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[1] Text with EEA relevance

EN

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DECISIONS

I

(Legislative acts)

REGULATIONS

REGULATION (EU) No 605/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 12 June 2013

amending Council Regulation (EC) No 1185/2003 on the removal of fins of sharks on board vessels

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) 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) Council Regulation (EC) No 1185/2003 [3] establishes a general prohibition of the practice of 'shark finning', whereby a shark's fins are removed and the remainder of the shark is discarded at sea.

(2) Fish belonging to the taxon *Elasmobranchii*, including sharks, skates and rays, are generally very vulnerable to overexploitation due to the characteristics of their life cycle, which include slow growth, late maturity and a small number of young, although biological productivity is not the same for all species. Generally, in recent years, some shark populations have been severely targeted, including by vessels flying the flag of a Member State that are operating in Union and non-Union waters, and put under serious threat as a result of a dramatic increase in demand for shark products, and for shark fins in particular.

(3) Shark fins do not constitute a traditional ingredient of the European diet, but sharks do constitute a necessary element of the Union's marine ecosystem. The management and conservation of shark stocks, as well as, more generally, the promotion of a fishing sector that is sustainably managed for the benefit of the environment and of the people working in the sector, should therefore be a priority.

(4) Current scientific knowledge, based on the examination of shark catch rates, generally indicates that many shark stocks are under serious threat, although the situation is not the same for all species or even for the same species in different maritime zones. According to the International Union for Conservation of Nature (IUCN), more than 25 % of all pelagic shark species, of which over 50 % are large oceanic-pelagic sharks, are threatened. In recent years, the capture, retention on board, transhipment, or landing of a growing number of shark species, including that of sharks whose fins are highly valuable in trade, has been prohibited under Union law or within the framework of regional fisheries management organisations.

(5) Blue shark (*Priconace glauca*) and shortfin mako (*Isurus oxyrinchus*), classified by the IUCN as 'near-threatened' and 'vulnerable' respectively, are currently the predominant species of shark captured by the Union fleet, with blue shark accounting for approximately 70 % of total reported shark landings. Other species, however, including hammerhead and silky sharks, are also subject to capture in Union and non-Union waters and contribute to the economic viability of fisheries.

[1] OJ C 181, 21.6.2012, p. 195.
[2] Position of the European Parliament of 22 November 2012 (not yet published in the Official Journal) and decision of the Council of 6 June 2013.
[3] OJ L 167, 4.7.2003, p. 1.

(6) Regulation (EC) No 1185/2003 currently allows Member States to issue special fishing permits allowing sharks to be processed on board by removing their fins from their bodies. In order to ensure that there is a correlation between the weight of a shark's fins and its body, a 'fin-to-carcass' ratio has been established. There are serious control and enforcement difficulties with the use of the 'fin-to-carcass' ratio. The use of such a ratio is insufficient to eliminate the practice of high-grading and, due to differences in fin-cutting techniques and the variability of the fin size and weight of different shark species, its use could lead to finning going undetected. Following processing operations, fins and bodies can be landed in different ports. In these circumstances, the collection of data, inter alia, on species identification and populations structure, underpinning scientific advice for the establishment of fisheries conservation and management measures, is hampered.

(7) In light of the International Action Plan for the Conservation and Management of Sharks adopted in 1999 by the Food and Agriculture Organisation of the United Nations (FAO), the Union should adopt all measures necessary for the conservation of sharks and to minimise waste and discards from shark catches. In its conclusions of 23 April 2009, the Council endorsed the Union's overall approach and specific objectives, as set out in the related Commission Communication on a European Community Action Plan for the Conservation and Management of Sharks of 5 February 2009. The Council also encouraged the Commission to pay particular attention to the issue of the removal of shark fins and to present, as soon as possible, a proposal for the amendment of Regulation (EC) No 1185/2003, in particular with reference to the derogations and the associated conditions laid down therein.

(8) The Scientific, Technical, and Economic Committee for Fisheries (STECF) acknowledges the problem of shark finning, calls for its eradication, without derogations, and advises that all elasmobranch species should be landed with their fins/wings naturally attached to their bodies.

(9) Regional fisheries management organisations are increasingly addressing the issue of shark finning. In addition, their scientific bodies are showing a preference for sharks to be landed with their fins naturally attached to their bodies and are noting that this is the best way to prevent finning and to facilitate the collection of data needed for stock assessments. The annual resolutions on sustainable fisheries issued by the United Nations General Assembly since 2007, the 2008 IUCN Global Policy against shark finning and the 2010 Meeting of the Fish Stocks Agreement Review Conference have all called on nations to take measures requiring that all sharks are landed with their fins naturally attached to their bodies.

(10) In 2010 and 2011, as part of the required impact assessment exercise, the Commission held a public consultation in order to gather information on the most appropriate manner in which to amend Regulation (EC) No 1185/2003. The Commission concluded in its impact assessment that, in order to achieve the basic objective of conserving shark stocks, that Regulation should provide that all sharks be landed with their fins naturally attached to their bodies.

(11) Regulation (EC) No 1185/2003 should therefore be amended accordingly,

HAVE ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 1185/2003 is hereby amended as follows:

(1) in Article 2, point 3 is deleted;

(2) in Article 3, the following paragraph is inserted:

'1a. Without prejudice to paragraph 1, in order to facilitate on-board storage, shark fins may be partially sliced through and folded against the carcass, but shall not be removed from the carcass before landing.';

(3) Articles 4 and 5 are deleted;

(4) Article 6 is replaced by the following:

'Article 6

Reports

1. Where vessels flying the flag of a Member State catch, retain on-board, tranship or land sharks, the flag Member State, in accordance with Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy (*) and Commission Implementing Regulation (EU) No 404/2011 of 8 April 2011 laying down detailed rules for the implementation of Council Regulation (EC) No 1224/2009 (**), shall send to the Commission, annually, by 1 May, a

comprehensive report on its implementation of this Regulation during the previous year. The report shall describe the monitoring by the flag Member State of compliance with this Regulation by its vessels in Union and non-Union waters, and the enforcement measures it has taken in cases of non-compliance. In particular, the flag Member State shall provide all of the following information:

— the number of landings of sharks,

— the number, date and place of the inspections that have been carried out,

— the number and nature of cases of non-compliance detected, including a full identification of the vessel(s) involved and the penalty applied for each case of non-compliance, and

— the total landings by species (weight/number) and by port.

2. After the submission by Member States of their second annual report in accordance with paragraph 1, the Commission shall, by 1 January 2016, report to the European Parliament and to the Council on the operation of this Regulation and the international developments in this field.

(*) OJ L 343, 22.12.2009, p. 1.
(**) OJ L 112, 30.4.2011, 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, 12 June 2013.

For the European Parliament
The President
M. SCHULZ

For the Council
The President
L. CREIGHTON

REGULATION (EU) No 606/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 12 June 2013

on mutual recognition of protection measures in civil matters

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 points (a), (e) and (f) of Article 81(2) thereof,

Having regard to the proposal from the European Commission,

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

After consulting the European Economic and Social Committee,

Having regard to the opinion of the Committee of the Regions [1],

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

Whereas:

(1) The Union has set itself the objective of maintaining and developing an area of freedom, security and justice in which the free movement of persons is ensured and access to justice is facilitated, in particular through the principle of mutual recognition of judicial and extrajudicial decisions in civil matters. For the gradual establishment of such an area, the Union is to adopt measures relating to judicial cooperation in civil matters having cross-border implications, particularly when necessary for the proper functioning of the internal market.

(2) Article 81(1) of the Treaty on the Functioning of the European Union (TFEU) provides that judicial cooperation in civil matters having cross-border implications is to be based on the principle of mutual recognition of judgments and of decisions in extrajudicial cases.

(3) In a common area of justice without internal borders, provisions to ensure rapid and simple recognition and, where applicable, enforcement in another Member State of protection measures ordered in a Member State are essential to ensure that the protection afforded to a natural person in one Member State is maintained and continued in any other Member State to which that person travels or moves. It is necessary to ensure that the legitimate exercise by citizens of the Union of their right to move and reside freely within the territory of Member States, in accordance with Article 3(2) of the Treaty on European Union (TEU) and Article 21 TFEU, does not result in a loss of that protection.

(4) Mutual trust in the administration of justice in the Union and the aim of ensuring quicker and less costly circulation of protection measures within the Union justify the principle according to which protection measures ordered in one Member State are recognised in all other Member States without any special procedure being required. As a result, a protection measure ordered in one Member State ('Member State of origin') should be treated as if it had been ordered in the Member State where its recognition is sought ('Member State addressed').

(5) In order to attain the objective of free movement of protection measures, it is necessary and appropriate that the rules governing the recognition and, where applicable, enforcement of protection measures be governed by a legal instrument of the Union which is binding and directly applicable.

(6) This Regulation should apply to protection measures ordered with a view to protecting a person where there exist serious grounds for considering that that person's life, physical or psychological integrity, personal liberty, security or sexual integrity is at risk, for example so as to prevent any form of gender-based violence or violence in close relationships such as physical violence, harassment, sexual aggression, stalking, intimidation or other forms of indirect coercion. It is important to underline that this Regulation applies to all victims, regardless of whether they are victims of gender-based violence.

(7) Directive 2012/29/EU of the European Parliament and of the Council of 25 October 2012 establishing minimum standards on the rights, support and protection of victims of crime [3] ensures that victims of crime receive appropriate information and support.

[1] OJ C 113, 18.4.2012, p. 56.

[2] Position of the European Parliament of 22 May 2013 (not yet published in the Official Journal) and decision of the Council of 6 June 2013.

[3] OJ L 315, 14.11.2012, p. 57.

(8) This Regulation complements Directive 2012/29/EU. The fact that a person is the object of a protection measure ordered in civil matters does not necessarily preclude that person from being defined as a 'victim' under that Directive.

(9) The scope of this Regulation is within the field of judicial cooperation in civil matters within the meaning of Article 81 TFEU. This Regulation applies only to protection measures ordered in civil matters. Protection measures adopted in criminal matters are covered by Directive 2011/99/EU of the European Parliament and of the Council of 13 December 2011 on the European Protection Order [1].

(10) The notion of civil matters should be interpreted autonomously, in accordance with the principles of Union law. The civil, administrative or criminal nature of the authority ordering a protection measure should not be determinative for the purpose of assessing the civil character of a protection measure.

(11) This Regulation should not interfere with the functioning of Council Regulation (EC) No 2201/2003 of 27 November 2003 concerning jurisdiction and the recognition and enforcement of judgments in matrimonial matters and the matters of parental responsibility [2] ('Brussels IIa Regulation'). Decisions taken under the Brussels IIa Regulation should continue to be recognised and enforced under that Regulation.

(12) This Regulation takes account of the different legal traditions of the Member States and does not interfere with the national systems for ordering protection measures. This Regulation does not oblige the Member States to modify their national systems so as to enable protection measures to be ordered in civil matters, or to introduce protection measures in civil matters for the application of this Regulation.

(13) In order to take account of the various types of authorities which order protection measures in civil matters in the Member States, and unlike in other areas of judicial cooperation, this Regulation should apply to decisions of both judicial authorities and administrative authorities provided that the latter offer guarantees with regard, in particular, to their impartiality and to the right of the parties to judicial review. In no event should police authorities be considered as issuing authorities within the meaning of this Regulation.

(14) Based on the principle of mutual recognition, protection measures ordered in civil matters in the Member State of origin should be recognised in the Member State addressed as protection measures in civil matters in accordance with this Regulation.

(15) According to the principle of mutual recognition, the recognition corresponds to the duration of the protection measure. However, taking into account the diversity of protection measures under the laws of the Member States, in particular in terms of their duration, and the fact that this Regulation will typically apply in urgent situations, the effects of recognition under this Regulation should, by way of exception, be limited to a period of 12 months from the issuing of the certificate provided for by this Regulation, irrespective of whether the protection measure itself (be it provisional, time-limited or indefinite in nature) has a longer duration.

(16) In cases where the duration of a protection measure is greater than 12 months, the limitation of the effects of recognition under this Regulation should be without prejudice to the right of the protected person to invoke that protection measure under any other available legal act of the Union providing for recognition or to apply for a national protection measure in the Member State addressed.

(17) The limitation of the effects of recognition is exceptional due to the special nature of the subject matter of this Regulation and should not serve as a precedent for other instruments in civil and commercial matters.

(18) This Regulation should deal only with the recognition of the obligation imposed by the protection measure. It should not regulate the procedures for implementation or enforcement of the protection measure, nor should it cover any potential sanctions that might be imposed if the obligation ordered by the protection measure is infringed in the Member State addressed. Those matters are left to the law of that Member State. However, in accordance with the general principles of Union law and particularly the principle of mutual recognition, Member States are to ensure that protection measures recognised under this Regulation can take effect in the Member State addressed.

[1] OJ L 338, 21.12.2011, p. 2.
[2] OJ L 338, 23.12.2003, p. 1.

(19) Protection measures covered by this Regulation should afford protection to the protected person at his or her place of residence or place of work, or at another place which that person visits on a regular basis, such as the residence of close relatives or the school or educational establishment attended by his or her child. Irrespective of whether the place in question or the extent of the area covered by the protection measure is described in the protection measure by one or more specific addresses or by reference to a circumscribed area which the person causing the risk may not approach or enter, respectively (or a combination of the two), the recognition of the obligation imposed by the protection measure relates to the purpose which the place serves for the protected person rather than to the specific address.

(20) In the light of the foregoing and provided that the nature and the essential elements of the protection measure are maintained, the competent authority of the Member State addressed should be allowed to adjust the factual elements of the protection measure where such adjustment is necessary in order for the recognition of the protection measure to be effective in practical terms in the Member State addressed. Factual elements include the address, the general location or the minimum distance the person causing the risk must keep from the protected person, the address or the general location. However, the type and the civil nature of the protection measure may not be affected by such adjustment.

(21) In order to facilitate any adjustment of a protection measure, the certificate should indicate whether the address specified in the protection measure constitutes the place of residence, the place of work or a place that the protected person visits on a regular basis. Furthermore, if relevant, the circumscribed area (approximate radius from the specific address) to which the obligation imposed by the protection measure on the person causing the risk applies should also be indicated in the certificate.

(22) In order to facilitate the free movement of protection measures within the Union, this Regulation should introduce a uniform model of certificate and provide for the establishment of a multilingual standard form for that purpose. The issuing authority should issue the certificate upon request by the protected person.

(23) Free text fields in the multilingual standard form for the certificate should be as limited as possible, so that translation or transliteration may be provided in most cases without imposing any costs on the protected person by making use of the standard form in the relevant language. Any costs for necessary translation that goes beyond the text of the multilingual standard form are to be allocated as provided under the law of the Member State of origin.

(24) Where a certificate contains free text, the competent authority of the Member State addressed should determine whether any translation or transliteration is required. This should not preclude the protected person or the issuing authority of the Member State of origin from providing a translation or transliteration on their own initiative.

(25) To ensure respect for the rights of defence of the person causing the risk, where the protection measure was ordered in default of appearance or under a procedure that does not provide for prior notice to that person ('*ex-parte* proceeding'), the issue of the certificate should only be possible if that person has had the opportunity to arrange for his or her defence against the protection measure. However, with a view to avoiding circumvention and taking into account the typical urgency of cases necessitating protection measures, it should not be required that the period for raising such defence has expired before a certificate may be issued. The certificate should be issued as soon as the protection measure is enforceable in the Member State of origin.

(26) Having regard to the objectives of simplicity and speed, this Regulation provides for simple and quick methods to be used for bringing procedural steps to the notice of the person causing the risk. Those specific methods of notification should apply only for the purposes of this Regulation due to the special nature of its subject matter, should not serve as a precedent for other instruments in civil and commercial matters and should not affect any obligations of a Member State concerning the service abroad of judicial and extrajudicial documents in civil matters arising from a bilateral or multilateral convention concluded between that Member State and a third country.

(27) When the certificate is brought to the notice of the person causing the risk and also when any adjustment is made to any factual elements of a protection measure in the Member State addressed, due regard should be paid to the interest of the protected person in not having his or her whereabouts or other contact details disclosed. Such details should not be disclosed to the person causing the risk unless such disclosure is necessary for compliance with, or the enforcement of, the protection measure.

(28) The issuing of the certificate should not be subject to appeal.

(29) The certificate should be rectified where, due to an obvious error or inaccuracy, such as a typing error or an error of transcription or copying, the certificate does not correctly reflect the protection measure, or should be withdrawn if it was clearly wrongly granted, for example where it was used for a measure that falls outside the scope of this Regulation or where it was issued in breach of the requirements for its issuing.

(30) The issuing authority of the Member State of origin should, upon request, assist the protected person in obtaining information on the authorities of the Member State addressed before which the protection measure is to be invoked or enforcement is to be sought.

(31) The harmonious functioning of justice requires that irreconcilable decisions should not be delivered in two Member States. To that end, this Regulation should provide for a ground for refusal of recognition or enforcement of the protection measure in cases of irreconcilability with a judgment given or recognised in the Member State addressed.

(32) Public interest considerations may, in exceptional circumstances, justify a refusal by the court of the Member State addressed to recognise or enforce a protection measure where its application would be manifestly incompatible with the public policy of that Member State. However, the court should not be able to apply the public-policy exception in order to refuse recognition or enforcement of a protection measure when to do so would be contrary to the rights set out in the Charter of Fundamental Rights of the European Union, and in particular Article 21 thereof.

(33) In the event of suspension or withdrawal of the protection measure or withdrawal of the certificate in the Member State of origin, the competent authority of the Member State addressed should, upon submission of the relevant certificate, suspend or withdraw the effects of recognition and, where applicable, the enforcement of the protection measure.

(34) A protected person should have effective access to justice in other Member States. To ensure such effective access in procedures covered by this Regulation, legal aid is to be provided in accordance with Council Directive 2003/8/EC of 27 January 2003 to improve access to justice in cross-border disputes by establishing minimum common rules relating to legal aid for such disputes [1].

(35) In order to facilitate the application of this Regulation, Member States should be required to provide certain information regarding their national rules and procedures concerning protection measures in civil matters within the framework of the European Judicial Network in civil and commercial matters established by Council Decision 2001/470/EC [2]. Access to the information provided by the Member States should be made available through the European e-Justice Portal.

(36) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission with regard to the establishment and subsequent amendment of the forms provided for in this Regulation. 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 [3].

(37) The examination procedure should be used for the adoption of implementing acts establishing and subsequently amending the forms provided for in this Regulation.

(38) This Regulation respects the fundamental rights and observes the principles recognised in the Charter of Fundamental Rights of the European Union. In particular, it seeks to ensure the rights of the defence and fair trial, as established in Articles 47 and 48 thereof. This Regulation should be applied according to those rights and principles.

(39) Since the objective of this Regulation, namely to establish rules for a simple and rapid mechanism for the recognition of protection measures ordered in a Member State in civil matters, 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 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 that objective.

(40) In accordance with Article 3 of Protocol No 21 on the position of the United Kingdom and Ireland in respect of the Area of Freedom, Security and Justice, annexed to the TEU and to the TFEU, those Member States have notified their wish to take part in the adoption and application of this Regulation.

[1] OJ L 26, 31.1.2003, p. 41.

[2] OJ L 174, 27.6.2001, p. 25.

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

(41) In accordance with Articles 1 and 2 of Protocol No 22 on the position of Denmark, annexed to the TEU and to the TFEU, Denmark is not taking part in the adoption of this Regulation and is not bound by it or subject to its application.

(42) The European Data Protection Supervisor delivered an opinion on 17 October 2011 [1], based on Article 41(2) of 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],

HAVE ADOPTED THIS REGULATION:

CHAPTER I

SUBJECT MATTER, SCOPE AND DEFINITIONS

Article 1

Subject matter

This Regulation establishes rules for a simple and rapid mechanism for the recognition of protection measures ordered in a Member State in civil matters.

Article 2

Scope

1. This Regulation shall apply to protection measures in civil matters ordered by an issuing authority within the meaning of point (4) of Article 3.

2. This Regulation shall apply to cross-border cases. For the purposes of this Regulation, a case shall be deemed to be a cross-border case where the recognition of a protection measure ordered in one Member State is sought in another Member State.

3. This Regulation shall not apply to protection measures falling within the scope of Regulation (EC) No 2201/2003.

Article 3

Definitions

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

(1) 'protection measure' means any decision, whatever it may be called, ordered by the issuing authority of the Member State of origin in accordance with its national law and imposing one or more of the following obligations on the person causing the risk with a view to protecting another person, when the latter person's physical or psychological integrity may be at risk:

(a) a prohibition or regulation on entering the place where the protected person resides, works, or regularly visits or stays;

(b) a prohibition or regulation of contact, in any form, with the protected person, including by telephone, electronic or ordinary mail, fax or any other means;

(c) a prohibition or regulation on approaching the protected person closer than a prescribed distance;

(2) 'protected person' means a natural person who is the object of the protection afforded by a protection measure;

(3) 'person causing the risk' means a natural person on whom one or more of the obligations referred to in point (1) have been imposed;

(4) 'issuing authority' means any judicial authority, or any other authority designated by a Member State as having competence in the matters falling within the scope of this Regulation, provided that such other authority offers guarantees to the parties with regard to impartiality, and that its decisions in relation to the protection measure may, under the law of the Member State in which it operates, be made subject to review by a judicial authority and have similar force and effects to those of a decision of a judicial authority on the same matter;

(5) 'Member State of origin' means the Member State in which the protection measure is ordered;

(6) 'Member State addressed' means the Member State in which the recognition and, where applicable, the enforcement of the protection measure is sought.

CHAPTER II

RECOGNITION AND ENFORCEMENT OF PROTECTION MEASURES

Article 4

Recognition and enforcement

1. A protection measure ordered in a Member State shall be recognised in the other Member States without any special procedure being required and shall be enforceable without a declaration of enforceability being required.

[1] OJ C 35, 9.2.2012, p. 10.
[2] OJ L 8, 12.1.2001, p. 1.

2. A protected person who wishes to invoke in the Member State addressed a protection measure ordered in the Member State of origin shall provide the competent authority of the Member State addressed with:

(a) a copy of the protection measure which satisfies the conditions necessary to establish its authenticity;

(b) the certificate issued in the Member State of origin pursuant to Article 5; and

(c) where necessary, a transliteration and/or a translation of the certificate in accordance with Article 16.

3. The certificate shall take effect only within the limits of the enforceability of the protection measure.

4. Irrespective of whether the protection measure has a longer duration, the effects of recognition pursuant to paragraph 1 shall be limited to a period of 12 months, starting from the date of the issuing of the certificate.

5. The procedure for the enforcement of protection measures shall be governed by the law of the Member State addressed.

Article 5

Certificate

1. The issuing authority of the Member State of origin shall, upon request by the protected person, issue the certificate using the multilingual standard form established in accordance with Article 19 and containing the information provided for in Article 7.

2. No appeal shall lie against the issuing of the certificate.

3. Upon request by the protected person, the issuing authority of the Member State of origin shall provide the protected person with a transliteration and/or a translation of the certificate by making use of the multilingual standard form established in accordance with Article 19.

Article 6

Requirements for the issuing of the certificate

1. The certificate may only be issued if the protection measure has been brought to the notice of the person causing the risk in accordance with the law of the Member State of origin.

2. Where the protection measure was ordered in default of appearance, the certificate may only be issued if the person causing the risk had been served with the document which instituted the proceeding or an equivalent document or, where relevant, had been otherwise informed of the initiation of the proceeding in accordance with the law of the Member State of origin in sufficient time and in such a way as to enable that person to arrange for his or her defence.

3. Where the protection measure was ordered under a procedure that does not provide for prior notice to be given to the person causing the risk ('*ex-parte* proceeding'), the certificate may only be issued if that person had the right to challenge the protection measure under the law of the Member State of origin.

Article 7

Contents of the certificate

The certificate shall contain the following information:

(a) the name and address/contact details of the issuing authority;

(b) the reference number of the file;

(c) the date of issue of the certificate;

(d) details concerning the protected person: name, date and place of birth, where available, and an address to be used for notification purposes, preceded by a conspicuous warning that that address may be disclosed to the person causing the risk;

(e) details concerning the person causing the risk: name, date and place of birth, where available, and address to be used for notification purposes;

(f) all information necessary for enforcement of the protection measure, including, where applicable, the type of the measure and the obligation imposed by it on the person causing the risk and specifying the function of the place and/or the circumscribed area which that person is prohibited from approaching or entering, respectively;

(g) the duration of the protection measure;

(h) the duration of the effects of recognition pursuant to Article 4(4);

(i) a declaration that the requirements laid down in Article 6 have been met;

(j) information on the rights granted under Articles 9 and 13;

(k) for ease of reference, the full title of this Regulation.

Article 8

Notification of the certificate to the person causing the risk

1. The issuing authority of the Member State of origin shall bring to the notice of the person causing the risk the certificate and the fact that the issuing of the certificate results in the recognition and, where applicable, in the enforceability of the protection measure in all Member States pursuant to Article 4.

2. Where the person causing the risk resides in the Member State of origin, the notification shall be effected in accordance with the law of that Member State. Where the person causing the risk resides in a Member State other than the Member State of origin or in a third country, the notification shall be effected by registered letter with acknowledgment of receipt or equivalent.

Situations in which the address of the person causing the risk is not known or in which that person refuses to accept receipt of the notification shall be governed by the law of the Member State of origin.

3. The whereabouts or other contact details of the protected person shall not be disclosed to the person causing the risk unless their disclosure is necessary for compliance with, or the enforcement of, the protection measure.

Article 9

Rectification or withdrawal of the certificate

1. Without prejudice to Article 5(2) and upon request by the protected person or the person causing the risk to the issuing authority of the Member State of origin or on that authority's own initiative, the certificate shall be:

(a) rectified where, due to a clerical error, there is a discrepancy between the protection measure and the certificate; or

(b) withdrawn where it was clearly wrongly granted, having regard to the requirements laid down in Article 6 and the scope of this Regulation.

2. The procedure, including any appeal, with regard to the rectification or withdrawal of the certificate shall be governed by the law of the Member State of origin.

Article 10

Assistance to the protected person

Upon request by the protected person, the issuing authority of the Member State of origin shall assist that person in obtaining information, as made available in accordance with Articles 17 and 18, concerning the authorities of the Member State addressed before which the protection measure is to be invoked or enforcement is to be sought.

Article 11

Adjustment of the protection measure

1. The competent authority of the Member State addressed shall, where and to the extent necessary, adjust the factual elements of the protection measure in order to give effect to the protection measure in that Member State.

2. The procedure for the adjustment of the protection measure shall be governed by the law of the Member State addressed.

3. The adjustment of the protection measure shall be brought to the notice of the person causing the risk.

4. Where the person causing the risk resides in the Member State addressed, the notification shall be effected in accordance with the law of that Member State. Where the person causing the risk resides in a Member State other than the Member State addressed or in a third country, the notification shall be effected by registered letter with acknowledgment of receipt or equivalent.

Situations in which the address of the person causing the risk is not known or in which that person refuses to accept receipt of the notification shall be governed by the law of the Member State addressed.

5. An appeal against the adjustment of the protection measure may be lodged by the protected person or the person causing the risk. The appeal procedure shall be governed by the law of the Member State addressed. However, the lodging of an appeal shall not have suspensive effect.

Article 12

No review as to substance

Under no circumstances may a protection measure ordered in the Member State of origin be reviewed as to its substance in the Member State addressed.

Article 13

Refusal of recognition or enforcement

1. The recognition and, where applicable, the enforcement of the protection measure shall be refused, upon application by the person causing the risk, to the extent such recognition is:

(a) manifestly contrary to public policy in the Member State addressed; or

(b) irreconcilable with a judgment given or recognised in the Member State addressed.

2. The application for refusal of recognition or enforcement shall be submitted to the court of the Member State addressed as communicated by that Member State to the Commission in accordance with point (a)(iv) of Article 18(1).

3. The recognition of the protection measure may not be refused on the ground that the law of the Member State addressed does not allow for such a measure based on the same facts.

Article 14

Suspension or withdrawal of recognition or enforcement

1. In the event of suspension or withdrawal of the protection measure in the Member State of origin, suspension or limitation of its enforceability, or withdrawal of the certificate in accordance with point (b) of Article 9(1), the issuing authority of the Member State of origin shall, upon request by the protected person or the person causing the risk, issue a certificate indicating that suspension, limitation or withdrawal using the multilingual standard form established in accordance with Article 19.

2. Upon submission by the protected person or the person causing the risk of the certificate issued in accordance with paragraph 1, the competent authority of the Member State addressed shall suspend or withdraw the effects of the recognition and, where applicable, the enforcement of the protection measure.

CHAPTER III

GENERAL AND FINAL PROVISIONS

Article 15

Legalisation and other similar formalities

No legalisation or other similar formality shall be required for documents issued in a Member State in the context of this Regulation.

Article 16

Transliteration or translation

1. Any transliteration or translation required under this Regulation shall be into the official language or one of the official languages of the Member State addressed or into any other official language of the institutions of the Union which that Member State has indicated it can accept.

2. Subject to Article 5(3), any translation under this Regulation shall be done by a person qualified to do translations in one of the Member States.

Article 17

Information made available to the public

The Member States shall provide, within the framework of the European Judicial Network in civil and commercial matters established by Decision 2001/470/EC and with a view to making the information available to the public, a description of the national rules and procedures concerning protection measures in civil matters, including information on the type of authorities which are competent in the matters falling within the scope of this Regulation.

The Member States shall keep that information updated.

Article 18

Communication of information by the Member States

1. By 11 July 2014, Member States shall communicate to the Commission the following information:

(a) the type of authorities which are competent in the matters falling within the scope of this Regulation, specifying, where applicable:

(i) the authorities which are competent to order protection measures and issue certificates in accordance with Article 5;

(ii) the authorities before which a protection measure ordered in another Member State is to be invoked and/or which are competent to enforce such a measure;

(iii) the authorities which are competent to effect the adjustment of protection measures in accordance with Article 11(1);

(iv) the courts to which the application for refusal of recognition and, where applicable, enforcement is to be submitted in accordance with Article 13;

(b) the language or languages accepted for translations as referred to in Article 16(1).

2. The Commission shall make the information referred to in paragraph 1 available to the public through any appropriate means, in particular through the website of the European Judicial Network in civil and commercial matters.

Article 19

Establishment and subsequent amendment of the forms

The Commission shall adopt implementing acts establishing and subsequently amending the forms referred to in Articles 5 and 14. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 20.

Article 20

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.

Article 21

Review

By 11 January 2020, the Commission shall submit to the European Parliament, the Council and the European Economic and Social Committee a report on the application of this Regulation. If necessary, the report shall be accompanied by proposals for amendments.

Article 22

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 11 January 2015.

This Regulation shall apply to protection measures ordered on or after 11 January 2015, irrespective of when proceedings have been instituted.

This Regulation shall be binding in its entirety and directly applicable in the Member States in accordance with the Treaties.

Done at Strasbourg, 12 June 2013.

For the European Parliament
The President
M. SCHULZ

For the Council
The President
L. CREIGHTON

REGULATION (EU) No 607/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 12 June 2013

repealing Council Regulation (EC) No 552/97 temporarily withdrawing access to generalised tariff preferences from Myanmar/Burma

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the European Commission,

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

Acting in accordance with the ordinary legislative procedure [1],

Whereas:

(1) Article 1 of Council Regulation (EC) No 552/97 of 24 March 1997 temporarily withdrawing access to generalized tariff preferences from the Union of Myanmar [2], as amended by Article 28(1) of Council Regulation (EC) No 732/2008 of 22 July 2008 applying a scheme of generalised tariff preferences from 1 January 2009 [3], provides that Myanmar/Burma's access to the tariff preferences granted by Regulation (EC) No 732/2008 is temporarily withdrawn.

(2) Point (a) of Article 15(1) of Regulation (EC) No 732/2008 provides that the preferential arrangements provided for in that Regulation may be withdrawn temporarily, in respect of all or of certain products originating in a beneficiary country, for the serious and systematic violation of principles laid down in the conventions listed in Part A of Annex III to that Regulation, on the basis of the conclusions of the relevant monitoring bodies.

(3) The International Labour Organisation (ILO) Convention concerning Forced or Compulsory Labour, 1930 (No 29), is listed in Part A of Annex III to Regulation (EC) No 732/2008.

(4) Pursuant to Article 2 of Regulation (EC) No 552/97, the application of that Regulation should be brought to an end in the light of a Commission report on forced labour in Myanmar/Burma, showing that the practices referred to in point (a) of Article 15(1) of Regulation (EC) No 732/2008 no longer exist.

(5) On 13 June 2012 the International Labour Conference (ILC) adopted a resolution 'Concerning the measures on the subject of Myanmar adopted under article 33 of the ILO Constitution' (ILC resolution). Taking note of the conclusions adopted on 4 June 2012 by the ILC Committee on the Application of Standards and considering that maintaining the existing measures would no longer help attaining the desired result, the ILC decided to lift restrictions, which excluded the Government of Myanmar/Burma from receiving ILO technical cooperation and assistance. It also suspended for one year the ILO request of its members to review their relationships with Myanmar/Burma to ensure forced labour is not being used in those relationships.

(6) On 17 September 2012, the Commission published a report pursuant to Article 2 of Council Regulation (EC) No 552/97 with respect to the forced labour in Myanmar/Burma, containing its findings ('the Report'). The Report concludes that the progress made by Myanmar/Burma towards complying with the ILO recommendations, which has been acknowledged by the competent ILO monitoring bodies, means that violations of the principles laid down in ILO Convention No 29 are no longer considered as 'serious and systematic' and recommends that access to generalised tariff preferences should be reinstated to Myanmar/Burma.

(7) In view of the ILC resolution and of the Report, and pursuant to Article 2 of Regulation (EC) No 552/97, the temporary withdrawal of Myanmar/Burma's access to the tariff preferences granted by Regulation (EC) No 732/2008 should therefore be repealed, as of the date of the adoption of the ILC resolution.

(8) The Commission should continue to monitor developments in Myanmar/Burma with respect to forced labour and react to them in accordance with the procedures in force, including, if necessary, with renewed withdrawal procedures,

HAVE ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 552/97 is hereby repealed.

[1] Position of the European Parliament of 23 May 2013 (not yet published in the Official Journal) and decision of the Council of 10 June 2013.

[2] OJ L 85, 27.3.1997, p. 8.

[3] OJ L 211, 6.8.2008, p. 1.

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 13 June 2012.

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

Done at Strasbourg, 12 June 2013.

For the European Parliament	*For the Council*
The President	*The President*
M. SCHULZ	L. CREIGHTON

REGULATION (EU) No 608/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 12 June 2013

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

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the European Commission,

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

Acting in accordance with the ordinary legislative procedure [1],

Whereas:

(1) The Council requested, in its Resolution of 25 September 2008 on a comprehensive European anti-counterfeiting and anti-piracy plan, that Council Regulation (EC) No 1383/2003 of 22 July 2003 concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights [2], be reviewed.

(2) The marketing of goods infringing intellectual property rights does considerable damage to right-holders, users or groups of producers, and to law-abiding manufacturers and traders. Such marketing could also be deceiving consumers, and could in some cases be endangering their health and safety. Such goods should, in so far as is possible, be kept off the Union market and measures should be adopted to deal with such unlawful marketing without impeding legitimate trade.

(3) The review of Regulation (EC) No 1383/2003 showed that, in the light of economic, commercial and legal developments, certain improvements to the legal framework are necessary to strengthen the enforcement of intellectual property rights by customs authorities, as well as to ensure appropriate legal certainty.

(4) The customs authorities should be competent to enforce intellectual property rights with regard to goods, which, in accordance with Union customs legislation, are liable to customs supervision or customs control, and to carry out adequate controls on such goods with a view to preventing operations in breach of intellectual property rights laws. Enforcing intellectual property rights at the border, wherever the goods are, or should have been, under customs supervision or customs control is an efficient way to quickly and effectively provide legal protection to the right-holder as well as the users and groups of producers. Where the release of goods is suspended or goods are detained by customs authorities at the border, only one legal proceeding should be required, whereas several separate proceedings should be required for the same level of enforcement for goods found on the market, which have been disaggregated and delivered to retailers. An exception should be made for goods released for free circulation under the end-use regime, as such goods remain under customs supervision, even though they have been released for free circulation. This Regulation should not apply to goods carried by passengers in their personal luggage provided that those goods are for their own personal use and there are no indications that commercial traffic is involved.

(5) Regulation (EC) No 1383/2003 does not cover certain intellectual property rights and certain infringements are excluded from its scope. In order to strengthen the enforcement of intellectual property rights, customs intervention should be extended to other types of infringements not covered by Regulation (EC) No 1383/2003. This Regulation should therefore, in addition to the rights already covered by Regulation (EC) No 1383/2003, also include trade names in so far as they are protected as exclusive property rights under national law, topographies of semiconductor products and utility models and devices which are primarily designed, produced or adapted for the purpose of enabling or facilitating the circumvention of technological measures.

(6) Infringements resulting from so-called illegal parallel trade and overruns are excluded from the scope of Regulation (EC) No 1383/2003. Goods subject to illegal parallel trade, namely goods that have been manufactured with the consent of the right-holder but placed

[1] Position of the European Parliament of 3 July 2012 (not yet published in the Official Journal) and position of the Council at first reading of 16 May 2013 (not yet published in the Official Journal). Position of the European Parliament of 11 June 2013 (not yet published in the Official Journal).

[2] OJ L 196, 2.8.2003, p. 7.

on the market for the first time in the European Economic Area without his consent, and overruns, namely goods that are manufactured by a person duly authorised by a right-holder to manufacture a certain quantity of goods, in excess of the quantities agreed between that person and the right-holder, are manufactured as genuine goods and it is therefore not appropriate that customs authorities focus their efforts on such goods. Illegal parallel trade and overruns should therefore also be excluded from the scope of this Regulation.

(7) Member States should, in cooperation with the Commission, provide appropriate training for customs officials, in order to ensure the correct implementation of this Regulation.

(8) This Regulation, when fully implemented, will further contribute to an internal market which ensures right-holders a more effective protection, fuels creativity and innovation and provides consumers with reliable and high-quality products, which should in turn strengthen cross-border transactions between consumers, businesses and traders.

(9) Member States face increasingly limited resources in the field of customs. Therefore, the promotion of risk management technologies and strategies to maximise resources available to customs authorities should be supported.

(10) This Regulation solely contains procedural rules for customs authorities. Accordingly, this Regulation does not set out any criteria for ascertaining the existence of an infringement of an intellectual property right.

(11) Under the 'Declaration on the TRIPS Agreement and Public Health' adopted by the Doha WTO Ministerial Conference on 14 November 2001, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all. Consequently, in line with the Union's international commitments and its development cooperation policy, with regard to medicines, the passage of which across the customs territory of the Union, with or without transhipment, warehousing, breaking bulk, or changes in the mode or means of transport, is only a portion of a complete journey beginning and terminating beyond the territory of the Union, customs authorities should, when assessing a risk of infringement of intellectual property rights, take account of any substantial likelihood of diversion of such medicines onto the market of the Union.

(12) This Regulation should not affect the provisions on the competence of courts, in particular, those of Regulation (EU) No 1215/2012 of the European Parliament and of the Council of 12 December 2012 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters [1].

(13) Persons, users, bodies or groups of producers, who are in a position to initiate legal proceedings in their own name with respect to a possible infringement of an intellectual property right, should be entitled to submit an application.

(14) In order to ensure that intellectual property rights are enforced throughout the Union, it is appropriate to allow persons or entities seeking enforcement of Union-wide rights to apply to the customs authorities of a single Member State. Such applicants should be able to request that those authorities decide that action be taken to enforce the intellectual property right both in their own Member State and in any other Member State.

(15) In order to ensure the swift enforcement of intellectual property rights, it should be provided that, where the customs authorities suspect, on the basis of reasonable indications, that goods under their supervision infringe intellectual property rights, they may suspend the release of or detain the goods whether at their own initiative or upon application, in order to enable a person or entity entitled to submit an application to initiate proceedings for determining whether an intellectual property right has been infringed.

(16) Regulation (EC) No 1383/2003 allowed Member States to provide for a procedure allowing the destruction of certain goods without there being any obligation to initiate proceedings to establish whether an intellectual property right has been infringed. As recognised in the European Parliament Resolution of 18 December 2008 on the impact of counterfeiting on international trade [2], such procedure has proved very successful in

[1] OJ L 351, 20.12.2012, p. 1.
[2] OJ C 45 E, 23.2.2010, p. 47.

the Member States where it has been available. Therefore, the procedure should be made compulsory with regard to all infringements of intellectual property rights and should be applied, where the declarant or the holder of the goods agrees to destruction. Furthermore, the procedure should provide that customs authorities may deem that the declarant or the holder of the goods has agreed to the destruction of the goods where he has not explicitly opposed destruction within the prescribed period.

(17) In order to reduce the administrative burden and costs to a minimum, a specific procedure should be introduced for small consignments of counterfeit and pirated goods, which should allow for such goods to be destroyed without the explicit agreement of the applicant in each case. However, a general request made by the applicant in the application should be required in order for that procedure to be applied. Furthermore, customs authorities should have the possibility to require that the applicant covers the costs incurred by the application of that procedure.

(18) For further legal certainty, it is appropriate to modify the timelines for suspending the release of or detaining goods suspected of infringing an intellectual property right and the conditions in which information about detained goods is to be passed on to persons and entities concerned by customs authorities, as provided for in Regulation (EC) No 1383/2003.

(19) Taking into account the provisional and preventive character of the measures adopted by the customs authorities when applying this Regulation and the conflicting interests of the parties affected by the measures, some aspects of the procedures should be adapted to ensure the smooth application of this Regulation, whilst respecting the rights of the concerned parties. Thus, with respect to the various notifications envisaged by this Regulation, the customs authorities should notify the relevant person, on the basis of the documents concerning the customs treatment or of the situation in which the goods are placed. Furthermore, since the procedure for destruction of goods implies that both the declarant or the holder of the goods and the holder of the decision should communicate their possible objections to destruction in parallel, it should be ensured that the holder of the decision is given the possibility to react to a potential objection to destruction by the declarant or the holder of the goods. It should therefore be ensured that the declarant or the holder of the goods is notified of the suspension of the release of the goods or their detention before, or on the same day as, the holder of the decision.

(20) Customs authorities and the Commission are encouraged to cooperate with the European Observatory on Infringements of Intellectual Property Rights in the framework of their respective competences.

(21) With a view to eliminating international trade in goods infringing intellectual property rights, the TRIPS Agreement provides that WTO Members are to promote the exchange of information between customs authorities on such trade. Accordingly, it should be possible for the Commission and the customs authorities of the Member States to share information on suspected breaches of intellectual property rights with the relevant authorities of third countries, including on goods which are in transit through the territory of the Union and originate in or are destined for those third countries.

(22) In the interest of efficiency, the provisions of Council Regulation (EC) No 515/97 of 13 March 1997 on mutual assistance between the administrative authorities of the Member States and cooperation between the latter and the Commission to ensure the correct application of the law on customs or agricultural matters [1], should apply.

(23) The liability of the customs authorities should be governed by the legislation of the Member States, though the granting by the customs authorities of an application should not entitle the holder of the decision to compensation in the event that goods suspected of infringing an intellectual property right are not detected by the customs authorities and are released or no action is taken to detain them.

(24) Given that customs authorities take action upon application, it is appropriate to provide that the holder of the decision should reimburse all the costs incurred by the customs authorities in taking action to enforce his intellectual property rights. Nevertheless, this should not preclude the holder of the decision from seeking compensation from the infringer or other persons that might be considered liable under the legislation of the Member State where the goods were found. Such persons might include intermediaries, where applicable. Costs and damages incurred by persons other than customs authorities as a result of a customs action, where the release of goods is suspended or the goods are detained on the basis of a claim of a third party based on intellectual property, should be governed by the specific legislation applicable in each particular case.

(25) This Regulation introduces the possibility for customs authorities to allow goods which are to be destroyed to be moved, under customs supervision, between different places within the customs territory of the Union. Customs authorities may furthermore decide to release such goods for free circulation with a view

[1] OJ L 82, 22.3.1997, p. 1.

to further recycling or disposal outside commercial channels including for awareness-raising, training and educational purposes.

(26) Customs enforcement of intellectual property rights entails the exchange of data on decisions relating to applications. Such processing of data covers also personal data and should be carried out in accordance with Union law, as set out in Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data [1] and Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by Community institutions and bodies and on the free movement of such data [2].

(27) The exchange of information relating to decisions on applications and to customs actions should be made via a central electronic database. The entity which will control and manage that database and the entities in charge of ensuring the security of the processing of the data contained in the database should be defined. Introducing any type of possible interoperability or exchange should first and foremost comply with the purpose limitation principle, namely that data should be used for the purpose for which the database has been established, and no further exchange or interconnection should be allowed other than for that purpose.

(28) In order to ensure that the definition of small consignments can be adapted if it proves to be impractical, taking into account the need to ensure the effective operation of the procedure, or where necessary to avoid any circumvention of this procedure as regards the composition of consignments, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of amending the non-essential elements of the definition of small consignments, namely the specific quantities set out in that definition. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

(29) In order to ensure uniform conditions for the implementation of the provisions concerning defining the elements of the practical arrangements for the exchange of data with third countries and the provisions concerning the forms for the application and for requesting the extension of the period during which customs authorities are to take action, implementing powers should be conferred on the Commission, namely to define those elements of the practical arrangements and to establish standard forms. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers [3]. For establishing the standard forms, although the subject of the provisions of this Regulation to be implemented falls within the scope of the common commercial policy, given the nature and impacts of those implementing acts, the advisory procedure should be used for their adoption, because all details of what information to include in the forms follows directly from the text of this Regulation. Those implementing acts will therefore only establish the format and structure of the form and will have no further implications for the common commercial policy of the Union.

(30) Regulation (EC) No 1383/2003 should be repealed.

(31) The European Data Protection Supervisor was consulted in accordance with Article 28(2) of Regulation (EC) No 45/2001 and delivered an opinion on 12 October 2011 [4],

HAVE ADOPTED THIS REGULATION:

CHAPTER I

SUBJECT MATTER, SCOPE AND DEFINITIONS

Article 1

Subject matter and scope

1. This Regulation sets out the conditions and procedures for action by the customs authorities where goods suspected of infringing an intellectual property right are, or should have been, subject to customs supervision or customs control within the customs territory of the Union in accordance with Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code [5], particularly goods in the following situations:

(a) when declared for release for free circulation, export or re-export;

[1] OJ L 281, 23.11.1995, p. 31.
[2] OJ L 8, 12.1.2001, p. 1.
[3] OJ L 55, 28.2.2011, p. 13.
[4] OJ C 363, 13.12.2011, p. 3.
[5] OJ L 302, 19.10.1992, p. 1.

(b) when entering or leaving the customs territory of the Union;

(c) when placed under a suspensive procedure or in a free zone or free warehouse.

2. In respect of the goods subject to customs supervision or customs control, and without prejudice to Articles 17 and 18, the customs authorities shall carry out adequate customs controls and shall take proportionate identification measures as provided for in Article 13(1) and Article 72 of Regulation (EEC) No 2913/92 in accordance with risk analysis criteria with a view to preventing acts in breach of intellectual property laws applicable in the territory of the Union and in order to cooperate with third countries on the enforcement of intellectual property rights.

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

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

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

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

Article 2

Definitions

For the purposes of this Regulation:

(1) 'intellectual property right' means:

(a) a trade mark;

(b) a design;

(c) a copyright or any related right as provided for by national or Union law;

(d) a geographical indication;

(e) a patent as provided for by national or Union law;

(f) a supplementary protection certificate for medicinal products as provided for in Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products [1];

(g) a supplementary protection certificate for plant protection products as provided for in Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products [2];

(h) a Community plant variety right as provided for in Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights [3];

(i) a plant variety right as provided for by national law;

(j) a topography of semiconductor product as provided for by national or Union law;

(k) a utility model in so far as it is protected as an intellectual property right by national or Union law;

(l) a trade name in so far as it is protected as an exclusive intellectual property right by national or Union law;

(2) 'trade mark' means:

(a) a Community trade mark as provided for in Council Regulation (EC) No 207/2009 of 26 February 2009 on the Community trade mark [4];

(b) a trade mark registered in a Member State, or, in the case of Belgium, Luxembourg or the Netherlands, at the Benelux Office for Intellectual Property;

(c) a trade mark registered under international arrangements which has effect in a Member State or in the Union;

(3) 'design' means:

(a) a Community design as provided for in Council Regulation (EC) No 6/2002 of 12 December 2001 on Community designs [5];

[1] OJ L 152, 16.6.2009, p. 1.
[2] OJ L 198, 8.8.1996, p. 30.
[3] OJ L 227, 1.9.1994, p. 1.
[4] OJ L 78, 24.3.2009, p. 1.
[5] OJ L 3, 5.1.2002, p. 1.

(b) a design registered in a Member State, or, in the case of Belgium, Luxembourg or the Netherlands, at the Benelux Office for Intellectual Property;

(c) a design registered under international arrangements which has effect in a Member State or in the Union;

(4) 'geographical indication' means:

(a) a geographical indication or designation of origin protected for agricultural products and foodstuff as provided for in Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs ([1]);

(b) a designation of origin or geographical indication for wine as provided for in Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) ([2]);

(c) a geographical designation for aromatised drinks based on wine products as provided for in Council Regulation (EEC) No 1601/91 of 10 June 1991 laying down general rules on the definition, description and presentation of aromatized wines, aromatized wine-based drinks and aromatized wine-product cocktails ([3]);

(d) a geographical indication of spirit drinks as provided for in Regulation (EC) No 110/2008 of the European Parliament and of the Council of 15 January 2008 on the definition, description, presentation, labelling and the protection of geographical indications of spirit drinks ([4]);

(e) a geographical indication for products not falling under points (a) to (d) in so far as it is established as an exclusive intellectual property right by national or Union law;

(f) a geographical indication as provided for in Agreements between the Union and third countries and as such listed in those Agreements;

(5) 'counterfeit goods' means:

(a) goods which are the subject of an act infringing a trade mark in the Member State where they are found and bear without authorisation a sign which is identical to the trade mark validly registered in respect of the same type of goods, or which cannot be distinguished in its essential aspects from such a trade mark;

(b) goods which are the subject of an act infringing a geographical indication in the Member State where they are found and, bear or are described by, a name or term protected in respect of that geographical indication;

(c) any packaging, label, sticker, brochure, operating instructions, warranty document or other similar item, even if presented separately, which is the subject of an act infringing a trade mark or a geographical indication, which includes a sign, name or term which is identical to a validly registered trade mark or protected geographical indication, or which cannot be distinguished in its essential aspects from such a trade mark or geographical indication, and which can be used for the same type of goods as that for which the trade mark or geographical indication has been registered;

(6) 'pirated goods' means goods which are the subject of an act infringing a copyright or related right or a design in the Member State where the goods are found and which are, or contain copies, made without the consent of the holder of a copyright or related right or a design, or of a person authorised by that holder in the country of production;

(7) 'goods suspected of infringing an intellectual property right' means goods with regard to which there are reasonable indications that, in the Member State where those goods are found, they are prima facie:

(a) goods which are the subject of an act infringing an intellectual property right in that Member State;

(b) devices, products or components which are primarily designed, produced or adapted for the purpose of enabling or facilitating the circumvention of any technology, device or component that, in the normal course of its operation, prevents or restricts acts in respect of works which are not authorised by the holder of any copyright or any right related to copyright and which relate to an act infringing those rights in that Member State;

(c) any mould or matrix which is specifically designed or adapted for the manufacture of goods infringing an intellectual property right, if such moulds or matrices relate to an act infringing an intellectual property right in that Member State;

([1]) OJ L 343, 14.12.2012, p. 1.
([2]) OJ L 299, 16.11.2007, p. 1.
([3]) OJ L 149, 14.6.1991, p. 1.
([4]) OJ L 39, 13.2.2008, p. 16.

(8) 'right-holder' means the holder of an intellectual property right;

(9) 'application' means a request made to the competent customs department for customs authorities to take action with respect to goods suspected of infringing an intellectual property right;

(10) 'national application' means an application requesting the customs authorities of a Member State to take action in that Member State;

(11) 'Union application' means an application submitted in one Member State and requesting the customs authorities of that Member State and of one or more other Member States to take action in their respective Member States;

(12) 'applicant' means the person or entity in whose name an application is submitted;

(13) 'holder of the decision' means the holder of a decision granting an application;

(14) 'holder of the goods' means the person who is the owner of the goods suspected of infringing an intellectual property right or who has a similar right of disposal, or physical control, over such goods;

(15) 'declarant' means the declarant as defined in point (18) of Article 4 of Regulation (EEC) No 2913/92;

(16) 'destruction' means the physical destruction, recycling or disposal of goods outside commercial channels, in such a way as to preclude damage to the holder of the decision;

(17) 'customs territory of the Union' means the customs territory of the Community as defined in Article 3 of Regulation (EEC) No 2913/92;

(18) 'release of the goods' means the release of the goods as defined in point (20) of Article 4 of Regulation (EEC) No 2913/92;

(19) 'small consignment' means a postal or express courier consignment, which:

(a) contains three units or less;

or

(b) has a gross weight of less than two kilograms.

For the purpose of point (a), 'units' means goods as classified under the Combined Nomenclature in accordance with Annex I to Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff [1] if unpackaged, or the package of such goods intended for retail sale to the ultimate consumer.

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

(20) 'perishable goods' means goods considered by customs authorities to deteriorate by being kept for up to 20 days from the date of their suspension of release or detention;

(21) 'exclusive licence' means a licence (whether general or limited) authorising the licensee to the exclusion of all other persons, including the person granting the licence, to use an intellectual property right in the manner authorised by the licence.

CHAPTER II

APPLICATIONS

SECTION 1

Submission of applications

Article 3

Entitlement to submit an application

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

(1) a national or a Union application:

(a) right-holders;

(b) intellectual property collective rights management bodies as referred to in point (c) of Article 4(1) of Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights [2];

(c) professional defence bodies as referred to in point (d) of Article 4(1) of Directive 2004/48/EC;

[1] OJ L 256, 7.9.1987, p. 1.
[2] OJ L 157, 30.4.2004, p. 45.

(d) groups within the meaning of point (2) of Article 3, and Article 49(1) of Regulation (EU) No 1151/2012, groups of producers within the meaning of Article 118e of Regulation (EC) No 1234/2007 or similar groups of producers provided for in Union law governing geographical indications representing producers of products with a geographical indication or representatives of such groups, in particular Regulations (EEC) No 1601/91 and (EC) No 110/2008 and operators entitled to use a geographical indication as well as inspection bodies or authorities competent for such a geographical indication;

(2) a national application:

(a) persons or entities authorised to use intellectual property rights, which have been authorised formally by the right-holder to initiate proceedings in order to determine whether the intellectual property right has been infringed;

(b) groups of producers provided for in the legislation of the Member States governing geographical indications representing producers of products with geographical indications or representatives of such groups and operators entitled to use a geographical indication, as well as inspection bodies or authorities competent for such a geographical indication;

(3) a Union application: holders of exclusive licenses covering the entire territory of two or more Member States, where those licence holders have been authorised formally in those Member States by the right-holder to initiate proceedings in order to determine whether the intellectual property right has been infringed.

Article 4

Intellectual property rights covered by Union applications

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

Article 5

Submission of applications

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

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

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

(a) it is submitted to the competent customs department within four working days of the notification of the suspension of the release or detention of the goods;

(b) it is a national application;

(c) it contains the information referred to in Article 6(3). The applicant may, however, omit the information referred to in point (g), (h) or (i) of that paragraph.

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

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

6. Where computerised systems are available for the purpose of receiving and processing applications, applications as well as attachments shall be submitted using electronic data-processing techniques. Member States and the Commission shall develop, maintain and employ such systems in accordance with the multi-annual strategic plan referred to in Article 8(2) of Decision No 70/2008/EC of the European Parliament and of the Council of 15 January 2008 on a paperless customs environment for customs and trade [1].

Article 6

Application form

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

[1] OJ L 23, 26.1.2008, p. 21.

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

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

(a) details concerning the applicant;

(b) the status, within the meaning of Article 3, of the applicant;

(c) documents providing evidence to satisfy the competent customs department that the applicant is entitled to submit the application;

(d) where the applicant submits the application by means of a representative, details of the person representing him and evidence of that person's powers to act as representative, in accordance with the legislation of the Member State in which the application is submitted;

(e) the intellectual property right or rights to be enforced;

(f) in the case of a Union application, the Member States in which customs action is requested;

(g) specific and technical data on the authentic goods, including markings such as bar-coding and images where appropriate;

(h) the information needed to enable the customs authorities to readily identify the goods in question;

(i) information relevant to the customs authorities' analysis and assessment of the risk of infringement of the intellectual property right or the intellectual property rights concerned, such as the authorised distributors;

(j) whether information provided in accordance with point (g), (h) or (i) of this paragraph is to be marked for restricted handling in accordance with Article 31(5);

(k) the details of any representative designated by the applicant to take charge of legal and technical matters;

(l) an undertaking by the applicant to notify the competent customs department of any of the situations laid down in Article 15;

(m) an undertaking by the applicant to forward and update any information relevant to the customs authorities' analysis and assessment of the risk of infringement of the intellectual property right(s) concerned;

(n) an undertaking by the applicant to assume liability under the conditions laid down in Article 28;

(o) an undertaking by the applicant to bear the costs referred to in Article 29 under the conditions laid down in that Article;

(p) an agreement by the applicant that the data provided by him may be processed by the Commission and by the Member States;

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

SECTION 2

Decisions on applications

Article 7

Processing of incomplete applications

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

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

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

Article 8

Fees

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

Article 9

Notification of decisions granting or rejecting applications

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

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

Article 10

Decisions concerning applications

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

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

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

(a) in the Member State in which the application was submitted, on the day following the date of adoption;

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

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

Article 11

Period during which the customs authorities are to take action

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

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

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

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

Article 12

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

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

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

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

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

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

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

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

Article 13

Amending the decision with regard to intellectual property rights.

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

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

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

Article 14

Notification obligations of the competent customs department

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

(a) decisions granting the application;

(b) decisions revoking decisions granting the application;

(c) decisions amending decisions granting the application;

(d) decisions extending the period during which the customs authorities are to take action.

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

(a) decisions granting the application;

(b) decisions revoking decisions granting the application;

(c) decisions amending decisions granting the application;

(d) decisions extending the period during which the customs authorities are to take action.

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

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

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

Article 15

Notification obligations of the holder of the decision

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

(a) an intellectual property right covered by the application ceases to have effect;

(b) the holder of the decision ceases for other reasons to be entitled to submit the application;

(c) modifications to the information referred to in Article 6(3).

Article 16

Failure of the holder of the decision to fulfil his obligations

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

(a) revoke any decision adopted by it granting a national application to that holder of the decision, and refuse to extend the period during which the customs authorities are to take action;

(b) suspend in their territory, during the period during which the customs authorities are to take action, any decision granting a Union application to that holder of the decision.

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

(a) does not fulfil the notification obligations set out in Article 15;

(b) does not fulfil the obligation on returning samples set out in Article 19(3);

(c) does not fulfil the obligations on costs and translation set out in Article 29(1) and (3);

(d) without valid reason does not initiate proceedings as provided for in Article 23(3) or Article 26(9).

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

CHAPTER III

ACTION BY THE CUSTOMS AUTHORITIES

SECTION 1

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

Article 17

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

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

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

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

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

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

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

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

Article 18

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

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

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

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

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

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

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

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

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

(a) where they have not identified any person or entity entitled to submit an application concerning the alleged infringement of intellectual property rights within one working day from the suspension of the release or the detention of the goods;

(b) where they have not received an application in accordance with Article 5(3), or where they have rejected such an application.

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

Article 19

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

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

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

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

Article 20

Conditions for storage

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

Article 21

Permitted use of certain information by the holder of the decision

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

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

(b) in connection with criminal investigations related to the infringement of an intellectual property right and undertaken by public authorities in the Member State where the goods are found;

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

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

(e) to agree with the declarant or the holder of the goods that the goods be destroyed in accordance with Article 23(1);

(f) to agree with the declarant or the holder of the goods of the amount of the guarantee referred to in point (a) of Article 24(2).

Article 22

Sharing of information and data between customs authorities

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

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

(a) nature and quantity of goods;

(b) suspected intellectual property right infringed;

(c) origin, provenance and destination of the goods;

(d) information on movements of means of transport, in particular:

(i) name of vessel or registration of means of transport;

(ii) reference numbers of freight bill or other transport document;

(iii) number of containers;

(iv) weight of load;

(v) description and/or coding of goods;

(vi) reservation number;

(vii) seal number;

(viii) place of first loading;

(ix) place of final unloading;

(x) places of transhipment;

(xi) expected date of arrival at place of final unloading;

(e) information on movements of containers, in particular:

(i) container number;

(ii) container loading status;

(iii) date of movement;

(iv) type of movement (loaded, unloaded, transhipped, entered, left, etc.);

(v) name of vessel or registration of means of transport;

(vi) number of voyage/journey;

(vii) place;

(viii) freight bill or other transport document.

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

SECTION 2

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

Article 23

Destruction of goods and initiation of proceedings

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

(a) the holder of the decision has confirmed in writing to the customs authorities, within 10 working days, or three working days in the case of perishable goods, of notification of the suspension of the release or the detention of the goods, that, in his conviction, an intellectual property right has been infringed;

(b) the holder of the decision has confirmed in writing to the customs authorities, within 10 working days, or three working days in the case of perishable goods, of notification of the suspension of the release or the detention of the goods, his agreement to the destruction of the goods;

(c) the declarant or the holder of the goods has confirmed in writing to the customs authorities, within 10 working days, or three working days in the case of perishable goods, of notification of the suspension of the release or the detention of the goods, his agreement to the destruction of the goods. Where the declarant or the holder of the goods has not confirmed his agreement to the destruction of the goods nor notified his opposition thereto to the customs authorities, within those deadlines, the customs authorities may deem the declarant or the holder of the goods to have confirmed his agreement to the destruction of those goods.

The customs authorities shall grant the release of the goods or put an end to their detention, immediately after completion of all customs formalities, where within the periods referred to in points (a) and (b) of the first subparagraph, they have not received both the written confirmation from the holder of the decision that, in his conviction, an intellectual property right has been infringed and his agreement to destruction, unless those authorities have been duly informed about the initiation of proceedings to determine whether an intellectual property right has been infringed.

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

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

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

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

Article 24

Early release of goods

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

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

(a) the declarant or the holder of the goods has provided a guarantee that is of an amount sufficient to protect the interests of the holder of the decision;

(b) the authority competent to determine whether an intellectual property right has been infringed has not authorised precautionary measures;

(c) all customs formalities have been completed.

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

Article 25

Goods for destruction

1. Goods to be destroyed under Article 23 or 26 shall not be:

(a) released for free circulation, unless customs authorities, with the agreement of the holder of the decision, decide that it is necessary in the event that the goods are to be recycled or disposed of outside commercial channels, including for awareness-raising, training and educational purposes. The conditions under which the goods can be released for free circulation shall be determined by the customs authorities;

(b) brought out of the customs territory of the Union;

(c) exported;

(d) re-exported;

(e) placed under a suspensive procedure;

(f) placed in a free zone or free warehouse.

2. The customs authorities may allow the goods referred to in paragraph 1 to be moved under customs supervision between different places within the customs territory of the Union with a view to their destruction under customs control.

Article 26

Procedure for the destruction of goods in small consignments

1. This Article shall apply to goods where all of the following conditions are fulfilled:

(a) the goods are suspected of being counterfeit or pirated goods;

(b) the goods are not perishable goods;

(c) the goods are covered by a decision granting an application;

(d) the holder of the decision has requested the use of the procedure set out in this Article in the application;

(e) the goods are transported in small consignments.

2. When the procedure set out in this Article is applied, Article 17(3) and (4) and Article 19(2) and (3) shall not apply.

3. The customs authorities shall notify the declarant or the holder of the goods of the suspension of the release of the goods or their detention within one working day of the suspension of the release or of the detention of the goods. The notification of the suspension of the release or the detention of the goods shall include the following information:

(a) that the customs authorities intend to destroy the goods;

(b) the rights of the declarant or the holder of the goods under paragraphs 4, 5 and 6.

4. The declarant or the holder of the goods shall be given the opportunity to express his point of view within 10 working days of notification of the suspension of the release or the detention of the goods.

5. The goods concerned may be destroyed where, within 10 working days of notification of the suspension of the release or the detention of the goods, the declarant or the holder of the goods has confirmed to the customs authorities his agreement to the destruction of the goods.

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

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

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

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

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

CHAPTER IV

LIABILITY, COSTS AND PENALTIES

Article 27

Liability of the customs authorities

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

Article 28

Liability of the holder of the decision

Where a procedure duly initiated pursuant to this Regulation is discontinued owing to an act or omission on the part of the holder of the decision, where samples taken pursuant to Article 19(2) are either not returned or are damaged and beyond use owing to an act or omission on the part of the holder of the decision, or where the goods in question are subsequently found not to infringe an intellectual property right, the holder of the decision shall be liable towards any holder of the goods or declarant, who has suffered damage in that regard, in accordance with specific applicable legislation.

Article 29

Costs

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

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

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

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

Article 30

Penalties

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

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

CHAPTER V

EXCHANGE OF INFORMATION

Article 31

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

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

(a) decisions granting applications, including the application and its attachments;

(b) decisions extending the period during which the customs authorities are to take action or decisions revoking the decision granting the application or amending it;

(c) the suspension of a decision granting the application.

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

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

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

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

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

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

Article 32

Establishment of a central database

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

Article 33

Data protection provisions

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

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

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

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

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

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

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

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

CHAPTER VI

COMMITTEE, DELEGATION AND FINAL PROVISIONS

Article 34

Committee procedure

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

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

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

Article 35

Exercise of the delegation

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

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

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

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

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

Article 36

Mutual administrative assistance

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

Article 37

Reporting

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

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

Article 38

Repeal

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

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

Article 39

Transitional provisions

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

Article 40

Entry into force and application

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

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

(a) Article 6, Article 12(7) and Article 22(3), which shall apply from 19 July 2013;

(b) Article 31(1) and (3) to (7) and Article 33, which shall apply from the date on which the central database referred to in Article 32 is in place. The Commission shall make that date public.

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

Done at Strasbourg, 12 June 2013.

For the European Parliament
The President
M. SCHULZ

For the Council
The President
L. CREIGHTON

ANNEX

Correlation table

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

REGULATION (EU) No 609/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 12 June 2013

on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009

(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) Article 114 of the Treaty on the Functioning of the European Union (TFEU) provides that, for measures having as their object the establishment and functioning of the internal market, and which concern, inter alia, health, safety and consumer protection, the Commission is to take as a base a high level of protection taking account in particular of any new development based on scientific facts.

(2) The free movement of safe and wholesome food is an essential aspect of the internal market and contributes significantly to the health and well-being of citizens, and to their social and economic interests.

(3) Union law applicable to food is intended, inter alia, to ensure that no food is placed on the market if it is unsafe. Therefore, any substances that are considered to be injurious to the health of the population groups concerned or unfit for human consumption should be excluded from the composition of the categories of food covered by this Regulation.

(4) Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses ([3]) lays down general rules on the composition and preparation of foods that are specially designed to meet the particular nutritional requirements of the persons for whom they are intended. The majority of the provisions laid down in that Directive date back to 1977 and need to be reviewed.

(5) Directive 2009/39/EC establishes a common definition for 'foodstuffs for particular nutritional uses', and general labelling requirements, including that such foods should bear an indication of their suitability for the nutritional purposes being claimed.

(6) The general compositional and labelling requirements laid down in Directive 2009/39/EC are complemented by a number of non-legislative Union acts, which are applicable to specific categories of food. In that respect, harmonised rules are laid down in Commission Directives 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction ([4]) and 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes ([5]). Similarly, Commission Directive 2006/125/EC ([6]) lays down certain harmonised rules with respect to processed cereal-based foods and baby foods for infants and young children. Commission Directive 2006/141/EC ([7]) lays down harmonised rules with respect to infant formulae and follow-on formulae and Commission Regulation (EC) No 41/2009 ([8]) lays down harmonised rules concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten.

([1]) OJ C 24, 28.1.2012, p. 119.
([2]) Position of the European Parliament of 14 June 2012 (not yet published in the Official Journal) and position of the Council at first reading of 22 April 2013 (not yet published in the Official Journal). Position of the European Parliament of 11 June 2013 (not yet published in the Official Journal).
([3]) OJ L 124, 20.5.2009, p. 21.
([4]) OJ L 55, 6.3.1996, p. 22.
([5]) OJ L 91, 7.4.1999, p. 29.
([6]) OJ L 339, 6.12.2006, p. 16.
([7]) OJ L 401, 30.12.2006, p. 1.
([8]) OJ L 16, 21.1.2009, p. 3.

(7) In addition, harmonised rules are laid down in Council Directive 92/52/EEC of 18 June 1992 on infant formulae and follow-on formulae intended for export to third countries [1] and in Commission Regulation (EC) No 953/2009 of 13 October 2009 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses [2].

(8) Directive 2009/39/EC requires a general notification procedure at national level for food presented by food business operators as coming within the definition of 'foodstuffs for particular nutritional uses' for which no specific provisions have been laid down in Union law, prior to its being placed on the Union market, in order to facilitate the efficient monitoring of such food by the Member States.

(9) A report from the Commission of 27 June 2008 to the European Parliament and to the Council on the implementation of that notification procedure showed that difficulties can arise from the definition of 'foodstuffs for particular nutritional uses' which appeared to be open to differing interpretations by the national authorities. It therefore concluded that a revision of Directive 2009/39/EC would be required to ensure a more effective and harmonised implementation of Union legal acts.

(10) A study report of 29 April 2009 by Agra CEAS Consulting, concerning the revision of Directive 2009/39/EC, confirmed the findings of the Commission report of 27 June 2008 on the implementation of the notification procedure and indicated that an increasing number of foodstuffs are currently marketed and labelled as foodstuffs suitable for particular nutritional uses, due to the broad definition laid down in that Directive. The study report also pointed out that food regulated under that Directive differs significantly between Member States; similar food could at the same time be marketed in different Member States as food for particular nutritional uses and/or as food for normal consumption, including food supplements, addressed to the population in general or to certain subgroups thereof such as pregnant women, postmenopausal women, older adults, growing children, adolescents, variably active individuals and others. This state of affairs undermines the functioning of the internal market, creates legal uncertainty for competent authorities, food business operators, in particular small and medium-sized enterprises (SMEs), and consumers, while the risks of marketing abuse and distortion of competition cannot be ruled out. There is therefore a need to eliminate differences in interpretation by simplifying the regulatory environment.

(11) It appears that other, recently adopted, Union legal acts are more adapted to an evolving and innovative food market than Directive 2009/39/EC. Of particular relevance and importance in that respect are: Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements [3], Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods [4] and Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods [5]. Furthermore, the provisions of those Union legal acts would adequately regulate a number of the categories of food covered by Directive 2009/39/EC with less of an administrative burden and more clarity as to scope and objectives.

(12) Moreover, experience shows that certain rules included in, or adopted under, Directive 2009/39/EC are no longer effective in ensuring the functioning of the internal market.

(13) Therefore, the concept of 'foodstuffs for particular nutritional uses' should be abolished and Directive 2009/39/EC should be replaced by this act. To simplify the application of this act and to ensure consistency of application throughout the Member States, this act should take the form of a Regulation.

(14) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [6] establishes common principles and definitions for Union food law. Certain definitions laid down in that Regulation should also apply in the context of this Regulation.

(15) A limited number of categories of food constitute a partial or the sole source of nourishment for certain population groups. Such categories of food are vital for the management of certain conditions and/or are essential to satisfy the nutritional requirements of certain clearly identified vulnerable population groups. Those categories of food include infant formula and follow-on formula, processed cereal-based food and baby food, and food for special medical purposes. Experience has shown that the provisions laid down in

[1] OJ L 179, 1.7.1992, p. 129.
[2] OJ L 269, 14.10.2009, p. 9.
[3] OJ L 183, 12.7.2002, p. 51.
[4] OJ L 404, 30.12.2006, p. 9.
[5] OJ L 404, 30.12.2006, p. 26.
[6] OJ L 31, 1.2.2002, p. 1.

Directives 1999/21/EC, 2006/125/EC and 2006/141/EC ensure the free movement of those categories of food in a satisfactory manner, while ensuring a high level of protection of public health. It is therefore appropriate that this Regulation focuses on the general compositional and information requirements for those categories of food, taking into account Directives 1999/21/EC, 2006/125/EC and 2006/141/EC.

(16) In addition, in view of the growing rates of people with problems related to being overweight or obese, an increasing number of foods are placed on the market as total diet replacement for weight control. Currently, for such foods present in the market a distinction can be made between products intended for low calorie diets, which contain between 3 360 kJ (800 kcal) and 5 040 kJ (1 200 kcal), and products intended for very low calorie diets, which normally contain fewer than 3 360 kJ (800 kcal). Given the nature of the foods in question it is appropriate to lay down certain specific provisions for them. Experience has shown that the relevant provisions laid down in Directive 96/8/EC ensure the free movement of foods presented as total diet replacement for weight control in a satisfactory manner while ensuring a high level of protection of public health. It is therefore appropriate that this Regulation focuses on the general compositional and information requirements for foods intended to replace the whole of the daily diet including foods of which the energy content is very low, taking into account the relevant provisions of Directive 96/8/EC.

(17) This Regulation should establish, inter alia, definitions of infant formula and follow-on formula, processed cereal-based food and baby food, food for special medical purposes, and total diet replacement for weight control, taking into account relevant provisions in Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC.

(18) Regulation (EC) No 178/2002 establishes the principles of risk analysis in relation to food and establishes the structures and mechanisms for the scientific and technical evaluations which are undertaken by the European Food Safety Authority ('the Authority'). For the purpose of this Regulation, the Authority should be consulted on all matters likely to affect public health.

(19) It is important that ingredients used in the manufacture of food covered by this Regulation are appropriate for satisfying the nutritional requirements of, and are suitable for, the persons for whom such food is intended and that their nutritional adequacy has been established by generally accepted scientific data. Such adequacy should be demonstrated through a systematic review of the available scientific data.

(20) Maximum residue levels of pesticides set out in relevant Union law, in particular Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin [1], should apply without prejudice to specific provisions set out in this Regulation and delegated acts adopted pursuant to this Regulation.

(21) The use of pesticides can lead to pesticide residues in food that is covered by this Regulation. Such use should, therefore, be restricted as much as possible, taking into account the requirements of Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market [2]. However, a restriction on, or a prohibition of, use would not necessarily guarantee that food covered by this Regulation, including food for infants and young children, is free from pesticides, since some pesticides contaminate the environment and their residues can be found in such food. Therefore, the maximum residue levels in such food should be set at the lowest achievable level to protect vulnerable population groups, taking into account good agricultural practices as well as other sources of exposure, such as environmental contamination.

(22) Restrictions on and prohibitions of certain pesticides equivalent to those currently established in the Annexes to Directives 2006/125/EC and 2006/141/EC should be taken into account in delegated acts adopted pursuant to this Regulation. Those restrictions and prohibitions should be updated regularly, with particular attention to be paid to pesticides containing active substances, safeners or synergists classified in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures [3] as mutagen category 1A or 1B, carcinogen category 1A or 1B, toxic for reproduction category 1A or 1B, or considered to have endocrine-disrupting properties that can cause adverse effects in humans.

[1] OJ L 70, 16.3.2005, p. 1.
[2] OJ L 309, 24.11.2009, p. 1.
[3] OJ L 353, 31.12.2008, p. 1.

(23) Substances falling within the scope of Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients [1] should not be added to food covered by this Regulation unless such substances fulfil the conditions for being placed on the market under Regulation (EC) No 258/97 in addition to the conditions set out in this Regulation and delegated acts adopted pursuant to this Regulation. When there is a significant change in the production method of a substance that has been used in accordance with this Regulation or a change in particle size of such a substance, for example through nanotechnology, that substance should be considered different from the one that has been used in accordance with this Regulation and should be re-evaluated under Regulation (EC) No 258/97 and subsequently under this Regulation.

(24) Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers [2] lays down general labelling requirements. Those labelling requirements should, as a general rule, apply to the categories of food covered by this Regulation. However, this Regulation should also provide for additional requirements to, or derogations from, Regulation (EU) No 1169/2011, where necessary, in order to meet the specific objectives of this Regulation.

(25) The labelling, presentation or advertising of food covered by this Regulation should not attribute to such food the property of preventing, treating or curing a human disease nor should they imply such properties. Food for special medical purposes, however, is intended for the dietary management of patients with a limited, impaired or disturbed capacity, for example, to take ordinary food because of a specific disease, disorder or medical condition. Reference to the dietary management of diseases, disorders or medical conditions for which the food is intended should not be considered as attribution of the property of preventing, treating or curing a human disease.

(26) In the interest of protecting vulnerable consumers, labelling requirements should ensure accurate product identification for consumers. In the case of infant formula and follow-on formula, all written and pictorial information should enable a clear distinction to be made between different formulae. Difficulty in identifying the precise age of an infant pictured on labelling could confuse consumers and impede product identification. That risk should be avoided by appropriate restrictions on labelling. Furthermore, taking into account that infant formula constitutes food that satisfies by itself the nutritional requirements of infants from birth until introduction of appropriate complementary feeding, proper product identification is crucial for the protection of consumers. Appropriate restrictions should, therefore, be introduced concerning the presentation and advertising of infant formula.

(27) This Regulation should provide the criteria for the establishment of the specific compositional and information requirements for infant formula, follow-on formula, processed cereal-based food and baby food, food for special medical purposes, and total diet replacement for weight control, taking into account Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC.

(28) Regulation (EC) No 1924/2006 establishes the rules and conditions for the use of nutrition and health claims on food. Those rules should apply as a general rule to the categories of food covered by this Regulation, unless otherwise specified in this Regulation or delegated acts adopted pursuant to this Regulation.

(29) According to the recommendations of the World Health Organisation (WHO), low birth weight infants should be fed mother's milk. Nonetheless, low birth weight infants and pre-term infants may have special nutritional requirements which cannot be met by mother's milk or standard infant formula. In fact, the nutritional requirements of a low birth weight infant and a pre-term infant can depend on the medical condition of that infant, in particular on that infant's weight in comparison with that of an infant in good health, and on the number of weeks the infant is premature. It is to be decided on a case-by-case basis whether the infant's condition requires the consumption, under medical supervision, of a food for special medical purposes developed to satisfy the nutritional requirements of infants (formula) and adapted for the dietary management of that infant's specific condition.

[1] OJ L 43, 14.2.1997, p. 1.
[2] OJ L 304, 22.11.2011, p. 18.

(30) Directive 1999/21/EC requires that certain compositional requirements for infant formula and for follow-on formula as set out in Directive 2006/141/EC apply to food for special medical purposes intended for infants, depending on their age. However, certain provisions, including those relating to labelling, presentation, advertising, and promotional and commercial practices, set out in Directive 2006/141/EC currently do not apply to such food. Developments in the market accompanied by a significant increase of such food make it necessary to review requirements for formulae intended for infants such as requirements on the use of pesticides in products intended for production of such formulae, pesticide residues, labelling, presentation, advertising, and promotional and commercial practices that should also apply, as appropriate, to food for special medical purposes developed to satisfy the nutritional requirements of infants.

(31) There is an increasing number of milk-based drinks and similar products on the Union market which are promoted as being particularly suitable for young children. Such products, which can be derived from protein of animal or vegetable origin such as cows' milk, goats' milk, soy or rice, are often marketed as 'growing up milks' or 'toddlers' milks' or with similar terminology. While these products are currently regulated by different legal acts of the Union, such as Regulations (EC) No 178/2002, (EC) No 1924/2006 and (EC) No 1925/2006, and Directive 2009/39/EC, they are not covered by the existing specific measures applying to food intended for infants and young children. Different views exist as to whether such products satisfy the specific nutritional requirements of the population group they target. The Commission should therefore, after consulting the Authority, present to the European Parliament and to the Council a report on the necessity, if any, of special provisions regarding the composition, labelling and other types of requirements, if appropriate, of those products. This report should consider, inter alia, the nutritional requirements of young children and the role of those products in their diet, taking into account the pattern of consumption, the nutritional intake and the levels of exposure of young children to contaminants and pesticides. The report should also consider the composition of such products and whether they have any nutritional benefits when compared to a normal diet for a child who is being weaned. The Commission could accompany this report with a legislative proposal.

(32) Directive 2009/39/EC provides that specific provisions can be adopted regarding the following two specific categories of food falling within the definition of foodstuffs for particular nutritional uses: 'food intended to meet the expenditure of intense muscular effort, especially for sportsmen' and 'food for persons suffering from carbohydrate metabolism disorders (diabetes)'. As regards special provisions for food for persons suffering from carbohydrate metabolism disorders (diabetes), a Commission report to the European Parliament and to the Council of 26 June 2008 on foods for persons suffering from carbohydrate metabolism disorders (diabetes) concluded that the scientific basis for setting specific compositional requirements is lacking. With regard to food intended to meet the expenditure of intense muscular effort, especially for sportsmen, no successful conclusion could be reached as regards the development of specific provisions due to widely diverging views among the Member States and stakeholders concerning the scope of specific legislation, the number of subcategories of food to be included, the criteria for establishing compositional requirements and the potential impact on innovation in product development. Therefore, specific provisions should not be developed at this stage. Meanwhile, on the basis of requests submitted by food business operators, relevant claims have been considered for authorisation in accordance with Regulation (EC) No 1924/2006.

(33) However, different views exist as to whether additional rules are needed to ensure an adequate protection of consumers of food intended for sportsmen, also called food intended to meet the expenditure of intense muscular effort. The Commission should, therefore, be invited, after consulting the Authority, to submit to the European Parliament and to the Council a report on the necessity, if any, of provisions concerning food intended for sportsmen. The consultation of the Authority should take into account the report of 28 February 2001 of the Scientific Committee on Food on composition and specification of food intended to meet the expenditure of intense muscular effort, especially for sportsmen. In its report, the Commission should, in particular, evaluate whether provisions are necessary to ensure the protection of consumers.

(34) The Commission should be able to adopt technical guidelines aimed at facilitating compliance by food business operators, in particular SMEs, with this Regulation.

(35) Taking into account the existing situation on the market and Directives 2006/125/EC and 2006/141/EC, and Regulation (EC) No 953/2009, it is appropriate to establish and include in the Annex to this Regulation a Union list of substances belonging to the following categories of substances: vitamins, minerals, amino acids, carnitine and taurine, nucleotides, choline and inositol. Among the substances belonging to those categories, it should only be permissible for those included in the Union list to be added to the categories of food covered by this Regulation. When substances are included in the Union list, it should be specified to which category of food covered by this Regulation such substances may be added.

(36) The inclusion of substances in the Union list should not mean that their addition to one or more categories of food covered by this Regulation is necessary or desirable. The Union list is intended only to reflect which substances belonging to certain categories of substances are authorised to be added to one or more categories of food covered by this Regulation, whereas the specific compositional requirements are intended to establish the composition of each category of food covered by this Regulation.

(37) A number of the substances that may be added to food covered by this Regulation could be added for technological purposes as food additives, colourings or flavourings, or for other such purposes, including authorised oenological practices and processes, provided for by relevant Union legal acts applicable to food. In this context specifications are adopted for those substances at Union level. It is appropriate that those specifications should be applicable to the substances whatever the purpose of their use in food unless otherwise provided for by this Regulation.

(38) For the substances included in the Union list for which purity criteria have not yet been adopted at Union level, and in order to ensure a high level of protection of public health, generally acceptable purity criteria recommended by international organisations or agencies including but not limited to the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and European Pharmacopoeia should apply. Member States should be permitted to maintain national rules setting stricter purity criteria, without prejudice to the rules set out in the TFEU.

(39) In order to specify requirements for the categories of food covered by this Regulation, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the laying down of specific compositional and information requirements with regard to the categories of food covered by this Regulation, including additional labelling requirements to, or derogations from, Regulation (EU) No 1169/2011 and with regard to the authorisation of nutrition and health claims. Furthermore, in order to enable consumers to benefit rapidly from technical and scientific progress, especially in relation to innovative products, and thus to stimulate innovation the power to adopt acts in accordance with Article 290 TFEU should also be delegated to the Commission in respect of the regular updating of those specific requirements, taking into account all relevant data, including data provided by interested parties. In addition, in order to take into account technical progress, scientific developments or consumers' health, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the addition of categories of substances that have a nutritional or physiological effect to be covered by the Union list, or in respect of the removal of such categories from the categories of substances covered by the Union list. For the same purposes and subject to additional requirements laid down in this Regulation, the power to adopt delegated acts in accordance with Article 290 TFEU should also be delegated to the Commission in respect of amending the Union list by adding a new substance, removing a substance or adding, removing or amending the elements in the Union list related to a substance. 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.

(40) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission to decide whether a given food falls within the scope of this Regulation and to which category of food it belongs. 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]).

(41) Currently, the rules on the use of the statements 'gluten-free' and 'very low gluten' are specified in Regulation (EC) No 41/2009. That Regulation harmonises the information that is provided to consumers on the absence or reduced presence of gluten in food and sets specific rules for food that is specially produced, prepared and/or processed in order to reduce the gluten content of one or more gluten-containing ingredients or to substitute such gluten-containing ingredients and other food that is made exclusively from ingredients that are naturally free of gluten. Regulation (EU) No 1169/2011 sets out rules on information to be provided for all food, including non-prepacked food, on the presence of ingredients, such as gluten-containing ingredients, with

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

a scientifically proven allergenic or intolerance effect in order to enable consumers, particularly those suffering from a food allergy or intolerance such as gluten-intolerant people, to make informed choices which are safe for them. For the sake of clarity and consistency, the rules on the use of the statements 'gluten-free' and 'very low gluten' should also be regulated under Regulation (EU) No 1169/2011. The legal acts to be adopted pursuant to Regulation (EU) No 1169/2011, which are to transfer the rules on the use of the statements 'gluten-free' and 'very low gluten', as contained in Regulation (EC) No 41/2009, should ensure at least the same level of protection for people who are intolerant to gluten as currently provided for under Regulation (EC) No 41/2009. That transfer of rules should be completed before this Regulation applies. Furthermore, the Commission should consider how to ensure that people who are intolerant to gluten are adequately informed of the difference between a food that is specially produced, prepared and/or processed in order to reduce the gluten content of one or more gluten-containing ingredients and other food that is made exclusively from ingredients naturally free of gluten.

(42) Labelling and compositional rules indicating the absence or reduced presence of lactose in food are currently not harmonised at Union level. Those indications are, however, important for people who are intolerant to lactose. Regulation (EU) No 1169/2011 sets out rules on information to be provided concerning substances with a scientifically proven allergenic or intolerant effect, to enable consumers, such as lactose-intolerant people, to make informed choices which are safe for them. For the sake of clarity and consistency, the establishment of rules on the use of statements indicating the absence or reduced presence of lactose in food should be regulated under Regulation (EU) No 1169/2011, taking into account the Scientific Opinion of the Authority of 10 September 2010 on lactose thresholds in lactose intolerance and galactosaemia.

(43) 'Meal replacement for weight control' intended to replace part of the daily diet is considered as food for particular nutritional uses and is currently governed by specific rules under Directive 96/8/EC. However, more and more foods intended for the general population have appeared on the market carrying similar statements which are presented as health claims for weight control. In order to eliminate any potential confusion within this group of foods marketed for weight control and in the interests of legal certainty and coherence of Union legal acts, such statements should be regulated solely under Regulation (EC) No 1924/2006 and comply with requirements set out in that Regulation. It is necessary that technical adaptations made pursuant to Regulation (EC) No 1924/2006, relating to health claims referring to control of body weight and made in respect of food presented as 'meal replacement for weight control', and to the conditions of use of such claims, as regulated by Directive 96/8/EC, be completed prior to the application of this Regulation.

(44) This Regulation does not affect the obligation to respect fundamental rights and fundamental legal principles, including the freedom of expression, as enshrined in Article 11, in conjunction with Article 52, of the Charter of Fundamental Rights of the European Union, and in other relevant provisions.

(45) Since the objectives of this Regulation, namely, the establishment of compositional and information requirements for certain categories of food, the establishment of a Union list of substances that may be added to certain categories of food and the establishment of the rules for the update of the Union list, cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale of the proposed action, 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 those objectives.

(46) Directive 92/52/EEC provides that infant formulae and follow-on formulae exported or re-exported from the Union are to comply with Union law unless otherwise requested or stipulated by provisions established by the importing country. That principle has already been established for food in Regulation (EC) No 178/2002. For the sake of simplification and legal certainty, Directive 92/52/EEC should therefore be repealed.

(47) Directives 96/8/EC, 1999/21/EC, 2006/125/EC, 2006/141/EC, 2009/39/EC and Regulations (EC) No 41/2009 and (EC) No 953/2009 should also be repealed.

(48) Adequate transitional measures are necessary to enable food business operators to adapt to the requirements of this Regulation,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter

1. This Regulation establishes compositional and information requirements for the following categories of food:

(a) infant formula and follow-on formula;

(b) processed cereal-based food and baby food;

(c) food for special medical purposes;

(d) total diet replacement for weight control.

2. This Regulation establishes a Union list of substances that may be added to one or more of the categories of food referred to in paragraph 1 and lays down the rules applicable to the updating of that list.

Article 2

Definitions

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

(a) the definitions of 'food', 'food business operator', 'retail' and 'placing on the market' set out respectively in Article 2 and points (3), (7) and (8) of Article 3 of Regulation (EC) No 178/2002;

(b) the definitions of 'prepacked food', 'labelling' and 'engineered nanomaterial' set out respectively in points (e), (j) and (t) of Article 2(2) of Regulation (EU) No 1169/2011;

(c) the definitions of 'nutrition claim' and 'health claim' set out respectively in points (4) and (5) of Article 2(2) of Regulation (EC) No 1924/2006.

2. The following definitions shall also apply:

(a) 'infant' means a child under the age of 12 months;

(b) 'young child' means a child aged between one and three years;

(c) 'infant formula' means food intended for use by infants during the first months of life and satisfying by itself the nutritional requirements of such infants until the introduction of appropriate complementary feeding;

(d) 'follow-on formula' means food intended for use by infants when appropriate complementary feeding is introduced and which constitutes the principal liquid element in a progressively diversified diet of such infants;

(e) 'processed cereal-based food' means food:

(i) intended to fulfil the particular requirements of infants in good health while they are being weaned, and of young children in good health as a supplement to their diet and/or for their progressive adaptation, to ordinary food; and

(ii) pertaining to one of the following categories:

— simple cereals which are or have to be reconstituted with milk or other appropriate nutritious liquids,

— cereals with an added high protein food which are or have to be reconstituted with water or other protein-free liquid,

— pastas which are to be used after cooking in boiling water or other appropriate liquids,

— rusks and biscuits which are to be used either directly or, after pulverisation, with the addition of water, milk or other suitable liquids;

(f) 'baby food' means food intended to fulfil the particular requirements of infants in good health while they are being weaned, and of young children in good health as a supplement to their diet and/or for their progressive adaptation to ordinary food, excluding:

(i) processed cereal-based food; and

(ii) milk-based drinks and similar products intended for young children;

(g) 'food for special medical purposes' means food specially processed or formulated and intended for the dietary management of patients, including infants, to be used

under medical supervision; it is intended for the exclusive or partial feeding of patients with a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients contained therein, or metabolites, or with other medically-determined nutrient requirements, whose dietary management cannot be achieved by modification of the normal diet alone;

(h) 'total diet replacement for weight control' means food specially formulated for use in energy restricted diets for weight reduction which, when used as instructed by the food business operator, replaces the whole daily diet.

Article 3

Interpretation decisions

In order to ensure the uniform implementation of this Regulation, the Commission may decide, by means of implementing acts:

(a) whether a given food falls within the scope of this Regulation;

(b) to which specific category of food referred to in Article 1(1) a given food belongs.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 17(2).

Article 4

Placing on the market

1. Food referred to in Article 1(1) may only be placed on the market if it complies with this Regulation.

2. Food referred to in Article 1(1) shall only be allowed on the retail market in the form of prepacked food.

3. Member States may not restrict or forbid the placing on the market of food which complies with this Regulation, for reasons related to its composition, manufacture, presentation or labelling.

Article 5

Precautionary principle

In order to ensure a high level of health protection in relation to the persons for whom the food referred to in Article 1(1) of this Regulation is intended, the precautionary principle as set out in Article 7 of Regulation (EC) No 178/2002 shall apply.

CHAPTER II

COMPOSITIONAL AND INFORMATION REQUIREMENTS

SECTION 1

General requirements

Article 6

General provisions

1. Food referred to in Article 1(1) shall comply with any requirement of Union law applicable to food.

2. The requirements laid down in this Regulation shall prevail over any conflicting requirement of Union law applicable to food.

Article 7

Opinions of the Authority

The Authority shall provide scientific opinions in accordance with Articles 22 and 23 of Regulation (EC) No 178/2002 for the purpose of the application of this Regulation. Those opinions shall serve as the scientific basis for any Union measure adopted pursuant to this Regulation which is likely to have an effect on public health.

Article 8

Access to documents

The Commission shall apply Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents [1] to applications for access to any document covered by this Regulation.

Article 9

General compositional and information requirements

1. The composition of food referred to in Article 1(1) shall be such that it is appropriate for satisfying the nutritional requirements of, and is suitable for, the persons for whom it is intended, in accordance with generally accepted scientific data.

2. Food referred to in Article 1(1) shall not contain any substance in such quantity as to endanger the health of the persons for whom it is intended.

[1] OJ L 145, 31.5.2001, p. 43.

For substances which are engineered nanomaterials, compliance with the requirement referred to in the first subparagraph shall be demonstrated on the basis of adequate test methods, where appropriate.

3. On the basis of generally accepted scientific data, substances added to food referred to in Article 1(1) for the purposes of the requirements under paragraph 1 of this Article shall be bio-available for use by the human body, have a nutritional or physiological effect and be suitable for the persons for whom the food is intended.

4. Without prejudice to Article 4(1) of this Regulation, food referred to in Article 1(1) of this Regulation may contain substances covered by Article 1 of Regulation (EC) No 258/97, provided that those substances fulfil the conditions under that Regulation for being placed on the market.

5. The labelling, presentation and advertising of food referred to in Article 1(1) shall provide information for the appropriate use of such food, and shall not mislead, or attribute to such food the property of preventing, treating or curing a human disease, or imply such properties.

6. Paragraph 5 shall not prevent the dissemination of any useful information or recommendations exclusively intended for persons having qualifications in medicine, nutrition, pharmacy, or for other healthcare professionals responsible for maternal care and childcare.

Article 10

Additional requirements for infant formula and follow-on formula

1. The labelling, presentation and advertising of infant formula and follow-on formula shall be designed so as not to discourage breast-feeding.

2. The labelling, presentation and advertising of infant formula, and the labelling of follow-on formula shall not include pictures of infants, or other pictures or text which may idealise the use of such formulae.

Without prejudice to the first subparagraph, graphic representations for easy identification of infant formula and follow-on formula and for illustrating methods of preparation shall be permitted.

SECTION 2

Specific requirements

Article 11

Specific compositional and information requirements

1. Subject to the general requirements set out in Articles 6 and 9, to the additional requirements of Article 10, and taking into account relevant technical and scientific progress, the Commission shall be empowered to adopt delegated acts in accordance with Article 18, with respect to the following:

(a) the specific compositional requirements applicable to food referred to in Article 1(1), with the exception of requirements as set out in the Annex;

(b) the specific requirements on the use of pesticides in products intended for the production of food referred to in Article 1(1) and on pesticide residues in such food. The specific requirements for the categories of food referred to in points (a) and (b) of Article 1(1) and food for special medical purposes developed to satisfy the nutritional requirements of infants and young children shall be updated regularly and include, inter alia, provisions to restrict the use of pesticides as much as possible;

(c) the specific requirements on labelling, presentation and advertising of food referred to in Article 1(1), including the authorisation of nutrition and health claims in relation thereto;

(d) the notification requirements for the placing on the market of food referred to in Article 1(1), in order to facilitate the efficient official monitoring of such food, and on the basis of which food business operators shall notify the competent authorities of Member States where that food is being marketed;

(e) the requirements concerning promotional and commercial practices relating to infant formula;

(f) the requirements concerning information to be provided in relation to infant and young child feeding in order to ensure adequate information on appropriate feeding practices;

(g) the specific requirements for food for special medical purposes developed to satisfy the nutritional requirements of infants, including compositional requirements and

requirements on the use of pesticides in products intended for the production of such food, pesticide residues, labelling, presentation, advertising, and promotional and commercial practices, as appropriate.

These delegated acts shall be adopted by 20 July 2015.

2. Subject to the general requirements set out in Articles 6 and 9, to the additional requirements of Article 10, and taking into account relevant technical and scientific progress, including data provided by interested parties in relation to innovative products, the Commission shall be empowered to adopt delegated acts in accordance with Article 18 in order to update the acts referred to in paragraph 1 of this Article.

Where in the case of emerging health risks, imperative grounds of urgency so require, the procedure provided for in Article 19 shall apply to delegated acts adopted pursuant to this paragraph.

Article 12

Milk-based drinks and similar products intended for young children

By 20 July 2015, the Commission shall, after consulting the Authority, present to the European Parliament and to the Council a report on the necessity, if any, of special provisions for milk-based drinks and similar products intended for young children regarding compositional and labelling requirements and, if appropriate, other types of requirements. The Commission shall consider in the report, inter alia, the nutritional requirements of young children, the role of those products in the diet of young children and whether those products have any nutritional benefits when compared to a normal diet for a child who is being weaned. Such a report may, if necessary, be accompanied by an appropriate legislative proposal.

Article 13

Food intended for sportspeople

By 20 July 2015, the Commission shall, after consulting the Authority, present to the European Parliament and to the Council a report on the necessity, if any, of provisions for food intended for sportspeople. Such a report may, if necessary, be accompanied by an appropriate legislative proposal.

Article 14

Technical guidelines

The Commission may adopt technical guidelines to facilitate compliance by food business operators, in particular SMEs, with this Chapter and Chapter III.

CHAPTER III

UNION LIST

Article 15

Union list

1. Substances belonging to the following categories of substances may be added to one or more of the categories of food referred to in Article 1(1), provided that these substances are included in the Union list set out in the Annex and comply with the elements contained in the Union list in accordance with paragraph 3 of this Article:

(a) vitamins;

(b) minerals;

(c) amino acids;

(d) carnitine and taurine;

(e) nucleotides;

(f) choline and inositol.

2. Substances that are included in the Union list shall meet the general requirements set out in Articles 6 and 9 and, where applicable, the specific requirements established in accordance with Article 11.

3. The Union list shall contain the following elements:

(a) the category of food referred to in Article 1(1) to which substances belonging to the categories of substances listed in paragraph 1 of this Article may be added;

(b) the name, the description of the substance and, where appropriate, the specification of its form;

(c) where appropriate, the conditions of use of the substance;

(d) where appropriate, the purity criteria applicable to the substance.

4. Purity criteria established by Union law applicable to food, which apply to the substances included in the Union list when they are used in the manufacture of food for purposes other than those covered by this Regulation, shall also apply to those substances when they are used for purposes covered by this Regulation unless otherwise specified in this Regulation.

5. For substances included in the Union list for which purity criteria are not established by Union law applicable to food, generally acceptable purity criteria recommended by international bodies shall apply until the establishment of such criteria.

Member States may maintain national rules setting stricter purity criteria.

6. In order to take into account technical progress, scientific developments or the protection of consumers' health, the Commission shall be empowered to adopt, in relation to the categories of substances listed in paragraph 1 of this Article, delegated acts in accordance with Article 18 with respect to the following:

(a) the removal of a category of substances;

(b) the addition of a category of substances that have a nutritional or physiological effect.

7. Substances belonging to categories not listed in paragraph 1 of this Article may be added to food referred to in Article 1(1), provided that they satisfy the general requirements set out in Articles 6 and 9 and, where applicable, the specific requirements established in accordance with Article 11.

Article 16

Updating the Union list

1. Subject to the general requirements set out in Articles 6 and 9 and, where applicable, the specific requirements established in accordance with Article 11, and in order to take into account technical progress, scientific developments or the protection of consumers' health, the Commission shall be empowered to adopt delegated acts in accordance with Article 18, to amend the Annex, with respect to the following:

(a) the addition of a substance to the Union list;

(b) the removal of a substance from the Union list;

(c) the addition, removal or amendment of the elements referred to in Article 15(3).

2. Where, in the case of emerging health risks, imperative grounds of urgency so require, the procedure provided for in Article 19 shall apply to delegated acts adopted pursuant to this Article.

CHAPTER IV

PROCEDURAL PROVISIONS

Article 17

Committee procedure

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health established by Regulation (EC) No 178/2002. 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.

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 18

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 11, Article 15(6) and Article 16(1) shall be conferred on the Commission for a period of five years from 19 July 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 11, Article 15(6) and Article 16(1) 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 11, Article 15(6) and Article 16(1) 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 19

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 18(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.

CHAPTER V

FINAL PROVISIONS

Article 20

Repeal

1. Directive 2009/39/EC is repealed with effect from 20 July 2016. References to the repealed act shall be construed as references to this Regulation.

2. Directive 92/52/EEC and Regulation (EC) No 41/2009 are repealed with effect from 20 July 2016.

3. Without prejudice to the first subparagraph of paragraph 4, Directive 96/8/EC shall not apply from 20 July 2016 to foods presented as a replacement for one or more meals of the daily diet.

4. Regulation (EC) No 953/2009 and Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC are repealed from the date of application of the delegated acts referred to in Article 11(1).

In the case of conflict between Regulation (EC) No 953/2009, Directives 96/8/EC, 1999/21/EC, 2006/125/EC, 2006/141/EC and this Regulation, this Regulation shall prevail.

Article 21

Transitional measures

1. Food referred to in Article 1(1) of this Regulation which does not comply with this Regulation but complies with Directive 2009/39/EC, and, as applicable, with Regulation (EC) No 953/2009 and Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, and which is placed on the market or labelled before 20 July 2016 may continue to be marketed after that date until stocks of such food are exhausted.

Where the date of application of the delegated acts referred to in Article 11(1) of this Regulation is after 20 July 2016, food referred to in Article 1(1) which complies with this Regulation and, as applicable, with Regulation (EC) No 953/2009 and Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC but does not comply with those delegated acts, and which is placed on the market or labelled before the date of application of those delegated acts, may continue to be marketed after that date until stocks of such food are exhausted.

2. Food which is not referred to in Article 1(1) of this Regulation but which is placed on the market or labelled in accordance with Directive 2009/39/EC and Regulation (EC) No 953/2009, and, as applicable, with Directive 96/8/EC and Regulation (EC) No 41/2009 before 20 July 2016 may continue to be marketed after that date until stocks of such food are exhausted.

Article 22

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 20 July 2016, with the exception of the following:

— Articles 11, 16, 18 and 19 which shall apply from 19 July 2013.

— Article 15 and the Annex to this Regulation which shall apply from the date of application of the delegated acts referred to in Article 11(1).

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

Done at Strasbourg, 12 June 2013.

For the European Parliament
The President
M. SCHULZ

For the Council
The President
L. CREIGHTON

ANNEX

Union list as referred to in Article 15(1)

Substance			Category of food			
			Infant formula and follow on formula	Processed cereal-based food and baby food	Food for special medical purposes	Total diet replacement for weight control
Vitamins						
	Vitamin A					
		retinol	X	X	X	X
		retinyl acetate	X	X	X	X
		retinyl palmitate	X	X	X	X
		beta-carotene		X	X	X
	Vitamin D					
		ergocalciferol	X	X	X	X
		cholecalciferol	X	X	X	X
	Vitamin E					
		D-alpha tocopherol	X	X	X	X
		DL-alpha tocopherol	X	X	X	X
		D-alpha tocopheryl acetate	X	X	X	X
		DL-alpha tocopheryl acetate	X	X	X	X
		D-alpha-tocopheryl acid succinate			X	X
		D-alpha-tocopheryl polyethylene glycol-1000 succinate (TPGS)			X	
	Vitamin K					
		phylloquinone (phytomenadione)	X	X	X	X
		Menaquinone [1]			X	X
	Vitamin C					
		L-ascorbic acid	X	X	X	X
		sodium-L-ascorbate	X	X	X	X
		calcium-L-ascorbate	X	X	X	X
		potassium-L-ascorbate	X	X	X	X
		L-ascorbyl 6-palmitate	X	X	X	X

Substance			Category of food			
			Infant formula and follow on formula	Processed cereal-based food and baby food	Food for special medical purposes	Total diet replacement for weight control
	Thiamin					
		thiamin hydrochloride	X	X	X	X
		thiamin mononitrate	X	X	X	X
	Riboflavin					
		riboflavin	X	X	X	X
		riboflavin 5'-phosphate, sodium	X	X	X	X
	Niacin					
		nicotinic acid	X	X	X	X
		nicotinamide	X	X	X	X
	Vitamin B_6					
		pyridoxine hydrochloride	X	X	X	X
		pyridoxine 5'-phosphate	X	X	X	X
		pyridoxine dipalmitate		X	X	X
	Folate					
		folic acid (pteroylmonoglutamic acid)	X	X	X	X
		calcium-L-methylfolate			X	X
	Vitamin B_{12}					
		cyanocobalamin	X	X	X	X
		hydroxocobalamin	X	X	X	X
	Biotin					
		D-biotin	X	X	X	X
	Pantothenic Acid					
		D-pantothenate, calcium	X	X	X	X
		D-pantothenate, sodium	X	X	X	X
		dexpanthenol	X	X	X	X
Minerals						
	Potassium					
		potassium bicarbonate	X		X	X
		potassium carbonate	X		X	X

Substance			Category of food			
			Infant formula and follow on formula	Processed cereal-based food and baby food	Food for special medical purposes	Total diet replacement for weight control
		potassium chloride	X	X	X	X
		potassium citrate	X	X	X	X
		potassium gluconate	X	X	X	X
		potassium glycerophosphate		X	X	X
		potassium lactate	X	X	X	X
		potassium hydroxide	X		X	X
		potassium salts of orthophosphoric acid	X		X	X
		magnesium potassium citrate			X	X
	Calcium					
		calcium carbonate	X	X	X	X
		calcium chloride	X	X	X	X
		calcium salts of citric acid	X	X	X	X
		calcium gluconate	X	X	X	X
		calcium glycerophosphate	X	X	X	X
		calcium lactate	X	X	X	X
		calcium salts of orthophosphoric acid	X	X	X	X
		calcium hydroxide	X	X	X	X
		calcium oxide		X	X	X
		calcium sulphate			X	X
		calcium bisglycinate			X	X
		calcium citrate malate			X	X
		calcium malate			X	X
		calcium L-pidolate			X	X

Substance			Category of food			
			Infant formula and follow on formula	Processed cereal-based food and baby food	Food for special medical purposes	Total diet replacement for weight control
	Magnesium					
		magnesium acetate			X	X
		magnesium carbonate	X	X	X	X
		magnesium chloride	X	X	X	X
		magnesium salts of citric acid	X	X	X	X
		magnesium gluconate	X	X	X	X
		magnesium glycerophosphate		X	X	X
		magnesium salts of orthophosphoric acid	X	X	X	X
		magnesium lactate		X	X	X
		magnesium hydroxide	X	X	X	X
		magnesium oxide	X	X	X	X
		magnesium sulphate	X	X	X	X
		magnesium L-aspartate			X	
		magnesium bisglycinate			X	X
		magnesium L-pidolate			X	X
		magnesium potassium citrate			X	X
	Iron					
		ferrous carbonate		X	X	X
		ferrous citrate	X	X	X	X
		ferric ammonium citrate	X	X	X	X
		ferrous gluconate	X	X	X	X
		ferrous fumarate	X	X	X	X
		ferric sodium diphosphate		X	X	X
		ferrous lactate	X	X	X	X

Substance			Category of food			
			Infant formula and follow on formula	Processed cereal-based food and baby food	Food for special medical purposes	Total diet replacement for weight control
		ferrous sulphate	X	X	X	X
		ferrous ammonium phosphate			X	X
		ferric sodium EDTA			X	X
		ferric diphosphate (ferric pyrophosphate)	X	X	X	X
		ferric saccharate		X	X	X
		elemental iron (carbonyl + electrolytic + hydrogen reduced)		X	X	X
		ferrous bisglycinate	X		X	X
		ferrous L-pidolate			X	X
	Zinc					
		zinc acetate	X	X	X	X
		zinc chloride	X	X	X	X
		zinc citrate	X	X	X	X
		zinc gluconate	X	X	X	X
		zinc lactate	X	X	X	X
		zinc oxide	X	X	X	X
		zinc carbonate			X	X
		zinc sulphate	X	X	X	X
		zinc bisglycinate			X	X
	Copper					
		cupric carbonate	X	X	X	X
		cupric citrate	X	X	X	X
		cupric gluconate	X	X	X	X
		cupric sulphate	X	X	X	X
		copper lysine complex	X	X	X	X
	Manganese					
		manganese carbonate	X	X	X	X
		manganese chloride	X	X	X	X

Substance			Category of food			
			Infant formula and follow on formula	Processed cereal-based food and baby food	Food for special medical purposes	Total diet replacement for weight control
		manganese citrate	X	X	X	X
		manganese gluconate	X	X	X	X
		manganese glycerophosphate		X	X	X
		manganese sulphate	X	X	X	X
	Fluoride					
		potassium fluoride			X	X
		sodium fluoride			X	X
	Selenium					
		sodium selenate	X		X	X
		sodium hydrogen selenite			X	X
		sodium selenite	X		X	X
		selenium enriched yeast [2]			X	X
	Chromium					
		chromium (III) chloride and its hexahydrate			X	X
		chromium (III) sulphate and its hexahydrate			X	X
		chromium picolinate			X	X
	Molybdenum					
		ammonium molybdate			X	X
		sodium molybdate			X	X
	Iodine					
		potassium iodide	X	X	X	X
		potassium iodate	X	X	X	X
		sodium iodide	X	X	X	X
		sodium iodate		X	X	X
	Sodium					
		sodium bicarbonate	X		X	X
		sodium carbonate	X		X	X

Substance			Category of food			
			Infant formula and follow on formula	Processed cereal-based food and baby food	Food for special medical purposes	Total diet replacement for weight control
		sodium chloride	X		X	X
		sodium citrate	X		X	X
		sodium gluconate	X		X	X
		sodium lactate	X		X	X
		sodium hydroxide	X		X	X
		sodium salts of orthophosphoric acid	X		X	X
	Boron					
		sodium borate			X	X
		boric acid			X	X
Amino acids [3]						
		L-alanine		—	X	X
		L-arginine	X and its hydrochloride	X and its hydrochloride	X	X
		L-aspartic acid			X	
		L-citrulline			X	
		L-cysteine	X and its hydrochloride	X and its hydrochloride	X	X
		Cystine [4]	X and its hydrochloride	X and its hydrochloride	X	X
		L-histidine	X and its hydrochloride	X and its hydrochloride	X	X
		L-glutamic acid			X	X
		L-glutamine			X	X
		glycine			X	
		L-isoleucine	X and its hydrochloride	X and its hydrochloride	X	X
		L-leucine	X and its hydrochloride	X and its hydrochloride	X	X
		L-lysine	X and its hydrochloride	X and its hydrochloride	X	X
		L-lysine acetate			X	X
		L-methionine	X	X	X	X
		L-ornithine			X	X
		L-phenylalanine	X	X	X	X
		L-proline			X	

Substance			Category of food			
			Infant formula and follow on formula	Processed cereal-based food and baby food	Food for special medical purposes	Total diet replacement for weight control
		L-threonine	X	X	X	X
		L-tryptophan	X	X	X	X
		L-tyrosine	X	X	X	X
		L-valine	X	X	X	X
		L-serine			X	
		L-arginine-L-aspartate			X	
		L-lysine-L-aspartate			X	
		L-lysine-L-glutamate			X	
		N-acetyl-L-cysteine			X	
		N-acetyl-L-methionine			X (in products intended for persons over 1 year of age)	
Carnitine and taurine						
		L-carnitine	X	X	X	X
		L-carnitine hydrochloride	X	X	X	X
		taurine	X		X	X
		L-carnitine-L-tartrate	X		X	X
Nucleotides						
		adenosine 5'-phosphoric acid (AMP)	X		X	X
		sodium salts of AMP	X		X	X
		cytidine 5'-monophosphoric acid (CMP)	X		X	X
		sodium salts of CMP	X		X	X
		guanosine 5'-phosphoric acid (GMP)	X		X	X
		sodium salts of GMP	X		X	X
		inosine 5'-phosphoric acid (IMP)	X		X	X
		sodium salts of IMP	X		X	X

Substance			Category of food			
			Infant formula and follow on formula	Processed cereal-based food and baby food	Food for special medical purposes	Total diet replacement for weight control
Choline and inositol		uridine 5'-phosphoric acid (UMP)	X		X	X
		sodium salts of UMP	X		X	X
		choline	X	X	X	X
		choline chloride	X	X	X	X
		choline bitartrate	X	X	X	X
		choline citrate	X	X	X	X
		inositol	X	X	X	X

(1) Menaquinone occurring principally as menaquinone-7 and, to a minor extent, menaquinone-6.

(2) Selenium-enriched yeasts produced by culture in the presence of sodium selenite as selenium source and containing, in the dried form as marketed, not more than 2,5 mg Se/g. The predominant organic selenium species present in the yeast is selenomethionine (between 60 and 85 % of total extracted selenium in the product). The content of other organic selenium compounds including selenocysteine must not exceed 10 % of total extracted selenium. Levels of inorganic selenium normally must not exceed 1 % of total extracted selenium.

(3) For amino acids used in infant formula, follow-on formula, processed cereal-based food and baby food only the hydrochloride specifically mentioned may be used. For amino acids used in food for special medical purposes and in total diet replacement for weight control, as far as applicable, also the sodium, potassium, calcium and magnesium salts as well as their hydrochlorides may be used.

(4) In the case of use in infant formula, follow-on formula, processed cereal-based food and baby food, only the form L-cystine may be used.

II

(Non-legislative acts)

DECISIONS

EUROPEAN COUNCIL DECISION

of 28 June 2013

establishing the composition of the European Parliament

(2013/312/EU)

THE EUROPEAN COUNCIL,

Having regard to the Treaty on European Union, and in particular Article 14(2) thereof,

Having regard to Article 2(3) of Protocol 36 on transitional provisions,

Having regard to the initiative of the European Parliament [1],

Having regard to the consent of the European Parliament [2],

Whereas:

(1) Article 2(1) and (2) of Protocol 36 on transitional provisions will expire at the end of the 2009-2014 parliamentary term.

(2) Article 19(1) of the Act concerning the conditions of accession of the Republic of Croatia and the adjustments to the Treaty on European Union, the Treaty on the Functioning of the European Union and the Treaty establishing the European Atomic Energy Community will expire at the end of the 2009-2014 parliamentary term.

(3) It is necessary to comply without delay with the provisions of Article 2(3) of Protocol 36 and therefore to adopt the decision provided for in the second subparagraph of Article 14(2) of the Treaty on European Union, in order to enable Member States to enact in good time the necessary domestic measures for organising the elections to the European Parliament for the 2014-2019 parliamentary term.

(4) The first subparagraph of Article 14(2) of the Treaty on European Union lays down the criteria for the composition of the European Parliament, namely that representatives of the Union's citizens are not to exceed 750 in number, plus the President, that representation is to be degressively proportional, with a minimum threshold of six members per Member State, and that no Member State is to be allocated more than 96 seats.

(5) Article 10 of the Treaty on European Union provides, inter alia, that the functioning of the Union shall be founded on representative democracy with citizens being directly represented at Union level in the European Parliament and Member States being represented by their governments, themselves being democratically accountable to their national Parliaments or citizens, in the Council. Article 14(2) of the Treaty on European Union on the composition of the European Parliament therefore applies within the context of the wider institutional arrangements set out in the Treaties, which also include the provisions on decision making in the Council,

HAS ADOPTED THIS DECISION:

Article 1

In the application of the principle of degressive proportionality provided for in the first subparagraph of Article 14(2) of the Treaty on European Union, the following principles shall apply:

— the allocation of seats in the European Parliament shall fully utilise the minimum and maximum numbers set by the Treaty on European Union in order to reflect as closely as possible the sizes of the respective populations of Member States,

[1] Initiative adopted on 13 March 2013 (not yet published in the Official Journal).

[2] Consent of 12 June 2013 (not yet published in the Official Journal).

— the ratio between the population and the number of seats of each Member State before rounding to whole numbers shall vary in relation to their respective populations in such a way that each Member of the European Parliament from a more populous Member State represents more citizens than each Member from a less populous Member State and, conversely, that the larger the population of a Member State, the greater its entitlement to a large number of seats.

Article 2

The total population of the Member States shall be calculated by the Commission (Eurostat) on the basis of data provided by the Member States, in accordance with a method established by means of a regulation of the European Parliament and of the Council.

Article 3

Pursuant to Article 1, the number of representatives in the European Parliament elected in each Member State is hereby set as follows for the 2014-2019 parliamentary term:

Belgium	21
Bulgaria	17
Czech Republic	21
Denmark	13
Germany	96
Estonia	6
Ireland	11
Greece	21
Spain	54
France	74
Croatia	11
Italy	73
Cyprus	6
Latvia	8
Lithuania	11
Luxembourg	6
Hungary	21
Malta	6
Netherlands	26
Austria	18
Poland	51
Portugal	21
Romania	32
Slovenia	8
Slovakia	13
Finland	13
Sweden	20
United Kingdom	73

Article 4

This Decision shall be revised sufficiently far in advance of the beginning of the 2019-2024 parliamentary term on the basis of an initiative of the European Parliament presented before the end of 2016 with the aim of establishing a system which in future will make it possible, before each fresh election to the European Parliament, to allocate the seats between Member States in an objective, fair, durable and transparent way, translating the principle of degressive proportionality as laid down in Article 1, taking account of any change in their number and demographic trends in their population, as duly ascertained thus respecting the overall balance of the institutional system as laid down in the Treaties.

Article 5

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

Done at Brussels, 28 June 2013.

For the European Council
The President
H. VAN ROMPUY

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