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## Legislation

Contents



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[1] Text with EEA relevance

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

I

*(Legislative acts)*

# REGULATIONS

## REGULATION (EU) No 1024/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

## of 25 October 2012

## on administrative cooperation through the Internal Market Information System and repealing Commission Decision 2008/49/EC ('the IMI Regulation')

**(Text with EEA relevance)**

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 114 thereof,

Having regard to the proposal from the European Commission,

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

Having regard to the opinion of the European Economic and Social Committee [1],

Acting in accordance with the ordinary legislative procedure [2],

Whereas:

(1) The application of certain Union acts governing the free movement of goods, persons, services and capital in the internal market requires Member States to cooperate more effectively and exchange information with one another and with the Commission. As practical means to implement such information exchange are often not specified in those acts, appropriate practical arrangements need to be made.

(2) The Internal Market Information System ('IMI') is a software application accessible via the internet, developed by the Commission in cooperation with the Member States, in order to assist Member States with the practical implementation of information exchange requirements laid down in Union acts by providing a centralised communication mechanism to facilitate cross-border exchange of information and mutual assistance. In particular, IMI helps competent authorities to identify their counterpart in another Member State, to manage the exchange of information, including personal data, on the basis of simple and unified procedures and to overcome language barriers on the basis of pre-defined and pre-translated workflows. Where available, the Commission should provide IMI users with any existing additional translation functionality that meets their needs, is compatible with the security and confidentiality requirements for the exchange of information in IMI and can be offered at a reasonable cost.

(3) In order to overcome language barriers, IMI should in principle be available in all official Union languages.

(4) The purpose of IMI should be to improve the functioning of the internal market by providing an effective, user-friendly tool for the implementation of administrative cooperation between Member States and between Member States and the Commission, thus facilitating the application of Union acts listed in the Annex to this Regulation.

(5) The Commission Communication of 21 February 2011 entitled 'Better governance of the Single Market through greater administrative cooperation: A strategy for expanding and developing the Internal Market Information System ("IMI")' sets out plans for the possible expansion of IMI to other Union acts. The Commission Communication of 13 April 2011 entitled 'Single Market Act: Twelve Levers to boost growth and strengthen confidence — "Working together to create new growth"' stresses the importance of IMI for strengthening cooperation among the actors involved, including at local level, thus contributing to better governance of the single market. It is therefore necessary to establish a sound legal framework for IMI and a set of common rules to ensure that IMI functions efficiently.

(6) Where the application of a provision of a Union act requires Member States to exchange personal data and

[1] OJ C 43, 15.2.2012, p. 14.

[2] Position of the European Parliament of 11 September 2012 (not yet published in the Official Journal) and decision of the Council of 4 October 2012.

provides for the purpose of this processing, such a provision should be considered an adequate legal basis for the processing of personal data, subject to the conditions set out in Articles 8 and 52 of the Charter of Fundamental Rights of the European Union. IMI should be seen primarily as a tool used for the exchange of information, including personal data, which would otherwise take place via other means, including regular mail, fax or electronic mail on the basis of a legal obligation imposed on Member States' authorities and bodies in Union acts. Personal data exchanged via IMI should only be collected, processed and used for purposes in line with those for which it was originally collected and should be subject to all relevant safeguards.

(7) Following the privacy-by-design principle, IMI has been developed with the requirements of data protection legislation in mind and has been data protection-friendly from its inception, in particular because of the restrictions imposed on access to personal data exchanged in IMI. Therefore, IMI offers a considerably higher level of protection and security than other methods of information exchange such as regular mail, telephone, fax or electronic mail.

(8) Administrative cooperation by electronic means between Member States and between Member States and the Commission should comply with the rules on the protection of personal data laid down 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 [1] and in 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 the Community institutions and bodies and on the free movement of such data [2]. The definitions used in Directive 95/46/EC and Regulation (EC) No 45/2001 should also apply for the purposes of this Regulation.

(9) The Commission supplies and manages the software and IT infrastructure for IMI, ensures the security of IMI, manages the network of national IMI coordinators and is involved in the training of and technical assistance to the IMI users. To that end, the Commission should only have access to such personal data that are strictly necessary to carry out its tasks within the responsibilities set out in this Regulation, such as the registration of national IMI coordinators. The Commission should also have access to personal data when retrieving, upon a request by another IMI actor, such data that have been blocked in IMI and to which the data subject has requested access. The Commission should not have access to personal data exchanged as part of administrative cooperation within IMI, unless a Union act provides for a role for the Commission in such cooperation.

(10) In order to ensure transparency, in particular for data subjects, the provisions of Union acts for which IMI is to be used should be listed in the Annex to this Regulation.

(11) IMI may be expanded in the future to new areas, where it can help to ensure effective implementation of a Union act in a cost-efficient, user-friendly way, taking account of technical feasibility and overall impact on IMI. The Commission should conduct the necessary tests to verify the technical readiness of IMI for any envisaged expansion. Decisions to expand IMI to further Union acts should be taken by means of the ordinary legislative procedure.

(12) Pilot projects are a useful tool for testing whether the expansion of IMI is justified and for adapting technical functionality and procedural arrangements to the requirements of IMI users before a decision on the expansion of IMI is taken. Member States should be fully involved in deciding which Union acts should be subject to a pilot project and on the modalities of that pilot project, in order to ensure that the pilot project reflects the needs of IMI users and that the provisions on processing of personal data are fully complied with. Such modalities should be defined separately for each pilot project.

(13) Nothing in this Regulation should preclude Member States and the Commission from deciding to use IMI for the exchange of information which does not involve the processing of personal data.

(14) This Regulation should set out the rules for using IMI for the purposes of administrative cooperation, which may cover, inter alia, the one-to-one exchange of information, notification procedures, alert mechanisms, mutual assistance arrangements and problem-solving.

(15) The right of the Member States to decide which national authorities carry out the obligations resulting from this Regulation should remain unaffected by this Regulation. Member States should be able to adapt functions and responsibilities in relation to IMI to their internal administrative structures, as well as to implement the needs of a specific IMI workflow. Member States should be able to appoint additional IMI coordinators to carry out the tasks of national IMI coordinators, alone or jointly with others, for a particular area of the internal market, a division of the administration, a geographic region, or according to another criterion. Member States should inform the Commission of the IMI coordinators they have appointed, but they should not be obliged to indicate additional IMI coordinators in IMI, where this is not required for its proper functioning.

(16) In order to achieve efficient administrative cooperation through IMI, Member States and the Commission should ensure that their IMI actors have the necessary resources to carry out their obligations in accordance with this Regulation.

[1] OJ L 281, 23.11.1995, p. 31.
[2] OJ L 8, 12.1.2001, p. 1.

(17) While IMI is in essence a communication tool for administrative cooperation between competent authorities, which is not open to the general public, technical means may need to be developed to allow external actors such as citizens, enterprises and organisations to interact with the competent authorities in order to supply information or retrieve data, or to exercise their rights as data subjects. Such technical means should include appropriate safeguards for data protection. In order to ensure a high level of security, any such public interface should be developed in such a way as to be technically fully separate from IMI, to which only IMI users should have access.

(18) The use of IMI for the technical support of the SOLVIT network should be without prejudice to the informal character of the SOLVIT procedure which is based on a voluntary commitment of the Member States, in accordance with the Commission Recommendation of 7 December 2001 on principles for using 'SOLVIT' — the Internal Market Problem Solving Network [1] ('the SOLVIT Recommendation'). To continue the functioning of the SOLVIT network on the basis of existing work arrangements, one or more tasks of the national IMI coordinator may be assigned to SOLVIT centres within the remit of their work, so that they can function independently from the national IMI coordinator. The processing of personal data and of confidential information as part of SOLVIT procedures should benefit from all guarantees set out in this Regulation, without prejudice to the non-binding character of the SOLVIT Recommendation.

(19) While IMI includes an internet-based interface for its users, in certain cases and at the request of the Member State concerned, it may be appropriate to consider technical solutions for the direct transfer of data from national systems to IMI, where such national systems have already been developed, notably for notification procedures. The implementation of such technical solutions should depend on the outcome of an assessment of their feasibility, costs and expected benefits. Those solutions should not affect the existing structures and the national order of competencies.

(20) Where Member States have fulfilled the obligation to notify under Article 15(7) of Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market [2] by using the procedure in accordance with Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services [3], they should not also be required to make the same notification through IMI.

(21) The exchange of information through IMI follows from the legal obligation on Member States' authorities to give mutual assistance. To ensure that the internal market functions properly, information received by a competent authority through IMI from another Member State should not be deprived of its value as evidence in administrative proceedings solely on the ground that it originated in another Member State or was received by electronic means, and it should be treated by that competent authority in the same way as similar documents originating in its Member State.

(22) In order to guarantee a high level of data protection, maximum retention periods for personal data in IMI need to be established. However, those periods should be well-balanced taking into due consideration the need for IMI to function properly, as well as the rights of the data subjects to fully exercise their rights, for instance by obtaining evidence that an information exchange took place in order to appeal against a decision. In particular, retention periods should not go beyond what is necessary to achieve the objectives of this Regulation.

(23) It should be possible to process the name and contact details of IMI users for purposes compatible with the objectives of this Regulation, including monitoring of the use of the system by IMI coordinators and the Commission, communication, training and awareness-raising initiatives, and gathering information on administrative cooperation or mutual assistance in the internal market.

(24) The European Data Protection Supervisor should monitor and seek to ensure the application of this Regulation, inter alia by maintaining contacts with national data protection authorities, including the relevant provisions on data security.

(25) In order to ensure the effective monitoring of, and reporting on, the functioning of IMI and the application of this Regulation, Member States should make relevant information available to the Commission.

(26) Data subjects should be informed about the processing of their personal data in IMI and of the fact that they have the right of access to the data relating to them and the right to have inaccurate data corrected and illegally processed data erased, in accordance with this Regulation and national legislation implementing Directive 95/46/EC.

(27) In order to make it possible for the competent authorities of the Member States to implement legal provisions for administrative cooperation and efficiently exchange information by means of IMI, it may be necessary to lay down practical arrangements for such an exchange. Those arrangements should be adopted by the Commission in the form of a separate implementing act for each Union act listed in the Annex or for each type of administrative cooperation procedure and should cover the essential technical functionality and procedural

[1] OJ L 331, 15.12.2001, p. 79.
[2] OJ L 376, 27.12.2006, p. 36.
[3] OJ L 204, 21.7.1998, p. 37.

arrangements required to implement the relevant administrative cooperation procedures via IMI. The Commission should ensure the maintenance and development of the software and IT infrastructure for IMI.

(28) In order to ensure sufficient transparency for data subjects, the predefined workflows, question and answer sets, forms and other arrangements relating to administrative cooperation procedures in IMI should be made public.

(29) Where Member States apply, in accordance with Article 13 of Directive 95/46/EC, any limitations on or exceptions to the rights of data subjects, information about such limitations or exceptions should be made public in order to ensure full transparency for data subjects. Such exceptions or limitations should be necessary and proportionate to the intended purpose and subject to adequate safeguards.

(30) Where international agreements are concluded between the Union and third countries that also cover the application of provisions of Union acts listed in the Annex to this Regulation, it should be possible to include the counterparts of IMI actors in such third countries in the administrative cooperation procedures supported by IMI, provided that it has been established that the third country concerned offers an adequate level of protection of personal data in accordance with Directive 95/46/EC.

(31) Commission Decision 2008/49/EC of 12 December 2007 concerning the implementation of the Internal Market Information System (IMI) as regards the protection of personal data [1] should be repealed. Commission Decision 2009/739/EC of 2 October 2009 setting out the practical arrangements for the exchange of information by electronic means between the Member States under Chapter VI of Directive 2006/123/EC of the European Parliament and of the Council on services in the internal market [2] should continue to apply to issues relating to the exchange of information under Directive 2006/123/EC.

(32) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. 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 the Member States of the Commission's exercise of implementing powers [3].

(33) The performance of the Member States regarding the effective application of this Regulation should be monitored in the annual report on the functioning of IMI based on statistical data from IMI and any other relevant data. The performance of Member States should be evaluated, inter alia, based on average reply times with the aim of ensuring rapid replies of good quality.

(34) Since the objective of this Regulation, namely laying down the rules for the use of IMI for administrative cooperation, cannot be sufficiently achieved by the Member States and can therefore, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.

(35) The European Data Protection Supervisor has been consulted in accordance with Article 28(2) of Regulation (EC) No 45/2001 and delivered an opinion on 22 November 2011 [4],

HAVE ADOPTED THIS REGULATION:

CHAPTER I

**GENERAL PROVISIONS**

*Article 1*

**Subject matter**

This Regulation lays down rules for the use of an Internal Market Information System ('IMI') for administrative cooperation, including processing of personal data, between competent authorities of the Member States and between competent authorities of the Member States and the Commission.

*Article 2*

**Establishment of IMI**

IMI is hereby formally established.

*Article 3*

**Scope**

1. IMI shall be used for administrative cooperation between competent authorities of the Member States and between competent authorities of the Member States and the Commission necessary for the implementation of Union acts in the field of the internal market, within the meaning of Article 26(2) of the Treaty on the Functioning of the European Union (TFEU), which provide for administrative cooperation, including the exchange of personal data, between Member States or between Member States and the Commission. Those Union acts are listed in the Annex.

2. Nothing in this Regulation shall have the effect of rendering mandatory the provisions of Union acts which have no binding force.

[1] OJ L 13, 16.1.2008, p. 18.
[2] OJ L 263, 7.10.2009, p. 32.
[3] OJ L 55, 28.2.2011, p. 13.
[4] OJ C 48, 18.2.2012, p. 2.

*Article 4*

**Expansion of IMI**

1. The Commission may carry out pilot projects in order to assess whether IMI would be an effective tool to implement provisions for administrative cooperation of Union acts not listed in the Annex. The Commission shall adopt an implementing act to determine which provisions of Union acts shall be subject to a pilot project and to set out the modalities of each project, in particular the basic technical functionality and procedural arrangements required to implement the relevant administrative cooperation provisions. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 24(3).

2. The Commission shall submit an evaluation of the outcome of the pilot project, including data protection issues and effective translation functionalities, to the European Parliament and the Council. Where appropriate, that evaluation may be accompanied by a legislative proposal to amend the Annex to expand the use of IMI to the relevant provisions of Union acts.

*Article 5*

**Definitions**

For the purposes of this Regulation, the definitions laid down in Directive 95/46/EC and Regulation (EC) No 45/2001 shall apply.

In addition, the following definitions shall also apply:

(a) 'IMI' means the electronic tool provided by the Commission to facilitate administrative cooperation between competent authorities of the Member States and between competent authorities of the Member States and the Commission;

(b) 'administrative cooperation' means the working in collaboration of competent authorities of the Member States or competent authorities of the Member States and the Commission, by exchanging and processing information, including through notifications and alerts, or by providing mutual assistance, including for the resolution of problems, for the purpose of better application of Union law;

(c) 'internal market area' means a legislative or functional field of the internal market, within the meaning of Article 26(2) TFEU, in which IMI is used in accordance with Article 3 of this Regulation;

(d) 'administrative cooperation procedure' means a pre-defined workflow provided for in IMI allowing IMI actors to communicate and interact with each other in a structured manner;

(e) 'IMI coordinator' means a body appointed by a Member State to perform support tasks necessary for the efficient functioning of IMI in accordance with this Regulation;

(f) 'competent authority' means any body established at either national, regional or local level and registered in IMI with specific responsibilities relating to the application of national law or Union acts listed in the Annex in one or more internal market areas;

(g) 'IMI actors' means the competent authorities, IMI coordinators and the Commission;

(h) 'IMI user' means a natural person working under the authority of an IMI actor and registered in IMI on behalf of that IMI actor;

(i) 'external actors' means natural or legal persons other than IMI users that may interact with IMI only through separate technical means and in accordance with a specific predefined workflow provided for that purpose;

(j) 'blocking' means applying technical means by which personal data become inaccessible to IMI users via the normal interface of IMI;

(k) 'formal closure' means applying the technical facility provided by IMI to close an administrative cooperation procedure.

CHAPTER II

**FUNCTIONS AND RESPONSIBILITIES IN RELATION TO IMI**

*Article 6*

**IMI coordinators**

1. Each Member State shall appoint one national IMI coordinator whose responsibilities shall include:

(a) registering or validating registration of IMI coordinators and competent authorities;

(b) acting as the main contact point for IMI actors of the Member States for issues relating to IMI, including providing information on aspects relating to the protection of personal data in accordance with this Regulation;

(c) acting as interlocutor of the Commission for issues relating to IMI including providing information on aspects relating to the protection of personal data in accordance with this Regulation;

(d) providing knowledge, training and support, including basic technical assistance, to IMI actors of the Member States;

(e) ensuring the efficient functioning of IMI as far as it is within their control, including the provision of timely and adequate responses by IMI actors of the Member States to requests for administrative cooperation.

2. Each Member State may, in addition, appoint one or more IMI coordinators in order to carry out any of the tasks listed in paragraph 1, in accordance with its internal administrative structure.

3. Member States shall inform the Commission of the IMI coordinators appointed in accordance with paragraphs 1 and 2 and of the tasks for which they are responsible. The Commission shall share that information with the other Member States.

4. All IMI coordinators may act as competent authorities. In such cases an IMI coordinator shall have the same access rights as a competent authority. Each IMI coordinator shall be a controller with respect to its own data processing activities as an IMI actor.

*Article 7*

**Competent authorities**

1. When cooperating by means of IMI, competent authorities, acting through IMI users in accordance with administrative cooperation procedures, shall ensure that, in accordance with the applicable Union act, an adequate response is provided within the shortest possible period of time, and in any event within the deadline set by that act.

2. A competent authority may invoke as evidence any information, document, finding, statement or certified true copy which it has received electronically by means of IMI, on the same basis as similar information obtained in its own country, for purposes compatible with the purposes for which the data were originally collected.

3. Each competent authority shall be a controller with respect to its own data processing activities performed by an IMI user under its authority and shall ensure that data subjects can exercise their rights in accordance with Chapters III and IV, where necessary, in cooperation with the Commission.

*Article 8*

**Commission**

1. The Commission shall be responsible for carrying out the following tasks:

(a) ensuring the security, availability, maintenance and development of the software and IT infrastructure for IMI;

(b) providing a multilingual system, including existing translation functionalities, training in cooperation with the Member States, and a helpdesk to assist Member States in the use of IMI;

(c) registering the national IMI coordinators and granting them access to IMI;

(d) performing processing operations on personal data in IMI, where provided for in this Regulation, in accordance with the purposes determined by the applicable Union acts listed in the Annex;

(e) monitoring the application of this Regulation and reporting back to the European Parliament, the Council and the European Data Protection Supervisor in accordance with Article 25.

2. For the purposes of performing the tasks listed in paragraph 1 and producing statistical reports, the Commission shall have access to the necessary information relating to the processing operations performed in IMI.

3. The Commission shall not participate in administrative cooperation procedures involving the processing of personal data except where required by a provision of a Union act listed in the Annex.

*Article 9*

**Access rights of IMI actors and users**

1. Only IMI users shall have access to IMI.

2. Member States shall designate the IMI coordinators and competent authorities and the internal market areas in which they have competence. The Commission may play a consultative role in that process.

3. Each IMI actor shall grant and revoke, as necessary, appropriate access rights to its IMI users in the internal market area for which it is competent.

4. Appropriate means shall be put in place by the Commission and the Member States to ensure that IMI users are allowed to access personal data processed in IMI only on a need-to-know basis and within the internal market area or areas for which they were granted access rights in accordance with paragraph 3.

5. The use of personal data processed in IMI for a specific purpose in a way that is incompatible with that original purpose shall be prohibited, unless explicitly provided for by national law in accordance with Union law.

6. Where an administrative cooperation procedure involves the processing of personal data, only the IMI actors participating in that procedure shall have access to such personal data.

*Article 10*

**Confidentiality**

1. Each Member State shall apply its rules of professional secrecy or other equivalent duties of confidentiality to its IMI actors and IMI users, in accordance with national or Union legislation.

2. IMI actors shall ensure that requests of other IMI actors for confidential treatment of information exchanged by means of IMI are respected by IMI users working under their authority.

*Article 11*

**Administrative cooperation procedures**

IMI shall be based on administrative cooperation procedures implementing the provisions of the relevant Union acts listed in the Annex. Where appropriate, the Commission may adopt implementing acts for a specific Union act listed in the Annex or for a type of administrative cooperation procedure, setting out the essential technical functionality and the procedural arrangements required to enable the operation of the relevant administrative cooperation procedures, including where applicable the interaction between external actors and IMI as referred to in Article 12. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 24(2).

*Article 12*

**External actors**

Technical means may be provided to allow external actors to interact with IMI where such interaction is:

(a) provided for by a Union act;

(b) provided for in an implementing act referred to in Article 11 in order to facilitate administrative cooperation between competent authorities in Member States for the application of the provisions of Union acts listed in the Annex; or

(c) necessary for submitting requests in order to exercise their rights as data subjects in accordance with Article 19.

Any such technical means shall be separate from IMI and shall not enable external actors to access IMI.

CHAPTER III

**PROCESSING OF PERSONAL DATA AND SECURITY**

*Article 13*

**Purpose limitation**

IMI actors shall exchange and process personal data only for the purposes defined in the relevant provisions of the Union acts listed in the Annex.

Data submitted to IMI by data subjects shall only be used for the purposes for which the data were submitted.

*Article 14*

**Retention of personal data**

1. Personal data processed in IMI shall be blocked in IMI as soon as they are no longer necessary for the purpose for which they were collected, depending on the specificities of each type of administrative cooperation and, as a general rule, no later than six months after the formal closure of the administrative cooperation procedure.

However, if a longer period is provided for in an applicable Union act listed in the Annex, personal data processed in IMI may be retained for a maximum of 18 months after the formal closure of an administrative cooperation procedure.

2. Where a repository of information for future reference by IMI actors is required pursuant to a binding Union act listed in the Annex, the personal data included in such a repository may be processed for as long as they are needed for this purpose either with the data subject's consent or where this is provided for in that Union act.

3. Personal data blocked pursuant to this Article shall, with the exception of their storage, only be processed for purposes of proof of an information exchange by means of IMI with the data subject's consent, unless processing is requested for overriding reasons in the public interest.

4. The blocked data shall be automatically deleted in IMI three years after the formal closure of the administrative cooperation procedure.

5. At the express request of a competent authority in a specific case and with the data subject's consent, personal data may be deleted before the expiry of the applicable retention period.

6. The Commission shall ensure by technical means the blocking and deletion of personal data and their retrieval in accordance with paragraph 3.

7. Technical means shall be put in place to encourage IMI actors to formally close administrative cooperation procedures as soon as possible after the exchange of information has been completed and to enable IMI actors to involve IMI coordinators responsible in any procedure which has been inactive without justification for longer than two months.

*Article 15*

**Retention of personal data of IMI users**

1. By way of derogation from Article 14, paragraphs 2 and 3 of this Article shall apply to the retention of personal data of IMI users. Those personal data shall include the full name and all electronic and other means of contact necessary for the purposes of this Regulation.

2. Personal data relating to IMI users shall be stored in IMI as long as they continue to be users of IMI and may be processed for purposes compatible with the objectives of this Regulation.

3. When a natural person ceases to be an IMI user, the personal data relating to that person shall be blocked by technical means for a period of three years. Those data shall, with the exception of their storage, only be processed for purposes of proof of an information exchange by means of IMI and shall be deleted at the end of the three-year period.

*Article 16*

**Processing of special categories of data**

1. The processing of special categories of data referred to in Article 8(1) of Directive 95/46/EC and Article 10(1) of Regulation (EC) No 45/2001 by means of IMI shall be allowed only on the basis of a specific ground mentioned in Article 8(2) and (4) of that Directive and Article 10(2) of that Regulation and subject to appropriate safeguards provided for in those Articles to ensure the rights of individuals whose personal data are processed.

2. IMI may be used for the processing of data relating to offences, criminal convictions or security measures referred to in Article 8(5) of Directive 95/46/EC and Article 10(5) of Regulation (EC) No 45/2001, subject to safeguards provided for in those Articles, including information on disciplinary, administrative or criminal sanctions or other information necessary to establish the good repute of an individual or a legal person, where the processing of such data is provided for in a Union act constituting the basis for the processing or with the explicit consent of the data subject, subject to specific safeguards referred to in Article 8(5) of Directive 95/46/EC.

*Article 17*

**Security**

1. The Commission shall ensure that IMI complies with the rules on data security adopted by the Commission pursuant to Article 22 of Regulation (EC) No 45/2001.

2. The Commission shall put in place the necessary measures to ensure security of personal data processed in IMI, including appropriate data access control and a security plan which shall be kept up-to-date.

3. The Commission shall ensure that, in the event of a security incident, it is possible to verify what personal data have been processed in IMI, when, by whom and for what purpose.

4. IMI actors shall take all procedural and organisational measures necessary to ensure the security of personal data processed by them in IMI in accordance with Article 17 of Directive 95/46/EC.

CHAPTER IV

**RIGHTS OF DATA SUBJECTS AND SUPERVISION**

*Article 18*

**Information to data subjects and transparency**

1. IMI actors shall ensure that data subjects are informed about processing of their personal data in IMI as soon as possible and that they have access to information on their rights and how to exercise them, including the identity and contact details of the controller and of the controller's representative, if any, in accordance with Article 10 or 11 of Directive 95/46/EC and national legislation which is in accordance with that Directive.

2. The Commission shall make publicly available in a way which is easily accessible:

(a) information concerning IMI in accordance with Articles 11 and 12 of Regulation (EC) No 45/2001, in a clear and understandable form;

(b) information on the data protection aspects of administrative cooperation procedures in IMI as referred to in Article 11 of this Regulation;

(c) information on exceptions to or limitations of the rights of data subjects as referred to in Article 20 of this Regulation;

(d) types of administrative cooperation procedures, essential IMI functionalities and categories of data that may be processed in IMI;

(e) a comprehensive list of all implementing or delegated acts regarding IMI, adopted pursuant to this Regulation or to another Union act, and a consolidated version of the Annex to this Regulation and its subsequent amendments by other Union acts.

*Article 19*

**Right of access, correction and deletion**

1. IMI actors shall ensure that data subjects may effectively exercise their right of access to data relating to them in IMI, and the right to have inaccurate or incomplete data corrected and unlawfully processed data deleted, in accordance with national legislation. The correction or deletion of data shall be carried out as soon as possible, and at the latest 30 days after the request by the data subject is received by the IMI actor responsible.

2. Where the accuracy or lawfulness of data blocked pursuant to Article 14(1) is contested by the data subject, this fact shall be recorded, as well as the accurate, corrected information.

*Article 20*

**Exceptions and limitations**

Member States shall inform the Commission where they provide for exceptions to, or limitations of, the rights of data subjects set out in this Chapter in national legislation in accordance with Article 13 of Directive 95/46/EC.

*Article 21*

**Supervision**

1. The national supervisory authority or authorities designated in each Member State and endowed with the powers referred to in Article 28 of Directive 95/46/EC (the 'National Supervisory Authority') shall independently monitor the lawfulness of the processing of personal data by the IMI actors of their Member State and, in particular, shall ensure that the rights of data subjects set out in this Chapter are protected in accordance with this Regulation.

2. The European Data Protection Supervisor shall monitor and seek to ensure that the personal data processing activities of the Commission, in its role as an IMI actor, are carried out in accordance with this Regulation. The duties and powers referred to in Articles 46 and 47 of Regulation (EC) No 45/2001 shall apply accordingly.

3. The National Supervisory Authorities and the European Data Protection Supervisor, each acting within the scope of their respective competencies, shall ensure coordinated supervision of IMI and its use by IMI actors.

4. The European Data Protection Supervisor may invite the National Supervisory Authorities to meet, where necessary, for the purposes of ensuring coordinated supervision of IMI and its use by IMI actors, as referred to in paragraph 3. The cost of such meetings shall be borne by the European Data Protection Supervisor. Further working methods for this purpose, including rules of procedure, may be developed jointly as necessary. A joint report of activities shall be sent to the European Parliament, the Council and the Commission at least every three years.

CHAPTER V

**GEOGRAPHIC SCOPE OF IMI**

*Article 22*

**National use of IMI**

1. A Member State may use IMI for the purpose of administrative cooperation between competent authorities within its territory, in accordance with national law, only where the following conditions are satisfied:

(a) no substantial changes to the existing administrative cooperation procedures are required;

(b) a notification of the envisaged use of IMI has been submitted to the National Supervisory Authority where required under national law; and

(c) it does not have a negative impact on the efficient functioning of IMI for IMI users.

2. Where a Member State intends to make systematic use of IMI for national purposes, it shall notify its intention to the Commission and seek its prior approval. The Commission shall examine whether the conditions set out in paragraph 1 are met. Where necessary, and in accordance with this Regulation, an agreement setting out, inter alia, the technical, financial and organisational arrangements for national use, including the responsibilities of the IMI actors, shall be concluded between the Member State and the Commission.

*Article 23*

**Information exchange with third countries**

1. Information, including personal data, may be exchanged in IMI pursuant to this Regulation between IMI actors within the Union and their counterparts in a third country only where the following conditions are satisfied:

(a) the information is processed pursuant to a provision of a Union act listed in the Annex and an equivalent provision in the law of the third country;

(b) the information is exchanged or made available in accordance with an international agreement providing for:

(i) the application of a provision of a Union act listed in the Annex by the third country;

(ii) the use of IMI; and

(iii) the principles and modalities of that exchange; and

(c) the third country in question ensures adequate protection of personal data in accordance with Article 25(2) of Directive 95/46/EC, including adequate safeguards that the data processed in IMI shall only be used for the purpose for which they were initially exchanged, and the Commission has adopted a decision in accordance with Article 25(6) of Directive 95/46/EC.

2. Where the Commission is an IMI actor, Article 9(1) and (7) of Regulation (EC) No 45/2001 shall apply to any exchange of personal data processed in IMI with its counterparts in a third country.

3. The Commission shall publish in the *Official Journal of the European Union* and keep up-to-date a list of third countries authorised to exchange information, including personal data, in accordance with paragraph 1.

CHAPTER VI

**FINAL PROVISIONS**

*Article 24*

**Committee procedure**

1. The Commission shall be assisted by a committee. 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 25*

**Monitoring and reporting**

1. The Commission shall report to the European Parliament and the Council on the functioning of IMI on a yearly basis.

2. By 5 December 2017 and every five years thereafter, the Commission shall report to the European Data Protection Supervisor on aspects relating to the protection of personal data in IMI, including data security.

3. For the purpose of producing the reports referred to in paragraphs 1 and 2, Member States shall provide the Commission with any information relevant to the application of this Regulation, including on the application in practice of the data protection requirements laid down in this Regulation.

*Article 26*

**Costs**

1. The costs incurred for the development, promotion, operation and maintenance of IMI shall be borne by the general budget of the European Union, without prejudice to arrangements under Article 22(2).

2. Unless otherwise stipulated in a Union act, the costs for the IMI operations at Member State level, including the human resources needed for training, promotion and technical assistance (helpdesk) activities, as well as for the administration of IMI at national level, shall be borne by each Member State.

*Article 27*

**Repeal**

Decision 2008/49/EC is repealed.

*Article 28*

**Effective application**

Member States shall take all necessary measures to ensure effective application of this Regulation by their IMI actors.

*Article 29*

**Exceptions**

1. Notwithstanding Article 4 of this Regulation, the IMI pilot project launched on 16 May 2011 to test the suitability of IMI for the implementation of Article 4 of Directive 96/71/EC of the European Parliament and of the Council of 16 December 1996 concerning the posting of workers in the framework of the provision of services [1] may continue to operate on the basis of the arrangements that were made prior to the entry into force of this Regulation.

[1] OJ L 18, 21.1.1997, p. 1.

2. Notwithstanding Article 8(3) and points (a) and (b) of the first paragraph of Article 12 of this Regulation, for the implementation of the administrative cooperation provisions of the SOLVIT Recommendation through IMI, the involvement of the Commission in administrative cooperation procedures and the existing facility for external actors may continue on the basis of the arrangements that were made prior to the entry into force of this Regulation. The period as referred to in Article 14(1) of this Regulation shall be 18 months for personal data processed in IMI for the purposes of the SOLVIT Recommendation.

3. Notwithstanding Article 4(1) of this Regulation, the Commission may launch a pilot project to assess whether IMI is an efficient, cost-effective and user-friendly tool to implement Article 3(4), (5) and (6) of Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (Directive on electronic commerce) ([1]). No later than two years after the launch of that pilot project, the Commission shall submit to the European Parliament and the Council the evaluation referred to in Article 4(2) of this Regulation, which shall also cover the interaction between administrative cooperation within the consumer protection cooperation system established in accordance with Regulation (EC) No 2006/2004 of the European Parliament and of the Council of 27 October 2004 on cooperation between national authorities responsible for the enforcement of consumer protection laws (the Regulation on consumer protection cooperation) ([2]) and within IMI.

4. Notwithstanding Article 14(1) of this Regulation, any periods up to a maximum of 18 months decided on the basis of Article 36 of Directive 2006/123/EC with regard to administrative cooperation pursuant to Chapter VI thereof shall continue to apply in that area.

*Article 30*

**Entry into force**

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

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

Done at Strasbourg, 25 October 2012.

*For the European Parliament*
*The President*
M. SCHULZ

*For the Council*
*The President*
A. D. MAVROYIANNIS

([1]) OJ L 178, 17.7.2000, p. 1.

([2]) OJ L 364, 9.12.2004, p. 1.

*ANNEX*

**PROVISIONS ON ADMINISTRATIVE COOPERATION IN UNION ACTS THAT ARE IMPLEMENTED BY MEANS OF IMI, REFERRED TO IN ARTICLE 3**

1. Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market ([1]): Chapter VI, Article 39(5), as well as Article 15(7), unless a notification, as provided for in that latter Article, is made in accordance with Directive 98/34/EC.

2. Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications ([2]): Article 8, Article 50(1), (2) and (3), and Article 56.

3. Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare ([3]): Article 10(4).

4. Regulation (EU) No 1214/2011 of the European Parliament and of the Council of 16 November 2011 on the professional cross-border transport of euro cash by road between euro-area Member States ([4]): Article 11(2).

5. Commission Recommendation of 7 December 2001 on principles for using 'SOLVIT' — the Internal Market Problem Solving Network ([5]): Chapters I and II.

([1]) OJ L 376, 27.12.2006, p. 36.
([2]) OJ L 255, 30.9.2005, p. 22.
([3]) OJ L 88, 4.4.2011, p. 45.
([4]) OJ L 316, 29.11.2011, p. 1.
([5]) OJ L 331, 15.12.2001, p. 79.

# REGULATION (EU) No 1025/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

## of 25 October 2012

## on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council

**(Text with EEA relevance)**

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 114 thereof,

Having regard to the proposal from the European Commission,

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

Having regard to the opinion of the European Economic and Social Committee [1],

Acting in accordance with the ordinary legislative procedure [2],

Whereas:

(1) The primary objective of standardisation is the definition of voluntary technical or quality specifications with which current or future products, production processes or services may comply. Standardisation can cover various issues, such as standardisation of different grades or sizes of a particular product or technical specifications in product or services markets where compatibility and interoperability with other products or systems are essential.

(2) European standardisation is organised by and for the stakeholders concerned based on national representation (the European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (Cenelec)) and direct participation (the European Telecommunications Standards Institute (ETSI)), and is founded on the principles recognised by the World Trade Organisation (WTO) in the field of standardisation, namely coherence, transparency, openness, consensus, voluntary application, independence from special interests and efficiency ('the founding principles'). In accordance with the founding principles, it is important that all relevant interested parties, including public authorities and small and medium-sized enterprises (SMEs), are appropriately involved in the national and European standardisation process. National standardisation bodies should also encourage and facilitate the participation of stakeholders.

(3) European standardisation also helps to boost the competitiveness of enterprises by facilitating in particular the free movement of goods and services, network interoperability, means of communication, technological development and innovation. European standardisation reinforces the global competitiveness of European industry especially when established in coordination with the international standardisation bodies, namely the International Organisation for Standardisation (ISO), the International Electrotechnical Commission (IEC) and the International Telecommunication Union (ITU). Standards produce significant positive economic effects, for example by promoting economic interpenetration on the internal market and encouraging the development of new and improved products or markets and improved supply conditions. Standards thus normally increase competition and lower output and sales costs, benefiting economies as a whole and consumers in particular. Standards may maintain and enhance quality, provide information and ensure interoperability and compatibility, thereby increasing safety and value for consumers.

(4) European standards are adopted by the European standardisation organisations, namely CEN, Cenelec and ETSI.

(5) European standards play a very important role within the internal market, for instance through the use of harmonised standards in the presumption of conformity of products to be made available on the market with the essential requirements relating to those products laid down in the relevant Union harmonisation legislation. Those requirements should be precisely defined in order to avoid misinterpretation on the part of the European standardisation organisations.

(6) Standardisation plays an increasingly important role in international trade and the opening-up of markets. The Union should seek to promote cooperation between European standardisation organisations and international standardisation bodies. The Union should also promote bilateral approaches with third countries to coordinate standardisation efforts and promote European standards, for instance when negotiating agreements or by seconding standardisation experts to third countries. Furthermore the Union should encourage contact

[1] OJ C 376, 22.12.2011, p. 69.

[2] Position of the European Parliament of 11 September 2012 (not yet published in the Official Journal) and decision of the Council of 4 October 2012.

between European standardisation organisations and private forums and consortia, while maintaining the primacy of European standardisation.

(7) European standardisation is governed by a specific legal framework consisting of three different legal acts, namely Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services ([1]), Decision No 1673/2006/EC of the European Parliament and of the Council of 24 October 2006 on the financing of European standardisation ([2]) and Council Decision 87/95/EEC of 22 December 1986 on standardisation in the field of information technology and telecommunications ([3]). However, the current legal framework is no longer up to date with developments in European standardisation over recent decades. Therefore, the current legal framework should be simplified and adapted in order to cover new aspects of standardisation to reflect those latest developments and future challenges in European standardisation. That relates in particular to the increased development of standards for services and the evolution of standardisation deliverables other than formal standards.

(8) The European Parliament's Resolution of 21 October 2010 on the future of European standardisation ([4]), as well as the report of the Expert Panel for the Review of the European Standardization System (Express) of February 2010 entitled 'Standardization for a competitive and innovative Europe: a vision for 2020', have set out an important number of strategic recommendations regarding the review of the European standardisation system.

(9) In order to ensure the effectiveness of standards and standardisation as policy tools for the Union, it is necessary to have an effective and efficient standardisation system which provides a flexible and transparent platform for consensus building between all participants and which is financially viable.

(10) Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market ([5]) establishes general provisions facilitating the exercise of the freedom of establishment for service providers and the free movement of services, while maintaining a high quality of services. It obliges the Member States to encourage, in cooperation with the Commission, the development of voluntary European standards with the aim of facilitating compatibility between services supplied by providers in different Member States, the provision of information to the recipient and the quality of service provision. However, Directive 98/34/EC only applies to standards for products while standards for services are not expressly covered by it. Furthermore, the delineation between services and goods is becoming less relevant in the reality of the internal market. In practice, it is not always possible to clearly distinguish standards for products from standards for services. Many standards for products have a service component while standards for services often also partly relate to products. Thus, it is necessary to adapt the current legal framework to these new circumstances by extending its scope to standards for services.

(11) Like other standards, standards for services are voluntary and should be market-driven, whereby the needs of the economic operators and stakeholders directly or indirectly affected by such standards prevail, and should take into account the public interest and be based on the founding principles, including consensus. They should primarily focus on services linked to products and processes.

(12) The legal framework allowing the Commission to request one or several European standardisation organisations to draft a European standard or European standardisation deliverable for services should be applied while fully respecting the distribution of competences between the Union and the Member States as laid down in the Treaties. This concerns in particular Articles 14, 151, 152, 153, 165, 166 and 168 of the Treaty on the Functioning of the European Union (TFEU) and Protocol (No 26) on Services of General Interest annexed to the Treaty on European Union (TEU) and to the TFEU in accordance with which it remains the exclusive competence of the Member States to define the fundamental principles of their social security, vocational training and health systems and to shape the framework conditions for the management, financing, organisation and delivery of the services supplied within those systems, including - without prejudice to Article 168(4) TFEU and to Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications ([6]) - the definition of requirements, quality and safety standards applicable to them. The Commission should not, by means of such a request, affect the right to negotiate, conclude and enforce collective agreements and to take industrial action in accordance with national law and practices which respect Union law.

(13) The European standardisation organisations are subject to competition law to the extent that they can be considered to be an undertaking or an association of undertakings within the meaning of Articles 101 and 102 TFEU.

([1]) OJ L 204, 21.7.1998, p. 37.
([2]) OJ L 315, 15.11.2006, p. 9.
([3]) OJ L 36, 7.2.1987, p. 31.
([4]) OJ C 70 E, 8.3.2012, p. 56.
([5]) OJ L 376, 27.12.2006, p. 36.
([6]) OJ L 255, 30.9.2005, p. 22.

(14) Within the Union, national standards are adopted by national standardisation bodies which could lead to conflicting standards and technical impediments in the internal market. Therefore, it is necessary for the internal market and for the effectiveness of standardisation within the Union to confirm the existing regular exchange of information between the national standardisation bodies, the European standardisation organisations and the Commission, about their current and future standardisation activities as well as the standstill principle applicable to the national standardisation bodies within the framework of the European standardisation organisations which provides for the withdrawal of national standards after the publication of a new European standard. The national standardisation bodies and European standardisation organisations should also observe the provisions on exchange of information in Annex 3 to the Agreement on Technical Barriers to Trade ([1]).

(15) The Member States' obligation to notify the Commission of their national standardisation bodies should not require the adoption of a specific national legislation for the purposes of recognition of those bodies.

(16) The regular exchange of information between the national standardisation bodies, the European standardisation organisations and the Commission should not prevent national standardisation bodies from complying with other obligations and commitments, and in particular with Annex 3 to the Agreement on Technical Barriers to Trade.

(17) The representation of societal interests and societal stakeholders in European standardisation activities refers to the activities of organisations and parties representing interests of greater societal relevance, for instance environmental, consumer interests or employee interests. However, the representation of social interests and social stakeholders in European standardisation activities refers particularly to the activities of organisations and parties representing employees and workers' basic rights, for instance trade unions.

(18) In order to speed up the decision-making process, national standardisation bodies and European standardisation organisations should facilitate accessible information on their activities through the promotion of the use of information and communication technologies (ICT) in their respective standardisation systems, for example by providing to all relevant stakeholders an easy-to-use online consultation mechanism for the submission of comments on draft standards and by organising virtual meetings, including by means of web conferencing or video conferencing, of technical committees.

([1]) Approved by Council Decision 94/800/EC of 22 December 1994 concerning the conclusion on behalf of the European Community, as regards matters within its competence, of the agreements reached in the Uruguay Round multilateral negotiations (1986-1994) (OJ L 336, 23.12.1994, p. 1).

(19) Standards can contribute to helping Union policy address the major societal challenges such as climate change, sustainable resource use, innovation, ageing population, integration of people with disabilities, consumer protection, workers' safety and working conditions. By driving the development of European or international standards for goods and technologies in the expanding markets in those areas, the Union could create a competitive advantage for its enterprises and facilitate trade, in particular for SMEs, which account for a large part of European enterprises.

(20) Standards are important tools for the competitiveness of undertakings and especially SMEs, whose participation in the standardisation process is important for technological progress in the Union. Therefore it is necessary that the standardisation framework encourage SMEs to actively participate in and provide their innovative technology solutions to standardisation efforts. This includes improving their participation at national level where they can be more effective due to lower costs and lack of linguistic barriers. Consequently this Regulation should improve representation and participation of SMEs in both national and European technical committees and should facilitate their effective access to and awareness of standards.

(21) European standards are of vital interest for the competitiveness of SMEs which, however, are in some cases under-represented in European standardisation activities. Thus, this Regulation should encourage and facilitate appropriate representation and participation of SMEs in the European standardisation process by an entity that is effectively in contact with, and duly representative of, SMEs and organisations representing SMEs at national level.

(22) Standards can have a broad impact on society, in particular on the safety and well-being of citizens, the efficiency of networks, the environment, workers' safety and working conditions, accessibility and other public policy fields. Therefore, it is necessary to ensure that the role and the input of societal stakeholders in the development of standards are strengthened, through the reinforced support of organisations representing consumers and environmental and social interests.

(23) The obligation of the European standardisation organisations to encourage and facilitate representation and effective participation of all relevant stakeholders does not entail any voting rights for these stakeholders unless such voting rights are prescribed by the internal rules of procedure of the European standardisation organisations.

(24) The European standardisation system should also fully take into account the United Nations Convention on the Rights of Persons with Disabilities [1]. It is therefore important that organisations representing the interests of consumers sufficiently represent and include the interests of people with disabilities. In addition, the participation of people with disabilities in the standardisation process should be facilitated by all available means.

(25) Due to the importance of standardisation as a tool to support Union legislation and policies and in order to avoid *ex-post* objections to and modifications of harmonised standards, it is important that public authorities participate in standardisation at all stages of the development of those standards where they may be involved and especially in the areas covered by Union harmonisation legislation for products.

(26) Standards should take into account environmental impacts throughout the life cycle of products and services. Important and publicly available tools for evaluating such impacts throughout the life cycle have been developed by the Commission's Joint Research Centre (JRC). Thus, this Regulation should ensure that the JRC can play an active role in the European standardisation system.

(27) The viability of the cooperation between the Commission and the European standardisation system depends on careful planning of future requests for the development of standards. This planning could be improved, in particular through the input of interested parties, including national market surveillance authorities, by introducing mechanisms for collecting opinions and facilitating the exchange of information among all interested parties. Since Directive 98/34/EC already provides for the possibility to request the European standardisation organisations to develop European standards, it is appropriate to put in place a better and more transparent planning in an annual work programme which should contain an overview of all requests for standards which the Commission intends to submit to European standardisation organisations. It is necessary to ensure a high level of cooperation between the European standardisation organisations and the European stakeholder organisations receiving Union financing in accordance with this Regulation and the Commission in the establishment of its annual Union work programme for standardisation and in the preparation of requests for standards in order to analyse the market relevance of the proposed subject matter and the policy objectives set by the legislator, and to allow the European standardisation organisations to respond more quickly to the requested standardisation activities.

(28) Before bringing a matter regarding requests for European standards or European standardisation deliverables, or objections to a harmonised standard before the committee set up by this Regulation, the Commission should consult experts of the Member States, for instance through the involvement of committees set up by the corresponding Union legislation or by other forms of consultation of sectoral experts, where such committees do not exist.

(29) Several directives harmonising the conditions for the marketing of products specify that the Commission may request the adoption, by the European standardisation organisations, of harmonised standards on the basis of which conformity with the applicable essential requirements is presumed. However, many of those directives contain a wide variety of provisions on objections to these standards when the latter do not, or do not entirely, cover all applicable requirements. Diverging provisions which lead to uncertainty for economic operators and European standardisation organisations are in particular contained in Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment [2], Council Directive 93/15/EEC of 5 April 1993 on the harmonisation of the provisions relating to the placing on the market and supervision of explosives for civil uses [3], Directive 94/9/EC of the European Parliament and the Council of 23 March 1994 on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres [4], Directive 94/25/EC of the European Parliament and of the Council of 16 June 1994 on the approximation of the laws, regulations and administrative provisions of the Member States relating to recreational craft [5], European Parliament and Council Directive 95/16/EC of 29 June 1995 on the approximation of the laws of the Member States relating to lifts [6], Directive 97/23/EC of the European Parliament and of the Council of 29 May 1997 on the approximation of the laws of the Member States concerning pressure equipment [7], Directive 2004/22/EC of the European Parliament and of the Council of 31 March 2004 on measuring instruments [8], Directive 2007/23/EC of the European Parliament and of the Council of 23 May 2007 on the placing on the market of pyrotechnic articles [9], Directive 2009/23/EC of the European Parliament and of the Council of

[1] Approved by Council Decision 2010/48/EC of 26 November 2009 concerning the conclusion, by the European Community, of the United Nations Convention on the Rights of Persons with Disabilities (OJ L 23, 27.1.2010, p. 35).

[2] OJ L 399, 30.12.1989, p. 18.
[3] OJ L 121, 15.5.1993, p. 20.
[4] OJ L 100, 19.4.1994, p. 1.
[5] OJ L 164, 30.6.1994, p. 15.
[6] OJ L 213, 7.9.1995, p. 1.
[7] OJ L 181, 9.7.1997, p. 1.
[8] OJ L 135, 30.4.2004, p. 1.
[9] OJ L 154, 14.6.2007, p. 1.

23 April 2009 on non-automatic weighing instruments [1] and Directive 2009/105/EC of the European Parliament and of the Council of 16 September 2009 relating to simple pressure vessels [2]. Therefore, it is necessary to include in this Regulation the uniform procedure provided for in Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products [3], delete the relevant provisions in those Directives and extend to the European Parliament the right to object to a harmonised standard in accordance with this Regulation.

(30) Public authorities should make best use of the full range of relevant technical specifications when procuring hardware, software and information technology services, for example by selecting technical specifications which can be implemented by all interested suppliers, allowing for more competition and reduced risk of lock-in. Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors [4], Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts [5], Directive 2009/81/EC of the European Parliament and of the Council of 13 July 2009 on the coordination of procedures for the award of certain works contracts, supply contracts and service contracts by contracting authorities or entities in the fields of defence and security [6] and Commission Regulation (EC, Euratom) No 2342/2002 of 23 December 2002 laying down detailed rules for the implementation of Council Regulation (EC, Euratom) No 1605/2002 on the Financial Regulation applicable to the general budget of the European Communities [7] specify that technical specifications in public procurement should be formulated by reference to national standards transposing European standards, European technical approvals, common technical specifications, international standards, other technical reference systems established by the European standardisation organisations or - when these do not exist - to national standards, national technical approvals or national technical specifications relating to the design, calculation and execution of the works and use of the products, or equivalent. ICT technical specifications, however, are often developed by other standard developing organisations and do not fall in any of the categories of standards and approvals laid down in Directives 2004/17/EC, 2004/18/EC or 2009/81/EC or Regulation (EC, Euratom) No 2342/2002. Therefore, it is necessary to provide for the possibility that technical specifications for public procurement could refer to ICT technical specifications, in order to respond to the fast evolution in the field of ICT, facilitate the provision of cross-border services, encourage competition and promote interoperability and innovation.

(31) Technical specifications not adopted by European standardisation organisations do not hold an equivalent status to European standards. Some ICT technical specifications are not developed in accordance with the founding principles. Therefore, this Regulation should lay down a procedure for the identification of ICT technical specifications that could be referenced in public procurement, involving a broad consultation of a large spectrum of stakeholders, including the European standardisation organisations, enterprises and public authorities. This Regulation should also lay down requirements, in the form of a list of criteria, for such technical specifications and their associated development processes. The requirements for the identification of ICT technical specifications should ensure that public policy objectives and societal needs are respected, and should be based on the founding principles.

(32) In order to further innovation and competition, the identification of a particular technical specification should not disqualify a competing technical specification from being identified in accordance with the provisions of this Regulation. Any identification should be subject to the criteria being fulfilled and to the technical specification having achieved a significant level of market acceptance.

(33) The identified ICT technical specifications could contribute to the implementation of Decision No 922/2009/EC of the European Parliament and of the Council of 16 September 2009 on interoperability solutions for European public administrations (ISA) [8] which establishes, for the period 2010-2015, a programme on interoperability solutions for European public administrations and institutions and bodies of the Union, providing common and shared solutions facilitating interoperability.

(34) Situations may arise in the field of ICT where it is appropriate to encourage the use of, or require compliance, with relevant standards at Union level in order to ensure interoperability in the single market and to improve freedom of choice for users. In other circumstances, it may also happen that specified European standards no longer meet consumers' needs or are hampering technological development. For these reasons, Directive 2002/21/EC of the European Parliament and of the Council of 7 March 2002 on a common regulatory framework for electronic communications networks and services [9] enables the

[1] OJ L 122, 16.5.2009, p. 6.
[2] OJ L 264, 8.10.2009, p. 12.
[3] OJ L 218, 13.8.2008, p. 82.
[4] OJ L 134, 30.4.2004, p. 1.
[5] OJ L 134, 30.4.2004, p. 114.
[6] OJ L 216, 20.8.2009, p. 76.
[7] OJ L 357, 31.12.2002, p. 1.
[8] OJ L 260, 3.10.2009, p. 20.
[9] OJ L 108, 24.4.2002, p. 33.

Commission, where necessary, to request European standardisation organisations to draw up standards, to establish and publish in the *Official Journal of the European Union* a list of standards or specifications with the view to encourage their use, or to make their implementation compulsory, or to remove standards or specifications from that list.

(35) This Regulation should not prevent European standardisation organisations from continuing to develop standards in the field of ICT and to increase their cooperation with other standard developing bodies, especially in the field of ICT, in order to ensure coherence and avoid fragmentation or duplication during implementation of standards and specifications.

(36) The procedure for identification of ICT technical specifications provided for in this Regulation should not undermine the coherence of the European standardisation system. Therefore, this Regulation should also lay down the conditions under which it can be considered that a technical specification does not conflict with other European standards.

(37) Before identifying ICT technical specifications which may be eligible for referencing in public procurement, the Multi Stakeholder Platform established by the Commission Decision of 28 November 2011 [1] should be used as a forum for consultation of European and national stakeholders, European standardisation organisations and Member States in order to ensure legitimacy of the process.

(38) Decision No 1673/2006/EC establishes the rules concerning the contribution of the Union to the financing of European standardisation in order to ensure that European standards and other European standardisation deliverables are developed and revised in support of the objectives, legislation and policies of the Union. It is appropriate, for the purpose of administrative and budgetary simplification, to incorporate the provisions of that Decision into this Regulation and to use wherever possible the least burdensome procedures.

(39) In view of the very broad field of involvement of European standardisation in support of Union legislation and policies and the different types of standardisation activity, it is necessary to provide for different financing arrangements. This mainly concerns grants without calls for proposals to the European standardisation organisations and national standardisation bodies in accordance with the second subparagraph of Article 110(1) of Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities [2] and point (d) of Article 168(1) of Regulation (EC, Euratom) No 2342/2002. Furthermore, the same provisions should apply to those bodies which, whilst not recognised as European standardisation organisations in this Regulation, have been mandated in a basic act and have been entrusted with carrying out preliminary work in support of European standardisation in cooperation with the European standardisation organisations.

(40) Inasmuch as European standardisation organisations provide ongoing support for Union activities, they should have effective and efficient central secretariats. The Commission should therefore be allowed to provide grants to those organisations that are pursuing an objective of general European interest without applying, in the case of operating grants, the principle of annual reduction provided for in Article 113(2) of Regulation (EC, Euratom) No 1605/2002.

(41) Decision No 1639/2006/EC of the European Parliament and of the Council of 24 October 2006 establishing a Competitiveness and Innovation Framework Programme (2007 to 2013) [3], Decision No 1926/2006/EC of the European Parliament and of the Council of 18 December 2006 establishing a programme of Community action in the field of consumer policy (2007-2013) [4] and Regulation (EC) No 614/2007 of the European Parliament and of the Council of 23 May 2007 concerning the Financial Instrument for the Environment (LIFE+) [5] already provide for the possibility of financial support of European organisations representing SMEs, consumers and environmental interests in standardisation, while specific grants are paid to European organisations representing social interests in standardisation. The financing under Decision No 1639/2006/EC, Decision No 1926/2006/EC and Regulation (EC) No 614/2007 will end on 31 December 2013. It is essential for the development of European standardisation to continue fostering and encouraging the active participation of European organisations representing SMEs, consumers and environmental and social interests. Such organisations pursue an aim of general European interest and constitute, by virtue of the specific mandate that national non-profit organisations have given them, a European network representing non-profit organisations active in the Member States and promoting principles and policies consistent with the objectives of the Treaties. Because of the context in which they operate and their statutory objectives, European organisations representing SMEs, consumers and environmental and social interests in European standardisation have a permanent role which is essential for Union objectives and policies. Therefore, the Commission should be in a position to continue providing grants to those organisations without

[1] OJ C 349, 30.11.2011, p. 4.

[2] OJ L 248, 16.9.2002, p. 1.
[3] OJ L 310, 9.11.2006, p. 15.
[4] OJ L 404, 30.12.2006, p. 39.
[5] OJ L 149, 9.6.2007, p. 1.

applying, in the case of operating grants, the principle of annual reduction provided for in Article 113(2) of Regulation (EC, Euratom) No 1605/2002.

(42) The financing of standardisation activities should also be capable of covering preliminary or ancillary activities in connection with the establishment of European standards or European standardisation deliverables for products and for services. This is necessary primarily for work involving research, the preparation of preliminary documents for legislation, inter-laboratory tests and the validation or evaluation of standards. The promotion of standardisation at European and international level should also continue through programmes relating to the technical assistance to, and cooperation with, third countries. With a view to improving market access and boosting the competitiveness of enterprises in the Union, it should be possible to give grants to other bodies through calls for proposals or, where necessary, by awarding contracts.

(43) Union financing should seek to establish European standards or European standardisation deliverables for products and for services, to facilitate their use by enterprises through the enhanced support for their translation into the various official Union languages, in order to allow SMEs to fully benefit from the understanding and application of the European standards, to strengthen the cohesion of the European standardisation system and to ensure fair and transparent access to European standards for all market players throughout the Union. This is especially important in cases where the use of standards enables compliance with relevant Union legislation.

(44) In order to ensure the effective application of this Regulation, there should be the possibility of using the requisite expertise, particularly with regard to auditing and financial management, as well as administrative support resources capable of facilitating implementation, and of evaluating on a regular basis the relevance of the activities receiving Union financing in order to ensure their usefulness and impact.

(45) Appropriate measures should also be taken to avoid fraud and irregularities and to recover funds unduly paid in accordance with Council Regulations (EC, Euratom) No 2988/95 of 18 December 1995 on the protection of the European Communities financial interests ([1]) and (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities ([2]) and Regulation (EC) No 1073/1999 of the European Parliament and of the Council of 25 May 1999 concerning investigations conducted by the European Anti-Fraud Office (OLAF) ([3]).

(46) In order to update the list of European standardisation organisations and to adapt the criteria for organisations representing SMEs and societal stakeholders to further developments as regards their non-profit making nature and representativity, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of amendments to the Annexes to this Regulation. It 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.

(47) The committee set up by this Regulation should assist the Commission in all matters related to the implementation of this Regulation, having due regard for the views of sectoral experts.

(48) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. 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 ([4]).

(49) The advisory procedure should be used for the adoption of implementing acts with respect to the objections to harmonised standards and where the references to the harmonised standard concerned have not yet been published in the *Official Journal of the European Union*, given that the relevant standard has not yet led to the presumption of conformity with the essential requirements set out in the applicable Union harmonisation legislation.

(50) The examination procedure should be used for each standardisation request submitted to European standardisation organisations and the adoption of implementing acts with respect to the objections to harmonised standards and where the references to the harmonised standard concerned have already been published in the *Official Journal of the European Union*, given that such decision could have consequences on the presumption of conformity with the applicable essential requirements.

([1]) OJ L 312, 23.12.1995, p. 1.
([2]) OJ L 292, 15.11.1996, p. 2.
([3]) OJ L 136, 31.5.1999, p. 1.
([4]) OJ L 55, 28.2.2011, p. 13.

(51) In order to achieve the main objectives of this Regulation and to facilitate speedy decision-making procedures as well as reducing the overall development time for standards, use should be made as far as possible of the procedural measures provided for in Regulation (EU) No 182/2011, which enables the chair of the relevant committee to lay down a time limit within which the committee should deliver its opinion, according to the urgency of the matter. Moreover, where justified, it should be possible for the opinion of the committee to be obtained by written procedure, and silence on the part of the committee member should be regarded as tacit agreement.

(52) Since the objectives of this Regulation, namely to ensure the effectiveness and efficiency of standards and standardisation as policy tools for the Union through cooperation between European standardisation organisations, national standardisation bodies, Member States and the Commission, the establishment of European standards and European standardisation deliverables for products and for services in support of Union legislation and policies, the identification of ICT technical specifications eligible for referencing, the financing of European standardisation and stakeholder participation in European standardisation cannot be sufficiently achieved by the Member States and can, therefore, by reason of their effect, be better achieved at the Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 TEU. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

(53) Directives 89/686/EEC, 93/15/EEC, 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC should therefore be amended accordingly.

(54) Decision No 1673/2006/EC and Decision 87/95/EEC should be repealed,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

**GENERAL PROVISIONS**

*Article 1*

**Subject matter**

This Regulation establishes rules with regard to the cooperation between European standardisation organisations, national standardisation bodies, Member States and the Commission, the establishment of European standards and European standardisation deliverables for products and for services in support of Union legislation and policies, the identification of ICT technical specifications eligible for referencing, the financing of European standardisation and stakeholder participation in European standardisation.

*Article 2*

**Definitions**

For the purposes of this Regulation, the following definitions shall apply:

(1) 'standard' means a technical specification, adopted by a recognised standardisation body, for repeated or continuous application, with which compliance is not compulsory, and which is one of the following:

(a) 'international standard' means a standard adopted by an international standardisation body;

(b) 'European standard' means a standard adopted by a European standardisation organisation;

(c) 'harmonised standard' means a European standard adopted on the basis of a request made by the Commission for the application of Union harmonisation legislation;

(d) 'national standard' means a standard adopted by a national standardisation body;

(2) 'European standardisation deliverable' means any other technical specification than a European standard, adopted by a European standardisation organisation for repeated or continuous application and with which compliance is not compulsory;

(3) 'draft standard' means a document containing the text of the technical specifications concerning a given subject, which is being considered for adoption in accordance with the relevant standards procedure, as that document stands after the preparatory work and as circulated for public comment or scrutiny;

(4) 'technical specification' means a document that prescribes technical requirements to be fulfilled by a product, process, service or system and which lays down one or more of the following:

(a) the characteristics required of a product including levels of quality, performance, interoperability, environmental protection, health, safety or dimensions, and including the requirements applicable to the product as regards the name under which the product is sold, terminology, symbols, testing and test methods, packaging, marking or labelling and conformity assessment procedures;

(b) production methods and processes used in respect of agricultural products as defined in Article 38(1) TFEU, products intended for human and animal consumption, and medicinal products, as well as production methods and processes relating to other products, where these have an effect on their characteristics;

(c) the characteristics required of a service including levels of quality, performance, interoperability, environmental protection, health or safety, and including the requirements applicable to the provider as regards the information to be made available to the recipient, as specified in Article 22(1) to (3) of Directive 2006/123/EC;

(d) the methods and the criteria for assessing the performance of construction products, as defined in point 1 of Article 2 of Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products [1], in relation to their essential characteristics;

(5) 'ICT technical specification' means a technical specification in the field of information and communication technologies;

(6) 'product' means any industrially manufactured product and any agricultural product, including fish products;

(7) 'service' means any self-employed economic activity normally provided for remuneration, as defined in Article 57 TFEU;

(8) 'European standardisation organisation' means an organisation listed in Annex I;

(9) 'international standardisation body' means the International Organisation for Standardisation (ISO), the International Electrotechnical Commission (IEC) and the International Telecommunication Union (ITU);

(10) 'national standardisation body' means a body notified to the Commission by a Member State in accordance with Article 27 of this Regulation.

CHAPTER II

**TRANSPARENCY AND STAKEHOLDER PARTICIPATION**

*Article 3*

**Transparency of work programmes of standardisation bodies**

1. At least once a year, each European standardisation organisation and national standardisation body shall establish its work programme. That work programme shall contain information on the standards and European standardisation deliverables which a European standardisation organisation or national standardisation body intends to prepare or amend, which it is preparing or amending and which it has adopted in the period of the preceding work programme, unless these are identical or equivalent transpositions of international or European standards.

2. The work programme shall indicate, in respect of each standard and European standardisation deliverable:

(a) the subject matter;

(b) the stage attained in the development of the standards and European standardisation deliverables;

(c) the references of any international standards taken as a basis.

3. Each European standardisation organisation and national standardisation body shall make its work programme available on its website or any other publicly available website, as well as make a notice of the existence of the work programme available in a national or, where appropriate, European publication of standardisation activities.

4. No later than at the time of publication of its work programme, each European standardisation organisation and national standardisation body shall notify the existence thereof to the other European standardisation organisations and national standardisation bodies and to the Commission. The Commission shall make that information available to the Member States via the committee referred to in Article 22.

5. National standardisation bodies may not object to a subject for standardisation in their work programme being considered at European level in accordance with the rules laid down by the European standardisation organisations and may not undertake any action which could prejudice a decision in this regard.

6. During the preparation of a harmonised standard or after its approval, national standardisation bodies shall not take any action which could prejudice the harmonisation intended and, in particular, shall not publish in the field in question a new or revised national standard which is not completely in line with an existing harmonised standard. After publication of a new harmonised standard, all conflicting national standards shall be withdrawn within a reasonable deadline.

*Article 4*

**Transparency of standards**

1. Each European standardisation organisation and national standardisation body shall send at least in electronic form any draft national standard, European standard or European standardisation deliverable to other European standardisation organisations, national standardisation bodies or the Commission, upon their request.

2. Each European standardisation organisation and national standardisation body shall within three months reply to, and take due account of, any comments received from any other

[1] OJ L 88, 4.4.2011, p. 5.

European standardisation organisation, national standardisation body or the Commission with respect to any draft referred to in paragraph 1.

3. When a national standardisation body receives comments indicating that the draft standard would have a negative impact on the internal market, it shall consult the European standardisation organisations and the Commission before adopting it.

4. National standardisation bodies shall:

(a) ensure access to draft national standards in such a way that all relevant parties in particular those established in other Member States have the opportunity to submit comments;

(b) allow other national standardisation bodies to be involved passively or actively, by sending an observer, in the planned activities.

*Article 5*

**Stakeholder participation in European standardisation**

1. European standardisation organisations shall encourage and facilitate an appropriate representation and effective participation of all relevant stakeholders, including SMEs, consumer organisations and environmental and social stakeholders in their standardisation activities. They shall in particular encourage and facilitate such representation and participation through the European stakeholder organisations receiving Union financing in accordance with this Regulation at the policy development level and at the following stages of the development of European standards or European standardisation deliverables:

(a) the proposal and acceptance of new work items;

(b) the technical discussion on proposals;

(c) the submission of comments on drafts;

(d) the revision of existing European standards or European standardisation deliverables;

(e) the dissemination of information of, and awareness-building about, adopted European standards or European standardisation deliverables.

2. In addition to the collaboration with market surveillance authorities in the Member States, research facilities of the Commission and the European stakeholder organisations receiving Union financing in accordance with this Regulation, European standardisation organisations shall encourage and facilitate appropriate representation, at technical level, of undertakings, research centres, universities and other legal entities, in standardisation activities concerning an emerging area with significant policy or technical innovation implications, if the legal entities concerned participated in a project that is related to that area and that is funded by the Union under a multi-annual framework programme for activities in the area of research, innovation and technological development, adopted pursuant to Article 182 TFEU.

*Article 6*

**Access of SMEs to standards**

1. National standardisation bodies shall encourage and facilitate the access of SMEs to standards and standards development processes in order to reach a higher level of participation in the standardisation system, for instance by:

(a) identifying, in their annual work programmes, the standardisation projects, which are of particular interests to SMEs;

(b) giving access to standardisation activities without obliging SMEs to become a member of a national standardisation body;

(c) providing free access or special rates to participate in standardisation activities;

(d) providing free access to draft standards;

(e) making available free of charge on their website abstracts of standards;

(f) applying special rates for the provision of standards or providing bundles of standards at a reduced price.

2. National standardisation bodies shall exchange best practices aiming to enhance the participation of SMEs in standardisation activities and to increase and facilitate the use of standards by SMEs.

3. National standardisation bodies shall send annual reports to the European standardisation organisations with regards to their activities in paragraphs 1 and 2 and all other measures to improve conditions for SMEs to use standards and to participate in the standards development process. The national standardisation bodies shall publish those reports on their websites.

*Article 7*

**Participation of public authorities in European standardisation**

Member States shall, where appropriate, encourage participation of public authorities, including market surveillance authorities, in national standardisation activities aimed at the development or revision of standards requested by the Commission in accordance with Article 10.

CHAPTER III

## EUROPEAN STANDARDS AND EUROPEAN STANDARDISATION DELIVERABLES IN SUPPORT OF UNION LEGISLATION AND POLICIES

*Article 8*

### The annual Union work programme for European standardisation

1. The Commission shall adopt an annual Union work programme for European standardisation which shall identify strategic priorities for European standardisation, taking into account Union long-term strategies for growth. It shall indicate the European standards and European standardisation deliverables that the Commission intends to request from the European standardisation organisations in accordance with Article 10.

2. The annual Union work programme for European standardisation shall define the specific objectives and policies for the European standards and European standardisation deliverables that the Commission intends to request from the European standardisation organisations in accordance with Article 10. In cases of urgency the Commission can issue requests without prior indication.

3. The annual Union work programme for European standardisation shall also include objectives for the international dimension of European standardisation, in support of Union legislation and policies.

4. The annual Union work programme for European standardisation shall be adopted after having conducted a broad consultation of relevant stakeholders, including European standardisation organisations and European stakeholder organisations receiving Union financing in accordance with this Regulation, and Member States via the committee referred to in Article 22 of this Regulation.

5. After its adoption, the Commission shall make the annual Union work programme for European standardisation available on its website.

*Article 9*

### Cooperation with research facilities

The Commission's research facilities shall contribute to the preparation of the annual Union work programme for European standardisation referred to in Article 8 and provide European standardisation organisations with scientific input, in their areas of expertise, to ensure that European standards take into account economic competitiveness and societal needs such as environmental sustainability and safety and security concerns.

*Article 10*

### Standardisation requests to European standardisation organisations

1. The Commission may within the limitations of the competences laid down in the Treaties, request one or several European standardisation organisations to draft a European standard or European standardisation deliverable within a set deadline. European standards and European standardisation deliverables shall be market-driven, take into account the public interest as well as the policy objectives clearly stated in the Commission's request and based on consensus. The Commission shall determine the requirements as to the content to be met by the requested document and a deadline for its adoption.

2. The decisions referred to in paragraph 1 shall be adopted in accordance with the procedure laid down in Article 22(3) after consultation of the European standardisation organisations and the European stakeholder organisations receiving Union financing in accordance with this Regulation as well as the committee set up by the corresponding Union legislation, when such a committee exists, or after other forms of consultation of sectoral experts.

3. The relevant European standardisation organisation shall indicate, within one month following its receipt, if it accepts the request referred to in paragraph 1.

4. Where a request for funding is made, the Commission shall inform the relevant European standardisation organisations, within two months following the receipt of the acceptance referred to in paragraph 3, about the award of a grant for drafting a European standard or a European standardisation deliverable.

5. The European standardisation organisations shall inform the Commission about the activities undertaken for the development of the documents referred to in paragraph 1. The Commission together with the European standardisation organisations shall assess the compliance of the documents drafted by the European standardisation organisations with its initial request.

6. Where a harmonised standard satisfies the requirements which it aims to cover and which are set out in the corresponding Union harmonisation legislation, the Commission shall publish a reference of such harmonised standard without delay in the *Official Journal of the European Union* or by other means in accordance with the conditions laid down in the corresponding act of Union harmonisation legislation.

*Article 11*

### Formal objections to harmonised standards

1. When a Member State or the European Parliament considers that a harmonised standard does not entirely satisfy the requirements which it aims to cover and which are set out in the relevant Union harmonisation legislation, it shall inform the Commission thereof with a detailed explanation and the Commission shall, after consulting the committee set up by the corresponding Union harmonisation legislation, if it exists, or after other forms of consultation of sectoral experts, decide:

(a) to publish, not to publish or to publish with restriction the references to the harmonised standard concerned in the *Official Journal of the European Union*;

(b) to maintain, to maintain with restriction or to withdraw the references to the harmonised standard concerned in or from the *Official Journal of the European Union*.

2. The Commission shall publish information on its website on the harmonised standards that have been subject to the decision referred to in paragraph 1.

3. The Commission shall inform the European standardisation organisation concerned of the decision referred to in paragraph 1 and, if necessary, request the revision of the harmonised standards concerned.

4. The decision referred to in point (a) of paragraph 1 of this Article shall be adopted in accordance with the advisory procedure referred to in Article 22(2).

5. The decision referred to in point (b) of paragraph 1 of this Article shall be adopted in accordance with the examination procedure referred to in Article 22(3).

*Article 12*

**Notification of stakeholder organisations**

The Commission shall establish a notification system for all stakeholders, including European standardisation organisations and European stakeholder organisations receiving Union financing in accordance with this Regulation in order to ensure proper consultation and market relevance prior to:

(a) adopting the annual Union work programme for European standardisation referred to in Article 8(1);

(b) adopting standardisation requests referred to in Article 10;

(c) taking a decision on formal objections to harmonised standards, as referred to in Article 11(1);

(d) taking a decision on identifications of ICT technical specifications referred to in Article 13;

(e) adopting delegated acts referred to in Article 20.

CHAPTER IV

**ICT TECHNICAL SPECIFICATIONS**

*Article 13*

**Identification of ICT technical specifications eligible for referencing**

1. Either on proposal from a Member State or on its own initiative the Commission may decide to identify ICT technical specifications that are not national, European or international standards, but meet the requirements set out in Annex II, which may be referenced, primarily to enable interoperability, in public procurement.

2. Either on proposal from a Member State or on its own initiative, when an ICT technical specification identified in accordance with paragraph 1 is modified, withdrawn or no longer meets the requirements set out in Annex II, the Commission may decide to identify the modified ICT technical specification or to withdraw the identification.

3. The decisions provided for in paragraphs 1 and 2 shall be adopted after consultation of the European multi-stakeholder platform on ICT standardisation, which includes European standardisation organisations, Member States and relevant stakeholders, and after consultation of the committee set up by the corresponding Union legislation, if it exists, or after other forms of consultation of sectoral experts, if such a committee does not exist.

*Article 14*

**Use of ICT technical specifications in public procurement**

The ICT technical specifications referred to in Article 13 of this Regulation shall constitute common technical specifications referred to in Directives 2004/17/EC, 2004/18/EC and 2009/81/EC, and Regulation (EC, Euratom) No 2342/2002.

CHAPTER V

**FINANCING OF EUROPEAN STANDARDISATION**

*Article 15*

**Financing of standardisation organisations by the Union**

1. The financing by the Union may be granted to the European standardisation organisations for the following standardisation activities:

(a) the development and revision of European standards or European standardisation deliverables which is necessary and suitable for the support of Union legislation and policies;

(b) the verification of the quality, and conformity to the corresponding Union legislation and policies, of European standards or European standardisation deliverables;

(c) the performance of preliminary or ancillary work in connection with European standardisation, including studies, cooperation activities, including international cooperation, seminars, evaluations, comparative analyses, research work, laboratory work, inter-laboratory tests, conformity evaluation work and measures to ensure that the periods for the development and the revision of European standards or European standardisation deliverables are shortened without prejudice to the founding principles, especially the principles of openness, quality, transparency and consensus among all stakeholders;

(d) the activities of the central secretariats of the European standardisation organisations, including policy development, the coordination of standardisation activities, the processing of technical work and the provision of information to interested parties;

(e) the translation of European standards or European standardisation deliverables used in support of Union legislation and policies into the official Union languages other than the working languages of the European standardisation organisations or, in duly justified cases into languages other than the official Union languages;

(f) the drawing up of information to explain, interpret and simplify European standards or European standardisation deliverables, including the drawing up of user guides, abstracts of standards, best practice information and awareness-building actions, strategies and training programmes;

(g) activities seeking to carry out programmes of technical assistance, cooperation with third countries and the promotion and enhancement of the European standardisation system and of European standards and European standardisation deliverables among interested parties in the Union and at international level.

2. The financing by the Union may also be granted to:

(a) national standardisation bodies for the standardisation activities referred to in paragraph 1, which they jointly undertake with the European standardisation organisations;

(b) other bodies which have been entrusted with contributing to the activities referred to in point (a) of paragraph 1, or carrying out the activities referred to in points (c) and (g) of paragraph 1, in cooperation with the European standardisation organisations.

*Article 16*

**Financing of other European organisations by the Union**

The financing by the Union may be granted to the European stakeholder organisations meeting the criteria set out in Annex III to this Regulation for the following activities:

(a) the functioning of these organisations and of their activities relating to European and international standardisation, including the processing of technical work and the provision of information to members and other interested parties;

(b) the provision of legal and technical expertise, including studies, in relation to assessment of the need for, and the development of, European standards and European standardisation deliverables and training of experts;

(c) the participation in the technical work with respect to the development and revision of European standards and European standardisation deliverables which is necessary and suitable for the support of Union legislation and policies;

(d) the promotion of European standards and European standardisation deliverables, and the information on, and use of, standards among interested parties, including SMEs and consumers.

*Article 17*

**Financing arrangements**

1. Financing by the Union shall be provided in the form of:

(a) grants without a call for proposals, or contracts after public procurement procedures, to:

(i) European standardisation organisations and national standardisation bodies to carry out the activities referred to in Article 15(1);

(ii) bodies identified by a basic act, within the meaning of Article 49 of Regulation (EC, Euratom) No 1605/2002, to carry out, in collaboration with the European standardisation organisations the activities referred to in point (c) of Article 15(1) of this Regulation;

(b) grants after a call for proposals, or contracts after public procurement procedures, to other bodies referred to in point (b) of Article 15(2):

(i) for contributing to the development and revision of European standards or European standardisation deliverables referred to in point (a) of Article 15(1);

(ii) for carrying out the preliminary or ancillary work referred to in point (c) of Article 15(1);

(iii) for carrying out the activities referred to in point (g) of Article 15(1);

(c) grants after a call for proposals to the European stakeholder organisations meeting the criteria set out in Annex III to this Regulation to carry out the activities referred to in Article 16.

2. The activities of the bodies referred to in paragraph 1 may be financed by:

(a) grants for actions;

(b) operating grants for the European standardisation organisations and the European stakeholder organisations meeting the criteria set out in Annex III to this Regulation in accordance with the rules set out in Regulation (EC, Euratom) No 1605/2002. In the event of renewal, operating grants shall not be automatically decreased.

3. The Commission shall decide on the financing arrangements referred to in paragraphs 1 and 2, on the amounts of the grants and, where necessary, on the maximum percentage of financing by type of activity.

4. Except in duly justified cases, grants awarded for the standardisation activities referred to in points (a) and (b) of Article 15(1) shall take the form of lump sums and for the standardisation activities referred to in point (a) of Article 15(1) shall be paid upon fulfilment of the following conditions:

(a) European standards or European standardisation deliverables requested by the Commission in accordance with Article 10 are adopted or revised within a period not exceeding the period specified in the request referred to in that Article;

(b) SMEs, consumer organisations and environmental and social stakeholders are appropriately represented and can participate in European standardisation activities, as referred to in Article 5(1).

5. The common cooperation objectives and the administrative and financial conditions relating to the grants awarded to European standardisation organisations and the European stakeholder organisations meeting the criteria set out in Annex III to this Regulation shall be defined in the framework partnership agreements between the Commission and those standardisation and stakeholder organisations, in accordance with Regulations (EC, Euratom) No 1605/2002 and (EC, Euratom) No 2342/2002. The Commission shall inform the European Parliament and the Council of the conclusion of those agreements.

*Article 18*

**Management**

The appropriations determined by the budgetary authority for the financing of standardisation activities may also cover the administrative expenses relating to the preparation, monitoring, inspection, auditing and evaluation which are directly necessary for the purposes of implementing Articles 15, 16 and 17, including studies, meetings, information and publication activities, expenses relating to informatics networks for the exchange of information and any other expenditure on administrative and technical assistance which the Commission may use for standardisation activities.

*Article 19*

**Protection of the financial interests of the Union**

1. The Commission shall ensure that, when the activities financed under this Regulation are implemented, the financial interests of the Union are protected by the application of preventive measures against fraud, corruption and other illegal activities, by effective checks and by the recovery of amounts unduly paid and, if irregularities are detected, by effective, proportionate and dissuasive penalties, in accordance with Regulations (EC, Euratom) No 2988/95, (Euratom, EC) No 2185/96 and (EC) No 1073/1999.

2. For the Union activities financed pursuant to this Regulation, the notion of irregularity defined in Article 1(2) of Regulation (EC, Euratom) No 2988/95 shall mean any infringement of a provision of Union law or any breach of a contractual obligation resulting from an act or omission by an economic operator which has, or would have, the effect of prejudicing the general budget of the Union or budgets managed by it by an unjustified item of expenditure.

3. Any agreements and contracts resulting from this Regulation shall provide for monitoring and financial control by the Commission or any representative which it authorises and for audits by the European Court of Auditors, which if necessary may be conducted on the spot.

CHAPTER VI

**DELEGATED ACTS, COMMITTEE AND REPORTING**

*Article 20*

**Delegated acts**

The Commission shall be empowered to adopt delegated acts in accordance with Article 21 concerning amendments to the Annexes, in order to:

(a) update the list of European standardisation organisations set out in Annex I to take into account changes in their name or structure;

(b) adapt the criteria for European stakeholder organisations set out in Annex III to this Regulation to further developments as regards their non-profit making nature and representativity. Such adaptations shall not have the effect of creating any new criteria or abolishing any existing criteria or category of organisation.

*Article 21*

**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 20 shall be conferred on the Commission for a period of five years from 1 January 2013. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in Article 20 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 20 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 at the initiative of the European Parliament or of the Council.

*Article 22*

**Committee procedure**

1. The Commission shall be assisted by a committee. 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.

4. Where the opinion of the committee is to be obtained by written procedure, that procedure shall be terminated without result when, within the time-limit for delivery of the opinion, the chair of the committee so decides or a simple majority of committee members so request.

*Article 23*

**Committee cooperation with standardisation organisations and stakeholders**

The committee referred to in Article 22(1) shall work in cooperation with the European standardisation organisations and the European stakeholder organisations receiving Union financing in accordance with this Regulation.

*Article 24*

**Reports**

1. The European standardisation organisations shall send an annual report on the implementation of this Regulation to the Commission. It shall contain detailed information on the following:

(a) the application of Articles 4, 5, 10, 15 and 17;

(b) the representation of SMEs, consumer organisations and environmental and social stakeholders in national standardisation bodies;

(c) the representation of SMEs on the basis of the annual reports referred to in Article 6(3);

(d) the use of ICT in the standardisation system;

(e) cooperation between the national standardisation bodies and European standardisation organisations.

2. The European stakeholder organisations that received Union financing in accordance with this Regulation shall send an annual report on their activities to the Commission. This report shall contain in particular detailed information about the membership of these organisations and the activities referred to in Article 16.

3. By 31 December 2015 and every five years thereafter, the Commission shall present a report to the European Parliament and to the Council on the implementation of this Regulation. This report shall contain an analysis of the annual reports referred to in paragraphs 1 and 2, an evaluation of the relevance of the standardisation activities receiving Union financing in the light of the requirements of Union legislation and policies as well as an assessment of potential new measures to simplify the financing of European standardisation and to reduce the administrative burden for the European standardisation organisations.

*Article 25*

**Review**

By 2 January 2015, the Commission shall evaluate the impact of the procedure established by Article 10 of this Regulation on the timeframe for issuing standardisation requests. The Commission shall present its conclusions in a report to the European Parliament and to the Council. Where appropriate, that report shall be accompanied by a legislative proposal to amend this Regulation.

CHAPTER VII

**FINAL PROVISIONS**

*Article 26*

**Amendments**

1. The following provisions are deleted:

(a) Article 6(1) of Directive 89/686/EEC;

(b) Article 5 of Directive 93/15/EEC;

(c) Article 6(1) of Directive 94/9/EC;

(d) Article 6(1) of Directive 94/25/EC;

(e) Article 6(1) of Directive 95/16/EC;

(f) Article 6 of Directive 97/23/EC;

(g) Article 14 of Directive 2004/22/EC;

(h) Article 8(4) of Directive 2007/23/EC;

(i) Article 7 of Directive 2009/23/EC;

(j) Article 6 of Directive 2009/105/EC.

References to those deleted provisions shall be construed as references to Article 11 of this Regulation.

2. Directive 98/34/EC is hereby amended as follows:

(a) in Article 1, paragraphs 6 to 10 are deleted;

(b) Articles 2, 3 and 4 are deleted;

(c) in Article 6(1), the words 'with the representatives of the standards institutions referred to in Annexes I and II' are deleted;

(d) in Article 6(3), the first indent is deleted;

(e) in Article 6(4), points (a), (b) and (e) are deleted;

(f) Article 7 is replaced by the following:

'*Article 7*

Member States shall communicate to the Commission, in accordance with Article 8(1), all requests made to standards institutions to draw up technical specifications or a standard for specific products for the purpose of enacting a technical regulation for such products as draft technical regulations, and shall state the grounds for their enactment.';

(g) in Article 11, the second sentence is replaced by the following sentence:

'The Commission shall publish annual statistics on the notifications received in the *Official Journal of the European Union*.';

(h) Annexes I and II are deleted.

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

*Article 27*

**National standardisation bodies**

Member States shall inform the Commission of their standardisation bodies.

The Commission shall publish a list of national standardisation bodies and any updates to that list in the *Official Journal of the European Union*.

*Article 28*

**Transitional provisions**

In Union acts that provide for a presumption of conformity with essential requirements through the application of harmonised standards adopted in accordance with Directive 98/34/EC, references to Directive 98/34/EC shall be construed as references to this Regulation, except references to the committee set up by Article 5 of Directive 98/34/EC regarding technical regulations.

Where a Union act provides for a procedure for objection to harmonised standards, Article 11 of this Regulation shall not apply to that act.

*Article 29*

**Repeal**

Decision No 1673/2006/EC and Decision 87/95/EEC are hereby repealed.

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

*Article 30*

**Entry into force**

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

It shall apply from 1 January 2013.

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

Done at Strasbourg, 25 October 2012.

*For the European Parliament*
*The President*
M. SCHULZ

*For the Council*
*The President*
A. D. MAVROYIANNIS

*ANNEX I*

**EUROPEAN STANDARDISATION ORGANISATIONS**

1. CEN — European Committee for Standardisation
2. Cenelec — European Committee for Electrotechnical Standardisation
3. ETSI — European Telecommunications Standards Institute

*ANNEX II*

**REQUIREMENTS FOR THE IDENTIFICATION OF ICT TECHNICAL SPECIFICATIONS**

1. The technical specifications have market acceptance and their implementations do not hamper interoperability with the implementations of existing European or international standards. Market acceptance can be demonstrated by operational examples of compliant implementations from different vendors.

2. The technical specifications are coherent as they do not conflict with European standards, that is to say they cover domains where the adoption of new European standards is not foreseen within a reasonable period, where existing standards have not gained market uptake or where these standards have become obsolete, and where the transposition of the technical specifications into European standardisation deliverables is not foreseen within a reasonable period.

3. The technical specifications were developed by a non-profit making organisation which is a professional society, industry or trade association or any other membership organisation that within its area of expertise develops ICT technical specifications and which is not a European standardisation organisation, national or international standardisation body, through processes which fulfil the following criteria:

   (a) openness:

   the technical specifications were developed on the basis of open decision-making accessible to all interested parties in the market or markets affected by those technical specifications;

   (b) consensus:

   the decision-making process was collaborative and consensus based and did not favour any particular stakeholder. Consensus means a general agreement, characterised by the absence of sustained opposition to substantial issues by any important part of the concerned interests and by a process that involves seeking to take into account the views of all parties concerned and to reconcile any conflicting arguments. Consensus does not imply unanimity;

   (c) transparency:

   (i) all information concerning technical discussions and decision making was archived and identified;

   (ii) information on new standardisation activities was publicly and widely announced through suitable and accessible means;

   (iii) participation of all relevant categories of interested parties was sought with a view to achieving balance;

   (iv) consideration and response were given to comments by interested parties.

4. The technical specifications meet the following requirements:

   (a) maintenance: ongoing support and maintenance of published specifications are guaranteed over a long period;

   (b) availability: specifications are publicly available for implementation and use on reasonable terms (including for a reasonable fee or free of charge);

   (c) intellectual property rights essential to the implementation of specifications are licensed to applicants on a (fair) reasonable and non-discriminatory basis ((F)RAND), which includes, at the discretion of the intellectual property right-holder, licensing essential intellectual property without compensation;

   (d) relevance:

   (i) the specifications are effective and relevant;

   (ii) specifications need to respond to market needs and regulatory requirements;

   (e) neutrality and stability:

   (i) specifications whenever possible are performance oriented rather than based on design or descriptive characteristics;

   (ii) specifications do not distort the market or limit the possibilities for implementers to develop competition and innovation based upon them;

   (iii) specifications are based on advanced scientific and technological developments;

(f) quality:

(i) the quality and level of detail are sufficient to permit the development of a variety of competing implementations of interoperable products and services;

(ii) standardised interfaces are not hidden or controlled by anyone other than the organisations that adopted the technical specifications.

*ANNEX III*

**EUROPEAN STAKEHOLDER ORGANISATIONS ELIGIBLE FOR UNION FINANCING**

1. A European organisation representing SMEs in European standardisation activities which:

   (a) is non-governmental and non-profit-making;

   (b) has as its statutory objectives and activities to represent the interests of SMEs in the standardisation process at European level, to raise their awareness for standardisation and to motivate them to become involved in the standardisation process;

   (c) has been mandated by non-profit organisations representing SMEs in at least two thirds of the Member States, to represent the interests of SMEs in the standardisation process at European level.

2. A European organisation representing consumers in European standardisation activities which:

   (a) is non-governmental, non-profit-making, and independent of industry, commercial and business or other conflicting interests;

   (b) has as its statutory objectives and activities to represent consumer interests in the standardisation process at European level;

   (c) has been mandated by national non-profit consumer organisations in at least two thirds of the Member States, to represent the interests of consumers in the standardisation process at European level.

3. A European organisation representing environmental interests in European standardisation activities which:

   (a) is non-governmental, non-profit-making, and independent of industry, commercial and business or other conflicting interests;

   (b) has as its statutory objectives and activities to represent environmental interests in the standardisation process at European level;

   (c) has been mandated by national non-profit environmental organisations in at least two thirds of the Member States, to represent environmental interests in the standardisation process at European level.

4. A European organisation representing social interests in European standardisation activities which:

   (a) is non-governmental, non-profit-making, and independent of industry, commercial and business or other conflicting interests;

   (b) has as its statutory objectives and activities to represent social interests in the standardisation process at European level;

   (c) has been mandated by national non-profit social organisations in at least two thirds of the Member States, to represent social interests in the standardisation process at European level.

*ANNEX IV*

**CORRELATION TABLE**

| Directive 98/34/EC | This Regulation |
|---|---|
| Article 1, first paragraph, point (6) | Article 2(1) |
| Article 1, first paragraph, point (7) | — |
| Article 1, first paragraph, point (8) | Article 2(3) |
| Article 1, first paragraph, point (9) | Article 2(8) |
| Article 1, first paragraph, point (10) | Article 2(10) |
| Article 2(1) | Article 3(1) |
| Article 2(2) | Article 3(2) |
| Article 2(3) | Article 3(3) and (4) |
| Article 2(4) | Article 27 |
| Article 2(5) | Article 20(a) |
| Article 3 | Article 4(1) |
| Article 4(1) | Article 3(3) and (5) and Article 4(4) |
| Article 4(2) | — |
| Article 6(3), first indent | — |
| Article 6(4)(a) | Article 20(a) |
| Article 6(4)(b) | — |
| Article 6(4)(e) | Article 10(2) |
| Annex I | Annex I |
| Annex II | Article 27 |
| Decision No 1673/2006/EC | This Regulation |
| Article 1 | Article 1 |
| Articles 2 and 3 | Article 15 |
| Article 4 | — |
| Article 5 | Article 17 |
| Article 6(1) | Article 18 |
| Article 6(2) | Article 24(3) |
| Article 7 | Article 19 |
| Decision 87/95/EEC | This Regulation |
| Article 1 | Article 2 |
| Article 2 | Article 3 |
| Article 3 | Article 13 |

| Decision 87/95/EEC | This Regulation |
|---|---|
| Article 4 | Article 8 |
| Article 5 | Article 14 |
| Article 6 | — |
| Article 7 | — |
| Article 8 | Article 24(3) |
| Article 9 | — |

# REGULATION (EU) No 1026/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

## of 25 October 2012

## on certain measures for the purpose of the conservation of fish stocks in relation to countries allowing non-sustainable fishing

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 43(2) and Article 207 thereof,

Having regard to the proposal from the European Commission,

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

Having regard to the opinion of the European Economic and Social Committee [1],

Acting in accordance with the ordinary legislative procedure [2],

Whereas:

(1) As provided in the United Nations Convention on the Law of the Sea of 10 December 1982 ('UNCLOS') and in the United Nations Agreement for the Implementation of the Provisions of the United Nations Convention on the Law of the Sea of 10 December 1982 relating to the Conservation and Management of Straddling Fish Stocks and Highly Migratory Fish Stocks of 4 August 1995 ('UNFSA'), the management of certain shared, straddling and highly migratory fish stocks requires the cooperation of all the countries in whose waters the stock occurs (the coastal States) and the countries whose fleets exploit that stock (the fishing States). This cooperation may be established in the framework of regional fisheries management organisations ('RFMOs') or, where RFMOs have no competence for the stock in question, by means of ad hoc arrangements among the countries having an interest in the fishery.

(2) Where a third country with an interest in a fishery involving a stock of common interest to that country and to the Union allows, without due regard to existing fishing patterns or the rights, duties and interests of other countries and the Union, fisheries activities that jeopardise the sustainability of that stock, and fails to cooperate with other countries and the Union in its management, specific measures should be adopted in order to encourage that country to contribute to the conservation of that stock.

(3) Fish stocks should be considered to be in an unsustainable state when they are not continuously maintained at or above the levels that can produce maximum sustainable yield or, if these levels cannot be estimated, when the stocks are not continuously maintained within safe biological limits.

(4) It is necessary to define the conditions upon which a country can be considered to be a country allowing non-sustainable fishing and subject to measures under this Regulation, including a process granting the countries concerned the right to be heard and allowing them an opportunity to adopt corrective action.

(5) In addition, it is necessary to define the type of measures that may be taken with regard to countries allowing non-sustainable fishing and to establish general conditions for the adoption of such measures, so that they are based on objective criteria and are equitable, cost-effective and compatible with international law, in particular with the Agreement establishing the World Trade Organisation.

(6) Such measures should aim to remove the incentives for countries allowing non-sustainable fishing to fish the stock of common interest. This can be achieved inter alia by restricting the importation of fish products caught by vessels conducting fisheries on a stock of common interest under the control of the country allowing non-sustainable fishing, by restricting the access to ports for those vessels, or by preventing Union fishing vessels or Union fishing equipment from being used for fishing the stock of common interest under the control of the country allowing non-sustainable fishing.

(7) In order to ensure that Union action for the conservation of fish stocks is effective and coherent, it is important that the measures set out in Council Regulation (EC) No 1005/2008 of 29 September 2008 establishing a Community system to prevent, deter and eliminate illegal, unreported and unregulated fishing [3] are taken into consideration.

(8) In order to guarantee that measures adopted against a country under this Regulation are environmentally sound, effective, proportionate and compatible with international rules, it is necessary for their adoption to be preceded by an evaluation of their expected environmental, trade, economic and social effects.

(9) If measures adopted against a country under this Regulation are ineffective and that country continues to be considered to be a country allowing non-sustainable fishing, further measures may be adopted in accordance with this Regulation.

[1] OJ C 229, 31.7.2012, p. 112.

[2] Position of the European Parliament of 12 September 2012 (not yet published in the Official Journal) and decision of the Council of 25 September 2012.

[3] OJ L 286, 29.10.2008, p. 1.

(10) The measures adopted against a country under this Regulation should cease to apply when the country allowing non-sustainable fishing has adopted the measures necessary for its contribution to the conservation of the stock of common interest.

(11) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission with regard to identifying a country allowing non-sustainable fishing, to adopting measures in respect of such country and to deciding that such measures should cease to apply. 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 [1].

(12) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to the end of application of measures taken pursuant to this Regulation, imperative grounds of urgency so require,

HAVE ADOPTED THIS REGULATION:

*Article 1*

**Subject matter and scope**

1. This Regulation lays down a framework for the adoption of certain measures regarding the fisheries-related activities and policies of third countries in order to ensure the long-term conservation of stocks of common interest to the Union and those third countries.

2. The measures adopted pursuant to this Regulation may apply in all cases where cooperation between third countries and the Union is required for the joint management of the stocks of common interest, including where that cooperation takes place in the context of an RFMO or a similar body.

*Article 2*

**Definitions**

For the purposes of this Regulation the following definitions shall apply:

(a) 'stock of common interest' means a fish stock the geographical distribution of which makes it available to both the Union and third countries and the management of which requires the cooperation between such countries and the Union, in either bilateral or multilateral settings;

(b) 'associated species' means any fish that belongs to the same ecosystem as the stock of common interest and that preys upon that stock, is preyed on by it, competes with it for food and living space or co-occurs with it in the same fishing area, and that is exploited or accidentally taken in the same fishery or fisheries;

(c) 'regional fisheries management organisation' or 'RFMO' means a sub-regional, regional or a similar organisation with competence under international law to establish conservation and management measures for living marine resources placed under its responsibility by virtue of the convention or agreement by which it was established;

(d) 'importation' means the introduction of fish or fishery products into the territory of the Union, including for transhipment purposes at ports in its territory;

(e) 'transhipment' means the unloading of all or any fish or fishery products on board a fishing vessel to another fishing vessel;

(f) 'unsustainable state' means the condition where the stock is not continuously maintained at or above the levels that can produce maximum sustainable yield or, if these levels cannot be estimated, where the stock is not continuously maintained within safe biological limits; the stock levels determining whether the stock is in an unsustainable state are to be determined on the basis of best available scientific advice;

(g) 'safe biological limits' means the boundaries of the size of a stock within which the stock can replenish itself with high probability while allowing high yield fisheries on it;

(h) 'country' means a third country, including territories enjoying self-governing status and endowed with competencies in the area of conservation and management of living marine resources.

*Article 3*

**Countries allowing non-sustainable fishing**

A country may be identified as a country allowing non-sustainable fishing where:

(a) it fails to cooperate in the management of a stock of common interest in full compliance with the provisions of the UNCLOS and the UNFSA, or any other international agreement or norm of international law; and

(b) either:

(i) it fails to adopt necessary fishery management measures; or

(ii) it adopts fishery management measures without due regard to the rights, interests and duties of other countries and the Union, and those fishery management measures, when considered in conjunction with measures taken by other countries and the Union, lead to fishing activities which could result in the stock being in an unsustainable state. This condition is considered to be complied with also where the fishery management

[1] OJ L 55, 28.2.2011, p. 13.

measures adopted by that country did not lead to the stock being in an unsustainable state solely due to measures adopted by others.

*Article 4*

**Measures in respect of countries allowing non-sustainable fishing**

1. The Commission may adopt, by means of implementing acts, the following measures in respect of a country allowing non-sustainable fishing:

(a) identifying that country as a country allowing non-sustainable fishing;

(b) identifying, where necessary, the specific vessels or fleets of that country to which certain measures are to apply;

(c) imposing quantitative restrictions on importations of fish from the stock of common interest that have been caught under the control of that country and on importations of fishery products made of or containing such fish;

(d) imposing quantitative restrictions on importations of fish of any associated species, and fishery products made of or containing such fish, when caught while conducting fisheries on the stock of common interest under the control of that country; when adopting the measure, the Commission shall, in accordance with Article 5(4) of this Regulation, in application of the principle of proportionality, determine which species and their catches fall within the scope of the measure;

(e) imposing restrictions on the use of Union ports by vessels flying the flag of that country that fish the stock of common interest and/or associated species and by vessels transporting fish and fishery products stemming from the stock of common interest and/or associated species that have been caught either by vessels flying the flag of that country or by vessels authorised by it while flying another flag; such restrictions shall not apply in cases of *force majeure* or distress within the meaning of Article 18 of the UNCLOS for services strictly necessary to remedy those situations;

(f) prohibiting the purchase by Union economic operators of a fishing vessel flying the flag of that country;

(g) prohibiting the reflagging of fishing vessels flying the flag of a Member State to the flag of that country;

(h) prohibiting Member States from authorising the conclusion of chartering agreements whereby Union economic operators charter their vessels to economic operators of that country;

(i) prohibiting the exportation to that country of fishing vessels flying the flag of a Member State or of fishing equipment and supplies needed to fish on the stock of common interest;

(j) prohibiting the conclusion of private trade arrangements between Union economic operators and that country that enable a fishing vessel flying the flag of a Member State to use fishing opportunities of that country;

(k) prohibiting joint fishing operations involving fishing vessels flying the flag of a Member State and fishing vessels flying the flag of that country.

2. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 8(2).

*Article 5*

**General requirements concerning the measures adopted pursuant to this Regulation**

1. The measures referred to in Article 4 shall be:

(a) related to the conservation of the stock of common interest;

(b) made effective in conjunction with restrictions on fishing by Union vessels, or on production or consumption within the Union, applicable to fish and fishery products made of or containing such fish of the species for which the measures have been adopted;

(c) proportionate to the objectives pursued and compatible with the obligations imposed by international agreements to which the Union is a party and any other relevant norms of international law.

2. The measures referred to in Article 4 shall take into account measures already taken pursuant to Regulation (EC) No 1005/2008.

3. The measures referred to in Article 4 shall not be applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail or a disguised restriction on international trade.

4. When adopting the measures referred to in Article 4, the Commission shall, in order to ensure that those measures are environmentally sound, effective, proportionate and compatible with international rules, evaluate the environmental, trade, economic and social effects of those measures in the short and long terms and the administrative burden associated with their implementation.

5. The measures referred to in Article 4 shall provide for an appropriate system for their enforcement by competent authorities.

*Article 6*

**Procedures prior to the adoption of measures in respect to countries allowing non-sustainable fishing**

1. Where the Commission considers that it is necessary to adopt measures referred to in Article 4, it shall notify the country concerned of the intention to identify it as a country

allowing non-sustainable fishing. In such cases, the European Parliament and the Council shall be immediately informed.

2. That notification shall include information on the reasons for the identification of that country as a country allowing non-sustainable fishing and shall describe the possible measures that may be taken in relation to it pursuant to this Regulation.

3. Prior to adopting measures referred to in Article 4, the Commission shall provide the country concerned with a reasonable opportunity to respond to the notification in writing and to remedy the situation within one month of receiving that notification.

*Article 7*

**Period of application of the measures in respect to countries allowing non-sustainable fishing**

1. The measures referred to in Article 4 shall cease to apply when the country allowing non-sustainable fishing adopts appropriate corrective measures necessary for the conservation and management of the stock of common interest and those corrective measures:

(a) have either been adopted autonomously or have been agreed in the context of consultations with the Union and, where applicable, other countries concerned; and

(b) do not undermine the effect of measures taken by the Union either autonomously, or in cooperation with other countries, for the purpose of the conservation of the fish stocks concerned.

2. The Commission shall adopt implementing acts determining whether the conditions laid down in paragraph 1 have been complied with and, where necessary, providing that the measures adopted in respect of the country concerned pursuant to Article 4 cease to apply. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 8(2).

On duly justified imperative grounds of urgency relating to unforeseen economic or social disruption, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 8(3) to decide that the measures adopted pursuant to Article 4 are to cease to apply.

*Article 8*

**Committee procedure**

1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

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

3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

4. The results of the evaluation referred to in Article 5(4), shall be made available to the European Parliament and the Council, in accordance with the procedure provided for in Article 10(4) of Regulation (EU) No 182/2011, together with the documents referred to therein.

*Article 9*

**Entry into force**

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

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

Done at Strasbourg, 25 October 2012.

*For the European Parliament*
*The President*
M. SCHULZ

*For the Council*
*The President*
A. D. MAVROYIANNIS

# REGULATION (EU) No 1027/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

## of 25 October 2012

## amending Regulation (EC) No 726/2004 as regards pharmacovigilance

**(Text with EEA relevance)**

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 114 and Article 168(4)(c) thereof,

Having regard to the proposal from the European Commission,

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

Having regard to the opinion of the European Economic and Social Committee [1],

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure [2],

Whereas:

(1) In order to ensure transparency on the surveillance of authorised medicinal products, the list of medicinal products subject to additional monitoring established by Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency [3], should systematically include medicinal products that are subject to certain post-authorisation safety conditions.

(2) In addition, voluntary action by the marketing authorisation holder should not lead to a situation where concerns relating to the risks or benefits of a medicinal product authorised in the Union are not properly addressed in all Member States. Therefore, the marketing authorisation holder should be obliged to inform the European Medicines Agency of the reasons for withdrawing or interrupting the placing on the market of a medicinal product, for requesting that a marketing authorisation be revoked, or for not renewing a marketing authorisation.

(3) Since the objective of this Regulation, namely to provide for specific rules on pharmacovigilance and improve the safety of medicinal products for human use authorised pursuant to Regulation (EC) No 726/2004, cannot be sufficiently achieved by the Member States and can therefore be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.

(4) Regulation (EC) No 726/2004 should therefore be amended accordingly,

HAVE ADOPTED THIS REGULATION:

*Article 1*

Regulation (EC) No 726/2004 is hereby amended as follows:

(1) in Article 13(4), the second subparagraph is replaced by the following:

'The marketing authorisation holder shall notify the Agency if the product ceases to be placed on the market of a Member State, either temporarily or permanently. Such notification shall, other than in exceptional circumstances, be made no less than two months before the interruption in the placing on the market of the product. The marketing authorisation holder shall inform the Agency of the reasons for such action in accordance with Article 14b.';

(2) the following Article is inserted:

*'Article 14b*

1. The marketing authorisation holder shall notify the Agency forthwith of any action the holder takes to suspend the marketing of a medicinal product, to withdraw a medicinal product from the market, to request the withdrawal of a marketing authorisation or not to apply for the renewal of a marketing authorisation, together with the reasons for such action. The marketing authorisation holder shall in particular declare if such action is based on any of the grounds set out in Article 116 or Article 117(1) of Directive 2001/83/EC.

2. The marketing authorisation holder shall also make the notification pursuant to paragraph 1 of this Article if the action is taken in a third country and such action is based on any of the grounds set out in Article 116 or Article 117(1) of Directive 2001/83/EC.

3. In the cases referred to in paragraphs 1 and 2, the Agency shall forward the information to the competent authorities of the Member States without undue delay.';

(3) in Article 20, paragraph 8 is replaced by the following:

[1] OJ C 181, 21.6.2012, p. 202.
[2] Position of the European Parliament of 11 September 2012 (not yet published in the Official Journal) and decision of the Council of 4 October 2012.
[3] OJ L 136, 30.4.2004, p. 1.

'8. Where the procedure is initiated as a result of the evaluation of data relating to pharmacovigilance, the opinion of the Agency, in accordance with paragraph 2 of this Article, shall be adopted by the Committee for Medicinal Products for Human Use on the basis of a recommendation from the Pharmacovigilance Risk Assessment Committee and Article 107j(2) of Directive 2001/83/EC shall apply.';

(4) Article 23 is replaced by the following:

'*Article 23*

1. The Agency shall, in collaboration with the Member States, set up, maintain and make public a list of medicinal products that are subject to additional monitoring.

That list shall include the names and active substances of:

(a) medicinal products authorised in the Union that contain a new active substance which, on 1 January 2011, was not contained in any medicinal product authorised in the Union;

(b) any biological medicinal product not covered by point (a) that was authorised after 1 January 2011;

(c) medicinal products that are authorised pursuant to this Regulation, subject to the conditions referred to in point (cb) of Article 9(4), point (a) of the first subparagraph of Article 10a(1) or Article 14(7) or (8);

(d) medicinal products that are authorised pursuant to Directive 2001/83/EC, subject to the conditions referred to in points (b) and (c) of the first paragraph of Article 21a, Article 22, or point (a) of the first subparagraph of Article 22a(1) thereof.

1a. At the request of the Commission, following consultation with the Pharmacovigilance Risk Assessment Committee, medicinal products that are authorised pursuant to this Regulation, subject to the conditions referred to in points (c), (ca) or (cc) of Article 9(4), point (b) of the first subparagraph of Article 10a(1) or Article 21(2), may also be included in the list referred to in paragraph 1 of this Article.

At the request of a national competent authority, following consultation with the Pharmacovigilance Risk Assessment Committee, medicinal products that are authorised pursuant to Directive 2001/83/EC, subject to the conditions referred to in points (a), (d), (e) or (f) of the first paragraph of Article 21a, point (b) of the first subparagraph of Article 22a(1) or Article 104a(2) thereof, may also be included in the list referred to in paragraph 1 of this Article.

2. The list referred to in paragraph 1 shall include an electronic link to the product information and to the summary of the risk management plan.

3. In the cases referred to in points (a) and (b) of paragraph 1 of this Article, the Agency shall remove a medicinal product from the list five years after the Union reference date referred to in Article 107c(5) of Directive 2001/83/EC.

In the cases referred to in points (c) and (d) of paragraph 1 and in paragraph 1a of this Article, the Agency shall remove a medicinal product from the list once the conditions have been fulfilled.

4. For medicinal products included in the list referred to in paragraph 1, the summary of product characteristics and the package leaflet shall include the statement "This medicinal product is subject to additional monitoring". That statement shall be preceded by a black symbol which shall be selected by the Commission by 2 July 2013, following a recommendation of the Pharmacovigilance Risk Assessment Committee, and shall be followed by an appropriate standardised explanatory sentence.

4a. By 5 June 2018, the Commission shall present to the European Parliament and the Council a report on the use of the list referred to in paragraph 1 based on the experience and data provided by the Member States and the Agency.

The Commission shall, if appropriate, on the basis of that report, and after consultation with the Member States and other appropriate stakeholders, present a proposal in order to adjust the provisions relating to the list referred to in paragraph 1.';

(5) Article 57 is amended as follows:

(a) in the second subparagraph of paragraph 1, points (c) and (d) are replaced by the following:

'(c) coordinating the monitoring of medicinal products which have been authorised within the Union and providing advice on the measures necessary to ensure the safe and effective use of those medicinal products, in particular by coordinating the evaluation and implementation of pharmacovigilance obligations and systems and the monitoring of such implementation;

(d) ensuring the collation and dissemination of information on suspected adverse reactions to medicinal products authorised in the Union by means of a database which is permanently accessible to all Member States;';

(b) in the second subparagraph of paragraph 2, point (b) is replaced by the following:

'(b) marketing authorisation holders shall, by 2 July 2012 at the latest, electronically submit to the Agency information on all medicinal products for human use authorised in the Union, using the format referred to in point (a);'.

*Article 2*

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

It shall apply from 5 June 2013 with the exception of Article 23(4), points (c) and (d) of the second subparagraph of Article 57(1) and point (b) of the second subparagraph of Article 57(2) of Regulation (EC) No 726/2004, as amended by this Regulation, which shall apply from 4 December 2012.

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

Done at Strasbourg, 25 October 2012.

*For the European Parliament*
*The President*
M. SCHULZ

*For the Council*
*The President*
A. D. MAVROYIANNIS

# REGULATION (EU) No 1028/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

## of 25 October 2012

## amending Council Regulation (EC) No 1234/2007 as regards the regime of the single payment scheme and support to vine-growers

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 the first paragraph of Article 42 and Article 43(2) thereof,

Having regard to the proposal from the European Commission,

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

Having regard to the opinion of the European Economic and Social Committee [1],

Having regard to the opinion of the Committee of the Regions [2],

Acting in accordance with the ordinary legislative procedure [3],

Whereas:

(1) Article 103o of 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) [4] provides for a possibility for Member States to grant decoupled aid under the single payment scheme to vine-growers. Several Member States have used this specific support measure.

(2) However, the fact that Member States may modify transfers to the single payment scheme from the support programmes once a year and that support programmes have a five-year duration whilst payment entitlements giving rise to direct payments are granted for an indeterminate period of time has resulted in administrative and budgetary burdens.

(3) In order to simplify the management of this specific support measure and to ensure its consistency with the objectives of the rules for direct support schemes for farmers, it is appropriate to convert it into the possibility for Member States to definitively decrease the funds allocated to the support programmes in the wine sector and thereby increase the national ceilings for direct payments.

(4) It is appropriate to allow Member States to continue applying the support provided for in Article 103o of Regulation (EC) No 1234/2007 for 2014.

(5) Regulation (EC) No 1234/2007 should therefore be amended accordingly,

HAVE ADOPTED THIS REGULATION:

*Article 1*

Regulation (EC) No 1234/2007 is amended as follows:

(1) in Article 103n, the following paragraph is inserted:

'1a. By 1 August 2013, Member States may decide to reduce, from 2015, the amount available for the support programmes referred to in Annex Xb, in order to increase their national ceilings for direct payments referred to in Article 40 of Regulation (EC) No 73/2009.

The amount resulting from the decrease referred to in the first subparagraph shall definitively remain in the national ceilings for direct payments referred to in Article 40 of Regulation (EC) No 73/2009 and shall no longer be available for the measures listed in Articles 103p to 103y.';

(2) Article 103o is replaced by the following:

'*Article 103o*

**Single payment scheme and support to vine-growers**

1. Member States may decide, by 1 December 2012, to provide support to vine-growers for 2014 by allocating payment entitlements within the meaning of Chapter 1 of Title III of Regulation (EC) No 73/2009.

If the amount of the support referred to in the first subparagraph is greater than the amount of support that was provided for 2013, the Member State concerned shall use the difference to allocate payment entitlements within the meaning of Chapter 1 of Title III of Regulation (EC) No 73/2009 to vine-growers in accordance with point C of Annex IX to that Regulation.

2. Member States intending to provide support referred to in paragraph 1 shall make provision for such support in their support programmes in accordance with Article 103k(3).

3. The support for 2014 referred to in paragraph 1 shall:

(a) remain in the single payment scheme and no longer be available under Article 103k(3) for the measures listed in Articles 103p to 103y;

(b) reduce proportionately the amount of funds available for measures listed in Articles 103p to 103y in the support programmes.'.

[1] OJ C 191, 29.6.2012, p. 116.
[2] OJ C 225, 27.7.2012, p. 174.
[3] Position of the European Parliament of 11 September 2012 (not yet published in the Official Journal) and decision of the Council of 4 October 2012.
[4] OJ L 299, 16.11.2007, p. 1.

*Article 2*

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

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

Done at Strasbourg, 25 October 2012.

| *For the European Parliament* | *For the Council* |
| --- | --- |
| *The President* | *The President* |
| M. SCHULZ | A. D. MAVROYIANNIS |

# REGULATION (EU) No 1029/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

## of 25 October 2012

## introducing emergency autonomous trade preferences for Pakistan

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(2) 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 relationship between the European Union (hereinafter referred to as 'the Union') and the Islamic Republic of Pakistan (hereinafter referred to as 'Pakistan') builds on the Cooperation Agreement which entered into force on 1 September 2004 [2]. One of its main objectives is to secure the conditions for, and to promote the increase and development of, trade between the Parties to the Cooperation Agreement. Respect for human rights, including core labour rights, and democratic principles are also an essential element of that Agreement.

(2) In July and August 2010, following heavy monsoon rains, devastating floods affected extensive regions of Pakistan, notably the areas of Balochistan, Khyber Pakhtunkhwa, Punjab, Sindh and Gilgit-Baltistan. According to United Nations sources, the flooding affected some 20 million people and 20 per cent of Pakistan's land, equivalent to at least 160 000 square kilometres, and leaving up to 12 million people in need of urgent humanitarian aid.

(3) Humanitarian aid is of course the primary instrument in this kind of situation and the Union has been at the forefront in this field since the beginning of the emergency, committing in excess of EUR 423 million in emergency aid to Pakistan.

(4) It will be important to use all available means to support Pakistan's recovery from this emergency including the proposed exceptional trade measures to boost Pakistan's exports in order to contribute to its future economic development, while ensuring that consistency and coherence is maintained at all levels with a view to developing a sustainable long-term strategy.

(5) The severity of this natural disaster demands an immediate and substantial response, which would take into account the geostrategic importance of Pakistan's partnership with the Union, mainly through Pakistan's key role in the fight against terrorism, while contributing to the overall development, security and stability of the region.

(6) The effects of the autonomous trade preferences should be able to be measured concretely in terms of job creation, poverty eradication and the sustainable development of Pakistan's working population and poor.

(7) The European Council, in a Declaration on Pakistan attached to its Conclusions of 16 September 2010, resolved to mandate Ministers to agree urgently on a comprehensive package of short, medium and longer term measures which will help underpin Pakistan's recovery and future development, comprising inter alia ambitious trade measures essential for economic recovery and growth.

(8) In particular, the European Council underlined its firm commitment to grant exclusively to Pakistan increased market access to the Union through the immediate and time limited reduction of duties on key imports from Pakistan. In the light of that Declaration, the Commission proposed a package identifying 75 tariff lines specific to Pakistan's core export sectors in those areas worst hit by the floods, asserting that an increase in Pakistani exports to the Union of EUR 100 million or more a year would provide real, substantial and worthwhile assistance to the region.

(9) Pakistan's trade with the Union is mainly composed of textiles and clothing products which accounted for 73,7 % of Pakistani exports to the Union in 2009. Pakistan also exports ethanol and leather, which are in addition to textiles and clothing, sensitive industrial products in certain Member States where jobs in the industry have already been impacted to varying degrees by the global recession. Those industries are struggling to adapt to a new global trading environment.

(10) The textiles sector is of key importance to the Pakistani economy, accounting for 8,5 % of gross domestic product and employing 38 % of the labour force, about half of which is made up of women.

[1] Position of the European Parliament of 13 September 2012 (not yet published in the Official Journal) and decision of the Council of 4 October 2012.

[2] Council Decision 2004/870/EC of 29 April 2004 concerning the conclusion of the Cooperation Agreement between the European Community and the Islamic Republic of Pakistan (OJ L 378, 23.12.2004, p. 22).

(11) Given the hardship being suffered by the Pakistani people due to the devastating floods, it is therefore appropriate to extend exceptional autonomous trade preferences to Pakistan by suspending for a limited period of time all tariffs for certain products of export interest to Pakistan. The provision of such trade preferences should only cause limited adverse effects on the domestic market of the Union and should not affect negatively least developed Members of the World Trade Organisation (WTO).

(12) Those measures are proposed as part of an exceptional package, in response to the specific situation in Pakistan. Under no circumstances should they constitute a precedent for the Union's trade policy with other countries.

(13) The autonomous trade preferences will be either in the form of an exemption from customs duties upon import in the Union or in the form of tariff-rate quotas.

(14) Entitlement to benefit from the exceptional autonomous trade preferences is conditional on Pakistan's compliance with the relevant rules of origin of products and the procedures related thereto as well as involvement in effective administrative cooperation with the Union in order to prevent any risk of fraud. Serious and systematic violations of the conditions for the entitlement to the preferential arrangement, fraud or failure to provide administrative cooperation for the verification of origin of goods should constitute reasons for a temporary suspension of the preferences.

(15) For the purposes of defining the concept of originating products, certification of origin and administrative cooperation procedures, Part I, Title IV, Chapter 2, Section 1 and Section 1A of Commission Regulation (EEC) No 2454/93 of 2 July 1993 laying down provisions for the implementation of Council Regulation (EEC) No 2913/92 establishing the Community Customs Code [1], with the exception of Articles 68 to 71, 90 to 97i and 97j(2) of those Sections, should apply. However, as regards cumulation of origin, only materials originating in the Union should be allowed to be used for such purposes. Regional cumulation and other types of cumulation except that with the materials originating in the Union should not apply in relation to the determination of the originating status of products covered by the autonomous trade preferences established pursuant to this Regulation in order to ensure that sufficient transformation takes place in Pakistan.

(16) Extending autonomous trade preferences to Pakistan requires a waiver from the obligations of the Union under Articles I and XIII of the General Agreement on Tariffs and Trade 1994 (GATT) pursuant to Article IX of the Agreement establishing the WTO. The WTO General Council granted such a waiver on 14 February 2012.

(17) In order to ensure an immediate and sustainable impact on the economic recovery of Pakistan in the aftermath of the floods and in accordance with the WTO waiver, it is recommended to limit the duration of the autonomous trade preferences until 31 December 2013.

(18) In order to react swiftly and ensure the integrity and orderly functioning of the autonomous trade preferences for Pakistan and in order to ensure uniform conditions for the implementation of this Regulation concerning temporary suspension due to non-compliance with customs-related procedures and obligations, due to serious and systematic violations of the fundamental principles of human rights, democracy and the rule of law by Pakistan, or due to Pakistan not respecting the condition that it abstain from 1 July 2012 from introducing new or increasing existing export duties or charges having equivalent effect or any other restriction or prohibition on the export or sale for export of any materials used in the production of the products covered by this Regulation, powers should be conferred on the Commission to adopt immediately applicable implementing acts, where imperative grounds of urgency so require. 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 [2].

(19) In order to make the necessary technical adaptations to the list of goods for which the autonomous trade preferences apply and to remove products from the scope of this Regulation where volumes of imports covered by this Regulation increase beyond certain levels, 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 Annexes I and II to reflect changes in the combined nomenclature and to remove products from the scope of this Regulation. It 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.

(20) In order to address without delay significantly increased imports of the products exempted from customs duties when imported into the Union and which may have an adverse impact upon Union producers, the Commission should adopt delegated acts removing products from the scope of this Regulation under the urgency procedure.

[1] OJ L 253, 11.10.1993, p. 1.

[2] OJ L 55, 28.2.2011, p. 13.

(21) No later than two years after the expiry of this Regulation, the Commission should submit a report to the European Parliament and to the Council on the effects of these autonomous trade preferences. That report should include a detailed analysis of the effects of these preferences on the economy of Pakistan and their impact on trade and the Union's tariff income as well as on the Union economy and jobs. In reporting, the Commission should take into account in particular the effects of the autonomous trade preferences in terms of job creation, poverty eradication and the sustainable development of Pakistan's working population and poor,

HAVE ADOPTED THIS REGULATION:

*Article 1*

**Preferential arrangements**

1. Products originating in Pakistan and included in Annex I shall be exempt from customs duties upon import into the Union.

2. Products originating in Pakistan and included in Annex II shall be admitted for import into the Union subject to the special provisions laid down in Article 3.

*Article 2*

**Conditions for entitlement to the preferential arrangements**

1. Entitlement to benefit from the preferential arrangements introduced in Article 1 shall be subject to:

(a) compliance with the rules of origin of products and the procedures related thereto as provided for in Part I, Title IV, Chapter 2, Section 1 and Section 1A, subsections 1 and 2 of Regulation (EEC) No 2454/93, with the exception of Articles 68 to 71, 90 to 97i and Article 97j(2) of those Sections. However, as regards cumulation of origin for the purpose of the determination of the originating status of products covered by the arrangements introduced in Article 1 of this Regulation, only cumulation with the materials originating in the Union is allowed. Regional cumulation and other types of cumulation with the exception of the cumulation with materials originating in the Union, is not allowed;

(b) compliance with the methods of administrative cooperation as provided for in Part I, Title IV, Chapter 2, Section 1, subsection 3 of Regulation (EEC) No 2454/93;

(c) Pakistan not engaging in serious and systematic violations of human rights, including core labour rights, fundamental principles of democracy and the rule of law;

(d) Pakistan abstaining from introducing new or increasing existing export duties or charges having equivalent effect or any other restriction or prohibition on the export or sale for export of any materials primarily used in the production of any of the products covered by those preferential arrangements destined for the territory of the Union, from 1 July 2012.

2. Certificates of origin 'Form A' issued by the competent authorities of Pakistan pursuant to this Regulation shall bear the following endorsement in box 4 'Autonomous measure — Regulation (EU) No 1029/2012 [1]'.

*Article 3*

**Tariff quotas**

1. Products listed in Annex II shall be admitted for import into the Union with the exemption of customs duties within the limits of Union tariff quotas as set out in that Annex.

2. The tariff quotas referred to in paragraph 1 and listed in Annex II shall be administered by the Commission in accordance with Articles 308a, 308b and 308c of Regulation (EEC) No 2454/93.

*Article 4*

**Removal of products from the scope of this Regulation**

1. Where, in the calendar year 2012 or 2013, imports based on customs import data for a product originating from Pakistan and included in Annex I increase, in volume, by 25 % or more, as compared to the average of the years 2009 to 2011, that product shall be removed from the scope of this Regulation for the remainder of that year. For the purposes of this paragraph, the Commission shall be empowered to adopt delegated acts, in accordance with Article 6, to amend Annex I to remove that product from the scope of this Regulation for the remainder of that year.

2. Upon the entry into force of the delegated act, imports of the product referred to in paragraph 1 shall be subject to 'most-favoured-nation' or other applicable duties.

*Article 5*

**Technical adjustments to the Annexes**

The Commission shall be empowered to adopt delegated acts in accordance with Article 6 to amend the Annexes in order to incorporate amendments and technical adjustments made necessary by amendments to the Combined Nomenclature and to the TARIC subdivisions.

*Article 6*

**Exercise of the delegation**

1. The power to adopt the delegated acts referred to in Articles 4 and 5 is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Articles 4 and 5 shall be conferred on the Commission for the period of application of this Regulation.

[1] OJ L 316, 14.11.2012, p. 43.

3. The delegation of power referred to in Articles 4 and 5 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 Articles 4 and 5 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and to 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 at the initiative of the European Parliament or of the Council.

*Article 7*

**Urgency procedure**

1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.

2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 6(5). In such a case, the Commission shall repeal the act without delay following the notification of the decision to object by the European Parliament or by the Council.

*Article 8*

**Committee procedure**

1. The Commission shall be assisted by the Customs Code Committee established by Articles 247a(1) and 248a(1) of Council Regulation (EEC) No 2913/92 [1]. That Committee shall be a committee within the meaning of Regulation (EU) No 182/2011. That Committee may examine any matter relating to the application of this Regulation, raised by the Commission or at the request of a Member State.

2. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

[1] OJ L 302, 19.10.1992, p. 1.

*Article 9*

**Temporary suspension**

1. Where the Commission finds that there is sufficient evidence of failure to comply with the conditions set out in Article 2 it may, in order to respond to this urgency, by means of immediately applicable implementing acts suspend in whole or in part the preferential arrangements provided for in this Regulation for a period of not more than six months, provided that it has first:

(a) informed the Committee referred to in Article 8(1);

(b) called on the Member States to take such precautionary measures as are necessary in order to safeguard the financial interests of the Union or to secure Pakistan's compliance with Article 2;

(c) published a notice in the *Official Journal of the European Union* stating that there are grounds for reasonable doubt concerning the application of the preferential arrangements or Pakistan's compliance with Article 2 which may call into question its right to continue enjoying the benefits granted by this Regulation;

(d) informed Pakistan of any decision taken in accordance with this paragraph, before it becomes effective.

2. On conclusion of the period of temporary suspension, the Commission shall, by means of implementing acts, decide either to terminate the suspension or to extend its period of application.

3. The implementing acts referred to in paragraphs 1 and 2 shall be adopted in accordance with the procedure referred to in Article 8(2).

4. Member States shall communicate to the Commission all relevant information that may justify the temporary suspension of preferential arrangements or its extension.

*Article 10*

**Report**

No later than 31 December 2015, the Commission shall submit a report to the European Parliament and to the Council on the operation and effects of this Regulation.

*Article 11*

**Entry into force and application**

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

2. It shall apply from the date of its entry into force until 31 December 2013.

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

Done at Strasbourg, 25 October 2012.

*For the European Parliament*
*The President*
M. SCHULZ

*For the Council*
*The President*
A. D. MAVROYIANNIS

*ANNEX I*

**PRODUCTS FOR WHICH THE CUSTOMS DUTY IS EXEMPTED**

The products on which the measures are to apply are identified by their eight-digit CN codes. The description of those codes can be found in 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 [1]. The description of the CN codes is given for information purposes only.

| CN code | Description |
|---|---|
| 0712 39 00 | Dried mushrooms and truffles, whole, cut, sliced, broken or in powder, but not further prepared (other than mushrooms of the genus *Agaricus*, wood ears (*Auricularia* spp.) and jelly fungi (*Tremella* spp.)) |
| 5205 12 00 | Single cotton yarn, of uncombed fibres, containing 85 % or more by weight of cotton, measuring less than 714,29 decitex but not less than 232,56 decitex (exceeding 14 metric number but not exceeding 43 metric number), not put up for retail sale |
| 5205 22 00 | Single cotton yarn, of combed fibres, containing 85 % or more by weight of cotton, measuring less than 714,29 decitex but not less than 232,56 decitex (exceeding 14 metric number but not exceeding 43 metric number), not put up for retail sale |
| 5205 32 00 | Multiple folded or cabled cotton yarn, of uncombed fibres, containing 85 % or more by weight of cotton, measuring per single yarn less than 714,29 decitex but not less than 232,56 decitex (exceeding 14 metric number but not exceeding 43 metric number per single yarn), not put up for retail sale |
| 5205 42 00 | Multiple folded or cabled cotton yarn, of combed fibres, containing 85 % or more by weight of cotton, measuring per single yarn less than 714,29 decitex but not less than 232,56 decitex (exceeding 14 metric number but not exceeding 43 metric number per single yarn), not put up for retail sale |
| 5208 11 90 | Unbleached plain woven fabrics of cotton, containing 85 % or more by weight of cotton, weighing not more than 100 g/m$^2$, other than fabrics for the manufacture of bandages, dressings and medical gauzes |
| 5208 12 16 | Unbleached plain woven fabrics of cotton, containing 85 % or more by weight of cotton, weighing more than 100 g/m$^2$ but not more than 130 g/m$^2$, of a width not exceeding 165 cm |
| 5208 12 19 | Unbleached plain woven fabrics of cotton, containing 85 % or more by weight of cotton, weighing more than 100 g/m$^2$ but not more than 130 g/m$^2$, of a width exceeding 165 cm |
| 5208 13 00 | Unbleached woven fabrics of cotton, containing 85 % or more by weight of cotton, in 3-thread or 4-thread twill, including cross twill |
| 5208 19 00 | Other unbleached woven fabrics of cotton, containing 85 % or more by weight of cotton |
| 5208 21 90 | Bleached plain woven fabrics of cotton, containing 85 % or more by weight of cotton, weighing not more than 100 g/m$^2$, other than fabrics for the manufacture of bandages, dressings and medical gauzes |
| 5208 22 19 | Bleached plain woven fabrics of cotton, containing 85 % or more by weight of cotton, weighing more than 100 g/m$^2$ but not more than 130 g/m$^2$, of a width exceeding 165 cm |
| 5208 22 96 | Bleached plain woven fabrics of cotton, containing 85 % or more by weight of cotton, weighing more than 130 g/m$^2$, of a width not exceeding 165 cm |
| 5208 29 00 | Other bleached woven fabrics of cotton, containing 85 % or more by weight of cotton |
| 5208 51 00 | Printed plain woven fabrics of cotton, containing 85 % or more by weight of cotton, weighing not more than 100 g/m$^2$ |

[1] OJ L 256, 7.9.1987, p. 1.

| CN code | Description |
|---|---|
| 5208 52 00 | Printed plain woven fabrics of cotton, containing 85 % or more by weight of cotton, weighing more than 200 g/m$^2$ |
| 5208 59 90 | Other printed woven fabrics of cotton, containing 85 % or more by weight of cotton |
| 5209 11 00 | Unbleached plain woven fabrics of cotton, containing 85 % or more by weight of cotton, weighing more than 200 g/m$^2$ |
| 5209 12 00 | Unbleached woven fabrics of cotton, containing 85 % or more by weight of cotton, weighing more than 200 g/m$^2$, in 3-thread or 4-thread twill, including cross twill |
| 5209 19 00 | Other unbleached woven fabrics of cotton, containing 85 % or more by weight of cotton |
| 5209 22 00 | Bleached woven fabrics of cotton, containing 85 % or more by weight of cotton, weighing more than 200 g/m$^2$, in 3-thread or 4-thread twill, including cross twill |
| 5209 29 00 | Other bleached woven fabrics of cotton, containing 85 % or more by weight of cotton |
| 5209 32 00 | Dyed woven fabrics of cotton, containing 85 % or more by weight of cotton, weighing more than 200 g/m$^2$, in 3-thread or 4-thread twill, including cross twill |
| 5211 12 00 | Unbleached woven fabrics of cotton, containing less than 85 % by weight of cotton, mixed principally or solely with man-made fibres, weighing more than 200 g/m$^2$, in 3-thread or 4-thread twill, including cross twill |
| 5407 81 00 | Woven fabrics of yarn containing less than 85 % by weight of synthetic filaments, including woven fabrics obtained from synthetic monofilament of 67 decitex or more and of which no cross-sectional dimension exceeds 1 mm, mixed mainly or solely with cotton, unbleached or bleached |
| 5407 82 00 | Woven fabrics of yarn containing less than 85 % by weight of synthetic filaments, including woven fabrics obtained from synthetic monofilament of 67 decitex or more and of which no cross-sectional dimension exceeds 1 mm, mixed mainly or solely with cotton, dyed |
| 5513 11 20 | Woven fabrics of polyester staple fibres, containing less than 85 % by weight of such fibres, mixed mainly or solely with cotton, of a weight not exceeding 170 g/m$^2$, plain weave, unbleached or bleached, of a width of 165 cm or less |
| 5513 21 00 | Woven fabrics of polyester staple fibres, containing less than 85 % by weight of such fibres, mixed mainly or solely with cotton, of a weight not exceeding 170 g/m$^2$, plain weave, dyed |
| 5513 41 00 | Woven fabrics of polyester staple fibres, containing less than 85 % by weight of such fibres, mixed mainly or solely with cotton, of a weight not exceeding 170 g/m$^2$, printed |
| 6101 20 90 | Men's or boys' anoraks (including ski jackets), windcheaters, wind-jackets and similar articles, of cotton, knitted or crocheted |
| 6112 12 00 | Track-suits of synthetic fibres, knitted or crocheted |
| 6116 10 20 | Gloves impregnated, coated or covered with rubber, knitted or crocheted |
| 6116 10 80 | Mittens and mitts, impregnated, coated or covered with plastics or rubber, knitted or crocheted, and gloves, impregnated, coated or covered with plastics, knitted or crocheted |
| 6116 92 00 | Gloves, mittens and mitts, of cotton, knitted or crocheted |
| 6116 93 00 | Gloves, mittens and mitts, of synthetic fibres, knitted or crocheted |
| 6201 93 00 | Men's or boys' anoraks, windcheaters, wind-jackets and similar articles, of man-made fibres |

| CN code | Description |
|---|---|
| 6203 43 19 | Men's or boys' trousers and breeches of synthetic fibres (other than industrial and occupational) |
| 6204 22 80 | Women's or girls' ensembles, of cotton (other than industrial and occupational) |
| 6204 62 90 | Women's or girls' cotton shorts |
| 6207 91 00 | Men's or boys' singlets and other vests, bathrobes, dressing gowns and similar articles, of cotton |
| 6208 91 00 | Women's or girls' singlets and other vests, briefs, panties, negligees, bathrobes, dressing gowns and similar articles, of cotton |
| 6211 43 10 | Women's or girls' aprons, overalls, smock-overalls and other industrial and occupational clothing, of man-made fibres |
| 6216 00 00 | Gloves, mittens and mitts |
| 6303 91 00 | Curtains (including drapes) and interior blinds, curtain or bed valances, of cotton, not knitted or crocheted |
| 6303 92 90 | Curtains (including drapes) and interior blinds, curtain or bed valances, of synthetic fibres, not non-wovens, not knitted or crocheted |
| 6303 99 90 | Curtains (including drapes) and interior blinds, curtain or bed valances, not of cotton or synthetic fibres, not non-wovens, not knitted or crocheted |
| 6304 92 00 | Other furnishing articles, of cotton, not knitted or crocheted |
| 6307 10 90 | Floorcloths, dishcloths, dusters and similar cleaning cloths, not knitted or crocheted, not non-wovens |
| 6307 90 99 | Other made-up textile articles, including dress patterns, not knitted or crocheted, not of felt |

*ANNEX II*

**PRODUCT SUBJECT TO ANNUAL DUTY-FREE TARIFF QUOTAS REFERRED TO IN ARTICLE 3**

The products on which the measures are to apply are identified by their eight-digit CN codes. The description of those codes can be found in Annex I to Regulation (EEC) No 2658/87. The description of the CN codes is given for information purposes only.

| Order No | CN code | Description | From entry into force until end of 2012 | 1.1.2013 to 31.12.2013 |
|---|---|---|---|---|
| 09.2401 | 2207 10 00 | Undenatured ethyl alcohol, of actual alcoholic strength of ≥ 80 % | 18 750 tonnes | 75 000 tonnes |
| 09.2409 | 4107 92 10 | Grain splits of bovine (including buffalo) leather, without hair on, further prepared after tanning or crusting, other than whole hides and skins | 89 tonnes | 356 tonnes |
| 09.2410 | 4107 99 10 | Leather of bovine (including buffalo), without hair on, further prepared after tanning or crusting; other than whole hides and skins, other than unsplit full grains and grain splits | 90,25 tonnes | 361 tonnes |
| 09.2411 | 4203 21 00 | Gloves, mittens and mitts, of leather or composition leather, specially designed for use in sports | 361,75 tonnes | 1 447 tonnes |
| 09.2412 | 4203 29 10 | Gloves, mittens and mitts, of leather or composition leather, protective for all trades, other than specially designed for use in sports | 1 566,5 tonnes | 6 266 tonnes |
| 09.2413 | ex 4203 29 90 | Men's and boys' gloves, mittens and mitts, of leather or composition leather, other than specially designed for use in sports, other than protective for all trades | 62,75 tonnes | 251 tonnes |
| 09.2414 | ex 4203 29 90 | Gloves, mittens and mitts, of leather or composition leather, other than specially designed for use in sports, other than protective for all trades, other than men's and boys' | 135,5 tonnes | 542 tonnes |
| 09.2415 | 5205 23 00 | Single cotton yarn, of combed fibres, containing 85 % or more by weight of cotton, measuring less than 232,56 decitex but not less than 192,31 decitex (exceeding 43 metric number but not exceeding 52 metric number), not put up for retail sale | 1 790 tonnes | 7 160 tonnes |
| 09.2416 | 5205 24 00 | Single cotton yarn, of combed fibres, containing 85 % or more by weight of cotton, measuring less than 192,31 decitex but not less than 125 decitex (exceeding 52 metric number but not exceeding 80 metric number), not put up for retail sale | 1 276,25 tonnes | 5 105 tonnes |
| 09.2417 | 5208 39 00 | Other dyed woven fabrics of cotton, containing 85 % or more by weight of cotton | 421,25 tonnes | 1 685 tonnes |
| 09.2418 | 5209 39 00 | Other dyed woven fabrics of cotton, containing 85 % or more by weight of cotton, weighing more than 200 g/$m^2$ | 689,25 tonnes | 2 757 tonnes |
| 09.2419 | 5509 53 00 | Yarn (other than sewing thread) of polyester staple fibres, mixed mainly or solely with cotton, not put up for retail sale | 3 061 tonnes | 12 244 tonnes |

| Order No | CN code | Description | From entry into force until end of 2012 | 1.1.2013 to 31.12.2013 |
|---|---|---|---|---|
| 09.2420 | 6103 32 00 | Men's or boys' jackets and blazers, of cotton, knitted or crocheted | 249,75 tonnes | 999 tonnes |
| 09.2421 | 6103 42 00 | Men's or boys' trousers, bib and brace overalls, breeches and shorts (other than swimwear), of cotton, knitted or crocheted | 568,75 tonnes | 2 275 tonnes |
| 09.2422 | 6107 21 00 | Men's or boys' nightshirts and pyjamas, of cotton, knitted or crocheted | 167,5 tonnes | 670 tonnes |
| 09.2423 | 6108 31 00 | Women's or girls' nightdresses and pyjamas, of cotton, knitted or crocheted | 374,5 tonnes | 1 498 tonnes |
| 09.2424 | 6109 90 20 | T-shirts, singlets and other vests of wool or fine animal hair or man-made fibres, knitted or crocheted | 297,5 tonnes | 1 190 tonnes |
| 09.2425 | 6111 20 90 | Babies' garments and clothing accessories, of cotton, knitted or crocheted (other than gloves, mittens and mitts) | 153,5 tonnes | 614 tonnes |
| 09.2426 | 6115 95 00 | Pantyhose, tights, stockings, socks and other hosiery and footwear without applied soles, of cotton, knitted or crocheted (excluding graduated compression hosiery, pantyhose and tights, women's full-length or knee-length stockings, measuring per single yarn less than 67 decitex) | 2 263 tonnes | 9 052 tonnes |
| 09.2427 | 6204 62 31 | Women's or girls' cotton denim trousers and breeches (other than industrial and occupational) | 1 892,75 tonnes | 7 571 tonnes |
| 09.2428 | 6211 42 90 | Women's or girls' garments, of cotton | 96,5 tonnes | 386 tonnes |
| 09.2429 | 6302 60 00 | Toilet linen and kitchen linen, of terry towelling or similar terry fabrics, of cotton | 9 602 tonnes | 38 408 tonnes |
| 09.2430 | 6302 91 00 | Toilet linen and kitchen linen, of cotton, other than of terry towelling or similar terry fabrics | 2 499,25 tonnes | 9 997 tonnes |
| 09.2431 | 6403 99 93 | Footwear with outer soles of rubber, plastics or composition leather and uppers of leather, with in-soles of a length of 24 cm or more, which cannot be identified as men's or women's footwear, other than sports footwear and footwear incorporating a protective metal toecap, not covering the ankle, not made on a base or platform of wood (not having an inner sole), other than footwear with a vamp made of straps or which has one or several pieces cut out, other than slippers | 60,5 tonnes | 242 tonnes |
| 09.2432 | 6403 99 96 | Footwear with outer soles of rubber, plastics or composition leather and uppers of leather, with in-soles of a length of 24 cm or more, for men, other than sports footwear and footwear incorporating a protective metal toecap, not covering the ankle, not made on a base or platform of wood (not having an inner sole), other than footwear with a vamp made of straps or which has one or several pieces cut out, other than slippers | 363,25 tonnes | 1 453 tonnes |

| Order No | CN code | Description | From entry into force until end of 2012 | 1.1.2013 to 31.12.2013 |
|---|---|---|---|---|
| 09.2433 | 6403 99 98 | Footwear with outer soles of rubber, plastics or composition leather and uppers of leather, with in-soles of a length of 24 cm or more, for women, other than sports footwear and footwear incorporating a protective metal toecap, not covering the ankle, not made on a base or platform of wood (not having an inner sole), other than footwear with a vamp made of straps or which has one or several pieces cut out, other than slippers | 172,75 tonnes | 691 tonnes |

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