

Regulation (EU) No 608/2013 of the European Parliament and of the Council of 12 June 2013 concerning customs enforcement of intellectual property rights and repealing Council Regulation (EC) No 1383/2003

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concerning customs enforcement of intellectual property rights and repealing Council Regulation (EC) No 1383/2003

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 207 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Acting in accordance with the ordinary legislative procedure⁽¹⁾,

Whereas:

- (1) The Council requested, in its Resolution of 25 September 2008 on a comprehensive European anti-counterfeiting and anti-piracy plan, that 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 rights⁽²⁾, be reviewed.
- (2) The marketing of goods infringing intellectual property rights does considerable damage to right-holders, users or groups of producers, and to law-abiding manufacturers and traders. Such marketing could also be deceiving consumers, and could in some cases be endangering their health and safety. Such goods should, in so far as is possible, be kept off the Union market and measures should be adopted to deal with such unlawful marketing without impeding legitimate trade.
- (3) The review of Regulation (EC) No 1383/2003 showed that, in the light of economic, commercial and legal developments, certain improvements to the legal framework are necessary to strengthen the enforcement of intellectual property rights by customs authorities, as well as to ensure appropriate legal certainty.
- (4) The customs authorities should be competent to enforce intellectual property rights with regard to goods, which, in accordance with Union customs legislation, are liable to customs supervision or customs control, and to carry out adequate controls on such goods with a view to preventing operations in breach of intellectual property rights laws. Enforcing intellectual property rights at the border, wherever the goods are, or should have been, under customs supervision or customs control is an efficient way to quickly and effectively provide legal protection to the right-holder as well as the users and

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groups of producers. Where the release of goods is suspended or goods are detained by customs authorities at the border, only one legal proceeding should be required, whereas several separate proceedings should be required for the same level of enforcement for goods found on the market, which have been disaggregated and delivered to retailers. An exception should be made for goods released for free circulation under the end-use regime, as such goods remain under customs supervision, even though they have been released for free circulation. This Regulation should not apply to goods carried by passengers in their personal luggage provided that those goods are for their own personal use and there are no indications that commercial traffic is involved.

- (5) Regulation (EC) No 1383/2003 does not cover certain intellectual property rights and certain infringements are excluded from its scope. In order to strengthen the enforcement of intellectual property rights, customs intervention should be extended to other types of infringements not covered by Regulation (EC) No 1383/2003. This Regulation should therefore, in addition to the rights already covered by Regulation (EC) No 1383/2003, also include trade names in so far as they are protected as exclusive property rights under national law, topographies of semiconductor products and utility models and devices which are primarily designed, produced or adapted for the purpose of enabling or facilitating the circumvention of technological measures.
- (6) Infringements resulting from so-called illegal parallel trade and overruns are excluded from the scope of Regulation (EC) No 1383/2003. Goods subject to illegal parallel trade, namely goods that have been manufactured with the consent of the right-holder but placed on the market for the first time in the European Economic Area without his consent, and overruns, namely goods that are manufactured by a person duly authorised by a right-holder to manufacture a certain quantity of goods, in excess of the quantities agreed between that person and the right-holder, are manufactured as genuine goods and it is therefore not appropriate that customs authorities focus their efforts on such goods. Illegal parallel trade and overruns should therefore also be excluded from the scope of this Regulation.
- (7) Member States should, in cooperation with the Commission, provide appropriate training for customs officials, in order to ensure the correct implementation of this Regulation.
- (8) This Regulation, when fully implemented, will further contribute to an internal market which ensures right-holders a more effective protection, fuels creativity and innovation and provides consumers with reliable and high-quality products, which should in turn strengthen cross-border transactions between consumers, businesses and traders.
- (9) Member States face increasingly limited resources in the field of customs. Therefore, the promotion of risk management technologies and strategies to maximise resources available to customs authorities should be supported.
- (10) This Regulation solely contains procedural rules for customs authorities. Accordingly, this Regulation does not set out any criteria for ascertaining the existence of an infringement of an intellectual property right.

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- (11) Under the ‘Declaration on the TRIPS Agreement and Public Health’ adopted by the Doha WTO Ministerial Conference on 14 November 2001, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all. Consequently, in line with the Union’s international commitments and its development cooperation policy, with regard to medicines, the passage of which across the customs territory of the Union, with or without transshipment, warehousing, breaking bulk, or changes in the mode or means of transport, is only a portion of a complete journey beginning and terminating beyond the territory of the Union, customs authorities should, when assessing a risk of infringement of intellectual property rights, take account of any substantial likelihood of diversion of such medicines onto the market of the Union.
- (12) This Regulation should not affect the provisions on the competence of courts, in particular, those of Regulation (EU) No 1215/2012 of the European Parliament and of the Council of 12 December 2012 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters⁽³⁾.
- (13) Persons, users, bodies or groups of producers, who are in a position to initiate legal proceedings in their own name with respect to a possible infringement of an intellectual property right, should be entitled to submit an application.
- (14) In order to ensure that intellectual property rights are enforced throughout the Union, it is appropriate to allow persons or entities seeking enforcement of Union-wide rights to apply to the customs authorities of a single Member State. Such applicants should be able to request that those authorities decide that action be taken to enforce the intellectual property right both in their own Member State and in any other Member State.
- (15) In order to ensure the swift enforcement of intellectual property rights, it should be provided that, where the customs authorities suspect, on the basis of reasonable indications, that goods under their supervision infringe intellectual property rights, they may suspend the release of or detain the goods whether at their own initiative or upon application, in order to enable a person or entity entitled to submit an application to initiate proceedings for determining whether an intellectual property right has been infringed.
- (16) Regulation (EC) No 1383/2003 allowed Member States to provide for a procedure allowing the destruction of certain goods without there being any obligation to initiate proceedings to establish whether an intellectual property right has been infringed. As recognised in the European Parliament Resolution of 18 December 2008 on the impact of counterfeiting on international trade⁽⁴⁾, such procedure has proved very successful in the Member States where it has been available. Therefore, the procedure should be made compulsory with regard to all infringements of intellectual property rights and should be applied, where the declarant or the holder of the goods agrees to destruction. Furthermore, the procedure should provide that customs authorities may deem that the declarant or the holder of the goods has agreed to the destruction of the goods where he has not explicitly opposed destruction within the prescribed period.

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- (17) In order to reduce the administrative burden and costs to a minimum, a specific procedure should be introduced for small consignments of counterfeit and pirated goods, which should allow for such goods to be destroyed without the explicit agreement of the applicant in each case. However, a general request made by the applicant in the application should be required in order for that procedure to be applied. Furthermore, customs authorities should have the possibility to require that the applicant covers the costs incurred by the application of that procedure.
- (18) For further legal certainty, it is appropriate to modify the timelines for suspending the release of or detaining goods suspected of infringing an intellectual property right and the conditions in which information about detained goods is to be passed on to persons and entities concerned by customs authorities, as provided for in Regulation (EC) No 1383/2003.
- (19) Taking into account the provisional and preventive character of the measures adopted by the customs authorities when applying this Regulation and the conflicting interests of the parties affected by the measures, some aspects of the procedures should be adapted to ensure the smooth application of this Regulation, whilst respecting the rights of the concerned parties. Thus, with respect to the various notifications envisaged by this Regulation, the customs authorities should notify the relevant person, on the basis of the documents concerning the customs treatment or of the situation in which the goods are placed. Furthermore, since the procedure for destruction of goods implies that both the declarant or the holder of the goods and the holder of the decision should communicate their possible objections to destruction in parallel, it should be ensured that the holder of the decision is given the possibility to react to a potential objection to destruction by the declarant or the holder of the goods. It should therefore be ensured that the declarant or the holder of the goods is notified of the suspension of the release of the goods or their detention before, or on the same day as, the holder of the decision.
- (20) Customs authorities and the Commission are encouraged to cooperate with the European Observatory on Infringements of Intellectual Property Rights in the framework of their respective competences.
- (21) With a view to eliminating international trade in goods infringing intellectual property rights, the TRIPS Agreement provides that WTO Members are to promote the exchange of information between customs authorities on such trade. Accordingly, it should be possible for the Commission and the customs authorities of the Member States to share information on suspected breaches of intellectual property rights with the relevant authorities of third countries, including on goods which are in transit through the territory of the Union and originate in or are destined for those third countries.
- (22) In the interest of efficiency, the provisions of Council Regulation (EC) No 515/97 of 13 March 1997 on mutual assistance between the administrative authorities of the Member States and cooperation between the latter and the Commission to ensure the correct application of the law on customs or agricultural matters⁽⁵⁾, should apply.
- (23) The liability of the customs authorities should be governed by the legislation of the Member States, though the granting by the customs authorities of an application should

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not entitle the holder of the decision to compensation in the event that goods suspected of infringing an intellectual property right are not detected by the customs authorities and are released or no action is taken to detain them.

- (24) Given that customs authorities take action upon application, it is appropriate to provide that the holder of the decision should reimburse all the costs incurred by the customs authorities in taking action to enforce his intellectual property rights. Nevertheless, this should not preclude the holder of the decision from seeking compensation from the infringer or other persons that might be considered liable under the legislation of the Member State where the goods were found. Such persons might include intermediaries, where applicable. Costs and damages incurred by persons other than customs authorities as a result of a customs action, where the release of goods is suspended or the goods are detained on the basis of a claim of a third party based on intellectual property, should be governed by the specific legislation applicable in each particular case.
- (25) This Regulation introduces the possibility for customs authorities to allow goods which are to be destroyed to be moved, under customs supervision, between different places within the customs territory of the Union. Customs authorities may furthermore decide to release such goods for free circulation with a view to further recycling or disposal outside commercial channels including for awareness-raising, training and educational purposes.
- (26) Customs enforcement of intellectual property rights entails the exchange of data on decisions relating to applications. Such processing of data covers also personal data and should be carried out in accordance with Union law, as set out in Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data⁽⁶⁾ and Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by Community institutions and bodies and on the free movement of such data⁽⁷⁾.
- (27) The exchange of information relating to decisions on applications and to customs actions should be made via a central electronic database. The entity which will control and manage that database and the entities in charge of ensuring the security of the processing of the data contained in the database should be defined. Introducing any type of possible interoperability or exchange should first and foremost comply with the purpose limitation principle, namely that data should be used for the purpose for which the database has been established, and no further exchange or interconnection should be allowed other than for that purpose.
- (28) In order to ensure that the definition of small consignments can be adapted if it proves to be impractical, taking into account the need to ensure the effective operation of the procedure, or where necessary to avoid any circumvention of this procedure as regards the composition of consignments, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of amending the non-essential elements of the definition of small consignments, namely the specific quantities set out in that definition. It

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is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

- (29) In order to ensure uniform conditions for the implementation of the provisions concerning defining the elements of the practical arrangements for the exchange of data with third countries and the provisions concerning the forms for the application and for requesting the extension of the period during which customs authorities are to take action, implementing powers should be conferred on the Commission, namely to define those elements of the practical arrangements and to establish standard forms. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers⁽⁸⁾. For establishing the standard forms, although the subject of the provisions of this Regulation to be implemented falls within the scope of the common commercial policy, given the nature and impacts of those implementing acts, the advisory procedure should be used for their adoption, because all details of what information to include in the forms follows directly from the text of this Regulation. Those implementing acts will therefore only establish the format and structure of the form and will have no further implications for the common commercial policy of the Union.
- (30) Regulation (EC) No 1383/2003 should be repealed.
- (31) The European Data Protection Supervisor was consulted in accordance with Article 28(2) of Regulation (EC) No 45/2001 and delivered an opinion on 12 October 2011⁽⁹⁾,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

SUBJECT MATTER, SCOPE AND DEFINITIONS

Article 1

Subject matter and scope

1 This Regulation sets out the conditions and procedures for action by the customs authorities where goods suspected of infringing an intellectual property right are, or should have been, subject to customs supervision or customs control within the customs territory of the Union in accordance with Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code⁽¹⁰⁾, particularly goods in the following situations:

- a when declared for release for free circulation, export or re-export;
- b when entering or leaving the customs territory of the Union;
- c when placed under a suspensive procedure or in a free zone or free warehouse.

2 In respect of the goods subject to customs supervision or customs control, and without prejudice to Articles 17 and 18, the customs authorities shall carry out adequate customs controls

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and shall take proportionate identification measures as provided for in Article 13(1) and Article 72 of Regulation (EEC) No 2913/92 in accordance with risk analysis criteria with a view to preventing acts in breach of intellectual property laws applicable in the territory of the Union and in order to cooperate with third countries on the enforcement of intellectual property rights.

3 This Regulation shall not apply to goods that have been released for free circulation under the end-use regime.

4 This Regulation shall not apply to goods of a non-commercial nature contained in travellers' personal luggage.

5 This Regulation shall not apply to goods that have been manufactured with the consent of the right-holder or to goods manufactured, by a person duly authorised by a right-holder to manufacture a certain quantity of goods, in excess of the quantities agreed between that person and the right-holder.

6 This Regulation shall not affect national or Union law on intellectual property or the laws of the Member States in relation to criminal procedures.

Article 2

Definitions

For the purposes of this Regulation:

- (1) 'intellectual property right' means:
- (a) a trade mark;
 - (b) a design;
 - (c) a copyright or any related right as provided for by national or Union law;
 - (d) a geographical indication;
 - (e) a patent as provided for by national or Union law;
 - (f) a supplementary protection certificate for medicinal products as provided for in Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products⁽¹¹⁾;
 - (g) a supplementary protection certificate for plant protection products as provided for in Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products⁽¹²⁾;
 - (h) a Community plant variety right as provided for in Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights⁽¹³⁾;
 - (i) a plant variety right as provided for by national law;
 - (j) a topography of semiconductor product as provided for by national or Union law;
 - (k) a utility model in so far as it is protected as an intellectual property right by national or Union law;

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- (1) a trade name in so far as it is protected as an exclusive intellectual property right by national or Union law;
- (2) ‘trade mark’ means:
 - (a) a Community trade mark as provided for in Council Regulation (EC) No 207/2009 of 26 February 2009 on the Community trade mark⁽¹⁴⁾;
 - (b) a trade mark registered in a Member State, or, in the case of Belgium, Luxembourg or the Netherlands, at the Benelux Office for Intellectual Property;
 - (c) a trade mark registered under international arrangements which has effect in a Member State or in the Union;
- (3) ‘design’ means:
 - (a) a Community design as provided for in Council Regulation (EC) No 6/2002 of 12 December 2001 on Community designs⁽¹⁵⁾;
 - (b) a design registered in a Member State, or, in the case of Belgium, Luxembourg or the Netherlands, at the Benelux Office for Intellectual Property;
 - (c) a design registered under international arrangements which has effect in a Member State or in the Union;
- (4) ‘geographical indication’ means:
 - (a) a geographical indication or designation of origin protected for agricultural products and foodstuff as provided for in Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs⁽¹⁶⁾;
 - (b) a designation of origin or geographical indication for wine as provided for in Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation)⁽¹⁷⁾;
 - (c) a geographical designation for aromatised drinks based on wine products as provided for in Council Regulation (EEC) No 1601/91 of 10 June 1991 laying down general rules on the definition, description and presentation of aromatized wines, aromatized wine-based drinks and aromatized wine-product cocktails⁽¹⁸⁾;
 - (d) a geographical indication of spirit drinks as provided for in Regulation (EC) No 110/2008 of the European Parliament and of the Council of 15 January 2008 on the definition, description, presentation, labelling and the protection of geographical indications of spirit drinks⁽¹⁹⁾;
 - (e) a geographical indication for products not falling under points (a) to (d) in so far as it is established as an exclusive intellectual property right by national or Union law;
 - (f) a geographical indication as provided for in Agreements between the Union and third countries and as such listed in those Agreements;

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- (5) ‘counterfeit goods’ means:
- (a) goods which are the subject of an act infringing a trade mark in the Member State where they are found and bear without authorisation a sign which is identical to the trade mark validly registered in respect of the same type of goods, or which cannot be distinguished in its essential aspects from such a trade mark;
 - (b) goods which are the subject of an act infringing a geographical indication in the Member State where they are found and, bear or are described by, a name or term protected in respect of that geographical indication;
 - (c) any packaging, label, sticker, brochure, operating instructions, warranty document or other similar item, even if presented separately, which is the subject of an act infringing a trade mark or a geographical indication, which includes a sign, name or term which is identical to a validly registered trade mark or protected geographical indication, or which cannot be distinguished in its essential aspects from such a trade mark or geographical indication, and which can be used for the same type of goods as that for which the trade mark or geographical indication has been registered;
- (6) ‘pirated goods’ means goods which are the subject of an act infringing a copyright or related right or a design in the Member State where the goods are found and which are, or contain copies, made without the consent of the holder of a copyright or related right or a design, or of a person authorised by that holder in the country of production;
- (7) ‘goods suspected of infringing an intellectual property right’ means goods with regard to which there are reasonable indications that, in the Member State where those goods are found, they are prima facie:
- (a) goods which are the subject of an act infringing an intellectual property right in that Member State;
 - (b) devices, products or components which are primarily designed, produced or adapted for the purpose of enabling or facilitating the circumvention of any technology, device or component that, in the normal course of its operation, prevents or restricts acts in respect of works which are not authorised by the holder of any copyright or any right related to copyright and which relate to an act infringing those rights in that Member State;
 - (c) any mould or matrix which is specifically designed or adapted for the manufacture of goods infringing an intellectual property right, if such moulds or matrices relate to an act infringing an intellectual property right in that Member State;
- (8) ‘right-holder’ means the holder of an intellectual property right;
- (9) ‘application’ means a request made to the competent customs department for customs authorities to take action with respect to goods suspected of infringing an intellectual property right;
- (10) ‘national application’ means an application requesting the customs authorities of a Member State to take action in that Member State;
- (11) ‘Union application’ means an application submitted in one Member State and requesting the customs authorities of that Member State and of one or more other Member States to take action in their respective Member States;

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- (12) ‘applicant’ means the person or entity in whose name an application is submitted;
- (13) ‘holder of the decision’ means the holder of a decision granting an application;
- (14) ‘holder of the goods’ means the person who is the owner of the goods suspected of infringing an intellectual property right or who has a similar right of disposal, or physical control, over such goods;
- (15) ‘declarant’ means the declarant as defined in point (18) of Article 4 of Regulation (EEC) No 2913/92;
- (16) ‘destruction’ means the physical destruction, recycling or disposal of goods outside commercial channels, in such a way as to preclude damage to the holder of the decision;
- (17) ‘customs territory of the Union’ means the customs territory of the Community as defined in Article 3 of Regulation (EEC) No 2913/92;
- (18) ‘release of the goods’ means the release of the goods as defined in point (20) of Article 4 of Regulation (EEC) No 2913/92;
- (19) ‘small consignment’ means a postal or express courier consignment, which:
- (a) contains three units or less;
 - or
 - (b) has a gross weight of less than two kilograms.

For the purpose of point (a), ‘units’ means goods as classified under the Combined Nomenclature in accordance with Annex I to Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff⁽²⁰⁾ if unpackaged, or the package of such goods intended for retail sale to the ultimate consumer.

For the purpose of this definition, separate goods falling in the same Combined Nomenclature code shall be considered as different units and goods presented as sets classified in one Combined Nomenclature code shall be considered as one unit;

- (20) ‘perishable goods’ means goods considered by customs authorities to deteriorate by being kept for up to 20 days from the date of their suspension of release or detention;
- (21) ‘exclusive licence’ means a licence (whether general or limited) authorising the licensee to the exclusion of all other persons, including the person granting the licence, to use an intellectual property right in the manner authorised by the licence.

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CHAPTER II

APPLICATIONS

SECTION 1

Submission of applications

Article 3

Entitlement to submit an application

The following persons and entities shall, to the extent they are entitled to initiate proceedings, in order to determine whether an intellectual property right has been infringed, in the Member State or Member States where the customs authorities are requested to take action, be entitled to submit:

- (1) a national or a Union application:
 - (a) right-holders;
 - (b) intellectual property collective rights management bodies as referred to in point (c) of Article 4(1) of Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights⁽²¹⁾;
 - (c) professional defence bodies as referred to in point (d) of Article 4(1) of Directive 2004/48/EC;
 - (d) groups within the meaning of point (2) of Article 3, and Article 49(1) of Regulation (EU) No 1151/2012, groups of producers within the meaning of Article 118e of Regulation (EC) No 1234/2007 or similar groups of producers provided for in Union law governing geographical indications representing producers of products with a geographical indication or representatives of such groups, in particular Regulations (EEC) No 1601/91 and (EC) No 110/2008 and operators entitled to use a geographical indication as well as inspection bodies or authorities competent for such a geographical indication;
- (2) a national application:
 - (a) persons or entities authorised to use intellectual property rights, which have been authorised formally by the right-holder to initiate proceedings in order to determine whether the intellectual property right has been infringed;
 - (b) groups of producers provided for in the legislation of the Member States governing geographical indications representing producers of products with geographical indications or representatives of such groups and operators entitled to use a geographical indication, as well as inspection bodies or authorities competent for such a geographical indication;
- (3) a Union application: holders of exclusive licenses covering the entire territory of two or more Member States, where those licence holders have been authorised formally in

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those Member States by the right-holder to initiate proceedings in order to determine whether the intellectual property right has been infringed.

Article 4

Intellectual property rights covered by Union applications

A Union application may be submitted only with respect to intellectual property rights based on Union law producing effects throughout the Union.

Article 5

Submission of applications

1 Each Member State shall designate the customs department competent to receive and process applications ('competent customs department'). The Member State shall inform the Commission accordingly and the Commission shall make public a list of competent customs departments designated by the Member States.

2 Applications shall be submitted to the competent customs department. The applications shall be completed using the form referred to in Article 6 and shall contain the information required therein.

3 Where an application is submitted after notification by the customs authorities of the suspension of the release or detention of the goods in accordance with Article 18(3), that application shall comply with the following:

- a it is submitted to the competent customs department within four working days of the notification of the suspension of the release or detention of the goods;
- b it is a national application;
- c it contains the information referred to in Article 6(3). The applicant may, however, omit the information referred to in point (g), (h) or (i) of that paragraph.

4 Except in the circumstances referred to in point (3) of Article 3, only one national application and one Union application may be submitted per Member State for the same intellectual property right protected in that Member State. In the circumstances referred to in point (3) of Article 3, more than one Union application shall be allowed.

5 Where a Union application is granted for a Member State already covered by another Union application granted to the same applicant and for the same intellectual property right, the customs authorities of that Member State shall take action on the basis of the Union application first granted. They shall inform the competent customs department of the Member State where any subsequent Union application was granted, which shall, amend or revoke the decision granting that subsequent Union application.

6 Where computerised systems are available for the purpose of receiving and processing applications, applications as well as attachments shall be submitted using electronic data-processing techniques. Member States and the Commission shall develop, maintain and employ such systems in accordance with the multi-annual strategic plan referred to in Article 8(2) of Decision No 70/2008/EC of the European Parliament and of the Council of 15 January 2008 on a paperless customs environment for customs and trade⁽²²⁾.

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Article 6

Application form

1 The Commission shall establish an application form by means of implementing acts. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 34(2).

2 The application form shall specify the information that has to be provided to the data subject pursuant to Regulation (EC) No 45/2001 and national laws implementing Directive 95/46/EC.

3 The Commission shall ensure that the following information is required of the applicant in the application form:

- a details concerning the applicant;
- b the status, within the meaning of Article 3, of the applicant;
- c documents providing evidence to satisfy the competent customs department that the applicant is entitled to submit the application;
- d where the applicant submits the application by means of a representative, details of the person representing him and evidence of that person's powers to act as representative, in accordance with the legislation of the Member State in which the application is submitted;
- e the intellectual property right or rights to be enforced;
- f in the case of a Union application, the Member States in which customs action is requested;
- g specific and technical data on the authentic goods, including markings such as bar-coding and images where appropriate;
- h the information needed to enable the customs authorities to readily identify the goods in question;
- i information relevant to the customs authorities' analysis and assessment of the risk of infringement of the intellectual property right or the intellectual property rights concerned, such as the authorised distributors;
- j whether information provided in accordance with point (g), (h) or (i) of this paragraph is to be marked for restricted handling in accordance with Article 31(5);
- k the details of any representative designated by the applicant to take charge of legal and technical matters;
- l an undertaking by the applicant to notify the competent customs department of any of the situations laid down in Article 15;
- m an undertaking by the applicant to forward and update any information relevant to the customs authorities' analysis and assessment of the risk of infringement of the intellectual property right(s) concerned;
- n an undertaking by the applicant to assume liability under the conditions laid down in Article 28;
- o an undertaking by the applicant to bear the costs referred to in Article 29 under the conditions laid down in that Article;
- p an agreement by the applicant that the data provided by him may be processed by the Commission and by the Member States;

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- q whether the applicant requests the use of the procedure referred to in Article 26 and, where requested by the customs authorities, agrees to cover the costs related to destruction of goods under that procedure.

SECTION 2

Decisions on applications

Article 7

Processing of incomplete applications

1 Where, on receipt of an application, the competent customs department considers that the application does not contain all the information required by Article 6(3), the competent customs department shall request the applicant to supply the missing information within 10 working days of notification of the request.

In such cases, the time-limit referred to in Article 9(1) shall be suspended until the relevant information is received.

2 Where the applicant does not provide the missing information within the period referred to in the first subparagraph of paragraph 1, the competent customs department shall reject the application.

Article 8

Fees

The applicant shall not be charged a fee to cover the administrative costs resulting from the processing of the application.

Article 9

Notification of decisions granting or rejecting applications

1 The competent customs department shall notify the applicant of its decision granting or rejecting the application within 30 working days of the receipt of the application. In the event of rejection, the competent customs department shall provide reasons for its decision and include information on the appeal procedure.

2 If the applicant has been notified of the suspension of the release or the detention of the goods by the customs authorities before the submission of an application, the competent customs department shall notify the applicant of its decision granting or rejecting the application within two working days of the receipt of the application.

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Article 10

Decisions concerning applications

1 A decision granting a national application and any decision revoking or amending it shall take effect in the Member State in which the national application was submitted from the day following the date of adoption.

A decision extending the period during which customs authorities are to take action shall take effect in the Member State in which the national application was submitted on the day following the date of expiry of the period to be extended.

2 A decision granting a Union application and any decision revoking or amending it shall take effect as follows:

- a in the Member State in which the application was submitted, on the day following the date of adoption;
- b in all other Member States where action by the customs authorities is requested, on the day following the date on which the customs authorities are notified in accordance with Article 14(2), provided that the holder of the decision has fulfilled his obligations under Article 29(3) with regard to translation costs.

A decision extending the period during which customs authorities are to take action shall take effect in the Member State in which the Union application was submitted and in all other Member States where action by the customs authorities is requested the day following the date of expiry of the period to be extended.

Article 11

Period during which the customs authorities are to take action

1 When granting an application, the competent customs department shall specify the period during which the customs authorities are to take action.

That period shall begin on the day the decision granting the application takes effect, pursuant to Article 10, and shall not exceed one year from the day following the date of adoption.

2 Where an application submitted after notification by the customs authorities of the suspension of the release or detention of the goods in accordance with Article 18(3) does not contain the information referred to in point (g), (h) or (i) of Article 6(3), it shall be granted only for the suspension of the release or detention of those goods, unless that information is provided within 10 working days after the notification of the suspension of the release or detention of the goods.

3 Where an intellectual property right ceases to have effect or where the applicant ceases for other reasons to be entitled to submit an application, no action shall be taken by the customs authorities. The decision granting the application shall be revoked or amended accordingly by the competent customs department that granted the decision.

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Article 12

Extension of the period during which the customs authorities are to take action

1 On expiry of the period during which the customs authorities are to take action, and subject to the prior discharge by the holder of the decision of any debt owed to the customs authorities under this Regulation, the competent customs department which adopted the initial decision may, at the request of the holder of the decision, extend that period.

2 Where the request for extension of the period during which the customs authorities are to take action is received by the competent customs department less than 30 working days before the expiry of the period to be extended, it may refuse that request.

3 The competent customs department shall notify its decision on the extension to the holder of the decision within 30 working days of the receipt of the request referred to in paragraph 1. The competent customs department shall specify the period during which the customs authorities are to take action.

4 The extended period during which the customs authorities are to take action shall run from the day following the date of expiry of the previous period and shall not exceed one year.

5 Where an intellectual property right ceases to have effect or where the applicant ceases for other reasons to be entitled to submit an application, no action shall be taken by the customs authorities. The decision granting the extension shall be revoked or amended accordingly by the competent customs department that granted the decision.

6 The holder of the decision shall not be charged a fee to cover the administrative costs resulting from the processing of the request for extension.

7 The Commission shall establish an extension request form by means of implementing acts. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 34(2).

Article 13

Amending the decision with regard to intellectual property rights.

The competent customs department that adopted the decision granting the application may, at the request of the holder of that decision, modify the list of intellectual property rights in that decision.

Where a new intellectual property right is added, the request shall contain the information referred to in points (c), (e), (g), (h) and (i) of Article 6(3).

In the case of a decision granting a Union application, any modification consisting of the addition of intellectual property rights shall be limited to intellectual property rights covered by Article 4.

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Article 14

Notification obligations of the competent customs department

1 The competent customs department to which a national application has been submitted shall forward the following decisions to the customs offices of its Member State, immediately after their adoption:

- a decisions granting the application;
- b decisions revoking decisions granting the application;
- c decisions amending decisions granting the application;
- d decisions extending the period during which the customs authorities are to take action.

2 The competent customs department to which a Union application has been submitted shall forward the following decisions to the competent customs department of the Member State or Member States indicated in the Union application, immediately after their adoption:

- a decisions granting the application;
- b decisions revoking decisions granting the application;
- c decisions amending decisions granting the application;
- d decisions extending the period during which the customs authorities are to take action.

The competent customs department of the Member State or Member States indicated in the Union application shall immediately after receiving those decisions forward them to their customs offices.

3 The competent customs department of the Member State or Member States indicated in the Union application may request the competent customs department that adopted the decision granting the application to provide them with additional information deemed necessary for the implementation of that decision.

4 The competent customs department shall forward its decision suspending the actions of the customs authorities under point (b) of Article 16(1) and Article 16(2) to the customs offices of its Member State, immediately after its adoption.

Article 15

Notification obligations of the holder of the decision

The holder of the decision shall immediately notify the competent customs department that granted the application of any of the following:

- (a) an intellectual property right covered by the application ceases to have effect;
- (b) the holder of the decision ceases for other reasons to be entitled to submit the application;
- (c) modifications to the information referred to in Article 6(3).

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Article 16

Failure of the holder of the decision to fulfil his obligations

1 Where the holder of the decision uses the information provided by the customs authorities for purposes other than those provided for in Article 21, the competent customs department of the Member State where the information was provided or misused may:

- a revoke any decision adopted by it granting a national application to that holder of the decision, and refuse to extend the period during which the customs authorities are to take action;
- b suspend in their territory, during the period during which the customs authorities are to take action, any decision granting a Union application to that holder of the decision.

2 The competent customs department may decide to suspend the actions of the customs authorities until the expiry of the period during which those authorities are to take action, where the holder of the decision:

- a does not fulfil the notification obligations set out in Article 15;
- b does not fulfil the obligation on returning samples set out in Article 19(3);
- c does not fulfil the obligations on costs and translation set out in Article 29(1) and (3);
- d without valid reason does not initiate proceedings as provided for in Article 23(3) or Article 26(9).

In the case of a Union application, the decision to suspend the actions of the customs authorities shall have effect only in the Member State where such decision is taken.

CHAPTER III

ACTION BY THE CUSTOMS AUTHORITIES

SECTION 1

Suspension of the release or detention of goods suspected of infringing an intellectual property right

Article 17

Suspension of the release or detention of the goods following the grant of an application

1 Where the customs authorities identify goods suspected of infringing an intellectual property right covered by a decision granting an application, they shall suspend the release of the goods or detain them.

2 Before suspending the release of or detaining the goods, the customs authorities may ask the holder of the decision to provide them with any relevant information with respect to the goods. The customs authorities may also provide the holder of the decision with information about the actual or estimated quantity of goods, their actual or presumed nature and images thereof, as appropriate.

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3 The customs authorities shall notify the declarant or the holder of the goods of the suspension of the release of the goods or the detention of the goods within one working day of that suspension or detention.

Where the customs authorities opt to notify the holder of the goods and two or more persons are considered to be the holder of the goods, the customs authorities shall not be obliged to notify more than one of those persons.

The customs authorities shall notify the holder of the decision of the suspension of the release of the goods or the detention on the same day as, or promptly after, the declarant or the holder of the goods is notified.

The notifications shall include information on the procedure set out in Article 23.

4 The customs authorities shall inform the holder of the decision and the declarant or the holder of the goods of the actual or estimated quantity and the actual or presumed nature of the goods, including available images thereof, as appropriate, whose release has been suspended or which have been detained. The customs authorities shall also, upon request and where available to them, inform the holder of the decision of the names and addresses of the consignee, the consignor and the declarant or the holder of the goods, of the customs procedure and of the origin, provenance and destination of the goods whose release has been suspended or which have been detained.

Article 18

Suspension of the release or detention of the goods before the grant of an application

1 Where the customs authorities identify goods suspected of infringing an intellectual property right, which are not covered by a decision granting an application, they may, except for in the case of perishable goods, suspend the release of those goods or detain them.

2 Before suspending the release of or detaining the goods suspected of infringing an intellectual property right, the customs authorities may, without disclosing any information other than the actual or estimated quantity of goods, their actual or presumed nature and images thereof, as appropriate, request any person or entity potentially entitled to submit an application concerning the alleged infringement of the intellectual property rights to provide them with any relevant information.

3 The customs authorities shall notify the declarant or the holder of the goods of the suspension of the release of the goods or their detention within one working day of that suspension or detention.

Where the customs authorities opt to notify the holder of the goods and two or more persons are considered to be the holder of the goods, the customs authorities shall not be obliged to notify more than one of those persons.

The customs authorities shall notify persons or entities entitled to submit an application concerning the alleged infringement of the intellectual property rights, of the suspension of the release of the goods or their detention on the same day as, or promptly after, the declarant or the holder of the goods is notified.

The customs authorities may consult the competent public authorities in order to identify the persons or entities entitled to submit an application.

The notifications shall include information on the procedure set out in Article 23.

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4 The customs authorities shall grant the release of the goods or put an end to their detention immediately after completion of all customs formalities in the following cases:

- a where they have not identified any person or entity entitled to submit an application concerning the alleged infringement of intellectual property rights within one working day from the suspension of the release or the detention of the goods;
- b where they have not received an application in accordance with Article 5(3), or where they have rejected such an application.

5 Where an application has been granted, the customs authorities shall, upon request and where available to them, inform the holder of the decision of the names and addresses of the consignee, the consignor and the declarant or the holder of the goods, of the customs procedure and of the origin, provenance and destination of the goods whose release has been suspended or which have been detained.

Article 19

Inspection and sampling of goods whose release has been suspended or which have been detained

1 The customs authorities shall give the holder of the decision and the declarant or the holder of the goods the opportunity to inspect the goods whose release has been suspended or which have been detained.

2 The customs authorities may take samples that are representative of the goods. They may provide or send such samples to the holder of the decision, at the holder's request and strictly for the purposes of analysis and to facilitate the subsequent procedure in relation to counterfeit and pirated goods. Any analysis of those samples shall be carried out under the sole responsibility of the holder of the decision.

3 The holder of the decision shall, unless circumstances do not allow, return the samples referred to in paragraph 2 to the customs authorities on completion of the analysis, at the latest before the goods are released or their detention is ended.

Article 20

Conditions for storage

The conditions of storage of goods during a period of suspension of release or detention shall be determined by the customs authorities.

Article 21

Permitted use of certain information by the holder of the decision

Where the holder of the decision has received the information referred to in Article 17(4), Article 18(5), Article 19 or Article 26(8), he may disclose or use that information only for the following purposes:

- (a) to initiate proceedings to determine whether an intellectual property right has been infringed and in the course of such proceedings;

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- (b) in connection with criminal investigations related to the infringement of an intellectual property right and undertaken by public authorities in the Member State where the goods are found;
- (c) to initiate criminal proceedings and in the course of such proceedings;
- (d) to seek compensation from the infringer or other persons;
- (e) to agree with the declarant or the holder of the goods that the goods be destroyed in accordance with Article 23(1);
- (f) to agree with the declarant or the holder of the goods of the amount of the guarantee referred to in point (a) of Article 24(2).

Article 22

Sharing of information and data between customs authorities

1 Without prejudice to applicable provisions on data protection in the Union and for the purpose of contributing to eliminating international trade in goods infringing intellectual property rights, the Commission and the customs authorities of the Member States may share certain data and information available to them with the relevant authorities in third countries according to the practical arrangements referred to in paragraph 3.

2 The data and information referred to in paragraph 1 shall be exchanged to swiftly enable effective enforcement against shipments of goods infringing an intellectual property right. Such data and information may relate to seizures, trends and general risk information, including on goods which are in transit through the territory of the Union and which have originated in or are destined for the territory of third countries concerned. Such data and information may include, where appropriate, the following:

- a nature and quantity of goods;
- b suspected intellectual property right infringed;
- c origin, provenance and destination of the goods;
- d information on movements of means of transport, in particular:
 - (i) name of vessel or registration of means of transport;
 - (ii) reference numbers of freight bill or other transport document;
 - (iii) number of containers;
 - (iv) weight of load;
 - (v) description and/or coding of goods;
 - (vi) reservation number;
 - (vii) seal number;
 - (viii) place of first loading;
 - (ix) place of final unloading;
 - (x) places of transshipment;
 - (xi) expected date of arrival at place of final unloading;
- e information on movements of containers, in particular:

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- (i) container number;
- (ii) container loading status;
- (iii) date of movement;
- (iv) type of movement (loaded, unloaded, transhipped, entered, left, etc.);
- (v) name of vessel or registration of means of transport;
- (vi) number of voyage/journey;
- (vii) place;
- (viii) freight bill or other transport document.

3 The Commission shall adopt implementing acts defining the elements of the necessary practical arrangements concerning the exchange of data and information referred to in paragraphs 1 and 2 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 34(3).

SECTION 2

Destruction of goods, initiation of proceedings and early release of goods

Article 23

Destruction of goods and initiation of proceedings

1 Goods suspected of infringing an intellectual property right may be destroyed under customs control, without there being any need to determine whether an intellectual property right has been infringed under the law of the Member State where the goods are found, where all of the following conditions are fulfilled:

- a the holder of the decision has confirmed in writing to the customs authorities, within 10 working days, or three working days in the case of perishable goods, of notification of the suspension of the release or the detention of the goods, that, in his conviction, an intellectual property right has been infringed;
- b the holder of the decision has confirmed in writing to the customs authorities, within 10 working days, or three working days in the case of perishable goods, of notification of the suspension of the release or the detention of the goods, his agreement to the destruction of the goods;
- c the declarant or the holder of the goods has confirmed in writing to the customs authorities, within 10 working days, or three working days in the case of perishable goods, of notification of the suspension of the release or the detention of the goods, his agreement to the destruction of the goods. Where the declarant or the holder of the goods has not confirmed his agreement to the destruction of the goods nor notified his opposition thereto to the customs authorities, within those deadlines, the customs authorities may deem the declarant or the holder of the goods to have confirmed his agreement to the destruction of those goods.

The customs authorities shall grant the release of the goods or put an end to their detention, immediately after completion of all customs formalities, where within the periods referred to in points (a) and (b) of the first subparagraph, they have not received

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both the written confirmation from the holder of the decision that, in his conviction, an intellectual property right has been infringed and his agreement to destruction, unless those authorities have been duly informed about the initiation of proceedings to determine whether an intellectual property right has been infringed.

2 The destruction of the goods shall be carried out under customs control and under the responsibility of the holder of the decision, unless otherwise specified in the national law of the Member State where the goods are destroyed. Samples may be taken by competent authorities prior to the destruction of the goods. Samples taken prior to destruction may be used for educational purposes.

3 Where the declarant or the holder of the goods has not confirmed his agreement to the destruction in writing and where the declarant or the holder of the goods has not been deemed to have confirmed his agreement to the destruction, in accordance with point (c) of the first subparagraph of paragraph 1 within the periods referred to therein, the customs authorities shall immediately notify the holder of the decision thereof. The holder of the decision shall, within 10 working days, or three working days in the case of perishable goods, of notification of the suspension of the release or the detention of the goods, initiate proceedings to determine whether an intellectual property right has been infringed.

4 Except in the case of perishable goods the customs authorities may extend the period referred to in paragraph 3 by a maximum of 10 working days upon a duly justified request by the holder of the decision in appropriate cases.

5 The customs authorities shall grant the release of the goods or put an end to their detention, immediately after completion of all customs formalities, where, within the periods referred to in paragraphs 3 and 4, they have not been duly informed, in accordance with paragraph 3, on the initiation of proceedings to determine whether an intellectual property right has been infringed.

Article 24

Early release of goods

1 Where the customs authorities have been notified of the initiation of proceedings to determine whether a design, patent, utility model, topography of semiconductor product or plant variety has been infringed, the declarant or the holder of the goods may request the customs authorities to release the goods or put an end to their detention before the completion of those proceedings.

2 The customs authorities shall release the goods or put an end to their detention only where all the following conditions are fulfilled:

- a the declarant or the holder of the goods has provided a guarantee that is of an amount sufficient to protect the interests of the holder of the decision;
- b the authority competent to determine whether an intellectual property right has been infringed has not authorised precautionary measures;
- c all customs formalities have been completed.

3 The provision of the guarantee referred to in point (a) of paragraph 2 shall not affect the other legal remedies available to the holder of the decision.

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Article 25

Goods for destruction

- 1 Goods to be destroyed under Article 23 or 26 shall not be:
 - a released for free circulation, unless customs authorities, with the agreement of the holder of the decision, decide that it is necessary in the event that the goods are to be recycled or disposed of outside commercial channels, including for awareness-raising, training and educational purposes. The conditions under which the goods can be released for free circulation shall be determined by the customs authorities;
 - b brought out of the customs territory of the Union;
 - c exported;
 - d re-exported;
 - e placed under a suspensive procedure;
 - f placed in a free zone or free warehouse.
- 2 The customs authorities may allow the goods referred to in paragraph 1 to be moved under customs supervision between different places within the customs territory of the Union with a view to their destruction under customs control.

Article 26

Procedure for the destruction of goods in small consignments

- 1 This Article shall apply to goods where all of the following conditions are fulfilled:
 - a the goods are suspected of being counterfeit or pirated goods;
 - b the goods are not perishable goods;
 - c the goods are covered by a decision granting an application;
 - d the holder of the decision has requested the use of the procedure set out in this Article in the application;
 - e the goods are transported in small consignments.
- 2 When the procedure set out in this Article is applied, Article 17(3) and (4) and Article 19(2) and (3) shall not apply.
- 3 The customs authorities shall notify the declarant or the holder of the goods of the suspension of the release of the goods or their detention within one working day of the suspension of the release or of the detention of the goods. The notification of the suspension of the release or the detention of the goods shall include the following information:
 - a that the customs authorities intend to destroy the goods;
 - b the rights of the declarant or the holder of the goods under paragraphs 4, 5 and 6.
- 4 The declarant or the holder of the goods shall be given the opportunity to express his point of view within 10 working days of notification of the suspension of the release or the detention of the goods.
- 5 The goods concerned may be destroyed where, within 10 working days of notification of the suspension of the release or the detention of the goods, the declarant or the holder of the goods has confirmed to the customs authorities his agreement to the destruction of the goods.

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6 Where the declarant or the holder of the goods has not confirmed his agreement to the destruction of the goods nor notified his opposition thereto to the customs authorities, within the period referred to in paragraph 5, the customs authorities may deem the declarant or the holder of the goods to have confirmed his agreement to the destruction of the goods.

7 The destruction shall be carried out under customs control. The customs authorities shall, upon request and as appropriate, provide the holder of the decision with information about the actual or estimated quantity of destroyed goods and their nature.

8 Where the declarant or the holder of the goods has not confirmed his agreement to the destruction of the goods and where the declarant or the holder of the goods has not been deemed to have confirmed such agreement, in accordance with paragraph 6, the customs authorities shall immediately notify the holder of the decision thereof and of the quantity of goods and their nature, including images thereof, where appropriate. The customs authorities shall also, upon request and where available to them, inform the holder of the decision of the names and addresses of the consignee, the consignor and the declarant or the holder of the goods, of the customs procedure and of the origin, provenance and destination of the goods whose release has been suspended or which have been detained.

9 The customs authorities shall grant the release of the goods or put an end to their detention immediately after completion of all customs formalities where they have not received information from the holder of the decision on the initiation of proceedings to determine whether an intellectual property right has been infringed within 10 working days of the notification referred to in paragraph 8.

10 The Commission shall be empowered to adopt delegated acts in accordance with Article 35 concerning the amendment of quantities in the definition of small consignments in the event that the definition is found to be impractical in the light of the need to ensure the effective operation of the procedure set out in this Article, or where necessary in order to avoid any circumvention of this procedure as regards the composition of consignments.

CHAPTER IV

LIABILITY, COSTS AND PENALTIES

Article 27

Liability of the customs authorities

Without prejudice to national law, the decision granting an application shall not entitle the holder of that decision to compensation in the event that goods suspected of infringing an intellectual property right are not detected by a customs office and are released, or no action is taken to detain them.

Article 28

Liability of the holder of the decision

Where a procedure duly initiated pursuant to this Regulation is discontinued owing to an act or omission on the part of the holder of the decision, where samples taken pursuant to Article 19(2) are either not returned or are damaged and beyond use owing to an act or omission on the part of the holder of the decision, or where the goods in question

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are subsequently found not to infringe an intellectual property right, the holder of the decision shall be liable towards any holder of the goods or declarant, who has suffered damage in that regard, in accordance with specific applicable legislation.

Article 29

Costs

1 Where requested by the customs authorities, the holder of the decision shall reimburse the costs incurred by the customs authorities, or other parties acting on behalf of customs authorities, from the moment of detention or suspension of the release of the goods, including storage and handling of the goods, in accordance with Article 17(1), Article 18(1) and Article 19(2) and (3), and when using corrective measures such as destruction of goods in accordance with Articles 23 and 26.

The holder of a decision to whom the suspension of release or detention of goods has been notified shall, upon request, be given information by the customs authorities on where and how those goods are being stored and on the estimated costs of storage referred to in this paragraph. The information on estimated costs may be expressed in terms of time, products, volume, weight or service depending on the circumstances of storage and the nature of the goods.

2 This Article shall be without prejudice to the right of the holder of the decision to seek compensation from the infringer or other persons in accordance with the legislation applicable.

3 The holder of a decision granting a Union application shall provide and pay for any translation required by the competent customs department or customs authorities which are to take action concerning the goods suspected of infringing an intellectual property right.

Article 30

Penalties

The Member States shall ensure that the holders of decisions comply with the obligations set out in this Regulation, including, where appropriate, by laying down provisions establishing penalties. The penalties provided for shall be effective, proportionate and dissuasive.

The Member States shall notify those provisions and any subsequent amendment affecting them to the Commission without delay.

CHAPTER V

EXCHANGE OF INFORMATION

Article 31

Exchange of data on decisions relating to applications and detentions between the Member States and the Commission

1 The competent customs departments shall notify without delay the Commission of the following:

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- a decisions granting applications, including the application and its attachments;
- b decisions extending the period during which the customs authorities are to take action or decisions revoking the decision granting the application or amending it;
- c the suspension of a decision granting the application.

2 Without prejudice to point (g) of Article 24 of Regulation (EC) No 515/97, where the release of the goods is suspended or the goods are detained, the customs authorities shall transmit to the Commission any relevant information, except personal data, including information on the quantity and type of the goods, value, intellectual property rights, customs procedures, countries of provenance, origin and destination, and transport routes and means.

3 The transmission of the information referred to in paragraphs 1 and 2 of this Article and all exchanges of data on decisions concerning applications as referred to in Article 14 between customs authorities of the Member States shall be made via a central database of the Commission. The information and data shall be stored in that database.

4 For the purposes of ensuring processing of the information referred to in paragraphs 1 to 3 of this Article, the central database referred to in paragraph 3 shall be established in an electronic form. The central database shall contain the information, including personal data, referred to in Article 6(3), Article 14 and this Article.

5 The customs authorities of the Member States and the Commission shall have access to the information contained in the central database as appropriate for the fulfilment of their legal responsibilities in applying this Regulation. The access to information marked for restricted handling in accordance with Article 6(3) is restricted to the customs authorities of the Member States where action is requested. Upon justified request by the Commission, the customs authorities of the Member States may give access to the Commission to such information where it is strictly necessary for the application of this Regulation.

6 The customs authorities shall introduce into the central database information related to the applications submitted to the competent customs department. The customs authorities which have introduced information into the central database shall, where necessary, amend, supplement, correct or delete such information. Each customs authority that has introduced information in the central database shall be responsible for the accuracy, adequacy and relevancy of this information.

7 The Commission shall establish and maintain adequate technical and organisational arrangements for the reliable and secure operation of the central database. The customs authorities of each Member State shall establish and maintain adequate technical and organisational arrangements to ensure the confidentiality and security of processing with respect to the processing operations carried out by their customs authorities and with respect to terminals of the central database located on the territory of that Member State.

Article 32

Establishment of a central database

The Commission shall establish the central database referred to in Article 31. That database shall be operational as soon as possible and not later than 1 January 2015.

Status: Point in time view as at 31/01/2020.

Changes to legislation: There are outstanding changes not yet made to Regulation (EU) No 608/2013 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

Article 33

Data protection provisions

1 The processing of personal data in the central database of the Commission shall be carried out in accordance with Regulation (EC) No 45/2001 and under the supervision of the European Data Protection Supervisor.

2 Processing of personal data by the competent authorities in the Member States shall be carried out in accordance with Directive 95/46/EC and under the supervision of the public independent authority of the Member State referred to in Article 28 of that Directive.

3 Personal data shall be collected and used solely for the purposes of this Regulation. Personal data so collected shall be accurate and shall be kept up to date.

4 Each customs authority that has introduced personal data into the central database shall be the controller with respect to the processing of this data.

5 A data subject shall have a right of access to the personal data relating to him or her that are processed through the central database and, where appropriate, the right to the rectification, erasure or blocking of personal data in accordance with Regulation (EC) No 45/2001 or the national laws implementing Directive 95/46/EC.

6 All requests for the exercise of the right of access, rectification, erasure or blocking shall be submitted to and processed by the customs authorities. Where a data subject has submitted a request for the exercise of that right to the Commission, the Commission shall forward such request to the customs authorities concerned.

7 Personal data shall not be kept longer than six months from the date the relevant decision granting the application has been revoked or the relevant period during which the customs authorities are to take action has expired.

8 Where the holder of the decision has initiated proceedings in accordance with Article 23(3) or Article 26(9) and has notified the customs authorities of the initiation of such proceedings, personal data shall be kept for six months after proceedings have determined in a final way whether an intellectual property right has been infringed.

CHAPTER VI

COMMITTEE, DELEGATION AND FINAL PROVISIONS

Article 34

Committee procedure

1 The Commission shall be assisted by the Customs Code Committee established by Articles 247a and 248a of Regulation (EEC) No 2913/92. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2 Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

Status: Point in time view as at 31/01/2020.

Changes to legislation: There are outstanding changes not yet made to Regulation (EU) No 608/2013 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

3 Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Article 35

Exercise of the delegation

1 The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2 The power to adopt delegated acts referred to in Article 26(10) shall be conferred on the Commission for an indeterminate period of time from 19 July 2013.

3 The delegation of power referred to in Article 26(10) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4 As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5 A delegated act adopted pursuant to Article 26(10) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months on the initiative of the European Parliament or of the Council.

Article 36

Mutual administrative assistance

The provisions of Regulation (EC) No 515/97 shall apply *mutatis mutandis* to this Regulation.

Article 37

Reporting

By 31 December 2016, the Commission shall submit to the European Parliament and to the Council a report on the implementation of this Regulation. If necessary, that report shall be accompanied by appropriate recommendations.

That report shall refer to any relevant incidents concerning medicines in transit across the customs territory of the Union that might occur under this Regulation, including an assessment of its potential impact on the Union commitments on access to medicines under the 'Declaration on the TRIPS Agreement and Public Health' adopted by the Doha WTO Ministerial Conference on 14 November 2001, and the measures taken to address any situation creating adverse effects in that regard.

Status: Point in time view as at 31/01/2020.

Changes to legislation: There are outstanding changes not yet made to Regulation (EU) No 608/2013 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

Article 38

Repeal

Regulation (EC) No 1383/2003 is repealed with effect from 1 January 2014.

References to the repealed Regulation shall be construed as references to this Regulation and shall be read in accordance with the correlation table set out in the Annex.

Article 39

Transitional provisions

Applications granted in accordance with Regulation (EC) No 1383/2003 shall remain valid for the period specified in the decision granting the application during which the customs authorities are to take action and shall not be extended.

Article 40

Entry into force and application

1 This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

2 It shall apply from 1 January 2014, with the exception of:

- a Article 6, Article 12(7) and Article 22(3), which shall apply from 19 July 2013;
- b Article 31(1) and (3) to (7) and Article 33, which shall apply from the date on which the central database referred to in Article 32 is in place. The Commission shall make that date public.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg, 12 June 2013.

For the European Parliament

The President

M. SCHULZ

For the Council

The President

L. CREIGHTON

Status: Point in time view as at 31/01/2020.

Changes to legislation: There are outstanding changes not yet made to Regulation (EU) No 608/2013 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

ANNEX

CORRELATION TABLE

Regulation (EC) No 1383/2003	This Regulation
Article 1	Article 1
Article 2	Article 2
Article 3	Article 1
Article 4	Article 18
Article 5	Articles 3 to 9
Article 6	Articles 6 and 29
Article 7	Article 12
Article 8	Articles 10, 11, 12, 14 and 15
Article 9	Articles 17 and 19
Article 10	—
Article 11	Article 23
Article 12	Articles 16 and 21
Article 13	Article 23
Article 14	Article 24
Article 15	Article 20
Article 16	Article 25
Article 17	—
Article 18	Article 30
Article 19	Articles 27 and 28
Article 20	Articles 6, 12, 22 and 26
Article 21	Article 34
Article 22	Articles 31 and 36
Article 23	—
Article 24	Article 38
Article 25	Article 40

Status: Point in time view as at 31/01/2020.

Changes to legislation: There are outstanding changes not yet made to Regulation (EU) No 608/2013 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

- (1) Position of the European Parliament of 3 July 2012 (not yet published in the Official Journal) and position of the Council at first reading of 16 May 2013 (not yet published in the Official Journal). Position of the European Parliament of 11 June 2013 (not yet published in the Official Journal).
- (2) OJ L 196, 2.8.2003, p. 7.
- (3) OJ L 351, 20.12.2012, p. 1.
- (4) OJ C 45 E, 23.2.2010, p. 47.
- (5) OJ L 82, 22.3.1997, p. 1.
- (6) OJ L 281, 23.11.1995, p. 31.
- (7) OJ L 8, 12.1.2001, p. 1.
- (8) OJ L 55, 28.2.2011, p. 13.
- (9) OJ C 363, 13.12.2011, p. 3.
- (10) OJ L 302, 19.10.1992, p. 1.
- (11) OJ L 152, 16.6.2009, p. 1.
- (12) OJ L 198, 8.8.1996, p. 30.
- (13) OJ L 227, 1.9.1994, p. 1.
- (14) OJ L 78, 24.3.2009, p. 1.
- (15) OJ L 3, 5.1.2002, p. 1.
- (16) OJ L 343, 14.12.2012, p. 1.
- (17) OJ L 299, 16.11.2007, p. 1.
- (18) OJ L 149, 14.6.1991, p. 1.
- (19) OJ L 39, 13.2.2008, p. 16.
- (20) OJ L 256, 7.9.1987, p. 1.
- (21) OJ L 157, 30.4.2004, p. 45.
- (22) OJ L 23, 26.1.2008, p. 21.

Status:

Point in time view as at 31/01/2020.

Changes to legislation:

There are outstanding changes not yet made to Regulation (EU) No 608/2013 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.