



**COUNCIL OF
THE EUROPEAN UNION**

Brussels, 10 January 2013

5129/13

**Interinstitutional File:
2011/0137 (COD)**

**UD 1
PI 5
COMER 1
CODEC 44**

NOTE

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| from: | General Secretariat |
| to: | Delegations |
| No. Cion prop.: | 10880/11 UD 134 PI 64 COMER 110 + ADD 1 + ADD 2 + ADD 3 |
| No. previous doc. | 17974/12 UD 330 PI 179 COMER 274 + COR 1 |
| Subject: | Proposal for a regulation of the European Parliament and of the Council concerning customs enforcement of intellectual property rights |

Delegations will find attached the text of the above proposal as agreed by the Permanent Representatives Committee at its meeting on 21 December 2012.

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,

Having regard to the opinion of the European Data Protection Supervisor,

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

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) The Council of the European Union 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, be reviewed.
- (2) The marketing of goods infringing intellectual property rights does considerable damage to right-holders, users or groups of producers, or to law-abiding manufacturers and traders. It could also be deceiving consumers, and could in some cases endanger 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 certain improvements to the legal framework were necessary to strengthen the enforcement of intellectual property rights by customs authorities, as well as to ensure appropriate legal clarity, thereby taking economic, commercial and legal developments into account.
- (4) The customs authorities should be competent to enforce intellectual property rights with regard to goods, which, according to the 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 groups of producers. Where goods are detained by customs authorities at the border, only one legal proceeding is required, whereas several separate proceedings are 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. It is also appropriate not to apply the Regulation to goods carried by passengers in their personal luggage as long as these 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 excludes certain infringements from the scope of the Regulation. In order to strengthen the enforcement of intellectual property rights, customs intervention should therefore be extended to other types of infringements not covered by Regulation (EC) No 1383/2003. For this purpose it is appropriate to include in the scope of this Regulation, in addition to the rights already covered by Regulation (EC) No 1383/2003, 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, adapted or performed for the purpose of enabling or facilitating the circumvention of technological measures. Infringements resulting from so-called illegal parallel trade and “overruns” are excluded from the scope of Regulation (EC) No 1383/2003. The reason for this exclusion is that goods subject to illegal parallel trade, namely that the goods 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 that the goods 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 considered appropriate that customs authorities should focus their efforts on such goods. Illegal parallel trade and “overruns” should therefore also be excluded from the scope of this Regulation.
- (5a) Member States, in cooperation with the Commission, should provide appropriate training for customs officials, in order to ensure the correct implementation of this Regulation.
- (5b) This Regulation, when fully implemented, will further contribute to a single market which ensures more effective protection to right-holders, 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.

- (5d) Member States face increasingly limited resources in the field of customs. In this respect, the promotion of risk management technologies and strategies to maximise resources available to national authorities should be supported.
- (6) This Regulation contains solely 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.
- (6a) Under the "Declaration on the TRIPS Agreement and Public Health" adopted by the Doha WTO Ministerial Conference on 14 November 2001, the 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 under Article 208 of the Treaty on the Functioning of the European Union, 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 these goods onto the market of the Union.
- (7) This Regulation should not affect the provisions on the competence of courts, in particular, those of Council Regulation (EC) No 44/2001 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters.
- (8) Any person, whether or not the right-holder, user or group of producers, who is able to initiate legal proceedings in his own name with respect to a possible infringement of that right, should be entitled to submit an application.

- (9) In order to ensure that intellectual property rights are enforced throughout the Union, it is appropriate to provide that, where a person entitled to submit an application seeks enforcement of an intellectual property right covering the whole territory of the Union, that person may request the customs authorities of a Member State to take a decision requiring action by the customs authorities of that Member State and of any other Member State where enforcement of the intellectual property right is sought.
- (10) 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 entitled to submit an application to initiate proceedings for determining whether an intellectual property right has been infringed.
- (12) Regulation (EC) No 1383/2003 has 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, this procedure has proved very successful in the Member States where it has been available. Therefore, such procedure should be made compulsory with regard to all infringements of intellectual property rights and should be applied, where the declarant or holder of the goods does not object to destruction. Furthermore, this procedure should provide that customs authorities may deem that the declarant or holder of the goods has confirmed his agreement to the destruction of the goods where he has not specifically opposed destruction within the prescribed period (tacit consent).

- (13) 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 explicit agreement of the right-holder, user or group of producers. However, a general request by the applicant in the application should be required in order for that procedure to be applied. Also, customs authorities should have the possibility to require that the applicant covers the costs incurred by the application of this procedure.
- (13a) 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 non-legislative acts of general application 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 is of particular importance that the Commission carries 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 Council.
- (15) For further legal clarity, it is appropriate to modify the timelines for detaining goods suspected of infringing an intellectual property right and the conditions in which information about detained goods is to be passed on to right-holders, users or groups of producers by customs authorities .

- (16) 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 a 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 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 holder of the goods. It should therefore be ensured that the holder of the decision is notified on the same day or after the declarant or holder of the goods has been notified of the suspension of the release of the goods or their detention.
- (17b) 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.
- (17d) With a view to eliminating international trade in goods infringing intellectual property rights, Article 69 of 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 customs authorities of third countries, including on goods which are in transit through the territory of the Union and originate in or are destined for the territory of the authorities concerned.
- (18) 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, should apply.

- (19) 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 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.
- (20) 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 according to the legislation of the Member State concerned. These might include intermediaries, where applicable. Costs and damages incurred by persons other than customs authorities as a result of a customs action, where 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 in each particular case.
- (20a) This Regulation introduces the possibility for customs authorities to allow goods abandoned for destruction 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 for awareness-raising, training and educational purposes.
- (21) Customs enforcement of intellectual property rights will entail 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 data¹ 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 data².

¹ OJ L 281, 23.11.1995, p. 31.

² OJ L 8, 12.1.2001, p. 1.

- (21a) The following elements of the database should be defined: the entity which will control and manage the database and the entity in charge of ensuring the security of the processing of the data contained in the database. 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.
- (22) 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 182/2011³ of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers. 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 EU.
- (24) Regulation (EC) No 1383/2003 should accordingly be repealed,

HAVE ADOPTED THIS REGULATION:

³ OJ L 55, 28.2.2011, p. 13.

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, according to Council Regulation (EEC) No 2913/92⁴ establishing the Community Customs Code, subject to customs supervision or customs control within the customs territory of the Union, particularly goods in the following situations:
 - (a) when declared for release for free circulation, export or re-export in accordance with Articles 79 to 83, 161 to 162 and 182 of Regulation (EEC) No 2913/92;
 - (b) when entering or leaving the customs territory of the Union in accordance with Articles 37, 38 and 183 of Regulation (EEC) No 2913/92;
 - (c) when placed under a suspensive procedure or in a free zone or free warehouse in accordance with Articles 84, paragraph 1 a), and 166 of Regulation (EEC) No 2913/92.
- 1a. In respect of goods placed in one of the situations referred to in article 1(1), and without prejudice to articles 16 and 17, the customs authorities shall carry out adequate customs controls and shall take proportionate identification measures as provided for in articles 13(1) and 72 of Council Regulation (ECC) No 2913/92 establishing the Community Customs Code according to risk analysis criteria with a view to preventing operations 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.

⁴ OJ L 302, 19.10.1992, p. 1.

2. This Regulation shall not apply to goods that have been released for free circulation under the end-use regime within the meaning of Article 82 of Council Regulation (EEC) No 2913/92.
3. This Regulation shall not affect in any way the laws of the Member States or of the Union on intellectual property or the laws of the Member States in relation to criminal procedures.
4. This Regulation shall not apply to goods of a non-commercial nature contained in travellers' personal luggage.
- 4a. This Regulation shall not apply to goods that have been manufactured with the consent of the right-holder.

Nor shall this Regulation apply 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.

Article 2

Definitions

For the purposes of this Regulation:

- (1) 'intellectual property rights' 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;
 - (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;
 - (h) a Community plant variety right as provided for in Council Regulation (EC) No 2100/94;
 - (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;
 - (l) 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;
 - (b) a trade mark registered in a Member State, or, in the case of Belgium, the Netherlands or Luxembourg, at the Benelux Office for Intellectual Property;
 - (c) a trade mark registered under international arrangements which have effect in a Member State or in the Union;
- (3) 'design' means:
- (a) a Community design as provided for in Regulation (EC) No 6/2002;
 - (b) a design registered in a Member State, or, in the case of Belgium, the Netherlands or Luxembourg, at the Benelux Office for Intellectual Property
 - (c) a design registered under international arrangements which have 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 Council⁵;
 - (b) a designation of origin or geographical indication for wine as provided for in Council Regulation (EC) No 1234/2007;
 - (c) a geographical designation for aromatised drinks based on wine products as provided for in Council Regulation (EEC) No 1601/1991⁶;
 - (d) a geographical indication of spirit drinks as provided for in Regulation (EC) No 110/2008 of the European Parliament and of the Council;
 - (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;
- (5) ‘counterfeit goods’ means:
- (a) goods which are subject of an action infringing a trade mark in the Member State where the goods are found and bear without authorisation a sign 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 subject of an action infringing a geographical indication in the Member State where the goods are found and bear or are described by a name or term protected in respect of that geographical indication;

⁵ OJ L 343, 14.12.2012, p.1

⁶ OJ L 149, 14.6.1991, p. 1.

- (ba) any packaging, label, sticker, brochure, operating instructions, warranty document or other similar item, even if presented separately, which is the subject of an action infringing a trade mark or a geographical indication and which includes a sign, name or term 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, 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 subject of an action 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, regardless of whether it is registered, 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 these goods are found, they are *prima facie*:
- (a) goods which are subject of an action infringing an intellectual property right in that Member State;
- (b) devices, products or components which are primarily designed, produced, adapted or performed 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 right related to copyright and which relates to an action 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 action infringing the intellectual property rights of the right-holder, user or group of producers in that Member State;

- (7a) ‘right-holder’ means the holder of any of the intellectual property rights referred to in paragraph 1.
- (8) ‘application’ means a request made to the competent customs department for customs authorities to take action where goods are suspected of infringing an intellectual property right;
- (9) ‘national application’ means an application requesting the customs authorities of a Member State to take action in that Member State;
- (10) ‘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;
- (11) ‘applicant’ means the person in whose name an application is submitted;
- (11a) ‘holder of the decision’ means the holder of a decision according to which the competent customs department has, based on his application, agreed to take action with respect to goods suspected of infringing an intellectual property right.
- (12) ‘holder of the goods’ means the person who is the owner of the goods or who has a similar right of disposal over them or who has physical control over them;
- (13) ‘declarant’ means the declarant as referred to in Article 4(18) of Regulation (EEC) No 2913/92;
- (14) ‘destruction’ means the physical destruction, recycling or disposal of goods outside commercial channels, in such a way as to preclude injury to the holder of the decision;

(16) ‘customs territory of the Union’ means the customs territory of the Community as referred to in Article 3 of Regulation (EEC) No 2913/92;

(17) ‘release of the goods’ means the act by customs authorities as referred to in Article 4(20) of Regulation (EEC) No 2913/92;

(17a) ‘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), a “unit” shall be a good as classified under the Combined Nomenclature in accordance with Annex 1 of Council Regulation (EEC) No 2658/87 on the tariff and statistical nomenclature and on the Common Customs Tariff⁷ if unpackaged, or the package of such goods intended for retail sale to the ultimate consumer.

Within the meaning of this definition separate goods falling in the same Combined Nomenclature code are considered as different units and goods presented as sets classified in one Combined Nomenclature code are considered as one unit.

(17b) ‘perishable goods’ means any goods considered by customs authorities to deteriorate by being kept for up to 20 days from the date of suspension of release or detention.

(17c) ‘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.

⁷ OJ L 256, 7.9.1978, p.1

Article 3
(deleted)

CHAPTER II

APPLICATIONS

Section 1

SUBMISSION OF APPLICATIONS

Article 4

Persons entitled to submit an application

1. The persons entitled to submit a national or a Union application shall be any of the following:
 - (a) right-holders ;
 - (b) intellectual property collective rights management bodies as referred to in Article 4(1)(c) of Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights⁸;
 - (c) professional defence bodies as referred to in Article 4(1)(d) of Directive 2004/48/EC⁹;

⁸ OJ L 157/2004, p. 45

⁹ The references in letter b and c are to the same directive. The lawyer-linguists will ensure that the correct type(s) of reference(s) is/are inserted.

- (d) groups in the meaning of Article 5(1) of Regulation (EC) No 510/2006, groups of producers in the meaning of Article 118(e) of Regulation (EC) No 1234/2007 or similar groups of producers foreseen in the legislation of the Union governing geographical indications representing producers of products with a geographical indication or representatives of such groups, in particular Regulation (EC) No 1601/91 and Regulation (EC) No 110/2008; operators entitled to use a geographical indication; as well as inspection bodies or authorities competent for such a geographical indication;

2. In addition to the persons set out in paragraph 1, any of the following shall be entitled to submit a national application:

- (a) all other persons authorised to use intellectual property rights;
- (b) groups of producers foreseen in the legislation of the Member States governing geographical indications representing producers of products with geographical indications or representatives of such groups, operators entitled to use a geographical indication, as well as inspection bodies or authorities competent for such a geographical indication;

3. In addition to the persons set out in paragraph 1, the holder of an exclusive license covering the entire territory of two or more Member States shall be entitled to submit a Union application in those Member States.

4. The persons referred to in paragraphs 1, 2 and 3 shall be entitled to submit an application only if they are entitled to initiate proceedings, to determine whether an intellectual property right has been infringed, in the Member State(s) where the customs authorities are requested to take action.

In addition, the persons referred to in paragraphs 2(a) and 3, shall be entitled to submit an application only if the right-holder has formally authorized them to bring proceedings to determine whether an intellectual property right has been infringed.

Article 5

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 entire area of the Union.

Article 6

Submission of applications

1. The persons referred to in Article 4 may submit an application to the competent customs department. The application shall be made out on the form referred to in paragraph [3].
 - 1.a The persons referred to in Article 4 shall only be entitled to submit per Member State one national application and one Union application for the same intellectual property right protected in that Member State. More than one Union application shall be allowed in cases of Article 4(3).

In case a Union application is submitted or granted for a Member State already covered by another Union application granted for the same applicant and the same intellectual property right, the customs authorities of that Member State shall take action on the basis of the first Union application. They shall inform the competent customs department of the Member State where the second Union application was submitted which shall reject, amend or revoke that second Union application.

2. 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.

3. 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 29(2).

The application form shall contain the information that must be provided to the data subject pursuant to Regulation (EC) No 45/2001¹⁰ and national laws implementing Directive 95/46/EC¹¹.

The form shall, in particular, require the following information to be provided by the applicant:

- (a) details of the applicant;
- (b) status of the applicant within the meaning of Article 4;
- (c) documents providing evidence to satisfy the competent customs department that the applicant is a person entitled to submit the application;
- (d) where the applicant submits the application by means of a representative, details of the natural or legal persons representing him and evidence of their powers to act as representatives, in accordance with the legislation of the Member State in which the application is filed;
- (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;

¹⁰ OJ L 8, 12.1.2001, p. 1.

¹¹ OJ L 281, 23.11.1995, p. 31.

- (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(s) concerned, such as the authorised distributors;
- (i)(a) whether information provided according to letters (g), (h) or (i) is to be marked for restricted treatment in accordance with Article 31(4b) second sub-paragraph;
- (j) name(s) and address(es) of the representative(s) of the applicant in charge of legal and technical matters;
- (k) undertaking by the applicant to notify the competent customs department of any of the situations laid down in Article 14;
- (l) 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;
- (m) undertaking by the applicant to assume liability under the conditions laid down in Article 26;
- (n) undertaking by the applicant to bear the costs referred to in Article 27 under the conditions laid down in that Article;
- (o) agreement by the applicant that the data provided by him will be processed by the Commission and by the Member States;
- (p) whether the applicant requests the use of the procedure referred to in Article 24 and, where requested by the customs authorities, agrees to cover the costs related to destruction of goods under this procedure.

4. 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. ¹²
5. 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 17(4), that application shall comply with the following additional requirements:
 - (a) it shall be 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 shall be a national application;
 - (c) it shall contain the information required in paragraph [3]. However, the applicant shall be allowed to omit the particulars mentioned in paragraph [3], letters (g) to (i).

¹² OJ 2008, No L23, p 21.

Section 2

DECISIONS ON APPLICATIONS

Article 7

Processing of applications

1. Where, on receipt of an application, the competent customs department considers that it 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 8 first subparagraph 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 paragraph 1, the competent customs department shall reject the application.
3. The applicant shall not be charged a fee to cover the administrative costs resulting from the processing of the application.

Article 8

Notification of decisions granting or rejecting applications

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.

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.

Article 9

Decisions concerning applications

1. Decisions granting a national application and decisions revoking or amending them shall take effect in the Member State in which the national application was filed from the day following the date of their adoption. Decisions extending the period during which customs authorities are to take action shall take effect in the Member State in which the national application was filed the day following the date of expiry of the period to be extended.

2. Decisions granting a Union application and decisions revoking or amending them shall take effect as follows:
 - (a) in the Member State in which the application was filed, the day following the date of adoption;

 - (b) in all other Member States where action by the customs authorities is requested, the day following the date on which the customs authorities are notified in accordance with Article 13(2) and provided that the holder of the decision has fulfilled his obligations under Article 2[7](3).

Decisions extending the period during which customs authorities are to take action shall take effect in the Member State in which the Union application was filed 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 10

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 the day the decision granting the application takes effect according to Article 9 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 17([4]) does not contain the particulars referred to in Article 6([3]) (g) to (i), it shall be granted only for the suspension of the release or detention of those goods, unless those particulars are 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 the person 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.

Article 11

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 took 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 made less than 30 working days before the expiry of that decision, the competent customs department may refuse the extension.
4. 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 that request.
5. 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.

Where an intellectual property right ceases to have effect or where the applicant ceases for other reasons to be the person 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 29(2).

Article 12

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. In the case of adding a new intellectual property right, the request shall contain the information as listed in Article 6(3)(c), 6(3)(e) and 6(3)(g) to (i).

In the case of a decision granting a Union application, any modification consisting in adding intellectual property rights shall be limited to those intellectual property rights covered by Article 5.

Article 13

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(s) indicated in the Union application may request the competent customs department that adopted the decision to provide them with additional information deemed necessary for the implementation of the decision granting the application.

The competent customs department of the Member State(s) indicated in the Union application shall thereafter immediately forward those decisions to their customs offices.

- 2a. The competent customs department shall forward its decisions suspending the actions of the customs authorities under Article 15(1b) and (2) to the customs offices of its Member State, immediately after their adoption.

Article 14

Notification obligations of the holder of the decision

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

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

Article 15

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 19, 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 submitted by that person, and refuse to extend the period during which the customs authorities are to take action;
 - (b) suspend in their territory, during the period of validity, any decision granting a Union application submitted by that person.

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 his notification obligations under Article 14;
 - (b) does not comply with the requirements of Article 18(2) on returning samples;
 - (c) does not fulfil his obligations under Article 2[7](1) and (3) with respect to costs and translation;
 - (d) without valid reason does not initiate proceedings as provided for in Articles 20(3), or 24(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

PROVISIONS GOVERNING ACTION BY THE CUSTOMS AUTHORITIES

Section 1

SUSPENSION OF THE RELEASE OR DETENTION OF GOODS SUSPECTED OF INFRINGING AN INTELLECTUAL PROPERTY RIGHT

Article 16

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

1. Where the customs authorities identify, in one of the situations referred to in Article 1(1), 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 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. With this request, the customs authorities *may* also provide the holder of the decision with information about the actual or supposed number of items, their nature and images of those items as appropriate.
4. The customs authorities shall notify the declarant or 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 customs authorities shall notify the holder of the decision the same day, or after the declarant or holder of the goods has been notified.

The notification to the declarant or holder of the goods shall include information on the legal consequences provided by Article 20.

5. The customs authorities shall inform the holder of the decision and the declarant or holder of the goods of the actual or estimated quantity, the actual or supposed nature of the goods, including available images of those items as appropriate, whose release has been suspended or which have been detained. The customs authorities shall also, upon request and if known, inform the holder of the decision of the names and addresses of the consignee, the consignor, the declarant or the holder of the goods, the customs procedure and the origin, provenance and destination of the goods whose release has been suspended or which have been detained.
6. Where several persons are considered to be holder of the goods, the customs authorities shall not be obliged to inform more than one person.

Article 17

Suspension of the release or detention of the goods without the grant of an application

1. Where the customs authorities identify, in the course of action in one of the situations referred to in Article 1(1), goods suspected of infringing an intellectual property right, they may suspend the release of those goods or detain them before having been notified of a decision granting an application with respect to those goods.
2. Before suspending the release or detaining the goods, the customs authorities may, without disclosing any information other than the actual or supposed number of items, their nature and images of those items as appropriate, request any person possibly entitled to submit an application concerning the alleged infringement of intellectual property rights to provide them with any relevant information.

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

The notification to the declarant or holder of the goods shall include information on the legal consequences provided by Article 20.

The customs authorities shall notify any person entitled to submit an application concerning the alleged infringement of intellectual property rights of suspension of the release of the goods or their detention the same day, or after the declarant or holder of the goods has been notified.

Where the customs authorities cannot identify the person entitled to submit an application, they may consult with the competent public authorities in order to identify such a person.

- (4a) Where several persons are considered to be holder of the goods, the customs authorities shall not be obliged to inform more than one person.

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 in the following cases:

- (a) where they have not identified the person 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 or have rejected an application in accordance with Article 6(5).
- (5a) The customs authorities shall also, upon request and if known, inform the holder of the decision of the names and addresses of the consignee, the consignor, the declarant or the holder of the goods, the customs procedure and the origin, provenance and destination of the goods whose release has been suspended or which have been detained.

6. This Article shall not apply to perishable goods.

Article 18

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 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 representative to the goods and may provide or send such samples to the holder of the decision granting the application, at his request, 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 granting the application.

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

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

Article 19

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 16(5), 17(5a), 18 and 24(8), he may only disclose or use that information 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;

(a)(a) 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;

(a)(b) to initiate criminal proceedings and in the course of such proceedings;

(b) to seek compensation from the infringer or other persons;

(b)(a) in the course of agreeing with the declarant or holder of the goods to abandon the goods for destruction in accordance with Article 20(1);

(b)(b) in the course of agreeing with the declarant or holder of the goods of the amount of the guarantee referred to in Article 21 (3).

Article 19a

Sharing of information and data between customs authorities

1. Without prejudice to applicable provisions on data protection in the EU 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 information may refer to seizures, trends and general risk information, including on goods which are in transit through the territory of the Union and originated from or destined to the territory of the authorities concerned. These data and information may include, where appropriate, the following:

- Nature and quantity of goods,
- Suspected intellectual property right infringed,
- Origin, provenance and destination of the goods,
- Information on movements of means of transport, in particular,
 - Name of vessel or registration of means of transport,
 - Reference numbers of freight bill or other transport document,
 - Number of containers,
 - Weight of load,
 - Description and/or coding of goods,
 - Reservation number,
 - Seal number,
 - Place of first loading,
 - Place of final unloading,
 - Places of transshipment,
 - Expected date of arrival at place of final unloading;
- Information on movements of containers, in particular,
 - Container number,
 - Container loading status,
 - Date of movement,
 - Type of movement (loaded, unloaded, transhipped, entered, left, etc.),
 - Name of vessel or registration of means of transport,
 - Number of voyage/journey,
 - Place,
 - Freight bill or other transport document.

3. The Commission shall adopt implementing acts defining the elements of the practical arrangements necessary concerning the exchange of data and information referred to in paragraphs 1 and 2 of this Article. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 29(3).

Section 2

*DESTRUCTION OF GOODS, INITIATION OF PROCEEDINGS AND ANTICIPATED RELEASE
OF GOODS*

Article 20

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 that, in his conviction, an intellectual property right has been infringed, 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;
 - (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 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 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 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, the customs authorities may deem the declarant or holder of the goods to have confirmed his agreement to the destruction of the goods.

The customs authorities shall grant the release of the goods or put an end to their detention, as appropriate, immediately after completion of all customs formalities, where within the period referred to in paragraphs (a) and (b), they have not received 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 on the initiation of proceedings to determine whether an intellectual property right has been infringed.

2. The destruction 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 taken and 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 holder of the goods has not been deemed to have confirmed his agreement to the destruction, in accordance with paragraph 1(c), within the periods set out in paragraph 1(c), 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. The customs authorities may extend the period referred to in paragraph 3 by a maximum of 10 working days upon duly justified request by the holder of the decision in appropriate cases.

In the case of perishable goods this period shall not be extended.

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

Article 21

Anticipated release of goods

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 holder of the goods may request the customs authorities to release the goods or put an end to their detention.

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 holder of the goods has provided a guarantee;
- (b) the authority competent for determining whether an intellectual property right has been infringed has not authorised precautionary measures;
- (c) all customs formalities have been completed.

3. The amount of the guarantee shall be set at an amount sufficiently high to protect the interests of the holder of the decision.
4. The provision of the guarantee shall not affect the other legal remedies available to the holder of the decision.

Article 22

Prohibited customs-approved treatment and use of goods abandoned for destruction

1. Goods abandoned for destruction under Articles 20 or 24 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 where 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 24

Procedure for the destruction of goods in small consignments

1. This Article applies to goods where all of the following conditions are fulfilled:
 - (a) goods suspected of being counterfeit or pirated goods;
 - (b) goods that are not perishable goods;
 - (c) goods covered by a decision granting an application;
 - (ca) the holder of the decision has requested the use of the procedure set out in this article in his application;
 - (d) goods transported in small consignments.
2. Article 16 (4) and (5) and Article 18(2) shall not apply.
3. The customs authorities shall notify the declarant or 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) the customs authorities' intention to destroy the goods,
 - (b) the rights of the declarant or holder of the goods under paragraphs 4, 5 and 6.

4. The declarant or 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 holder of the goods has confirmed to the customs authorities his agreement to the destruction of the goods.
6. Where the declarant or 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 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, provide the holder of the decision with information about the actual or presumed number of destroyed items and their nature as appropriate to the holder of the decision.
8. Where the declarant or holder of the goods has not confirmed his agreement to the destruction of the goods and where the declarant or holder of the goods has not been deemed to have confirmed his agreement to the destruction, in accordance with paragraph 6, the customs authorities shall immediately notify the holder of the decision thereof and of the number of items and their nature, including images of those items where appropriate. The customs authorities shall also, upon request and if known, inform the holder of the decision of the names and addresses of the consignee, the consignor, the declarant or the holder of the goods, the customs procedure and 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, as appropriate, 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 notification, as described in paragraph 8.

10. The Commission shall be empowered to adopt delegated acts in accordance with Article 30 concerning the amendment of quantities in the definition of shall consignments as laid down in Article 2(17a) 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 25

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 26

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 18(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 are subsequently found not to infringe an intellectual property right, the holder of the decision shall be liable towards the persons involved in a situation referred to in Article 1(1) in accordance with national law of the Member State where the goods were found.

Article 27

Costs

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 Articles 16(1), 17(1) and 18(2) and when using corrective measures such as destruction of goods in accordance with Articles 20 and 24.

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 subparagraph. The information on estimated costs may be expressed per units such as time, products, volume, weight or service in accordance to the circumstances of storage and 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 of the Member State where the goods were found.
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 28

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 must 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

COMMITTEE, DELEGATION AND FINAL PROVISIONS

Article 29

Committee procedure

1. The Commission shall be assisted by the Customs Code Committee established by Articles 247a and 248a of Council Regulation (EC) 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.
3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Article 30

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 delegation of power referred to in Article 2[4](10) shall be conferred for an indeterminate period of time from the date of entry into force of this Regulation.
3. The delegation of powers referred to in Article 2[4](10) may be revoked at any time by the European Parliament or by the Council. A decision of revocation 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 2[4](10) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of 2 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 2 months on the initiative of the European Parliament or the Council.

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:
 - (b) decisions granting applications, including the application and its attachments;
 - (c) any decisions extending the period during which the customs authorities are to take action or decisions revoking the decision granting the application or amending it;
 - (d) any suspension of a decision granting the application.
2. Without prejudice to Article 24(g) of Council 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 nominal data, including information on the number 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 and all exchanges of data on decisions concerning applications as referred to in Article 13 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. The database shall be operational as soon as possible and not later than 1 January 2015.
- 4a. For the purposes of ensuring processing of the information referred to in paragraphs 1 to 3, 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 13 and Article 31.
- 4b. 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 treatment 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.
- 4c. 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.
- 4d. 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 organizational 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

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 this Directive.
 - 2a. 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.
 - 2b. Each customs authority that has introduced personal data into the central database shall be the controller with respect to the processing of this data.
 - 2c. 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) 45/2001 or the national laws implementing Directive 95/46/EC.
 - 2d. 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 the right of access, rectification, erasure or blocking to the Commission, the Commission shall forward such request to the customs authorities concerned
 - 2e. Personal data shall not be kept longer than 6 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.

2f. Where the holder of the decision has initiated proceedings in accordance with Article 20(3) or [24(9)] of this Regulation and has notified the customs authorities of the initiation of such proceedings, personal data shall be kept for 6 months after proceedings have determined in a final way whether an intellectual property right has been infringed.

Article 33

Periods, dates and time limits

The rules applicable to periods, dates and time limits set out in Regulation (EEC, Euratom) No 1182/71 of the Council shall apply.

Article 34

Mutual administrative assistance

The provisions of Regulation (EC) No 515/97 shall apply.

Article 35

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.

Article 35a

By 36 months after the entry into force of this Regulation, 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 that might occur under the application of the 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.

Article 36

Transitional provisions

Applications granted in accordance with Council 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 37

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. Articles 6(3), 11(7) and 19a (3) shall apply from the date of entry into force of this Regulation.
3. Notwithstanding paragraph 2 of this article, Articles 31 and 32 shall apply from the date on which the central database referred to in Article 31(3) is in place. The Commission shall make public that date.

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

Done at Brussels,

For the European Parliament
The President

For the Council
The President