significant consequences, as the definition of IP infringements does not usually cover acts done privately. The current statistics of customs detentions recorded at the external borders of the EU published by the Commission⁴² provide information only on “passenger’s traffic of goods of a commercial nature”.

There would be an impact in terms of costs for customs authorities, international trade service providers and right-holders. As the level of trade in these infringing goods is unknown, it is not possible to estimate the costs, though the cost of enforcing IPR at the border to an equivalent level in the internal market would be lower as the right-holder would need to initiate fewer legal proceedings, since the shipment of infringing goods would not have been disaggregated and delivered to retailers.

⁴² The statistics of customs detentions recorded at the external borders of the EU published by the EU Commission can be found at http://ec.europa.eu/taxation_customs/customs/customs_controls/counterfeit_piracy/statistics/index_en.htm

The risk of hindering legitimate trade by enforcing IPR at the border would be increased. It might be difficult for customs authorities to assess some of the IPR infringements that could be added, thus introducing an added risk that decisions to detain goods might be unfounded. For example, the likelihood of confusion of a trade mark encompasses easy cases and very complex cases⁴³. Illicit parallel trade may also be difficult to identify. Furthermore, the fact that goods covered by an IPR are brought into the EU without the authorisation of the right-holder does not mean that the rights of the right-holder are not exhausted with regards to those goods, as they could have been previously put in the EEA market by, or with the consent of, the right-holder. To counteract this risk, training for customs authorities should also be given on any extension of the legislative scope.

C.2 - Legislative measure sub-option ii: extension of the scope to cover goods involving all infringements of the IPR already covered and to include IPR which are not currently covered by the Regulation

Sub-option C1 provided for the extension of the possible types of infringements to rights already covered by the current Regulation, for example, goods involving any infringement of trade mark rights, not just to counterfeit goods. Sub-option C2 includes completely sub-option C1, but furthermore provides a complimentary, additional element. As well as the additional infringements foreseen under option C1, the level of IPR enforcement in the EU territory could be improved by extending the current scope of the Regulation in terms of IPR covered. Modifying the Regulation to include within its scope, goods involving complex IPR infringements, such as topographies of semi-conductor products, would not necessarily lead to a radical shift in the type of customs interceptions. However, empowering customs to enforce these IPR could improve the level of IPR enforcement, even if this improvement would not have a tangible impact overall. Option C2 therefore covers the possible extension outlined in sub-option C1, as well as the inclusion of additional IPR.

The impact in terms of costs for customs authorities, international trade service providers and right-holders would not be expected to be significant, as the number of actions would not be expected to be high. However, given the lack of data on the level of related infringements, it would not be possible to estimate these costs.

The risk of hindering legitimate trade by enforcing IPR at the border would be increased. As in the previous sub-option, it might be difficult for customs authorities to assess some of the IPR infringements that could be added. To counteract this risk, training for customs authorities should also be given on any extension of the legislative scope.

⁴³ See ECJ Case C-361/04 P, paragraph 18: “the assessment of the likelihood of confusion depends on numerous elements and, in particular, on the recognition of the trade mark on the market, on the association which can be made with the used or registered sign and on the degree of similarity between the trade mark and the sign and between the goods or services identified. The likelihood of confusion must therefore be appreciated globally, taking into account all factors relevant to the circumstances of the case”.

Summary Table for Problem 1: Some IPRs currently not enforced

Options \ Criteria	Level of IPR enforcement	Cost of IPR enforcement	Risk of hampering legitimate trade
A – Baseline	0	0	0
B – Non legislative approach	0	0	0
C 1 – Legislation (i) Any infringement of IPR already covered.	0/+	0/+	0/-
C 2 – Legislation (ii) (C1+other IPR)	+	0/+	0/-

Magnitude of effectiveness: ++ strongly positive, + positive, 0 no effect, - negative, -- strongly negative

Social and Environmental impacts for the legislative measure option (applicable to sub-options C1 and C2)

The extension of the Regulation to cover goods involving IPR infringements other than those currently covered is not expected to have tangible social or environmental impacts, taking into account the limited expected increase in customs action.

Possible impact on consumers, such as price and availability of products, resulting from the deletion of the derogation concerning parallel trade should not be addressed in this document. The regime of exhaustion of IPR within EU and MS's legislation is not provided for in the Regulation on customs enforcement of IPR; the adoption of a particular regime of exhaustion of IPR is decided when the EU or MS's substantive legislation on each type IPR is adopted. On the particular issue of the impact of customs detaining parallel trade where it is illegal according to the appropriate substantive rules on IPR, an estimate is not possible; there is no available evidence of the extent of infringements relating to parallel trade, on how this trade might be affecting the markets and to what extent customs could intervene effectively.

It is not possible to measure realistically the potential benefits, such as job creation, in relation to the enforcement by customs of new IPR at the border. The scale of the economic impact if customs would enforce new rights such as well-known trademarks, circumvention devices or topographies of semiconductor product at the border is difficult to measure as there is no data about enforcement of these IPR in the internal market. As customs authorities did not enforce these rights in the past, there is also no historical data contained in the customs statistics.

The enforcement of new IPR at the border is not expected to have a significant environmental impact. Effective enforcement could lead to more interceptions by customs of infringing goods, leading to more destruction of such goods and therefore more waste production. However, the introduction of infringing goods onto the internal market, would not preclude the possibility of their seizure and destruction by other enforcement authorities.

Furthermore, any decision on the disposal of detained goods is normally taken in the proceedings leading to determine the infringement by national courts. Any destruction of goods in waste facilities in MS will have to follow national or EU waste

management policies and have to respect environmental standards in the EU. The same will apply for goods destroyed under the simplified procedure. Destruction in MS includes possibilities such as recycling or disposal of goods outside commercial channels.

Experiences gained from recycling have shown that especially recycled counterfeit goods often pose equal significant threats to the environment or health of consumers because of their “unknown” composition. It is for this reason that stakeholders are not keen on giving permission to recycle goods instead of destroying them or to give permission to donate goods to charity.

As stated previously, due to lack of reliable data, it is not possible to measure the economic impact of enforcing new IPR at the border and therefore the impact on the environment would be equally difficult to measure.

6.3. Problem II: Administrative procedures to enforce IPR are burdensome to customs and right-holders

6.3.1. Lack of implementation of the simplified procedure in some Member States

In order to assess the options for this problem, the following criteria have been considered:

- Harmonisation of administrative procedures: as the border enforcement of IPR falls within the area of common commercial policy, all measures should be uniformly administered throughout the EU territory.
- Administrative burden: the standard procedure to enforce IPR is burdensome for customs authorities and right-holders. Once goods have been detained, customs must notify, amongst others, the right-holders of their actions. If the right-holders consider that the goods in question infringe their rights, they must initiate legal proceedings quickly or the goods are released. Under the simplified procedure, upon express or presumed agreement from the parties concerned, the goods may be deemed to be abandoned for destruction under customs supervision without there being a need to establish the IPR infringement through lengthy and costly legal proceedings.
- Cost of detentions: under the standard procedure, the right-holder must initiate costly legal actions and the goods must be stored for long periods. Under the simplified procedure the goods may be destroyed swiftly, avoiding costs of storage and legal costs.

A - Baseline option

The baseline scenario is that no action is taken: therefore the administrative procedures will not change.

The simplified procedure is optional for the Member States. Until now it has been implemented in different ways by most EU Member States except in Bulgaria, France, Italy, Luxembourg and Finland. By not changing the current administrative procedures the situation will not change and the Member States that have not introduced the simplified procedure, will have no obligation to do so. This means that:

- Harmonisation: certain IPR enforcement measures would not be harmonised across the EU and the confusing situation for stakeholders confronted with different procedures within the EU would remain;
- The administrative burden of lengthy legal procedures will not change in those EU Member States where the simplified procedure has not been implemented.
- The costs of detentions –legal costs and costs of storage in the EU Member States, which have not implemented the simplified procedure will remain a burden.

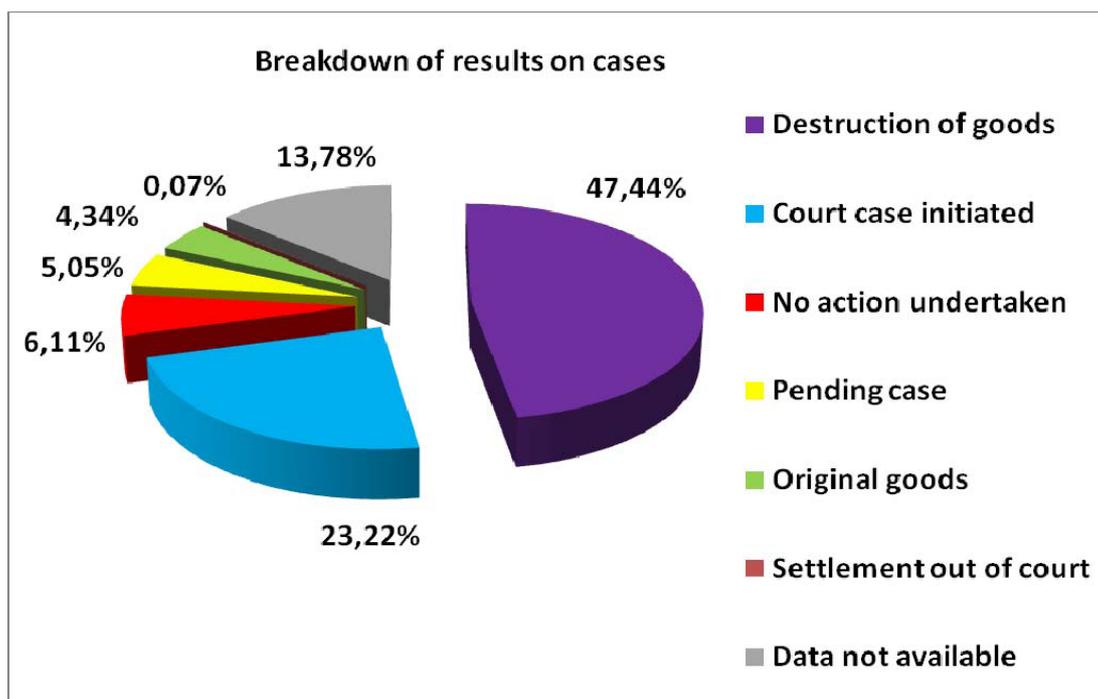
B - Legislative measure option

Introducing mandatory rules in the Regulation, providing for a simplified procedure:

- would harmonise the customs enforcement of IPR in the EU, and
- would reduce the administrative burdens of detentions relating to IPR enforcement, for all parties concerned, in the mentioned Member States.

Where the existence of an infringement is easily established and the concerned parties agree to the destruction of goods pursuant to the simplified procedure, or do not contest it in the case of presumed agreement, the cost of storing the goods for extensive periods of time could be avoided. Since in most cases judicial proceedings to determine the existence of an IPR infringement can take many years, the cost of storage can amount to very significant sums. In many cases, the residual value of the goods is lower than the cost to store them for years.

As some stakeholders stated in their submissions to the public consultation, the simplified procedure provides for a quick and cost effective destruction of infringing goods. It has been a successful tool in the practical management and handling of “uncontested cases” of IPR infringements. The fact that there have only been very few objections by importers to destructions in the framework of the simplified procedure, shows how many superfluous legal proceedings have been avoided since the introduction of the simplified procedure. The current figures in the EU demonstrate that the simplified procedure is already applied in almost half of all cases. In 2009, more than 47% of the cases were solved by destruction of the goods under the simplified procedure. (See graph 2)



Graph 2- Breakdown of results on customs interceptions by cases in 2009

Source: EU Commission Report on EU Customs Enforcement of Intellectual Property Rights (Results at the EU Border 2009)

However, in 23% of over 10 000 cases, a court procedure was initiated to determine the existence of an IPR infringement. Part of this figure includes proceedings in Member States that have not implemented the simplified procedure. If the simplified procedure were to become mandatory for all Member States, the amount of initiated court procedures should normally decrease as several of those cases could be handled and destroyed under the simplified procedure.

Therefore, by making the simplified procedure compulsory, the burdens and costs of enforcing IPR at the border, in relation to storage of detained goods under lengthy judicial procedures, would be reduced. A mandatory simplified procedure would require certain clarification to the existing procedure as the detailed implementation was until now, left to Member States. This would ensure a more uniform administration of the procedure by customs authorities across the EU and thereby increase legal certainty and predictability for operators.

A mandatory procedure, where both parties must be asked first to voluntarily abandon the suspected goods for destruction, would overcome the need for introducing national provisions for implementation, avoid the automatic application of criminal procedures and remain in line with the fundamental right of property.

Summary Table for Problem 2.1: Burdensome Administrative Procedures – where simplified procedure not implemented.

Criteria \ Options	Harmonisation of procedures	Administrative burden	Cost of detentions
A – Baseline	0	0	0
B – Legislation	++	++	++

Magnitude of effectiveness: ++ strongly positive, + positive, 0 no effect, - negative, -- strongly negative

6.3.2. Sales of IPR infringing goods on the internet

Options for this problem are assessed according to the following criteria:

- burden for customs.
- burden for right-holders.
- effectiveness to stop infringing goods sold via internet.

A-Baseline option

The baseline scenario is that no action is taken. The procedures to enforce IPR by Customs will remain disproportionate with regards to the value and amount of small consignments of goods sold via the internet and, therefore, the current procedures will remain burdensome for customs and for right holders, undermining the effectiveness of the system.

B - Non- legislative measures option

With regards to administrative procedures, non-legislative instruments could not introduce any change to the procedures as described in the Regulation. Accordingly, the possible impacts concerning administrative procedures covered by the Regulation would be the same as envisaged for the baseline scenario.

A number of non-legislative measures could be adopted to handle the phenomenon of trade in IPR infringing goods via the internet:

- the Member States could provide for a customs structure responsible for the fight against it, exploring the possibility of creating a national office dedicated to that purpose;
- the topic could be systematically integrated into all action plans concerning IPR enforcement;
- cooperation with other IPR enforcement authorities and developing partnerships with private stakeholders, notably right-holders, carriers, e-commerce operators and on-line payment providers could be fostered;

- rapid exchange of intelligence and operational information between customs authorities could be promoted, using to this end existing systems and establishing a network of national contact points;
- reinforcing customs controls at express freight and postal freight centres;
- developing investigations based upon suspect financial transactions related to the Internet, in order to dismantle criminal networks.

In addition, insofar this customs activity could affect the commercial activity of courier and post services providers, guidelines should be provided in order to:

- avoid impact on speed, processes and administration of the carriers;
- clarify the faculties and limits of customs to carry out physical examination of shipments where the postal secrecy obligations prohibit the carrier from opening shipments in some cases;
- ensure that the application of the procedure shall be proportionate, efficient and transparent.
- apply risk management for inspections in order to avoid undue disturbance of legitimate trade;
- define the obligation, as well as its limits, of carriers in stopping shipments or checking sender and addressee information;
- foster cooperation between carriers and customs.

However, as far as small consignments are concerned, the fruitful implementation of all these measures would not change the disproportionate application of the standard or the simplified procedure in the current Regulation.

C - Legislative measure option

Offering parties the possibility to abandon the goods in certain cases where the infringement appears to be clear, without the right-holders being involved, would reduce the burdens and costs for both right-holders and customs, significantly. The resources required by customs authorities and IPR owners to stop, detain, store, examine and destroy these goods may be disproportionate to the value of the goods for both customs authorities and IPR owners.

This measure should be accompanied by the non-legislative instruments described previously to tackle trade of IPR infringing goods via the internet.

Decreasing the administrative burdens on right-holders and customs would result in an increase of the effectiveness of the system with regards to small shipments sold via the internet.

Summary Table for Problem 2.2: Sales of infringing goods on the internet

Options \ Criteria	Burden for customs authorities	Burden for right-holders	Effectiveness
A – Baseline	0	0	0
B – Non legislative approach	0	0	0
C – Legislation	+	++	++

Magnitude of effectiveness: ++ strongly positive, + positive, 0 no effect, - negative, -- strongly negative

6.3.3. *Social and environmental impacts*

The changes in administrative procedures would impact on public authorities and the administrative burdens on business. All measures on administrative procedures are proposed in order to lower the burden on administrative procedures for government and business.

The introduction of a special administrative procedure for small consignments to fight the increasing number of goods ordered and shipped following a sale via the internet will have an effect on consumers in the sense that these infringing goods will not reach them.

The Commission’s most recent report on EU Customs enforcement of intellectual property, concerning 2009, noted that more and more potentially dangerous items, used by European consumers in their daily lives, were now being detained by customs. Counterfeit goods intercepted by customs are not tested to see if the products are also dangerous to the health and safety of the consumer. Therefore, the health and safety impact on consumers cannot be quantified. However, as these products are wilful infringements and are normally not produced under the same quality and safety standards as the original goods, they are considered to be a potential threat.

No environmental impacts can be associated with this problem.

6.4. **Problem III: Certain aspects of the administrative procedures could be interpreted in a manner that leads to an unbalanced approach towards different legitimate stakeholders**

Divergences by the customs authorities, in the interpretation and application of the Regulation would be disruptive for trade and could lead to tension in the EU's international relations with certain WTO partners and possibly to litigation. The lack of express codification of certain legal principles in the Regulation following the entry into force of the Lisbon Treaty could also lead to litigation before European Courts.

The application by EU customs authorities of provisions on restrictive or prohibitive measures to international trade, such as those related to the enforcement of IPR, must

respect international obligations and commitments, as well as the principles of EU law. Such measures, insofar they belong to the area of the common commercial policy, must be applied in a uniform way. In addition, those measures must be applied in a balanced manner, taking into consideration, on the one hand, the need to enforce the measures effectively and on the other hand, the facilitation as well as respect of legitimate business. To that end and to avoid unfounded action, the provisions must provide legal certainty.

In order to assess the options for this problem, the following criteria have been considered:

- legal certainty on the application of the Regulation
- uniformity of application
- risk of unfounded decisions for detention

6.4.1. *Situations in which customs are competent to act might be affecting the smooth transit of medicines across the EU territory towards third countries*

A - Baseline option

The baseline scenario is that no action is taken. The risk that the lack of clarity concerning certain provisions of the current Regulation, leading to unjustified detentions by EU customs of goods in transit that are not destined for the EU and a possible non uniform application of the Regulation in this regard, would remain. As this lack of clarity gave rise to the initiation of dispute settlement proceedings against the EU before the WTO, a continuation or escalation of the disputes cannot be excluded. Furthermore, as the dispute related to transiting generic medicines, the EU's policy of ensuring access to medicines for developing countries could be put unnecessarily into question.

B - Non-legislative measures option

Non-legislative instruments such as guidelines, could help address the problem of certain detentions of medicines in transit. These non-legislative instruments could help in clarifying the interpretation of Council Regulation (EC) 1383/2003 in the light of the EU's international obligations in the WTO context and in light of the relevant basic principles of EU law, as established and interpreted by the Court of Justice of the EU. In particular, guidelines could clarify the procedural nature of the Regulation with regard to the substantive IP law and the implications for border enforcement of IPR of the EU's obligation to guarantee freedom of transit. Whereas this would help in establishing a greater degree of legal certainty on the customs enforcement of IPRs with respect to medicines in transit, it is far from certain whether this option would be sufficient to address India and Brazil's concerns, and avoid further escalation of the dispute.

C - Legislative measure option

The legislative option would consist in introducing a new provision in the Regulation that would remedy the lack of clarity with respect to goods in transit⁴⁴, when these goods are suspected of infringing an IPR. As a result of this provision, customs authorities would ensure that access to medicines is not hampered, particularly with regard to medicines in transit through the EU.

Amending the Regulation would provide legal certainty and guarantee a uniform application throughout the EU, thereby allowing effective action against any situation covered by the Regulation, whilst applying the procedures in such a manner as to avoid undue disruptions to trade in non-infringing goods that are merely transiting the EU territory and are not destined for the EU market.

Summary Table for Problem 3.1 Situations in which customs might affect the transit of medicines across the EU territory towards third countries

Criteria \ Options	Legal certainty on the application of the Regulation	Uniformity of application	Risk of unfounded decisions for detention
A – Baseline	0	0	0
B – Non legislative approach	+	+	+
C – Legislation	++	++	++

Magnitude of effectiveness: ++ strongly positive, + positive, 0 no effect, - negative, -- strongly negative

6.4.2. Right to be heard

A - Baseline option

The baseline scenario is that no action is taken. The Regulation would therefore not provide for the codification of the general principle established by the Court of Justice of the EU, laid down in the Charter of Fundamental Rights and the laws of the Member States on the need to provide for the right of every person to be heard before any decision is taken which could adversely affect him. The principle would continue to be applied. However, due to the specificity of the customs procedures, legal certainty and predictability would be unnecessarily limited and could also be perceived as an unjustified unbalance of rights in favour of right-holders. The baseline

⁴⁴ **Article V GATT Freedom of Transit** . 1) *Goods (including baggage), and also vessels and other means of transport, shall be deemed to be in transit across the territory of a contracting party when the passage across such territory, with or without trans-shipment, warehousing, breaking bulk, or change in the mode of transport, is only a portion of a complete journey beginning and terminating beyond the frontier of the contracting party across whose territory the traffic passes. Traffic of this nature is termed in this article "traffic in transit".*

2. *There shall be freedom of transit through the territory of each contracting party, via the routes most convenient for international transit, for traffic in transit to or from the territory of other contracting parties. No distinction shall be made which is based on the flag of vessels, the place of origin, departure, entry, exit or destination, or on any circumstances relating to the ownership of goods, of vessels or of other means of transport.*

(...)

scenario would also imply the possible risk that the authorities in the Member States will introduce incorrect or non-uniform procedures in order to comply with this fundamental right.

B – Non-legislative measures option

With a view to achieving a satisfactory level of compliance of these rights of defence and their harmonised implementation in all EU Member States, some non-legislative instruments might be adopted, such as the issuance of guidelines. Such guidelines would remind the customs authorities of the pertinent EU jurisprudence and indicate that the interpretation of the Regulation must be done in the light of the relevant basic principles of EU law. Likewise, the issue could be addressed within the framework of the Customs Code Committee - Counterfeit and Pirated Goods Section, through the promotion of exchanging views and best practices between Member States. These non-legislative measures might be very effective with regards to the application of the Regulation by customs administrations but would not provide the desirable legal certainty on procedural steps with regard to other stakeholders.

C - Legislative measure option

In order to ensure that the application of the Regulation duly reflects the relevant fundamental procedural rights in EU law, provisions would need to be incorporated concerning the right to be heard in cases where customs authorities took decisions that adversely affected the person or persons to whom it was addressed.

In the same context, the Regulation needs to be adjusted with a provision that the person concerned, shall be notified, in the appropriate form, of the decision, which shall set out the grounds on which it is based and include information on procedural rights.

The Regulation falls within the scope of the EU common commercial policy, where the achievement of uniformity in the application of the measures is recognised as an essential condition to the implementation of that policy. The amendment of the Regulation would also ensure a uniform application of procedural rights in the context of customs enforcement of IPR.

Summary Table for Problem 3.2 Right to be heard

Criteria \ Options	Legal certainty on the application of the Regulation	Uniformity of application	Risk of unjustified decisions by customs authorities
A – Baseline	0	0	0
B – Non legislative approach	+	+	+
C – Legislation	++	++	++

Magnitude of effectiveness: ++ strongly positive, + positive, 0 no effect, - negative, -- strongly negative

6.4.3. *Liability of customs*

A - Baseline option

The baseline scenario is that no action is taken. The text of the Regulation, which does not currently codify the relevant general principles in national law, with regard to non-contractual liability of public administrations, would remain. This aspect of the Regulation would remain open to interpretation and could be applied differently across the EU.

B – Non-legislative measures option

The non-legislative option could attempt to address the issue as none of the provisions within the Regulation should be applied against common principles of the EU Member States, contrary to what might be expected from Article 19(2) of the Regulation. Explanatory notes or guidelines might explain that the non-contractual liability of the customs authorities is ruled by the law of the concerned Member State in accordance with the last part of the second subparagraph of such article: "except where provided for by the law of the Member State in which the application is made or, in the case of an application under Article 5(4), by the law of the Member State in which loss or damage is incurred".

C - Legislative measure option

Under the legislative measure option the provisions within article 19 of the Regulation would be deleted. The Member States shall make good any damage caused by its institutions or by its servants in the performance of their duties in accordance with the laws of the Member States concerned.

Summary Table for Problem 3.3 Liability of customs

Criteria \ Options	Legal certainty on the application of the Regulation	Uniformity of application	Risk of unjustified decisions by customs authorities
A – Baseline	0	0	0
B – Non legislative approach	+	+	+
C – Legislation	++	++	+

Magnitude of effectiveness: ++ strongly positive, + positive, 0 no effect, - negative, -- strongly negative

6.4.4. *Simplified procedure: procedure and scope.*

A - Baseline option

The baseline scenario is that no action is taken. The notification procedure described in Section 3.2.2.3.iv) remains unchanged and the possible risks, i.e. wrong party being informed, not being informed at all or being informed at a very late moment, to the legitimate interests of concerned parties, such as the owners of the goods, the holders of the goods or customs declarant, would remain.

The lack of clarity of the provisions on the procedural steps of the simplified procedure within the current Regulation might lead to different interpretations across the EU and to a non-uniform implementation of such a procedure in the Member States.

Furthermore, the possible decision to destroy the goods detained by customs, even in cases where the alleged infringement is difficult to assess, would, in the absence of express opposition from concerned parties to the abandonment of the goods for destruction, continue to rely only on the “confirmation” of infringement by the right-holder.

B - Legislative measure option

Under this option, the introduction of two complementary provisions should be considered:

i) The procedure should be streamlined with regards to notifications to concerned parties, identifying who these concerned parties are, shifting the responsibility of the notification from the right holder to the customs authorities and establishing clear time periods to effectively notify and to react to the notification.

ii) In the case of presumed agreement to destruction, where no judicial authority has made a determination of IPR infringement and the decision of destruction of goods relies only on the initial suspicion of customs authorities, the lack of reaction from concerned parties and the confirmation of one of the concerned parties (the right-holder), the simplified procedure could be limited to “clear cases” of IPR infringements, such as counterfeit and pirated products. As 94% of the detained articles in 2009 were suspected counterfeit and pirated products (see table 2), the impact of this measure would be minimal. The advantage of such a distinction in procedures would be that the interests of third parties in the more complex IPR are better guaranteed.

The fact that counterfeit and pirated products are considered willful infringements of trademarks and copyrights, undermining the interests of legitimate trade, would justify such a distinction in administrative procedures between different IPR. The only way to create such a distinction is by legislative measures.

Summary Table for Problem 3.4 *Simplified procedure: procedure and scope*

Criteria \ Options	Legal certainty on the application of the Regulation	Uniformity of application	Risk of unjustified decisions by customs authorities
A – Baseline	0	0	0
B – Legislation	++	++	++

Magnitude of effectiveness: ++ strongly positive, + positive, 0 no effect, - negative, -- strongly negative

6.4.5. Social and Environmental impacts

The problems concerning certain aspects of the administrative procedures that may have resulted in an unbalanced approach towards different legitimate stakeholders

must be seen in connection on the one hand to international obligations and on the other hand, to practical implementation of current procedures. These issues create more clarity in the administrative procedures and as such have a positive impact on consumers in case they are involved in the process, for example as recipients of consignments ordered via the internet. The right to be heard and liability of customs give the consumer the possibility to object or seek compensation against any decision by customs authorities that might adversely affect them. As there is no historical data available on these new provisions, it is not possible to assess further the possible impact on consumers.

The issue of situations in which customs are competent to act and which might affect the smooth transit of medicines across the EU territory towards third countries could have a social impact on consumers in these third countries, in the sense that no more medicines are to be detained in case of mere transit upon a suspicion of a patent infringement. Delays in the delivery of such medicines would therefore be avoided.

None of the problems relating to the above-mentioned aspects of the administrative procedures is considered to have an environmental impact.

6.5. Administrative burdens

6.5.1 Administrative burdens on business

EU customs IPR enforcement is based on an application for action having been submitted by the IP right-holder. It is for the offended person to initiate legal proceedings to enforce their IPR. Since the submission of an application is not compulsory, the system and the proposed new options do not place any extra cost and obligations on right-holders, when compared to the current features⁴⁵ of the Regulation, which already encourages right-holders to lodge applications electronically when electronic data interchange system exists.

In principle, whichever policy option is chosen with regard to the problems addressed in this assessment, the features presently associated with an administrative burden for right-holders would remain to a certain extent. Today, once suspected infringing goods have been detained by customs, the right-holders are expected to inspect the goods and if they are identified as infringing goods, to contact the concerned parties seeking for an agreement to have such goods abandoned for destruction under customs control, or to pursue criminal or civil actions against the alleged infringer. Introducing a specific simplified procedure for small consignments containing counterfeit and pirated products, where the goods might be destroyed without the

⁴⁵ In order to secure a balance between, on the one hand, the objective of making the system accessible by all right-holders – in particular SMEs - and, on the other hand, the need to ensure facilitation of legitimate trade and the effectiveness of customs controls, the current Council Regulation (EC) 1383/2003 provides for some features:

- The application for action from customs authorities can be granted for a period not exceeding one year and it is not linked to a particular consignment previously targeted by the applicant;
- In the case of European intellectual property rights providing uniform protection throughout the Union an application may, in addition to requesting action by the customs authorities of the Member State in which it is lodged, request action by the customs authorities of one or more other Member States.
- The right-holder may not be charged a fee to cover the administrative costs occasioned by the processing of the application.
- Where electronic data interchange systems exist, Customs authorities must encourage right-holders to lodge applications electronically.
- The application for must contain all the information needed to enable the goods in question to be readily recognised by the customs authorities and proof that the applicant holds the right for the goods in question.

involvement of the right-holder, would considerably reduce the burden on right-holders. It would avoid the exchange of notifications and communications with the customs authorities, as well as the other procedures including the inspection of the goods and the necessary steps to reach agreement or to initiate legal proceedings before the Court. In addition, if customs were requested to notify the detention directly to the concerned parties, it would reduce the burden of the right-holders in carrying out such notification.

6.5.2 *Administrative burdens on customs administrations*

As stated in point 6.2.2 it is not possible to analyse the impacts of the different options in relation to the different problems on administrative costs.

Customs authorities perform their duty at the border of the Union and officers will control a broad variety of laws covering different policy areas. Each law contains specific rules related to the protection of intellectual property rights, cash controls, safety, health, and security provisions, control on tax issues and tariff matters.

It is not possible to measure which part of each control is dedicated to a particular policy, so data concerning administrative costs solely related to IPR enforcement is not available. As customs officials would continue to carry out a broad range of activities, whether or not IPR enforcement activities were increased, the overall administrative budget is not expected to change; the impact would more likely be felt on the number of other tasks performed but this will depend largely on the frequency of infringing goods passing the border. However, the frequency cannot be predicted as the suggested new IPRs to be enforced have not been enforced by customs authorities until now.

Furthermore, the procedures to detain goods involving certain IPR infringements are in place in the EU since the 1st of January 1988. The extension of the scope of the Regulation would not therefore create a need to reorganise customs administrations.

The simplification of procedures for small consignments is expected to reduce the procedural steps and therefore the time spent on the treatment of each detention file. This is expected to counter-balance the possible increase of destruction costs for customs as a result of more efficient procedures.

The customs administrations of the Member States provide customs officers with continuous training. Training on IPR enforcement should be included in the programs for training; in particular, if the scope of the Regulation in terms of IPR infringements is extended. Training costs for customs personnel could be shared between national budget and the EU Customs programme, which already covers such activities.

7. COMPARING THE OPTIONS

Problem I: Some IPRs are not enforced by customs at the EU border	Baseline scenario	Non-legislative measures	Legislative measures
Some IPRs infringements are not currently covered by the Regulation	0	0	C1 + C2 ++
Problem II: Burdensome Administrative procedures	Baseline scenario	Non-legislative measures	Legislative measures
II.1 Non-implementation of the simplified procedure in some Member States	0	N/A	++
II.2 Sales of IPR infringing goods via the internet	0	+	++
Problem III: Certain administrative procedures could be interpreted in a manner leading to an unbalanced approach towards different legitimate stakeholders	Baseline scenario	Non-legislative measures	Legislative measures
III.1 Situations in which customs are competent to act might affect the smooth transit of medicines across the EU territory towards third countries.	0	+	++
III.2 Right to be heard	0	+	++
III. 3 Liability of customs	-/0	0/+	++
III.4 Simplified procedure: procedure and scope	-	N/A	++

As set out in section 6, the legislative option offers the best suitable solution to address the problems that emerged from the implementation of the present Regulation, such as non-harmonised or burdensome procedures, or those resulting from shortcomings, such as IP rights not covered by the Regulation. With regard to the issue of IPR not enforced by customs, the legislation option provided for two approaches; firstly, the extension of the possible types of infringements to rights

already covered by the current Regulation (option C1,) and secondly, to extend also the types of IPR to be enforced by customs (option C2). The most suitable option would be C2, the extension of possible infringements foreseen under C1, as well as the extension of IPR.

Introducing procedural clarifications into the Regulation would also provide the maximum legal certainty on the treatment of medicines in transit, when it comes to patent law. A Commission proposal to amend the present Regulation should preferably respond to all the problems addressed in this Impact Assessment, to ensure a balanced outcome in terms of benefits and constraints for all categories of affected persons.

Non-legislative measures would only partially address the identified problems. Explanatory notes or guidelines could help clarify the applicable procedure concerning the situation of transit through the EU, or how to apply the general principles of law, such as the right to be heard, in the context of the present Regulation. However, non-legislative measures cannot address the objective of widening the scope of IPRs to be enforced by customs.

In some instances, a combination of legislative and non-legislative measures should be envisaged to support the implementation of the new Regulation, as described in previous sections, and in section 8 below.

However, retaining the baseline should be excluded if the Commission is to respond adequately to the Council's request to review the legislation and to the concerns expressed by stakeholders during that process.

8. MONITORING AND EVALUATION

8.1. Monitoring the implementation of the Regulation

The Commission shall ensure that systems are in place to monitor the functioning of the system designed by the new Regulation. The monitoring and evaluation of the application of the new Regulation will be carried out through the following mechanisms.

8.1.1 Collecting, analysing and publishing statistics on customs actions under the Regulation

As in previous years, the Commission will analyse the data provided by EU Member States which forward results relating to IPR infringements to the Commission on a quarterly basis and will report yearly on statistics of customs interceptions of articles suspected of infringing intellectual property rights;

The system will be improved with the implementation of an electronic system (COPIS), which is currently being developed by the Commission, that shall facilitate the sharing of information between customs authorities, through the common registration and maintenance of the applications for action. COPIS will also register

customs detentions, thereby facilitating the collection and analysis of statistics on customs activities.

8.1.2 *Monitoring difficulties in implementation*

The Commission shall ensure that Member States communicate all relevant information on the application of the new Regulation to the Commission, including detailed case-studies on sensitive issues. These cases will be analyzed by the Commission together with the Member States through the Customs Code Committee (Counterfeit and Pirated Goods Section).

8.1.3 *Involvement of stakeholders*

The Commission shall ensure that all stakeholders are given the opportunity to express their views and concerns with regards to the application of the Regulation through the appropriate channels. In particular, the stakeholders will be invited to participate in some meetings of the Customs Code Committee together with the Commission and representatives of the Member States.

8.2. Supporting the implementation of the Regulation with accompanying measures

The Commission shall develop, together with the Member States experts and interested stakeholders, a number of accompanying measures to facilitate the implementation of the new Regulation.

8.2.1 *Guidelines and manuals*

The Commission shall update existing guidance documents and manuals for the implementation of the Regulation by customs and right-holders. Guidelines shall also be produced to clarify the present Regulation on transit through the EU.

8.2.2 *Training plan*

The Commission shall develop a training plan on the main new features of the new Regulation, to be implemented through existing instruments, such as the Customs 2013 Programme or the European Observatory on Counterfeiting and Piracy.

8.2.3 *Activities to tackle internet sales of IPR infringing goods*

Awareness-raising activities informing consumers on the risks and impacts of buying counterfeits via the internet, will be developed to curb the volume of counterfeit goods stopped by customs through postal and courier traffic. The Commission and Member States shall also implement the recommendations adopted in the context of the Seminar organised under the Customs 2013 Programme in October 2010, on Counterfeiting and the internet, by adapting national laws, creating a customs structure to deal with internet sales, and establishing an EU network of national correspondents to exchange information on internet sales of counterfeits. Other activities as described under section 6.3.2 under the non-legislative option, could also be envisaged.

8.3. Improving knowledge about the scale and impacts of trade in IPR infringing goods

One of the main constraints in assessing the impacts of any policy option in the field of IPR enforcement is the lack of reliable data. Existing data on the trade in IPR infringing goods is fragmented and not comparable, thus making it difficult to estimate the overall scale and scope of the problem, the impact on the EU and the impact of any policy measures put in place to tackle that problem.

To respond to this data shortage, the European Observatory on Counterfeit and Piracy has assumed, as one of its priority objectives, the aim of improving the collection and use of information and data. The Observatory was launched in 2009 and comprises of over 40 private stakeholder representatives, the 27 Member States and the Commission.

The current role of the Observatory was agreed by its private sector stakeholders and the Member States and is based on the 2008 Council Resolution, the Commission's Communication on enhancing the enforcement of intellectual property rights in the internal market⁴⁶ and the subsequent Council Resolution of 1 March 2010 on the enforcement of IPR in the internal market⁴⁷. These set out a series of practical initiatives on how the Observatory should respond to the effect that counterfeiting and piracy is having on the EU. Its primary functions are improving the collection and use of information and data; promoting and spreading best practice amongst public authorities, spreading successful private sector strategies and raising public awareness.

Within these primary functions, the Commission identified specific issues that require urgent action. For example, while numerous studies have concluded that the international trade in counterfeit and pirated goods has grown steadily over the last decade, they are often challenged for not being comprehensive or for using incomparable figures resulting from different methodologies. There is an urgent need to improve this situation by developing a common methodology, for use by private and public sector bodies, so that robust reports can be produced, which outline the true scope and scale of the problem. Such reports would be the basis for more evidence-based policy decisions and more focussed enforcement strategies.

As a result a tender was launched for experts to assess the scope, scale and impact of counterfeiting and piracy in the internal market, through a defined methodology for collecting, analysing and comparing data. The methodology proposed by the contractor should result in key indicators that would be applicable throughout all Member States and sectors and which could be used in future studies and analysis. The contractor began work in December 2010 and will firstly identify and compile existing studies and methodologies. Secondly on the basis of the research, the contractor will propose a preferred methodology, which will be used to quantify the scope and scale of counterfeiting and piracy in the internal market, in particular focusing on its implications on various areas, like innovation, growth and competitiveness, creativity and culture, public health and safety, employment, environment, tax revenues, crime.

⁴⁶ COM(2009)467final

⁴⁷ OJ C 56, 6.3.2010