I Legislative acts

REGULATIONS


★ Regulation (EU) No 332/2014 of the European Parliament and of the Council of 11 March 2014 on certain procedures for applying the Stabilisation and Association Agreement between the European Communities and their Member States, of the one part, and the Republic of Serbia, of the other part ............................................................... 10


★ Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014 amending Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, with regard to certain conditions for access to the market (¹) ...................... 22


(¹) Text with EEA relevance

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.
The titles of all other acts are printed in bold type and preceded by an asterisk.
I

(Legislative acts)

REGULATIONS

REGULATION (EU) No 331/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 11 March 2014

establishing an exchange, assistance and training programme for the protection of the euro against
counterfeiting (the 'Pericles 2020' programme) and repealing Council Decisions 2001/923/EC,

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 133 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 Central Bank (1),

Acting in accordance with the ordinary legislative procedure (2),

Whereas:

(1) The Union and the Member States have set themselves the objective of laying down the measures necessary for the
use of the euro as a single currency. Those measures include protecting the euro against counterfeiting and related
fraud, thus empowering the effectiveness of the Union’s economy and securing the sustainability of public finances.

(2) Council Regulation (EC) No 1338/2001 (3) provides for exchanges of information, cooperation and mutual
assistance, thereby establishing a harmonised framework for the protection of the euro. The effects of that
Regulation were extended by Council Regulation (EC) No 1339/2001 (4) to those Member States which have
not adopted the euro as their single currency, so as to provide an equivalent level of protection for the euro
throughout the Union.

(3) Actions with the aim of promoting exchanges of information and staff, technical and scientific assistance and
specialised training help significantly to protect the Union’s single currency against counterfeiting and related fraud
and therefore to attain a high and equivalent level of protection across the Union, whilst demonstrating the
Union’s ability to tackle serious organised crime.

(4) The programme for the protection of the euro against counterfeiting (the Pericles programme) contributes to
raising the awareness of Union citizens, improving the protection of the euro, especially through the constant
dissemination of results of actions supported by that programme.

(1) OJ C 137, 12.5.2012, p. 7.
(2) Position of the European Parliament of 11 December 2013 (not yet published in the Official Journal) and decision of the Council of
11 March 2014.
measures necessary for the protection of the euro against counterfeiting to those Member States which have not adopted the euro as
their single currency (OJ L 181, 4.7.2001, p. 11).
(5) Past support for such actions, through Council Decisions 2001/923/EC (1) and 2001/924/EC (2), which were subsequently amended and extended by Council Decisions 2006/75/EC (3), 2006/76/EC (4), 2006/849/EC (5) and 2006/850/EC (6), has made it possible to enhance the actions of the Union and the Member States in the field of the protection of the euro against counterfeiting. The objectives of the Pericles programme for both the period 2002-2006 and the period 2007-2013 have been successfully achieved.

(6) In its impact assessment, carried out in 2011, evaluating whether the Pericles programme should be continued, the Commission came to the conclusion that the Pericles programme should be renewed with improved objectives and methodology.

(7) The advice contained in the impact assessment was that actions should be continued and further developed at the level of the Union and the Member States in the field of the protection of the euro against counterfeiting, taking into account the new challenges in a context of budgetary austerity. Under the new programme, Pericles 2020 programme, proposals presented by the participating Member States may include participants from third countries, if their participation is important for the protection of the euro.

(8) It should be ensured that the Pericles 2020 programme is consistent with, and complementary to, other relevant programmes and actions. The Commission should therefore carry out all the necessary consultations with regard to evaluating needs for the protection of the euro with the principal parties involved (in particular the competent national authorities designated by the Member States, the European Central Bank and Europol) within the committee referred to in Regulation (EC) No 1338/2001, particularly as regards exchanges, assistance and training, for the purpose of the application of the Pericles 2020 programme.

(9) The Pericles 2020 programme should be implemented in full compliance with the provisions of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council (7). In accordance with that Regulation, a grant may not have as its sole purpose the purchase of equipment. A grant is meant to support financially an action intended to help to achieve a Union policy objective.

(10) The importance of the euro as a worldwide currency requires an adequate level of protection at international level, which can be achieved by making funds available for the purchase of equipment to be used by third countries’ agencies in investigating euro counterfeiting.

(11) The evaluation of the Pericles programme conducted with stakeholders demonstrates the added value of that programme, in terms of the high level of cooperation among Member States and with third countries, as well as complementarity with actions undertaken at national level, resulting in increased effectiveness. The continuation of the Pericles programme at Union level is expected to make a substantial contribution to maintaining and further improving the high level of protection of the euro associated with the intensification of cross-border cooperation, exchange and assistance. At the same time, overall savings will be achieved from the collectively organised actions and procurement, as compared with potential individual national initiatives.

(12) The Commission should present to the European Parliament and to the Council an independent mid-term evaluation report on the implementation of the Pericles 2020 programme and a final evaluation report on the achievement of its objectives.


This Regulation complies with the principles of added value and proportionality. The Pericles 2020 programme should facilitate cooperation among the Member States and between the Commission and the Member States in order to protect the euro against counterfeiting, without impinging on Member States' responsibilities, and using resources more efficiently than could be done at national level. Action at Union level is necessary and justified as it clearly assists Member States in collectively protecting the euro and encourages the use of common Union structures to increase cooperation and information exchange between competent authorities.

The Pericles 2020 programme should run for a period of seven years to align its duration with that of the multiannual financial framework laid down in Council Regulation (EU, Euratom) No 1311/2013 (1).

In order to ensure uniform conditions for the implementation of the Pericles 2020 programme, implementing powers should be conferred on the Commission. The Commission should adopt annual work programmes setting out the priorities, the budget breakdown and the evaluation criteria for the grants for actions. The Commission should discuss the application of this Regulation with the Member States within the framework of the committee referred to in Regulation (EC) No 1338/2001. The exceptional and duly justified cases, in which an increase in co-financing is necessary in order to give the Member States greater economic flexibility, thus enabling them to carry out and complete projects to protect and safeguard the euro in a satisfactory manner, should be part of the annual work programmes.

This Regulation lays down a financial envelope for the entire duration of the Pericles 2020 programme, which is to constitute the prime reference amount, within the meaning of point 17 of the Interinstitutional Agreement of 2 December 2013 between the European Parliament, the Council and the Commission on budgetary discipline, on cooperation in budgetary matters and on sound financial management (2), for the European Parliament and the Council during the annual budgetary procedure.

In order to provide for a degree of flexibility in the allocation of funds, 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 amendments to the indicative allocation of those funds. 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.

The financial interests of the Union should be protected through proportionate measures throughout the expenditure cycle, including the prevention, detection and investigation of irregularities, the recovery of funds lost, wrongly paid or incorrectly used and, where appropriate, administrative and financial penalties.

Decisions 2001/923/EC, 2001/924/EC, 2006/75/EC, 2006/76/EC, 2006/849/EC and 2006/850/EC should be repealed. Transitional measures should be provided to complete financial obligations relating to actions pursued under those Decisions.

It is appropriate to ensure a smooth transition without interruption between the Pericles programme and the Pericles 2020 programme and it is appropriate to align the duration of the Pericles 2020 programme with Regulation (EU, Euratom) No 1311/2013. Therefore, the Pericles 2020 programme should apply as from 1 January 2014.

HAVE ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter

The multiannual action programme to promote actions for the protection and safeguarding of the euro against counterfeiting and related fraud ‘Pericles 2020’ (the Programme) is hereby established for the period from 1 January 2014 to 31 December 2020.


Article 2

Added value

The Programme shall actively encourage and entail an increase in transnational cooperation for the protection of the euro inside and outside the Union and with the Union's trading partners, and with attention also being paid to those Member States or third countries that have the highest rates of euro counterfeiting, as shown by the relevant reports issued by the competent authorities. Such cooperation shall contribute to the greater effectiveness of the protection of the euro through the exchanging of best practice, common standards and joint specialised training.

Article 3

General objective

The general objective of the Programme shall be to prevent and combat counterfeiting and related fraud, thus enhancing the competitiveness of the Union's economy and securing the sustainability of public finances.

Article 4

Specific objective

The specific objective of the Programme shall be to protect euro banknotes and coins against counterfeiting and related fraud, by supporting and supplementing the measures undertaken by the Member States and assisting the competent national and Union authorities in their efforts to develop among themselves and with the Commission a close and regular cooperation and an exchange of best practice, where appropriate including third countries and international organisations.

That objective shall be measured, inter alia, through the effectiveness of action by financial, technical, law-enforcement and judicial authorities, as measured through the number of counterfeits detected, illegal workshops dismantled, individuals arrested and penalties imposed.

Article 5

Bodies eligible for funding

Bodies eligible for funding under the Programme shall be the competent national authorities as defined in point (b) of Article 2 of Regulation (EC) No 1338/2001.

Article 6

Participation in the Programme

1. Participating countries shall be the Member States having adopted the euro as their single currency.

2. The proposals presented by the Member States referred to in paragraph 1 may include participants from third countries, if that is important for the fulfilment of the general and specific objectives provided for in Articles 3 and 4 respectively.

Article 7

Target groups and joint actions

1. The Programme shall target the participation of the following groups:

(a) staff of agencies engaged in detecting and combating counterfeiting, in particular police forces and financial administrations, depending on their specific functions at national level;

(b) intelligence personnel;

(c) representatives of the national central banks, the mints, commercial banks and other financial intermediaries, in particular as regards the obligations of financial institutions;

(d) judicial officers, specialist lawyers and members of the judiciary in this field;

(e) any other group of specialists concerned, such as chambers of commerce and industry or comparable structures capable of providing access to small and medium-sized enterprises, retailers and cash-in-transit companies.
2. Actions under the Programme may be organised jointly by the Commission and other partners having relevant expertise, such as:

(a) the national central banks and the European Central Bank (ECB);

(b) the National Analysis Centres (NACs) and the Coin National Analysis Centres (CNACs);

(c) the European Technical and Scientific Centre (ETSC) and the mints;

(d) Europol, Eurojust and Interpol;

(e) the national central anti-counterfeiting offices provided for in Article 12 of the International Convention for the Suppression of Counterfeiting Currency signed at Geneva on 20 April 1929 (1) and other agencies specialising in prevention, detection and law-enforcement in connection with counterfeiting;

(f) specialist bodies concerned in the field of duplication and certification technologies, printers and engravers;

(g) bodies other than those referred to in points (a) to (f) offering specific expertise, including, where appropriate, such bodies from third countries and in particular from acceding States and candidate countries; and

(h) private entities that have developed and provided evidence of technical knowledge and teams specialising in detecting counterfeit banknotes and coins.

Article 8

Eligible actions

1. The Programme shall take into account the transnational and multidisciplinary aspects of the fight against counterfeiting and shall promote best practice adapted to the national specificities of each Member State.

2. The Programme shall provide, under the conditions set out in the annual work programmes referred to in Article 11, financial support for the following actions:

(a) exchange and dissemination of information, in particular through organising workshops, meetings and seminars, including training, targeted placements and exchanges of staff of competent national authorities and other similar actions. The exchange of information shall, inter alia, be targeted at:

— methodologies for monitoring and analysing the economic and financial impact of counterfeiting;

— operation of databases and early warning systems;

— use of detection tools with computer back-up;

— enquiry and investigation methods;

— scientific assistance, in particular scientific databases and technology watch/monitoring of new developments;

— protection of the euro outside the Union;

— research actions;

— provision of specific operational expertise;

(b) technical, scientific and operational assistance, as appears necessary as part of the Programme including in particular:

— any appropriate measure which establishes teaching resources at Union level, such as a handbook of Union legislation, information bulletins, practical manuals, glossaries and lexicons, databases, especially in the area of scientific assistance or technology watch or computer support applications, such as software;

— relevant studies with a multidisciplinary and transnational dimension;

— development of technical support instruments and methods to facilitate detection actions at Union level;

— financial support for cooperation in operations involving at least two States when such support is not available from other programmes of European institutions and bodies;

(c) grants to finance the purchase of equipment to be used by specialised anti-counterfeiting authorities for protecting the euro against counterfeiting, in compliance with Article 10(3).

CHAPTER II
FINANCIAL FRAMEWORK

Article 9

Financial envelope

1. The financial envelope for the implementation of the Programme for the period from 1 January 2014 to 31 December 2020 shall be EUR 7 344 000 (in current prices).

2. Within the financial envelope for the Programme, amounts shall be allocated to eligible actions listed in Article 8(2) in accordance with the indicative allocation of funds laid down in the Annex.

The Commission shall not depart from that indicative allocation of funds by more than 10 %. Should it prove necessary to exceed that limit, the Commission shall be empowered to adopt delegated acts in accordance with Article 14 to modify the indicative allocation of funds laid down in the Annex.

3. The annual appropriations shall be authorised by the European Parliament and the Council within the limits of the multiannual financial framework.

Article 10

Types of financial support and co-financing

1. The Commission shall implement the Programme in accordance with Regulation (EU, Euratom) No 966/2012.

2. Financial support under the Programme for eligible actions listed in Article 8(2) shall take the form of either:

(a) grants; or

(b) public procurement.

3. The purchase of equipment shall not be the sole component of the grant agreement.

4. The co-financing rate for grants awarded under the Programme shall not exceed 75 % of the eligible costs. In exceptional and duly justified cases, defined in the annual work programmes referred to in Article 11, the co-financing rate shall not exceed 90 % of the eligible costs.

5. Where eligible actions listed in Article 8(2) are organised jointly by the Commission and the ECB, Eurojust, Europol or Interpol, the ensuing expenses shall be divided among them. In any event, each of them shall bear the travel and accommodation costs of its own guest speakers.

Article 11

Annual work programmes

In order to implement the Programme, the Commission shall adopt annual work programmes.

Each annual work programme shall implement the general and specific objectives provided for in Articles 3 and 4 respectively by setting out the following:

(a) the actions to be undertaken in accordance with such general and specific objectives, including the indicative allocation of funds and the method of implementation;

(b) for grants: the essential selection criteria and the maximum possible rate of co-financing.
Funds allocated to communication actions under the Programme shall also contribute to covering the corporate communication of the Union’s political priorities, as far as they relate to the general objective set out in Article 3.

**Article 12**

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

1. The Commission shall take appropriate measures ensuring that, when actions financed under this Regulation are implemented, the financial interests of the Union are protected by the application of preventive measures against fraud, corruption and any other illegal activities by effective checks and, if irregularities are detected, by the recovery of the amounts wrongly paid and, where appropriate, by effective, proportionate and dissuasive administrative and financial penalties.

2. The Commission or its representatives and the Court of Auditors shall have the power of audit, on the basis of documents and on the spot, over all grant beneficiaries, contractors and subcontractors who have received Union funds under the Programme.

3. The European Anti-fraud Office (OLAF) may carry out investigations, including on-the-spot checks and inspections, in accordance with the provisions and procedures laid down in Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council (1) and Council Regulation (Euratom, EC) No 2185/96 (2) with a view to establishing whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the Union in connection with a grant agreement or grant decision or a contract funded under the Programme.

4. Without prejudice to paragraphs 1, 2 and 3, cooperation agreements with third countries and with international organisations, contracts, grant agreements and grant decisions resulting from the implementation of this Regulation shall contain provisions expressly empowering the Commission, the Court of Auditors and OLAF to conduct such audits and investigations, according to their respective competences.

**CHAPTER III**

**MONITORING, EVALUATION AND DELEGATED POWERS**

**Article 13**

**Monitoring and evaluation**

1. The Programme shall be implemented by the Commission in cooperation with the Member States, through regular consultations at different stages of the implementation of the Programme, within the committee referred to in Regulation (EC) No 1338/2001, taking into account relevant measures undertaken by other competent entities, in particular the ECB and Europol.

2. The Commission shall seek to ensure consistency and complementarity between the Programme and other relevant programmes and actions at Union level.

3. The Commission shall provide annual information on the results of the Programme to the European Parliament and to the Council. Information on consistency and complementarity with other relevant programmes and actions at Union level shall be included. The Commission shall constantly disseminate the results of the actions supported under the Programme. All participating countries and other beneficiaries shall provide the Commission with all the data and information necessary to permit the monitoring and evaluation of the Programme.

4. An evaluation of the Programme shall be carried out by the Commission. By 31 December 2017, an independent mid-term evaluation report shall be presented by the Commission on the achievement of the objectives of all the measures (at the level of results and impacts), the efficient and cost-effective use of resources and its added value for the Union. The evaluation report shall be prepared with a view to informing a decision on the renewal, modification or suspension of the measures. The evaluation shall additionally address the scope for simplification, its internal and external coherence, the continued relevance of all objectives, as well as the contribution of the measures to the Union’s priorities of smart, sustainable and inclusive growth. It shall take into account evaluation results on the long-term impact of the predecessor measures.


(2) Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities’ financial interests against fraud and other irregularities (OJ L 292, 15.11.1996, p. 2).
5. The long-term impact and the sustainability of effects of the Programme shall also be evaluated with a view to informing a decision on a possible renewal, modification or suspension of any subsequent programme.

6. In addition, by 31 December 2021, the Commission shall present to the European Parliament and to the Council a final evaluation report on the achievement of the objectives of the Programme.

Article 14

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 9 shall be conferred on the Commission from 1 January 2014 to 31 December 2020.

3. The delegation of power referred to in Article 9 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 9 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and 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.

CHAPTER IV

FINAL PROVISIONS

Article 15

Repeal

Decisions 2001/923/EC, 2001/924/EC, 2006/75/EC, 2006/76/EC, 2006/849/EC and 2006/850/EC are repealed. However, financial obligations relating to actions pursued under those Decisions shall continue to be governed by those Decisions until the fulfilment of those obligations.

Article 16

Entry into force

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

It shall apply from 1 January 2014.

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

Done at Strasbourg, 11 March 2014.

For the European Parliament
The President
M. SCHULZ

For the Council
The President
D. KOURKOULAS
ANNEX

Indicative allocation of funds for eligible actions listed in Article 8(2)

Within the financial envelope for the Programme as set out in Article 9, a minimum of 90 % of the budget shall be allocated to the following eligible actions listed in Article 8(2):

— Exchange and dissemination of information;
— Technical, scientific and operational assistance;
— Grants to finance the purchase of equipment to be used by specialised anti-counterfeiting authorities.
REGULATION (EU) No 332/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 11 March 2014

on certain procedures for applying the Stabilisation and Association Agreement between the European Communities and their Member States, of the one part, and the Republic of Serbia, of the other part

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 Stabilisation and Association Agreement between the European Communities and their Member States, of the one part, and the Republic of Serbia, of the other part (SAA) was signed on 29 April 2008 and concluded on 22 July 2013 (2). The SAA entered into force on 1 September 2013.

(2) It is necessary to lay down rules for the implementation of certain provisions of the SAA, as well as the procedures for the adoption of detailed rules of implementation.

(3) In order to ensure uniform conditions for the implementation of the SAA, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council (3). Given that the implementing acts form part of the common commercial policy, the examination procedure should in principle be used for their adoption. Where the SAA provides for the possibility, in exceptional and critical circumstances, to apply forthwith measures necessary to deal with the situation, the Commission should adopt such implementing acts immediately. The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to measures concerning agricultural and fishery products, imperative grounds of urgency so require.

(4) The SAA stipulates that certain agricultural and fishery products originating in Serbia may be imported into the Union at a reduced customs duty, within the limits of tariff quotas. It is therefore necessary to lay down provisions regulating the management and review of those tariff quotas in order to allow for their thorough assessment.


(6) Where a Member State provides information to the Commission on a possible case of fraud or failure to provide administrative cooperation, the relevant Union legislation, in particular Council Regulation (EC) No 515/97 (7), should apply.

(7) This Regulation contains implementing measures for the SAA, and should thus apply from the date of entry into force of the SAA.

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(7) 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 and agricultural matters (OJ L 82, 22.3.1997, p. 1).
(8) Upon the entry into force of the SAA, the SAA replaced the Interim Agreement on trade and trade-related matters between the European Community, of the one part, and the Republic of Serbia, of the other part (1) (‘Interim Agreement’), which had entered into force on 1 February 2010 and provided for the early entry into force of the trade and trade-related provisions of the SAA. In order to ensure the effective application and management of the tariff quotas granted under the Interim Agreement and the SAA, as well as to ensure legal certainty and equal treatment with regard to the levying of duties, certain provisions of this Regulation should apply from the date of entry into force of the Interim Agreement,

HAVE ADOPTED THIS REGULATION:

**Article 1**

**Subject matter**

1. This Regulation lays down the rules and procedures for the adoption of detailed rules for the implementation of certain provisions of the Stabilisation and Association Agreement between the European Communities and their Member States, of the one part, and the Republic of Serbia, of the other part (‘SAA’).

2. All references in this Regulation to provisions of the SAA shall, whenever applicable, be understood as referring to the corresponding provisions of the Interim Agreement.

**Article 2**

**Concessions for fish and fishery products**

The Commission shall adopt detailed rules on the implementation of Article 14 of the Interim Agreement, and thereafter Article 29 of the SAA, concerning the tariff quotas for fish and fishery products, by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 13(3) of this Regulation.

**Article 3**

**Tariff reductions**

1. Subject to paragraph 2, rates of preferential duty shall be rounded down to the first decimal place.

2. The preferential rate shall be considered a full exemption where the result of calculating the rate of preferential duty in accordance with paragraph 1 is one of the following:

   (a) 1 % or less in the case of ad valorem duties;

   (b) EUR 1 or less per individual amount in the specific duties.

**Article 4**

**Technical adaptations**

The Commission shall adopt amendments and technical adaptations to the provisions adopted pursuant to this Regulation which are necessary following changes to the Combined Nomenclature codes and to the TARIC subdivisions or arising from the conclusion of new or modified agreements, protocols, exchanges of letters or other acts between the Union and the Republic of Serbia by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 13(3).

**Article 5**

**General safeguard clause**

Without prejudice to Article 7, where the Union needs to take a measure as provided for in Article 41 of the SAA, the Commission shall adopt that measure by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 13(3) of this Regulation, unless otherwise specified in Article 41 of the SAA.

**Article 6**

**Shortage clause**

Without prejudice to Article 7, where the Union needs to take a measure provided for in Article 42 of the SAA, the Commission shall adopt that measure by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 13(3) of this Regulation.

Article 7

Exceptional and critical circumstances

Where exceptional and critical circumstances arise within the meaning of Article 41(5)(b) and Article 42(4) of the SAA, the Commission may take immediately applicable measures as provided for in Articles 41 and 42 of the SAA, in accordance with the procedure referred to in Article 13(4) of this Regulation.

Article 8

Safeguard clause for agricultural and fishery products

1. Notwithstanding the procedures provided for in Articles 5 and 6 of this Regulation, where the Union needs to take a measure as provided for in Article 32(2) or Article 41 of the SAA, concerning agricultural and fishery products, the Commission shall, at the request of a Member State or on its own initiative, decide upon the necessary measures after, where applicable, having had recourse to the referral procedure provided for in Article 41 of the SAA. Those measures shall be adopted by the Commission by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 13(3) of this Regulation.

On duly justified imperative grounds of urgency, including the case referred to in paragraph 2 of this Article, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 13(4) of this Regulation.

2. If the Commission receives the request referred to in paragraph 1 from a Member State, it shall take a decision thereon:

(a) within three working days following the receipt of that request, where the referral procedure provided for in Article 41 of the SAA does not apply; or

(b) within three days of the end of the 30-day period referred to in Article 41(5)(a) of the SAA, where the referral procedure provided for in Article 41 of the SAA applies.

Article 9

Surveillance

For the purposes of implementing Article 32(2) of the SAA, a Union surveillance of imports of goods listed in Annex V to Protocol 3 to the SAA shall be established. The procedure laid down in Article 308d of Commission Regulation (EEC) No 2454/93 (1) shall apply.

Article 10

Dumping and subsidy

In the event of a practice that may cause the Union to take the measures provided for in Article 40(2) of the SAA, the introduction of anti-dumping and/or countervailing measures shall be decided upon in accordance with the provisions laid down in, respectively, Regulation (EC) No 1225/2009 and Regulation (EC) No 597/2009.

Article 11

Competition

1. In the event of a practice which the Commission considers to be incompatible with Article 73 of the SAA, the Commission shall, after examining the case on its own initiative or on the request of a Member State, decide upon the appropriate measure provided for in Article 73 of the SAA.

The measures provided for in Article 73(10) of the SAA shall be adopted in the cases of aid in accordance with the procedures laid down in Regulation (EC) No 597/2009.

2. In the event of a practice that may cause measures to be applied to the Union by the Republic of Serbia on the basis of Article 73 of the SAA, the Commission shall, after examining the case, decide whether the practice is compatible with the principles set out in the SAA. Where necessary, it shall take appropriate decisions on the basis of criteria which result from the application of Articles 101, 102 and 107 of the Treaty.

Article 12
Fraud or failure to provide administrative cooperation

1. Where the Commission, on the basis of information provided by a Member State or on its own initiative, finds that the conditions laid down in Article 46 of the SAA are fulfilled, it shall, without undue delay:

(a) inform the European Parliament and the Council; and

(b) notify the Stabilisation and Association Committee of its finding together with the objective information it is based on, and enter into consultations within the Stabilisation and Association Committee.

2. Any publication under Article 46(5) of the SAA shall be done by the Commission in the Official Journal of the European Union.

3. The Commission may decide, by means of implementing acts adopted in accordance with the examination procedure referred to in Article 13(3) of this Regulation, to suspend temporarily the relevant preferential treatment of the products as provided for in Article 46(4) of the SAA.

Article 13
Committee procedure

1. For the purposes of Articles 2, 4 and 12 of this Regulation, the Commission shall be assisted by the Customs Code Committee set up by Article 184 of Regulation (EC) No 450/2008 of the European Parliament and of the Council (1). That Committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. For the purposes of Articles 5 to 8 of this Regulation, the Commission shall be assisted by the Committee set up by Article 4 of Regulation (EC) No 260/2009. That Committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

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

4. Where reference is made to this paragraph, paragraphs 1 to 4 of Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

Article 14
Notification

The Commission, acting on behalf of the Union, shall be responsible for notification to the Stabilisation and Association Council and the Stabilisation and Association Committee, respectively, as required by the SAA.

Article 15
Entry into force

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

It shall apply from 1 September 2013. However, Articles 2, 3 and 4 shall apply from 1 February 2010.

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

Done at Strasbourg, 11 March 2014.

For the European Parliament
The President
M. SCHULZ

For the Council
The President
D. KOURKOULAS
of 11 March 2014
amending Regulation (EC) No 443/2009 to define the modalities for reaching the 2020 target to reduce CO\(_2\) emissions from new passenger cars

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 192(1) thereof,

Having regard to the proposal from the European Commission,

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

Having regard to the opinion of the European Economic and Social Committee (1),

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure (2),

Whereas:

(1) Pursuant to Article 13(5) of Regulation (EC) No 443/2009 of the European Parliament and of the Council (3) the Commission is to review the modalities of achieving the 95 g CO\(_2\)/km target by 2020 in a cost-effective manner, including the formulae set out in Annex I to that Regulation and the derogations provided for in Article 11 thereof. It is appropriate that this Regulation be as neutral as possible from the point of view of competition, socially equitable and sustainable.

(2) The further development of the worldwide market for advanced technologies aimed at improving the efficiency of passenger cars is in line with the Commission's Communication of 21 January 2011 entitled: 'A resource-efficient Europe — Flagship initiative under the Europe 2020 strategy’, which supports the shift to a resource-efficient, low-carbon economy for achieving sustainable growth.

(3) It is appropriate to clarify that, for the purpose of verifying compliance with the target of 95 g CO\(_2\)/km, CO\(_2\) emissions should continue to be measured in accordance with Regulation (EC) No 715/2007 of the European Parliament and of the Council (4) and its implementing measures and innovative technologies.

(4) High fossil fuel prices have a negative impact on economic recovery and on energy security and affordability in the Union. Increasing, therefore, the efficiency and sustainability of new passenger cars and light commercial vehicles, thus reducing the dependency on oil, is a priority.

(5) In recognition of the high research and development and unit production costs of early generations of ultra-low emission vehicles, it is appropriate to accelerate and facilitate, on an interim basis and to a limited extent, the process of their introduction into the Union market at their initial stages of commercialisation. Actors at different levels should give appropriate attention to identifying and disseminating best practices for stimulating demand for ultra-low emission vehicles.

(6) The lack of alternative fuel infrastructure and of common technical specifications for the vehicle-infrastructure interface could be an obstacle to the market uptake of ultra-low emission vehicles. Ensuring the building-up of such infrastructure in the Union could facilitate the work of market forces and contribute to economic growth in Europe.

(7) In recognition of the disproportionate impact on the smallest manufacturers resulting from compliance with specific emissions targets defined on the basis of the utility of the vehicle, the high administrative burden of the derogation procedure, and the marginal resulting benefit in terms of CO\(_2\) emissions reduction from the vehicles sold by those manufacturers, manufacturers responsible for fewer than 1 000 new passenger cars registered in the Union annually should be excluded from the scope of the specific emissions target and the excess emissions premium. In order to ensure from the earliest point legal certainty for those manufacturers, it is essential that this derogation apply from 1 January 2012.

The procedure for granting a derogation to small-volume manufacturers should be simplified to allow for more flexibility in terms of when an application for a derogation is to be submitted by such manufacturers and when the Commission is to grant such a derogation.

The procedure for granting derogations to niche manufacturers should continue beyond 2020. However, in order to ensure that the reduction effort required by niche manufacturers is consistent with that of large volume manufacturers, a target 45% lower than the average specific emissions of niche manufacturers in 2007 should therefore apply from 2020.

To enable the automotive industry to engage in long-term investment and innovation, it is desirable to provide indications as to how Regulation (EC) No 443/2009 should be amended for the period beyond 2020. Those indications should be based on an assessment of the necessary rate of reduction in line with the Union’s long-term climate goals and the implications for the development of cost effective CO₂-reducing technology for cars. The Commission should, by 2015, review such aspects and submit a report to the European Parliament and to the Council on its findings. That report should include, where appropriate, proposals for amending Regulation (EC) No 443/2009 with a view to establishing CO₂ emission targets for new passenger cars beyond 2020, including the possible setting of a realistic and achievable target for 2025, based on a comprehensive impact assessment that will consider the continued competitiveness of the car industry and its dependent industries, while maintaining a clear emissions-reduction trajectory comparable to that achieved in the period up to 2020. When developing such proposals, the Commission should ensure they are as neutral as possible from the point of view of competition and are socially equitable and sustainable.

Under Regulation (EC) No 443/2009, the Commission is required to carry out an impact assessment in order to review the test procedures with a view to reflecting adequately the real CO₂ emissions behaviour of cars. There is a need to amend the currently used ‘New European Driving Cycle’ (NEDC), to ensure its representativeness regarding real driving conditions and to avoid the underestimation of real CO₂ emissions and fuel consumption. A new, more realistic and reliable test procedure should be agreed as soon as feasible. Work in this direction is proceeding through the development of a Worldwide harmonized Light vehicles Test Procedure (WLTP) in the framework of the United Nations Economic Commission for Europe but has not yet been completed. In order to ensure that specific CO₂ emissions quoted for new passenger cars are brought more closely into line with the emissions actually generated during normal conditions of use, the WLTP should be applied at the earliest opportunity. In view of that context, Annex I to Regulation (EC) No 443/2009 establishes emission limits for 2020 as measured in accordance with Regulation (EC) No 715/2007 and Annex XII to Commission Regulation (EC) No 692/2008 (1). When the test procedures are amended, the limits set in Annex I to Regulation (EC) No 443/2009 should be adjusted to ensure comparable stringency for manufacturers and classes of vehicles. Accordingly, the Commission should carry out a robust correlation study between the NEDC and the new WLTP test cycles to ensure its representativeness regarding real driving conditions.

With a view to ensuring that real world emissions are adequately reflected, and measured CO₂ values are strictly comparable, the Commission should ensure that those elements in the testing procedure that have a significant influence on measured CO₂ emissions are strictly defined in order to prevent the utilisation of test cycle flexibilities by manufacturers. The deviations between type-approval CO₂ emission values and emissions derived from vehicles offered for sale should be addressed, including by considering an in-service conformity test procedure that should ensure independent testing of a representative sample of vehicles for sale, as well as ways of addressing cases of demonstrated substantial divergence between survey and initial type-approval CO₂ emissions.

The wording of Article 3(2) of Regulation (EC) No 443/2009 should be adjusted to ensure that the concept of connected undertakings is in line with Council Regulation (EC) No 139/2004 (2) as well as with Article 3(2) of Regulation (EU) No 510/2011 of the European Parliament and of the Council (3).

Regulation (EC) No 443/2009 confers powers on the Commission to implement some of its provisions in accordance with the procedures laid down in Council Decision 1999/468/EC (1). As a consequence of the entry into force of the Treaty of Lisbon, those powers need to be aligned to Articles 290 and 291 of the Treaty on the Functioning of the European Union (TFEU).

In order to ensure uniform conditions for the implementation of Regulation (EC) No 443/2009, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council (2).

The power to adopt acts in accordance with Article 290 of the TFEU should be delegated to the Commission in order to amend Annex II to Regulation (EC) No 443/2009 as regards data requirements and data parameters; supplement the rules on the interpretation of the eligibility criteria for derogations from the specific emissions targets, on the content of applications for a derogation and on the content and assessment of programmes for the reduction of specific emissions of CO₂; adjust the figure of $M_0$, referred to in Annex I to Regulation (EC) No 443/2009, to the average mass of new passenger cars in the previous three calendar years; and adapt the formulae in Annex I to Regulation (EC) No 443/2009. 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.

It is appropriate to retain the approach of setting the target based on a linear relationship between the utility of the car and its target CO₂ emissions as expressed by the formulae set out in Annex I to Regulation (EC) No 443/2009, since this allows the diversity of the passenger car market and the ability of manufacturers to address different consumer needs to be maintained, thus avoiding any unjustified distortion of competition.

In its impact assessment, the Commission assessed the availability of footprint data and the use of footprint as the utility parameter in the formulae set out in Annex I to Regulation (EC) No 443/2009. On the basis of that assessment, the Commission has concluded that the utility parameter used in the formula for 2020 should be mass. Nevertheless, the lower cost and merits of a change to footprint as the utility parameter should be considered in the future review.

Greenhouse gas emissions related to energy supply and vehicle manufacturing and disposal are significant components of the current overall road transport carbon footprint and are likely to significantly increase in importance in the future. Policy action should therefore be taken to guide manufacturers towards optimal solutions taking account of, in particular, greenhouse gas emissions associated with the generation of energy supplied to vehicles such as electricity and alternative fuels, and to ensure that those upstream emissions do not erode the benefits related to the improved operational energy use of vehicles aimed for under Regulation (EC) No 443/2009.

Since the objective of this Regulation, namely to define the modalities for reaching the 2020 target to reduce CO₂ emissions from new passenger cars, cannot be sufficiently achieved by the Member States but can rather, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.

Regulation (EC) No 443/2009 should therefore be amended accordingly,

HAVE ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 443/2009 is amended as follows:

(1) in Article 1, the second paragraph is replaced by the following:

‘From 2020 onwards, this Regulation sets a target of 95 g CO₂/km for the average emissions of the new car fleet as measured in accordance with Regulation (EC) No 715/2007 and Annex XII to Regulation (EC) No 692/2008 and its implementing measures and innovative technologies.’

(2) in Article 2, the following paragraph is added:

‘4. With effect from 1 January 2012, Article 4, Article 8(4)(b) and (c), Article 9 and Article 10(1)(a) and (c) shall not apply to a manufacturer which, together with all of its connected undertakings, is responsible for fewer than 1 000 new passenger cars registered in the Union in the previous calendar year.’

(3) in point (a) of Article 3(2), the first indent is replaced by the following:

‘— the power to exercise more than half the voting rights, or’;

(4) in Article 4, the second paragraph is replaced by the following:

‘For the purposes of determining each manufacturer's average specific emissions of CO₂, the following percentages of each manufacturer's new passenger cars registered in the relevant year shall be taken into account:

— 65 % in 2012,
— 75 % in 2013,
— 80 % in 2014,
— 100 % from 2015 to 2019,
— 95 % in 2020,
— 100 % by the end of 2020 onwards.’

(5) the following Article is inserted:

‘Article 5a

Super-credits for 95 g CO₂/km target

In calculating the average specific emissions of CO₂, each new passenger car with specific emissions of CO₂ of less than 50 g CO₂/km shall be counted as:

— 2 passenger cars in 2020,
— 1.67 passenger cars in 2021,
— 1.33 passenger cars in 2022,
— 1 passenger car from 2023,

for the year in which it is registered in the period from 2020 to 2022, subject to a cap of 7.5 g CO₂/km over that period for each manufacturer.’

(6) in Article 8, paragraph 9 is replaced by the following:

‘9. The Commission shall adopt detailed rules on the procedures for monitoring and reporting of data under this Article and on the application of Annex II by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 14(2).

The Commission shall be empowered to adopt delegated acts in accordance with Article 14a in order to amend the data requirements and data parameters set out in Annex II.’
(7) in Article 9, paragraph 3 is replaced by the following:

‘3. The Commission shall determine the means for collecting excess emissions premiums under paragraph 1 by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 14(2).’

(8) Article 11 is amended as follows:

(a) in paragraph 3, the last sentence is deleted;

(b) in paragraph 4, point (b) of the second subparagraph is replaced by the following:

‘(b) if the application is in relation to points (a) and (b) of point 1 of Annex I, a target which is a 25 % reduction on the average specific emissions of CO₂ in 2007 or, where a single application is made in respect of a number of connected undertakings, a 25 % reduction on the average of those undertakings' average specific emissions of CO₂ in 2007.’

(c) in paragraph 4, second subparagraph, the following point is added:

‘(c) if the application is in relation to point (c) of point 1 of Annex I, a target which is a 45 % reduction on the average specific emissions of CO₂ in 2007 or, where a single application is made in respect of a number of connected undertakings, a 45 % reduction on the average of those undertakings' average specific emissions of CO₂ in 2007.’

(d) paragraph 8 is replaced by the following:

‘8. The Commission shall be empowered to adopt delegated acts in accordance with Article 14a laying down rules to supplement paragraphs 1 to 7 of this Article, as regards the interpretation of the eligibility criteria for derogations, the content of the applications, and the content and assessment of programmes for the reduction of specific emissions of CO₂.’

(9) Article 12 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. Upon application by a supplier or a manufacturer, CO₂ savings achieved through the use of innovative technologies or a combination of innovative technologies ("innovative technology packages") shall be considered. Such technologies shall be taken into consideration only if the methodology used to assess them is capable of producing verifiable, repeatable and comparable results.

The total contribution of those technologies to reducing the specific emissions target of a manufacturer may be up to 7 g CO₂/km.’

(b) in paragraph 2, the first sentence is replaced by the following:

‘The Commission shall adopt, by means of implementing acts, detailed provisions for a procedure to approve the innovative technologies or innovative technology packages referred to in paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 14(2) of this Regulation.’

(c) paragraph 3 is replaced by the following:

‘3. A supplier or a manufacturer who applies for a measure to be approved as an innovative technology or innovative technology package shall submit a report, including a verification report undertaken by an independent and certified body, to the Commission. In the event of a possible interaction of the measure with another innovative technology or innovative technology package already approved, the report shall mention that interaction and the verification report shall evaluate to what extent that interaction modifies the reduction achieved by each measure.’

(10) Article 13 is amended as follows:

(a) in paragraph 2, the third subparagraph is replaced by the following:

‘The Commission shall, by means of delegated acts, adopt those measures in accordance with Article 14a.’
(b) the second subparagraph of paragraph 3 is deleted;

(c) paragraph 5 is replaced by the following:

‘5. By 31 December 2015, the Commission shall review the specific emissions targets and the modalities set out herein, as well as the other aspects of this Regulation, including whether a utility parameter is still needed and whether mass or footprint is the more sustainable utility parameter, in order to establish the CO\textsubscript{2} emissions targets for new passenger cars for the period beyond 2020. In that regard, the assessment of the necessary rate of reduction shall be in line with the Union’s long-term climate goals and the implications for the development of cost effective CO\textsubscript{2}-reducing technology for cars. The Commission shall submit a report to the European Parliament and to the Council with the result of that review. That report shall include any appropriate proposals for amending this Regulation, including the possible setting of a realistic and achievable target, based on a comprehensive impact assessment that will consider the continued competitiveness of the car industry and its dependent industries. When developing such proposals, the Commission shall ensure they are as neutral as possible from the point of view of competition and are socially equitable and sustainable.’;

(d) paragraph 7 is replaced by the following:

‘7. The Commission shall, by means of implementing acts, determine the correlation parameters necessary in order to reflect any change in the regulatory test procedure for the measurement of specific CO\textsubscript{2} emissions referred to in Regulation (EC) No 715/2007 and Regulation (EC) No 692/2008. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 14(2) of this Regulation. The Commission shall be empowered to adopt delegated acts in accordance with Article 14a in order to adapt the formulae set out in Annex I, using the methodology adopted pursuant to the first subparagraph, while ensuring that reduction requirements of comparable stringency for manufacturers and vehicles of different utility are required under the old and new test procedures.’;

(11) Article 14 is replaced by the following:

‘Article 14

Committee procedure

1. The Commission shall be assisted by the Climate Change Committee established by Article 9 of Decision No 280/2004/EC of the European Parliament and of the Council (*). That committee shall be a committee within the meaning of Regulation (EU) No 182/2011 of the European Parliament and of the Council (**).

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

3. Where the Committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.


(12) the following Article is inserted:

‘Article 14a

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 adapt delegated acts referred to in the second subparagraph of Article 8(9), Article 11(8), the third subparagraph of Article 13(2) and the second subparagraph of Article 13(7) shall be conferred on the Commission for a period of five years from 8 April 2014. 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 the second subparagraph of Article 8(9), Article 11(8), the third subparagraph of Article 13(2) and the second subparagraph of Article 13(7) 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 the second subparagraph of Article 8(9), Article 11(8), the third subparagraph of Article 13(2) and the second subparagraph of Article 13(7) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and 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.'

(13) in point 1 of Annex I, the following point is added:

‘(c) From 2020:

\[ \text{Specific emissions of CO}_2 = 95 + a \times (M - M_0) \]

Where:

\[ M = \text{mass of the vehicle in kilograms (kg)} \]

\[ M_0 = \text{the value adopted pursuant to Article 13(2)} \]

\[ a = 0.0333. \]

(14) Annex II is amended as follows:

(a) in point 1 of Part A, the following point is added:

‘(n) maximum net power.’;

(b) in the table ‘Detailed data specified in point 1 of Part A’, the following column is added:

‘Maximum net power (kW)’.

### Article 2

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

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

Done at Strasbourg, 11 March 2014.

For the European Parliament
The President
M. SCHULZ

For the Council
The President
D. KOURKOULAS
of 11 March 2014
amending Regulation (EU) No 528/2012 concerning the making available on the market and use of
biocidal products, with regard to certain conditions for access to the market
(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 2 of Regulation (EU) No 528/2012 of the European Parliament and of the Council (3) sets out the scope of
that Regulation, and, among other things, excludes from its application biocidal products when used as processing
aids. Article 2(5) should be amended to clarify beyond doubt that 'processing aids' means those defined in

(2) Point(s) of Article 3(1) and Article 19(6) of Regulation (EU) No 528/2012 should be amended to allow similar
biocidal products to be part of a biocidal product family if they can be satisfactorily assessed based on identifiable
maximum risks and minimum level of efficacy.

(3) In point (e) of Article 19(1) and in Article 19(7) of Regulation (EU) No 528/2012, it should be clarified that the
limits required to be established in accordance with Regulation (EC) No 1935/2004 of the European Parliament
and of the Council (6) are specific migration limits or limits for the residual content in food contact materials.

(4) To ensure consistency between Regulation (EU) No 528/2012 and Regulation (EC) No 1272/2008 of the European
Parliament and of the Council (7), point (b) of Article 19(4) of Regulation (EU) No 528/2012 should be amended
to include specific target organ toxicity by single or repeated exposure category 1 as a classification criterion,
in order to preclude authorisation for the making available on the market for use by the general public of a biocidal
product meeting the criteria for this classification. Point (c) of Article 19(4) of Regulation (EU) No 528/2012
prohibits authorisation for making available on the market for use by the general public of biocidal products
meeting the criteria for being persistent, bioaccumulative and toxic ('PBT'), or very persistent and very bioaccumu-
lative ('vPvB') in accordance with Annex XIII to Regulation (EC) No 1907/2006 of the European Parliament and of
the Council (8). However, whereas biocidal products are often mixtures and sometimes articles, those criteria apply
only to substances. Point (c) of Article 19(4) of Regulation (EU) No 528/2012 should therefore refer to biocidal
products consisting of, containing or generating, substances meeting those criteria.

(2) Position of the European Parliament of 25 February 2014 (not yet published in the Official Journal) and Decision of the Council of
10 March 2014.
(3) Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on
p. 1).
(5) As comparative assessment is not referred to in Annex VI to Regulation (EU) No 528/2012, the reference to that Annex in Article 23(3) of that Regulation should be deleted.

(6) Article 34(4) of Regulation (EU) No 528/2012 should be amended to correct the cross reference to Article 30.

(7) Pursuant to Article 35(3) of Regulation (EU) No 528/2012, where all Member States concerned have reached an agreement with the reference Member State on mutual recognition, a biocidal product is to be authorised in accordance with Article 33(4) or 34(6) thereof. However, the provisions referring to decisions by all Member States concerned to grant authorisations by mutual recognition are laid down in Articles 33(3) and 34(6) of that Regulation. Article 35(3) should therefore be amended accordingly.

(8) The second subparagraph of Article 45(1) of Regulation (EU) No 528/2012 requires an application for renewal of Union authorisation to be accompanied by the fees payable under Article 80(1) of that Regulation. However, fees can only be paid subsequent to the information about their level provided by the European Chemicals Agency (the Agency) in accordance with the second subparagraph of Article 45(3) of that Regulation. Therefore, and to ensure consistency with Articles 7(1), 13(1) and 43(1) of that Regulation, the second subparagraph of Article 45(1) should be deleted.

(9) The use of the word ‘disposal’ in Articles 52, 89 and 95 of Regulation (EU) No 528/2012 could be misleading and could result in problems of interpretation, having regard to the obligations imposed by Directive 2008/98/EC of the European Parliament and of the Council (1). It should therefore be deleted.

(10) Some technical corrections should be made to Article 54 of Regulation (EU) No 528/2012 in order to avoid duplication between Article 54(1) and (3) as regards the payment of the applicable fees under Article 80(1).

(11) The first and second subparagraphs of Article 60(3) of Regulation (EU) No 528/2012 refer to authorisations granted in accordance with Article 30(4), 34(6) or 44(4) thereof. However, the provisions referring to decisions to grant authorisations are laid down in Articles 30(1), 33(3), 33(4), 34(6), 34(7), 36(4), 37(2), 37(3) and 44(5) of that Regulation. Furthermore, the second subparagraph of Article 60(3) of that Regulation does not indicate any period for protection of data referred to in point (b) of Article 20(1) submitted in an application pursuant to Article 26(1) thereof. Article 60(3) should therefore also refer to Articles 26(3), 30(1), 33(3), 33(4), 34(6), 34(7), 36(4), 37(2), 37(3) and 44(5) of that Regulation.

(12) Article 66(4) of Regulation (EU) No 528/2012 should be amended to correct the cross reference to Article 67.

(13) In order to facilitate good cooperation, coordination and exchange of information between the Member States, the Agency and the Commission regarding enforcement, the Agency should also be given the task of providing support and assistance to Member States with regard to control and enforcement activities by making use of existing structures, where appropriate.

(14) In order to allow the preparation of applications for biocidal product authorisations by the date of approval of an active substance, as provided for by the second subparagraph of Article 89(3) of Regulation (EU) No 528/2012, the electronic public access to information on active substances, provided for by Article 67 thereof, should be available from the day when the Commission adopts the Regulation providing that the active substance is approved.

(15) The first subparagraph of Article 77(1) of Regulation (EU) No 528/2012 provides for appeals against decisions of the Agency taken pursuant to Article 26(2) thereof. However, since Article 26(2) does not empower the Agency to take any decision, the reference to that Article in Article 77(1) should be deleted.

(16) Article 86 of Regulation (EU) No 528/2012 refers to active substances included in Annex I to Directive 98/8/EC of the European Parliament and of the Council (1). It should be clarified that that Article applies to all active substances for which the Commission has adopted a directive including them in that Annex, that the conditions for such inclusion are applicable to the approval, and that the approval date is the date of inclusion.

(17) The first subparagraph of Article 89(2) of Regulation (EU) No 528/2012 allows Member States to apply their current system for up to two years after the date of approval of an active substance. The first subparagraph of Article 89(3) thereof requires Member States to ensure that biocidal product authorisations are granted, modified or cancelled within two years of approval of an active substance. However, taking into account the time required for the various steps of the authorisation process, in particular where a disagreement on mutual recognition persists between Member States and therefore has to be referred to the Commission for a decision, it is appropriate to extend those deadlines to three years and to reflect that extension in the second subparagraph of Article 37(3) of that Regulation.

(18) The first subparagraph of Article 89(2) of Regulation (EU) No 528/2012 allows Member States to apply their current system to existing active substances. A biocidal product could contain a combination of new active substances which have been approved and existing active substances which have not yet been approved. For the purpose of rewarding innovation by granting such products access to the market, Member States should be allowed to apply their current systems to such products until the existing active substance has been approved, and those products are consequently eligible for authorisation in accordance with Regulation (EU) No 528/2012.

(19) Articles 89(4) and 93(2) of Regulation (EU) No 528/2012 provide phase-out periods for biocidal products for which no authorisation is granted. The same periods should apply for phasing out a biocidal product already on the market, where an authorisation is granted but the conditions of the authorisation require the biocidal product to be changed.

(20) Article 93 of Regulation (EU) No 528/2012 should clarify that the derogation provided for therein applies only subject to Member States' national rules.

(21) Article 94(1) of Regulation (EU) No 528/2012 seeks to allow the placing on the market of articles treated with biocidal products containing active substances which, albeit not yet approved, are being evaluated, either in the context of the work programme referred to in Article 89(1) of that Regulation or based on an application submitted pursuant to Article 94(1). However, the reference in Article 94(1) to Article 58 of Regulation (EU) No 528/2012 could be interpreted as an unintended derogation from the labelling and information requirements in Article 58(3) and (4). Article 94(1) of that Regulation should therefore refer only to Article 58(2).

(22) As Article 94(1) of Regulation (EU) No 528/2012 applies only to treated articles already placed on the market, an unintended ban on most new treated articles was introduced from 1 September 2013 until the approval of the last active substance contained in those treated articles. The scope of Article 94(1) should therefore be extended to include new treated articles. That Article should also provide for a phasing-out period for treated articles for which no application for the approval of the active substance for the relevant product-type is submitted by 1 September 2016. To avoid potentially serious adverse effects on economic operators and whilst fully respecting the principle of legal certainty, provision should be made for those modifications to apply from 1 September 2013.

(23) The first subparagraph of Article 95(1) of Regulation (EU) No 528/2012 requires the submission of a complete substance dossier. It should be possible for such a complete dossier to include data referred to in Annex IIIA or IVA to Directive 98/8/EC.

(24) Under the third subparagraph of Article 95(1) of Regulation (EU) No 528/2012, the right to refer to data provided for in the second subparagraph of Article 63(3) thereof is extended to all studies required for the human health and environmental risk assessment, to allow prospective relevant persons to be included in the list referred to in Article 95(2) thereof. Without such a right to refer, many prospective relevant persons would not be able to comply with Article 95(1) in time to be included in that list by the date referred to in Article 95(3). However, the third subparagraph of Article 95(1) fails to include studies on environmental fate and behaviour. Moreover, since prospective relevant persons are to pay for the right to refer in accordance with Article 63(3), they should be entitled to fully benefit from that right by passing it onto applicants for product authorisation. Article 95 should therefore be amended accordingly.

(25) The fifth subparagraph of Article 95(1) of Regulation (EU) No 528/2012 intends to limit the protection period for
data which can be shared from 1 September 2013 for the purpose of compliance with the first subparagraph of
Article 95(1), but which on that date could not yet be shared for the purpose of substantiating applications for
product authorisations. Such is the case for data relating to active substance/product-type combinations for which
a decision on inclusion in Annex I to Directive 98/8/EC was not taken before 1 September 2013. Article 95(1) of
that Regulation should therefore refer to that date.

(26) Pursuant to Article 95(2) of Regulation (EU) No 528/2012, the list published by the Agency is to contain the
names of the participants in the work programme referred to in Article 89(1) thereof. Article 95(2) thereby allows
those participants to benefit from the cost compensation mechanism set out in that Regulation. The possibility of
benefitting from a cost compensation mechanism should be open to all persons who have submitted a complete
substance dossier in accordance with Regulation (EU) No 528/2012 or with Directive 98/8/EC, or a letter of access
to such a dossier. It should be open to those who submitted dossiers for any substance which is not itself an active
substance but which generates active substances.

(27) The first subparagraph of Article 95(3) of Regulation (EU) No 528/2012 prohibits the placing on the market of
biocidal products containing active substances for which the manufacturer or importer (the relevant person) is not
included in the list referred to in that Article. By virtue of Articles 89(2) and 93(2) of that Regulation, certain active
substances will be legally present on the market in biocidal products even though no complete substance dossier
has yet been submitted. The prohibition under Article 95(3) should not apply to such substances. Furthermore,
where no substance manufacturer or importer is listed for a substance for which a complete substance dossier has
been submitted, the possibility should be allowed for another person to place biocidal products containing that
substance on the market, subject to the submission of a dossier, or a letter of access to a dossier, by that person or
the manufacturer or importer of the biocidal product.

(28) Article 95(4) of Regulation (EU) No 528/2012 provides that Article 95 applies to active substances listed under
category 6 in Annex I to that Regulation. Those substances have been included in that Annex based on
submissions of complete substance dossiers, the owners of which should be entitled to benefit from the cost
compensation mechanism established under that Article. In the future, other substances may be included in that
Annex based on such submissions. Category 6 of that Annex should therefore regulate all such substances.

(29) The description in Annex V to Regulation (EU) No 528/2012 of biocidal products used in food contact materials
should be consistent with the terminology used in Regulation (EC) No 1935/2004.

(30) It should be clarified in the first paragraph of Article 96 of Regulation (EU) No 528/2012 that Directive 98/8/EC is
repealed without prejudice to the provisions of Regulation (EU) No 528/2012 referring to Directive 98/8/EC.

(31) Regulation (EU) No 528/2012 should therefore be amended accordingly,

HAVE ADOPTED THIS REGULATION:

Article 1

Regulation (EU) No 528/2012 is amended as follows:

(1) in Article 2(5), point (b) is replaced by the following:

‘(b) biocidal products when used as processing aids within the meaning of Regulation (EC) No 1831/2003 and
Regulation (EC) No 1333/2008.’;

(2) Article 3(1) is amended as follows:

(a) point (s) is replaced by the following:

‘(s) “biocidal product family” means a group of biocidal products having:

(i) similar uses;

(ii) the same active substances;

(iii) similar composition with specified variations; and

(iv) similar levels of risk and efficacy;’;
(b) point (v) is deleted;

(3) Article 19 is amended as follows:

(a) paragraph 1 is amended as follows:

(i) point (a) is replaced by the following:

'(a) the active substances are included in Annex I or approved for the relevant product-type and any
conditions specified for those active substances are met;'

(ii) point (e) is replaced by the following:

'(e) where appropriate, maximum residue limits for food and feed have been established with respect to
active substances contained in a biocidal product in accordance with Council Regulation (EEC) No
European Parliament and of the Council (****), or specific migration limits or limits for the residual
content in food contact materials have been established with respect to such active substances in

(b) in paragraph 4, points (b) and (c) are replaced by the following:

'(b) it meets the criteria according to Regulation (EC) No 1272/2008 for classification as:

— acute oral toxicity category 1, 2 or 3,

— acute dermal toxicity category 1, 2 or 3,

— acute inhalation toxicity (gases and dust/mist) category 1, 2 or 3,

— acute inhalation toxicity (vapours) category 1 or 2,

— specific target organ toxicity by single or repeated exposure category 1,

— a category 1A or 1B carcinogen,

— a category 1A or 1B mutagen, or

— toxic for reproduction category 1A or 1B;

(c) it consists of, contains or generates, a substance that meets the criteria for being PBT or vPvB in accordance
with Annex XIII to Regulation (EC) No 1907/2006;�:

(*) Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for

on maximum residue levels of pesticides in or on food and feed of plant and animal origin and

down Community procedures for the establishment of residue limits of pharmacologically active
substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and


on materials and articles intended to come into contact with food and repealing Directives
6. The assessment of the biocidal product family conducted according to the common principles set out in Annex VI shall consider the maximum risks to human health, animal health and the environment and the minimum level of efficacy over the whole potential range of products within the biocidal product family.

A biocidal product family shall be authorised only if:

(a) the application explicitly identifies the maximum risks to human health, animal health and the environment, and the minimum level of efficacy, on which the assessment is based, as well as the permitted variations in composition and uses referred to in point (s) of Article 31 together with their respective classification, hazard and precautionary statements and any appropriate risk mitigation measures; and

(b) it can be established based on the assessment referred to in the first subparagraph of this paragraph that all the biocidal products within the family comply with the conditions set out in paragraph 1.


(4) in Article 23(3), the introductory part is replaced by the following:

‘3. The receiving competent authority or, in the case of a decision on an application for a Union authorisation, the Commission, shall prohibit or restrict the making available on the market or the use of a biocidal product containing an active substance that is a candidate for substitution where a comparative assessment, performed in accordance with the technical guidance notes referred to in Article 24, demonstrates that both of the following criteria are met:’;

(5) in Article 34(4), the second subparagraph is replaced by the following:

‘Within 365 days of validating an application, the reference Member State shall evaluate the application and draft an assessment report in accordance with Article 30 and shall send its assessment report and the summary of biocidal product characteristics to the Member States concerned and to the applicant:’;

(6) Article 35(3) is replaced by the following:

‘3. Within the coordination group, all Member States referred to in paragraph 2 of this Article shall use their best endeavours to reach agreement on the action to be taken. They shall allow the applicant the opportunity to make its point of view known. Where they reach agreement within 60 days of the referral of the points of disagreement referred to in paragraph 2 of this Article, the reference Member State shall record the agreement in the Register for Biocidal Products. The procedure shall then be considered to be closed and the reference Member State and each of the Member States concerned shall authorise the biocidal product in accordance with Article 33(3) or 34(6) as appropriate:’;

(7) in Article 37(3), the second subparagraph is replaced by the following:

‘While the procedure under this Article is ongoing, the Member States' obligation to authorise a biocidal product within three years of the date of approval, referred to in the first subparagraph of Article 89(3), shall be temporarily suspended:’;

(8) in Article 45(1), the second subparagraph is deleted;

(9) Article 52 is replaced by the following:

‘Article 52

 Period of grace

Notwithstanding Article 89, where the competent authority or, in the case of a biocidal product authorised at Union level, the Commission, cancels or amends an authorisation or decides not to renew it, it shall grant a period of grace for the making available on the market and use of existing stocks, except in cases where continued making available on the market or use of the biocidal product would constitute an unacceptable risk to human health, animal health or the environment.'
The period of grace shall not exceed 180 days for the making available on the market and an additional maximum period of 180 days for the use of existing stocks of the biocidal products concerned.

(10) in Article 53(1), the first subparagraph is replaced by the following:

'1. By way of derogation from Article 17, a competent authority of a Member State ("Member State of introduction") shall, at the request of the applicant, grant a parallel trade permit for a biocidal product that is authorised in another Member State ("Member State of origin") to be made available on the market and used in the Member State of introduction, if it determines in accordance with paragraph 3 that the biocidal product is identical to a biocidal product already authorised in the Member State of introduction ("the reference product").

(11) Article 54 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. Where it is necessary to establish the technical equivalence of active substances, the person seeking to establish that equivalence ("the applicant") shall submit an application to the Agency.';

(b) paragraph 3 is replaced by the following:

'3. The Agency shall inform the applicant of the fees payable under Article 80(1) and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant accordingly.';

(12) in Article 56(1), the first subparagraph is replaced by the following:

'1. By way of derogation from Article 17, an experiment or a test for the purposes of scientific or product and process-orientated research and development involving an unauthorised biocidal product or a non-approved active substance intended exclusively for use in a biocidal product ("experiment" or "test") may take place only under the conditions provided for in this Article.';

(13) in Article 58(3), the introductory part is replaced by the following:

'3. The person responsible for the placing on the market of a treated article shall ensure that the label provides the information listed in the second subparagraph, where:

(14) in Article 60(3), the first and second subparagraphs are replaced by the following:

'3. The protection period for data submitted with a view to the authorisation of a biocidal product containing only existing active substances shall end 10 years from the first day of the month following the first decision concerning the authorisation of the product taken in accordance with Article 26(3), 30(1), 33(3), 33(4), 34(6), 34(7), 36(4), 37(2), 37(3) or 44(5).

The protection period for data submitted with a view to the authorisation of a biocidal product containing a new active substance shall end 15 years from the first day of the month following the first decision concerning the authorisation of the product taken in accordance with Article 26(3), 30(1), 33(3), 33(4), 34(6), 34(7), 36(4), 37(2), 37(3) or 44(5).';

(15) Article 66(4) is replaced by the following:

'4. Any person submitting information related to an active substance or a biocidal product to the Agency or a competent authority for the purposes of this Regulation may request that the information in Article 67(3) and (4) not be made available, including a justification as to why the disclosure of the information could be harmful for that person's commercial interests or those of any other party concerned.';

(16) Article 67 is amended as follows:

(a) in paragraph 1, the introductory part is replaced by the following:

'1. From the date on which the Commission adopts an implementing Regulation providing that an active substance is approved, as referred to in point (a) of Article 9(1), the following up-to-date information held by the Agency or the Commission on that active substance shall be made publicly and easily available free of charge:

(b) in paragraph 3, the introductory part is replaced by the following:
3. From the date on which the Commission adopts an implementing Regulation providing that an active substance is approved, as referred to in point (a) of Article 9(1), the Agency shall, except where the data supplier submits a justification in accordance with Article 66(4) accepted as valid by the competent authority or the Agency as to why such publication is potentially harmful for its commercial interests or any other party concerned, make publicly available, free of charge, the following up-to-date information on that active substance:

(17) in Article 76(1), the following point is added:

‘(l) providing support and assistance to Member States with regard to control and enforcement activities;’

(18) in Article 77(1), the first subparagraph is replaced by the following:

‘1. Appeals against decisions of the Agency taken pursuant to Articles 7(2), 13(3), 43(2) and 45(3), Article 54(3), (4) and (5), and Articles 63(3) and 64(1) shall lie with the Board of Appeal set up in accordance with Regulation (EC) No 1907/2006;’

(19) in Article 78(2), the second subparagraph is replaced by the following:

‘Revenues of the Agency as referred to in Article 96(1) of Regulation (EC) No 1907/2006 shall not be used for carrying out tasks under this Regulation, unless for a joint purpose or a temporary transfer to ensure the proper functioning of the Agency. Revenues of the Agency as referred to in paragraph 1 of this Article shall not be used for carrying out tasks under Regulation (EC) No 1907/2006, unless for a joint purpose or a temporary transfer to ensure the proper functioning of the Agency;’

(20) Article 86 is replaced by the following:

‘Article 86

Active substances included in Annex I to Directive 98/8/EC

Active substances for which the Commission has adopted directives including them in Annex I to Directive 98/8/EC shall be deemed to have been approved under this Regulation on the date of inclusion and shall be included in the list referred to in Article 9(2). Approval shall be subject to the conditions set out in those Commission directives;’

(21) Article 89 is amended as follows:

(a) paragraph 2 is replaced by the following:

‘2. By way of derogation from Articles 17(1), 19(1) and 20(1) of this Regulation, and without prejudice to paragraphs 1 and 3 of this Article, a Member State may continue to apply its current system or practice of making available on the market or using a given biocidal product for up to three years after the date of approval of the last of the active substances to be approved in that biocidal product. The Member State concerned may, in accordance with its national rules, authorise the making available on the market or use in its territory only of a biocidal product containing only:

(a) existing active substances which:

(i) have been evaluated under Commission Regulation (EC) No 1451/2007 (*), but which have not yet been approved for that product-type; or

(ii) are being evaluated, under Regulation (EC) No 1451/2007, but which have not yet been approved for that product-type;

or

(b) a combination of active substances referred to in point (a) and active substances approved in accordance with this Regulation.

By way of derogation from the first subparagraph, in the case of a decision not to approve an active substance, a Member State may continue to apply its current system or practice of making biocidal products available on the market for up to 12 months after the date of the decision not to approve an active substance in accordance with the third subparagraph of paragraph 1, and may continue to apply its current system or practice of using biocidal products for up to 18 months after that decision.

paragraph 3 is replaced by the following:

‘3. Following a decision to approve a particular active substance for a specific product-type, Member States shall ensure that authorisations for biocidal products of that product-type and containing that active substance are granted, modified or cancelled, as appropriate, in accordance with this Regulation within three years of the date of approval.

To that effect, those wishing to apply for the authorisation or mutual recognition in parallel of biocidal products of that product-type containing no active substances other than existing active substances shall submit applications for authorisation or mutual recognition in parallel no later than the date of approval of the active substance(s). In the case of biocidal products containing more than one active substance, applications shall be submitted no later than the date of approval of the last active substance for that product-type.

Where no application for authorisation or mutual recognition in parallel has been submitted in accordance with the second subparagraph:

(a) the biocidal product shall no longer be made available on the market with effect from 180 days after the date of approval of the active substance(s); and

(b) use of existing stocks of the biocidal product may continue for up to 365 days after the date of approval of the active substance(s).’;

paragraph 4 is replaced by the following:

‘4. Where a Member State’s competent authority, or where relevant, the Commission, decides to reject an application submitted in accordance with paragraph 3 for authorisation of a biocidal product already made available on the market, or decides not to grant an authorisation or to impose conditions for the authorisation making it necessary to change such a product, the following shall apply:

(a) a biocidal product which has not been authorised or, where relevant, which does not comply with the conditions of the authorisation, shall no longer be made available on the market with effect from 180 days after the date of the decision of the authority; and

(b) use of existing stocks of the biocidal product may continue for up to 365 days after the date of the decision of the authority.’;

in Article 92(2), the following sentence is added:

‘Biocidal products authorised in accordance with Article 3 or 4 of Directive 98/8/EC shall be considered as authorised in accordance with Article 17 of this Regulation.’;

Article 93 is replaced by the following:

‘Article 93

Transitional measures concerning biocidal products not covered by the scope of Directive 98/8/EC

By way of derogation from Article 17(1), a Member State may continue to apply its current system or practice of making available on the market and using a biocidal product not covered by the scope of Directive 98/8/EC, but falling within the scope of this Regulation, and consisting of, containing or generating only active substances that were available on the market, or used in biocidal products, on 1 September 2013. The derogation shall apply until one of the following dates:

(a) where applications for approval of all those active substances, which the biocidal product consists of, contains or generates, are submitted for the relevant product-type by 1 September 2016, the deadlines provided for in the second subparagraph of Article 89(2), in Article 89(3) and in Article 89(4); or

(b) where an application is not submitted in accordance with point (a) for one of the active substances, until 1 September 2017.’;
(24) Articles 94 and 95 are replaced by the following:

‘Article 94

Transitional measures concerning treated articles

1. By way of derogation from Article 58(2), a treated article treated with or intentionally incorporating one or more biocidal products containing only active substances that are under examination for the relevant product-type in the work programme referred to in Article 89(1) on 1 September 2016 or for which an application for approval for the relevant product-type is submitted by that date, or containing only a combination of such substances and active substances included in the list drawn up in accordance with Article 9(2) for the relevant product-type and use or included in Annex I, may be placed on the market until one of the following dates:

(a) in the case of a decision adopted after 1 September 2016 to reject the application for approval of, or not to approve, one of the active substances for the relevant use, the date falling 180 days after such a decision;

(b) in other cases, the date of approval for the relevant product-type and use of the last active substance to be approved and contained in the biocidal product.

2. By way of further derogation from Article 58(2), a treated article treated with or intentionally incorporating one or more biocidal products containing any active substances other than those referred to in paragraph 1 of this Article or those included in the list drawn up in accordance with Article 9(2) for the relevant product-type and use or included in Annex I, may be placed on the market until 1 March 2017.

Article 95

Transitional measures concerning access to the active substance dossier

1. As of 1 September 2013, the Agency shall make publicly available and shall regularly update a list of all active substances, and all substances generating an active substance, for which a dossier complying with Annex II to this Regulation or with Annex IIA or IVA to Directive 98/8/EC and, where relevant, Annex IIIA to that Directive ("the complete substance dossier") has been submitted and accepted or validated by a Member State in a procedure provided for by this Regulation or that Directive ("the relevant substances"). For each relevant substance, the list shall also include all persons having made such a submission or a submission to the Agency in accordance with the second subparagraph of this paragraph, and indicate their role as specified in that subparagraph, and the product-type(s) for which they have made a submission, as well as the date of inclusion of the substance in the list.

A person established within the Union who manufactures or imports a relevant substance, on its own or in biocidal products ("the substance supplier") or who manufactures or makes available on the market a biocidal product consisting of, containing or generating that relevant substance ("the product supplier"), may at any time submit to the Agency either a complete substance dossier for that relevant substance, a letter of access to a complete substance dossier, or a reference to a complete substance dossier for which all data protection periods have expired. Following the renewal of the approval of an active substance, any substance supplier or product supplier may submit to the Agency a letter of access to all the data which was considered by the evaluating competent authority as relevant for the purpose of the renewal, and for which the protection period has not yet expired ("the relevant data").

The Agency shall inform the submitting supplier of the fees payable under Article 80(1). It shall reject the application if the submitting supplier fails to pay those fees within 30 days and shall inform the submitting supplier accordingly.

Upon receipt of the fees payable under Article 80(1), the Agency shall verify whether the submission complies with the second subparagraph of this paragraph and shall inform the submitting supplier accordingly.

2. As of 1 September 2015, a biocidal product consisting of, containing or generating a relevant substance, included in the list referred to in paragraph 1, shall not be made available on the market unless either the substance supplier or the product supplier is included in the list referred to in paragraph 1 for the product-type(s) to which the product belongs.
3. For the purposes of making a submission in accordance with the second subparagraph of paragraph 1 of this article, Article 63(3) of this Regulation shall apply to all toxicological, ecotoxicological and environmental fate and behaviour studies relating to substances listed in Annex II to Regulation (EC) No 1451/2007, including any such studies not involving tests on vertebrates.

4. A substance supplier or a product supplier included in the list referred to in paragraph 1 to whom a letter of access has been issued for the purpose of this Article or a right to refer to a study has been granted in accordance with paragraph 3 shall be entitled to allow applicants for the authorisation of a biocidal product to make reference to that letter of access or that study for the purposes of Article 20(1).

5. By way of derogation from Article 60, all data protection periods for active substance/product-type combinations listed in Annex II to Regulation (EC) No 1451/2007, but for which a decision on inclusion in Annex I to Directive 98/8/EC was not taken before 1 September 2013, shall end on 31 December 2025.

6. Paragraphs 1 to 5 shall not apply to substances listed in Annex I in categories 1 to 5 and category 7 or to biocidal products containing only such substances.

7. The Agency shall regularly update the list referred to in paragraph 1 of this Article. Following the renewal of the approval of an active substance, the Agency shall remove from the list any substance supplier or product supplier who has not, within 12 months of the renewal, submitted all the relevant data or a letter of access to all the relevant data, either in accordance with the second subparagraph of paragraph 1 of this Article or in an application in accordance with Article 13.

(25) in Article 96, the first paragraph is replaced by the following:

‘Without prejudice to Articles 86, 89 to 93 and 95 of this Regulation, Directive 98/8/EC is hereby repealed with effect from 1 September 2013.’

(26) in Annex I, the title of category 6 is replaced by the following:

‘Category 6 — Substances for which a Member State has validated an active substance dossier in accordance with Article 7(3) of this Regulation or accepted such a dossier in accordance with Article 11(1) of Directive 98/8/EC;’

(27) in Annex V, the second paragraph under the heading ‘Product-type 4: Food and feed area’ is replaced by the following:

‘Products used to be incorporated into materials which may enter into contact with food.’

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.

Point 24 of Article 1 shall apply from 1 September 2013.

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

Done at Strasbourg, 11 March 2014.

For the European Parliament

The President

M. SCHULZ

For the Council

The President

D. KOURKOULAS
REGULATION (EU) No 335/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 11 March 2014

amending Council Regulation (EC) No 1198/2006 on the European Fisheries Fund, as regards certain provisions relating to financial management for certain Member States experiencing or threatened with serious difficulties with respect to their financial stability

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) The unprecedented global financial crisis and economic downturn have seriously damaged economic growth and financial stability and provoked a strong deterioration in financial and economic conditions in several Member States. In particular, certain Member States are experiencing serious difficulties, or are threatened with such difficulties. In particular, they face problems in their economic growth and financial stability and a deterioration in their deficit and debt position.

(2) Important measures have been taken pursuant to Article 122(2) and Articles 136 and 143 of the Treaty on the Functioning of the European Union in order to counterbalance the negative effects of the crisis. However, pressure on national financial resources is increasing and appropriate steps are needed to alleviate it through the maximum and optimal use of funding from the European Fisheries Fund, established by Council Regulation (EC) No 1198/2006 (3).

(3) In order to facilitate the management of Union funding, to help accelerate investments in Member States and regions and to improve the availability of funding to the economy, Regulation (EC) No 1198/2006 was amended by Regulation (EU) No 387/2012 of the European Parliament and of the Council (4). That amendment allowed the increase of interim and final payments from the European Fisheries Fund by an amount corresponding to 10 percentage points above the actual co-financing rate for each priority axis for Member States which are facing serious difficulties with respect to their financial stability and which request to benefit from that measure.

(4) Regulation (EC) No 1198/2006 allows for the application of that increased co-financing rate until 31 December 2013. However, since certain Member States still face serious difficulties with respect to their financial stability, the application of the increased co-financing rate should not be limited to the end of 2013.

(1) OJ C 341, 21.11.2013, p. 75.
(5) Member States receiving financial assistance should also benefit from the increase of the co-financing rate until the end of the eligibility period and should be able to claim it in their requests for payment of the final balance, even if the financial assistance is no longer provided.

(6) Regulation (EC) No 1198/2006 should therefore be amended accordingly.

(7) Given the unprecedented nature of the crisis, swift adoption of support measures is needed. Therefore it is appropriate that this Regulation should enter into force on the day of its publication in the Official Journal of the European Union.

HAVE ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 1198/2006 is amended as follows:

(1) in Article 76(3), the introductory phrase is replaced by the following:

‘3. By way of derogation from Article 53(3), at the request of a Member State, interim payments shall be increased by an amount corresponding to 10 percentage points above the co-financing rate applicable to each priority axis, up to a maximum of 100 %, to be applied to the amount of eligible public expenditure newly declared in each certified statement of expenditure submitted provided that the Member State, on or after 31 December 2013, fulfils one of the following conditions;’

(2) in Article 77, paragraph 2 is replaced by the following:

‘2. By way of derogation from Article 53(3), at the request of a Member State, payments of the final balance shall be increased by an amount corresponding to 10 percentage points above the co-financing rate applicable to each priority axis, up to a maximum of 100 %, to be applied to the amount of eligible public expenditure newly declared in each certified statement of expenditure submitted provided that the Member State, on or after 31 December 2013, fulfils one of the conditions laid down in points (a), (b) and (c) of Article 76(3);’

(3) Article 77a is amended as follows:

(a) paragraph 2 is replaced by the following:

‘2. The derogation referred to in Articles 76(3) and 77(2) shall be granted by the Commission upon the written request of a Member State fulfilling one of the conditions laid down in points (a), (b) and (c) of Article 76(3);’

(b) paragraph 5 is deleted.

Article 2

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

This Regulation shall apply from 1 January 2014.

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

Done at Strasbourg, 11 March 2014.

For the European Parliament

The President

M. SCHULZ

For the Council

The President

D. KOURKOULAS