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SUMMARY OF THE IMPACT ASSESSMENT

Accompanying document to the

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

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1. BACKGROUND

A fundamental component of the EU system to enforce intellectual property rights (IPR) is 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 rights¹ (hereafter, “the Regulation”).

The Regulation implements the border enforcement measures contained within the Agreement on Trade Related aspects of Intellectual Property Rights (TRIPS). The TRIPS Agreement was approved by the EU Council in 1994 as part of the multilateral negotiations of the Uruguay Round and concluded in the framework of the World Trade Organisation. In fact, the Regulation goes further in terms of border enforcement than the basic requirements in TRIPS, thereby reflecting the EU’s commitment to high protection of IPR.

Under the Regulation, EU customs authorities are able to take action against goods suspected of infringing certain intellectual property rights which are under customs supervision. The mechanism envisaged is that once suspected goods have been detained by customs, customs authorities notify the right-holder of their action and provide him with a short period to initiate legal proceedings (standard procedure) or, if the simplified procedure has been implemented by the Member State where the goods have been detained, to reach an agreement with the other concerned parties to have the goods abandoned for destruction under customs supervision.

The EU and other developed economies represent attractive markets for IPR infringing goods and customs have identified a steady increase in the quantity of such goods over the last 10 years. In September 2008 the Council invited the Commission and the Member States to review the Regulation and to develop a new customs action plan to combat IPR infringements for the years 2009-2012. This Action Plan², prepared by the Commission and endorsed by the Council, was developed to tackle four main challenges: dangerous counterfeit goods, organised crime, globalisation of counterfeiting and the sale of counterfeits over the internet. The review of the Regulation was incorporated into the plan and was carried out by the Commission, in close collaboration with the Member States through an expert group under the Customs 2013 Programme.

The Commission also carried out a public consultation to give all stakeholders an opportunity to contribute to the review. The period of the consultation was from 25 March, 2010 to 7 June 2010 and the Commission received 89 contributions. Of these, 43 were from organisations and enterprises registered in the register of interest representatives of the European Commission, 42 from non-registered organizations, companies and citizens and 4 from national public authorities.

¹ OJ L 196, 2.8.2003, p. 7–14.

² Council Resolution of 16 March 2009 on the EU Customs Action Plan to combat IPR infringements for the years 2009 to 2012 (OJ C 71, 25.3.2009, p. 1).

Certain instances of detentions by customs authorities of shipments of medicines in transit through the EU, which occurred at the end of 2008, gave 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 have shown that the relevant EU legislation for intellectual property enforcement by customs authorities could benefit from further clarification to increase legal certainty.

2. PROBLEM DEFINITION

The above mentioned Action Plan detailed several elements of the Regulation that should be examined. These elements included provisions related to simplified procedures, small consignments, destruction, costs and storage and a potential extension of the scope of the Regulation, all of which were examined in the course of the review. Three main issues were identified in the review, in relation to combating IPR infringing goods.

- Problem I - Some IPRs 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 law, 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.

- Problem II - Administrative procedures to enforce IPR are considered to be burdensome to customs and right-holders, especially in relation to small consignments resulting from internet sales.

- Problem III - Certain aspects of the administrative procedures could be interpreted in a manner that leads to an unbalanced approach towards different legitimate stakeholders. Certain general legal principles as developed and interpreted through the jurisprudence of the Court of Justice of the EU are not presently codified sufficiently in the Regulation (e.g. right to be heard or liability of customs authorities). These principles emerge from the EU's international obligations in the framework of the WTO, as well as the Lisbon Treaty and in particular, the Charter of Fundamental Rights.

3. THE RIGHT OF THE EU TO ACT

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

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.
- (ii) limit administrative and economic burdens on customs and right-holders, especially small and medium enterprises.
- (iii) clarify and revisit any provision which may be perceived as imbalances in administrative procedures.

5. POLICY OPTIONS

Three main options emerge as those most realistic and feasible:

- i) Policy option A – Baseline scenario, where no action is taken.
- ii) Policy option B – Use of non-legislative instruments, such as training, guidelines, explanatory notes, exchange of best practices, regular contacts with the stakeholders.
- iii) Policy option C – Amendment of the Regulation, where the existing legal framework would be modified. Different options could be available for each of the different identified problems. Amendments to all or some of the following provisions could be envisaged:
 - with regard to problem I, concerning the extension of the scope of customs enforcement, two sub-options could be taken into consideration: (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, and (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;
 - with regard to problem II, 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 regards to problem III, 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.

However, it is not the intention of the assessment to compare the likely merits of those three options, 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 each specific problem against relevant criteria, with a view to finding the appropriate mix of possible solutions.

6. ASSESSMENT OF IMPACTS OF OPTIONS

6.1. Introduction

There is consensus across the board that there is a lack of credible data in this field. The main source of information is the annual report³ on EU customs enforcement of IPR. However, there is little credible information on illicit activities and 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.

The assessment considers the impacts of addressing the three general problems identified in the review, which may require amendments to the Regulation. These technical problems are not necessarily closely inter-linked, therefore policy options for each separate problem were drawn up and assessed with specific criteria.

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

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.

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 less legal proceedings, since the shipment of infringing goods would not have been disaggregated and delivered to retailers.

³ The reports on statistics 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.

The enforcement of new IPR at the border is not expected to have a significant social and environmental impact.

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

Currently, the simplified procedure, whereby goods may be abandoned for destruction, is provided for in the Regulation on an optional basis and in consequence has not been implemented in all Member States. 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 those Member States, where this has not been implemented.

6.3.2. Sales of IPR infringing goods on the internet

Significant quantities of small shipments containing suspected IPR infringing goods, are sent by post or courier and relate to goods being ordered or sold via the internet. The application of the standard, as well as the simplified procedure, is disproportionate in relation to the amount and value of the infringing goods, as far as small consignments are concerned (baseline scenario). Amending the Regulation by providing the parties with the possibility to abandon the goods in certain cases where the infringement appears to be clear, without the right-holders being involved, would reduce significantly the burden for right-holders and customs. This would increase the effectiveness of customs to stop goods sold via internet.

Some non-legislative measures could be adopted in an attempt to tackle the increasing flow of small parcels, but new administrative procedures could not be introduced without making legislative changes to the procedures as described in the Regulation.

6.3.3. Social and environmental impacts

All measures on administrative procedures are proposed in order to lower the administrative burden for government and business.

The introduction of a special administrative procedure for small consignments (legislative measures option) 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 (baseline scenario and non legislative instruments).

No environmental impacts were identified 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

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.

The legislative option would provide legal certainty on the application of the Regulation, uniformity of application throughout the EU and would avoid the risk of unfounded detentions with regard to the identified problems.

Non-legislative options could address some of the identified problems by clarifying the interpretation of the Regulation in the light of the EU's international obligations in the WTO and in light of the relevant basic principles of EU law, as established and interpreted by the Court of Justice of the EU. However, the risk of misinterpretation of the Regulation would remain.

6.4.1. *Social and Environmental impacts*

The clarification, via non-legislative measures or legislative measures, on certain aspects of the administrative procedures could have a positive impact on consumers in cases where they are involved in the process, for example as recipients of consignments ordered via the internet. The right to be heard and the question of customs' liability, give consumers the possibility to object or seek compensation against any decision by customs authorities that might adversely affect them.

The clarification of the Regulation concerning the issue of transit of shipments across the EU territory towards third countries, particularly with regard to medicines, could have a positive impact on consumers in those third countries. The likelihood of delays in the delivery of such medicines would thus be reduced.

No environmental impacts were identified with these administrative procedures.

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 persons 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 features 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. Introducing a specific simplified procedure for small consignments containing counterfeit and pirated products, where the goods might be destroyed without the involvement of the right-holder, would considerably reduce this burden.

6.5.2. *Administrative burdens on customs administrations*

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.

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.

7. THE PREFERRED OPTION

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. Introducing procedural clarifications into the Regulation would also provide the maximum legal certainty on the treatment of generic 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. However, retaining the *status quo* 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. LESSON LEARNED: THE NEED TO IMPROVE 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 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.