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## II

(Non-legislative acts)

## INTERNATIONAL AGREEMENTS

## COUNCIL DECISION

of 28 February 2012

**on the conclusion of the Protocol agreed between the European Union and the Republic of Guinea-Bissau setting out fishing opportunities and the financial contribution provided for in the Fisheries Partnership Agreement between the two parties currently in force**

(2012/145/EU)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 43(2) in conjunction with Article 218(6)(a) thereof,

Having regard to the proposal from the European Commission,

Having regard to the consent of the European Parliament,

Whereas:

- (1) On 17 March 2008, the Council adopted Regulation (EC) No 241/2008 on the conclusion of the Fisheries Partnership Agreement between the European Community and the Republic of Guinea-Bissau <sup>(1)</sup>.
- (2) The Union has negotiated with the Republic of Guinea-Bissau a new protocol granting EU vessels fishing opportunities in waters in which Guinea-Bissau exercises its sovereignty or jurisdiction as regards fishing (hereinafter 'the Protocol').
- (3) At the end of those negotiations, the Protocol was initialled on 15 June 2011.
- (4) The Protocol was signed in accordance with Council Decision 2011/885/EU <sup>(2)</sup> and has been applied on a provisional basis since 16 June 2011.
- (5) The Protocol should be concluded,

HAS ADOPTED THIS DECISION:

*Article 1*

The Protocol agreed between the European Union and the Republic of Guinea-Bissau setting out fishing opportunities and the financial contribution provided for in the Fisheries Partnership Agreement concluded between the European Community and the Republic of Guinea-Bissau in force between the two parties (hereinafter 'the Protocol') is hereby approved on behalf of the European Union <sup>(3)</sup>.

*Article 2*

The President of the Council shall, on behalf of the Union, give the notification provided for in Article 14 of the Protocol with a view to expressing the Union's consent to be bound by the Protocol <sup>(4)</sup>.

*Article 3*

This Decision shall take effect on the day of its publication in the *Official Journal of the European Union*.

Done at Brussels, 28 February 2012.

*For the Council*  
*The President*  
N. WAMMEN

<sup>(1)</sup> OJ L 75, 18.3.2008, p. 49.

<sup>(2)</sup> OJ L 344, 28.12.2011, p. 1.

<sup>(3)</sup> The Protocol was published, together with the Decision on signing, in OJ L 344, 28.12.2011, p. 1.

<sup>(4)</sup> The date of entry into force of the Protocol will be published in the *Official Journal of the European Union* by the General Secretariat of the Council.

## REGULATIONS

## COMMISSION DELEGATED REGULATION (EU) No 205/2012

of 6 January 2012

**amending Annex II to Regulation (EU) No 510/2011 of the European Parliament and of the Council with regard to the data source and the data parameters to be reported by Member States**

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 510/2011 of the European Parliament and of the Council of 11 May 2011 setting emission performance standards for new light commercial vehicles as part of the Union's integrated approach to reduce CO<sub>2</sub> emissions from light-duty vehicles<sup>(1)</sup>, and in particular the second subparagraph of Article 8(9) thereof,

Whereas:

- (1) Pursuant to Articles 18 and 26 of Directive 2007/46/EC of the European Parliament and of the Council of 5 September 2007 establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles<sup>(2)</sup>, a manufacturer must ensure that each new light commercial vehicle placed on the market in the Union is accompanied by a valid certificate of conformity and a Member State may not register such a vehicle unless it is accompanied by such a certificate. In accordance with Annex II to Regulation (EU) No 510/2011, data collected by a Member State to monitor the manufacturer's compliance with Articles 4 and 11 of that Regulation are to be consistent with a certificate of conformity and based on this document only.
- (2) Regulation (EC) No 443/2009 of the European Parliament and of the Council of 23 April 2009 setting emission performance standards for new passenger cars as part of the Community's integrated approach to reduce CO<sub>2</sub> emissions from light-duty vehicles<sup>(3)</sup> requires the Member States to use the certificate of conformity as a data source but allows for the use of other documents providing equivalent accuracy for the monitoring and reporting of CO<sub>2</sub> emissions from passenger cars. In order to ensure cost-efficient and accurate monitoring and reporting of CO<sub>2</sub>

emissions data for light commercial vehicles, it is appropriate in the short-term to allow Member States to use the same procedure and data sources for the monitoring and reporting under Regulation (EU) No 510/2011 as those used for reporting under Regulation (EC) No 443/2009. Therefore, Annex II to Regulation (EU) No 510/2011 should, where duly justified, allow for the use of other data sources providing equivalent accuracy for CO<sub>2</sub> monitoring and reporting purposes. The Member States should put the necessary measures in place to ensure adequate accuracy in the monitoring procedure.

- (3) Based on the experience gained from the monitoring of CO<sub>2</sub> emissions from passenger cars, it is appropriate, in order to improve the means for verifying the accuracy of the data, to add type-approval number as a detailed data parameter to be reported by Member States. It has also become evident that there is no need for the parameter 'commercial name' which therefore should be deleted from the detailed monitoring data.
- (4) In order to ensure clarity and precision in the monitoring and reporting by Member States, it is also necessary to ensure consistency between the different requirements specified in Annex II to Regulation (EU) No 510/2011. The detailed data requirements are specified in the reporting formats set out in Part C of Annex II. Parts A and B of that Annex should therefore be adjusted to reflect those detailed data requirements accurately.
- (5) Annex II to Regulation (EU) No 510/2011 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

*Article 1*

Annex II to Regulation (EU) No 510/2011 is amended in accordance with the Annex to this Regulation.

*Article 2*This Regulation shall enter into force on the third day following its publication in the *Official Journal of the European Union*.<sup>(1)</sup> OJ L 145, 31.5.2011, p. 1.<sup>(2)</sup> OJ L 263, 9.10.2007, p. 1.<sup>(3)</sup> OJ L 140, 5.6.2009, p. 1.

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

Done at Brussels, 6 January 2012.

*For the Commission*  
*The President*  
José Manuel BARROSO

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## ANNEX

Annex II to Regulation (EU) No 510/2011 is amended as follows:

(1) Part A is amended as follows:

(a) in point 2, the first sentence is replaced by the following:

‘The details referred to in point 1 shall be taken from the certificate of conformity or be consistent with the certificate of conformity issued by the manufacturer of the relevant light commercial vehicle. Where the certificate of conformity is not used, Member States shall put the necessary measures in place to ensure adequate accuracy in the monitoring procedure.’;

(b) point 3 is amended as follows:

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

‘(b) The number of new light commercial vehicles having values for each of the following parameters:

(i) CO<sub>2</sub> emissions;

(ii) mass;

(iii) wheelbase;

(iv) track width steering axle;

(v) track width other axle.’;

(ii) point (c) is deleted;

(iii) in point (d), points (iv) and (v) are replaced by the following:

‘(iv) technically permissible maximum laden mass;

(v) wheelbase;

(vi) track width steering axle;

(vii) track width other axle.’;

(2) in Part B, points 2, 3, 5 and 6 are deleted;

(3) in Part C, Section 2 on detailed monitoring data is replaced by the following:

Section 2 — Detailed monitoring data

Manufacturer name — EU standard denomination	Manufacturer name — Manufacturer denomination	Manufacturer name — National Registry denomination	Type-approval number and its extension(s)	Type	Variant	Version	Make	Category of vehicle type-approved	Category of vehicle registered	Total number of new registrations	Specific emissions of CO <sub>2</sub> (g/km)	Mass (kg)	Technically permissible maximum laden mass (kg)	Wheelbase (mm)	Track width steering axle (mm)	Track width other axle (mm)	Fuel type	Fuel mode	Capacity (cm <sup>3</sup> )	Electric energy consumption (Wh/ km)	Innovative technology or group of innovative technologies code	Emissions reduction through innovative technologies
Manuf. 1	Manuf. 1	Manuf. 1	Number 1	Type 1	Variant 1	Version 1	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮
Manuf. 1	Manuf. 1	Manuf. 1	Number 1	Type 1	Variant 2	Version 1	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮
Manuf. 1	Manuf. 1	Manuf. 1	Number 1	Type 1	Variant 2	Version 2	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮
Manuf. 1	Manuf. 1	Manuf. 1	Number 2	Type 2	Variant 1	Version 1	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮
Manuf. 1	Manuf. 1	Manuf. 1	Number 2	Type 2	Variant 1	Version 2	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮
Manuf. 1	Manuf. 1	Manuf. 1	Number 2	Type 2	Variant 2	Version 1	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮
Manuf. 1	Manuf. 1	Manuf. 1	Number 2	Type 2	Variant 2	Version 2	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮

		Manufacturer name — EU standard denomination																			
		Manufacturer name — Manufacturer denomination																			
		Manufacturer name — National Registry denomination																			
		Type-approval number and its extension(s)	Manuf. 2	Manuf. 2	Manuf. 2	Manuf. 2	Manuf. 2	Manuf. 2	Manuf. 2	Manuf. 2	Manuf. 2	Manuf. 2	Manuf. 2	Manuf. 2	Manuf. 2	Manuf. 2	Manuf. 2	Manuf. 2	Manuf. 2	Manuf. 2	Manuf. 2
		Type	Number 1	Number 1	Number 1	Number 1	Number 1	Number 1	Number 1	Number 1	Number 1	Number 1	Number 1	Number 1	Number 1	Number 1	Number 1	Number 1	Number 1	Number 1	Number 1
		Variant	Type 1	Type 1	Type 1	Type 1	Type 1	Type 1	Type 1	Type 1	Type 1	Type 1	Type 1	Type 1	Type 1	Type 1	Type 1	Type 1	Type 1	Type 1	Type 1
		Version	Variant 1	Variant 1	Variant 1	Variant 1	Variant 1	Variant 1	Variant 1	Variant 1	Variant 1	Variant 1	Variant 1	Variant 1	Variant 1	Variant 1	Variant 1	Variant 1	Variant 1	Variant 1	Variant 1
		Make	Version 1	Version 1	Version 1	Version 1	Version 1	Version 1	Version 1	Version 1	Version 1	Version 1	Version 1	Version 1	Version 1	Version 1	Version 1	Version 1	Version 1	Version 1	Version 1
		Category of vehicle type-approved	Version 2	Version 2	Version 2	Version 2	Version 2	Version 2	Version 2	Version 2	Version 2	Version 2	Version 2	Version 2	Version 2	Version 2	Version 2	Version 2	Version 2	Version 2	Version 2
		Category of vehicle registered	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...
		Total number of new registrations	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...
		Specific emissions of CO <sub>2</sub> (g/km)	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...
		Mass (kg)	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...
		Technically permissible maximum laden mass (kg)	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...
		Wheelbase (mm)	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...
		Track width steering axle (mm)	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...
		Track width other axle (mm)	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...
		Fuel type	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...
		Fuel mode	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...
		Capacity (cm <sup>3</sup> )	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...
		Electric energy consumption (Wh/ km)	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...
		Innovative technology or group of innovative technologies code	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...
		Emissions reduction through innovative technologies	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...



## COMMISSION REGULATION (EU) No 206/2012

of 6 March 2012

## implementing Directive 2009/125/EC of the European Parliament and of the Council with regard to ecodesign requirements for air conditioners and comfort fans

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products<sup>(1)</sup>, and in particular Article 15(1) thereof,

After consulting the Ecodesign Consultation Forum,

Whereas:

- (1) Under Directive 2009/125/EC ecodesign requirements should be set by the Commission for energy-related products representing significant volumes of sales and trade, having significant environmental impact and presenting significant potential for improvement through design in terms of their environmental impact, without entailing excessive costs.
- (2) Point (a) of Article 16(2) of Directive 2009/125/EC provides that in accordance with the procedure referred to in Article 19(3) and the criteria set out in Article 15(2), and after consulting the Ecodesign Consultation Forum, the Commission shall, as appropriate, introduce implementing measures offering a high potential for cost-effective reduction of greenhouse gas emissions, such as for products in heating, ventilation and air-conditioning systems.
- (3) The Commission has carried out a preparatory study to analyse the technical, environmental and economic aspects of air conditioners and comfort fans typically used in households and small commercial establishments. The study has been developed together with stakeholders and interested parties from the EU and third countries, and the results have been made publicly available.
- (4) The main environmental aspects of the products covered, identified as significant for the purposes of this Regulation, are energy consumption in use phase and sound power level. The preparatory study also identified

possible refrigerant leakage as a significant environmental aspect in form of direct greenhouse gas emissions, representing on average 10-20 % of the combined direct and indirect greenhouse gas emissions.

- (5) As shown in the preparatory study and confirmed during the impact assessment, there is a lack of information on the efficiency of comfort fans. However, in order to provide market surveillance authorities important information and allow efficient monitoring of the market for the purposes of setting minimum energy efficiency requirements in the future, product information requirements on comfort fans will ensure that the efficiency of the appliance and the measurement method used be well visible on the product. Furthermore, standby and off mode requirements are set for comfort fans.
- (6) The annual electricity consumption of products subject to this Regulation was estimated to have been 30 TWh in the EU in 2005. Unless specific measures are taken, annual electricity consumption is predicted to be 74 TWh in 2020. The preparatory study shows that the electricity consumption of products subject to this Regulation can be significantly reduced.
- (7) The preparatory study shows that requirements regarding other ecodesign parameters referred to in Annex I, Part 1, to Directive 2009/125/EC are not necessary as electricity consumption and sound power level of air conditioners in the use phase are the most significant environmental aspects.
- (8) As refrigerants are addressed under Regulation (EC) No 842/2006 of the European Parliament and of the Council of 17 May 2006 on certain fluorinated greenhouse gases<sup>(2)</sup> no specific requirements on refrigerants are set in this Regulation. However, a bonus is proposed under the ecodesign requirements to steer the market towards the use of refrigerants with reduced harmful impact on the environment. The bonus will lead to lower minimum energy efficiency requirements for appliances using low-global warming potential (GWP) refrigerants.
- (9) Air conditioners can be part of systems installed in buildings. National legislation based inter alia on Directive 2010/31/EU of the European Parliament and of the Council of 19 May 2010 on the energy performance of buildings<sup>(3)</sup> may set new stricter requirements on those air conditioning systems, using

<sup>(1)</sup> OJ L 285, 31.10.2009, p. 10.

<sup>(2)</sup> OJ L 161, 14.6.2006, p. 1.

<sup>(3)</sup> OJ L 153, 18.6.2010, p. 13.

the calculation and measurement methods defined in this Regulation as regards the efficiency of the air conditioner.

- (10) Standby and off-mode functions can be responsible for an important part of the total power consumption of these appliances. For air conditioners, except for double and single duct air conditioners, power consumption of these functions is part of the minimum energy performance requirements and of the seasonal efficiency measurement method. Standby and off-mode requirements for double and single duct air conditioners are set on the basis of the Ecodesign requirements of Commission Regulation (EC) No 1275/2008 <sup>(1)</sup>.
- (11) The combined effect of ecodesign requirements set out in this Regulation and Commission Delegated Regulation (EU) No 626/2011 of 4 May 2011 supplementing Directive 2010/30/EU of the European Parliament and of the Council with regard to energy labelling of air conditioners <sup>(2)</sup> is expected to result in annual electricity savings of 11 TWh by 2020, compared to the situation if no measures are taken.
- (12) Products subject to this Regulation should be made more energy efficient by applying existing non-proprietary cost-effective technologies that can reduce the combined costs of purchasing and operating these products.
- (13) The ecodesign requirements should not affect functionality from the end-user's perspective and should not negatively affect health, safety or the environment. In particular, the benefits of reducing electricity consumption during the use phase should more than offset any possible additional environmental impact during the production phase.
- (14) The ecodesign requirements should be introduced gradually in order to provide a sufficient timeframe for manufacturers to re-design products subject to this Regulation. The timing should be such as to avoid negative impacts on the functionalities of equipment on the market, and to take into account cost impacts for end-users and manufacturers, in particular small and medium-sized enterprises, while ensuring timely achievement of the objectives of this Regulation.
- (15) Measurements of the relevant product parameters should be performed through reliable, accurate and reproducible measurement methods, which take into account the recognised state of the art measurement methods including, where available, harmonised standards

adopted by the European standardisation bodies, as listed in Annex I to Directive 98/48/EC of the European Parliament and of the Council of 20 July 1998 amending Directive 98/34/EC laying down a procedure for the provision of information in the field of technical standards and regulations <sup>(3)</sup>.

- (16) In accordance with Article 8 of Directive 2009/125/EC, this Regulation specifies the applicable conformity assessment procedures.
- (17) In order to facilitate compliance checks, manufacturers should provide information in the technical documentation referred to in Annexes IV and V to Directive 2009/125/EC in so far as this information relates to the requirements laid down in this Regulation.
- (18) In addition to the legally binding requirements laid down in this Regulation, indicative benchmarks for best available technologies should be identified to ensure the wide availability and easy accessibility of information on the life-cycle environmental performance of products subject to this Regulation.
- (19) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 19(1) of Directive 2009/125/EC,

HAS ADOPTED THIS REGULATION:

#### *Article 1*

##### **Subject matter and scope**

1. This Regulation establishes eco-design requirements for the placing on the market of electric mains-operated air conditioners with a rated capacity of  $\leq 12$  kW for cooling, or heating if the product has no cooling function, and comfort fans with an electric fan power input  $\leq 125$ W.
2. This Regulation shall not apply to:
  - (a) appliances that use non-electric energy sources;
  - (b) air conditioners of which the condenser-side or evaporator-side, or both, do not use air for heat transfer medium.

#### *Article 2*

##### **Definitions**

For the purposes of this Regulation, the definitions in Article 2 of Directive 2009/125/EC of the European Parliament and of the Council shall apply.

<sup>(1)</sup> OJ L 339, 18.12.2008, p. 45.

<sup>(2)</sup> OJ L 178, 6.7.2011, p. 1.

<sup>(3)</sup> OJ L 217, 5.8.1998, p. 18.

In addition, the following definitions shall apply:

1. 'air conditioner' means a device capable of cooling or heating, or both, indoor air, using a vapour compression cycle driven by an electric compressor, including air conditioners that provide additional functionalities such as dehumidification, air-purification, ventilation or supplemental air-heating by means of electric resistance heating, as well as appliances that may use water (either condensate water that is formed on the evaporator side or externally added water) for evaporation on the condenser, provided that the device is also able to function without the use of additional water, using air only;
2. 'double duct air conditioner' means an air conditioner in which, during cooling or heating, the condenser (or evaporator) intake air is introduced from the outdoor environment to the unit by a duct and rejected to the outdoor environment by a second duct, and which is placed wholly inside the space to be conditioned, near a wall;
3. 'single duct air conditioner' means an air conditioner in which, during cooling or heating, the condenser (or evaporator) intake air is introduced from the space containing the unit and discharged outside this space;
4. 'rated capacity' ( $P_{\text{rated}}$ ) means the cooling or heating capacity of the vapour compression cycle of the unit at standard rating conditions;
5. 'comfort fan' means an appliance primarily designed for creating air movement around or on part of a human body for personal cooling comfort, including comfort fans that can perform additional functionalities such as lighting;
6. 'fan power input' ( $P_f$ ) means the electric power input of a comfort fan in Watt operating at the declared maximum fan flow rate, measured with the oscillating mechanism active (if/when applicable).

For the purposes of the Annexes, additional definitions are set out in Annex I.

#### Article 3

##### Ecodesign requirements and timetable

1. The ecodesign requirements for air conditioners and comfort fans are set out in Annex I.
2. Each ecodesign requirement shall apply in accordance with the following timetable:

From 1 January 2013:

single duct and double duct air conditioners shall correspond to requirements as indicated in Annex I, point 2(a).

From 1 January 2013:

- (a) air conditioners, except single and double duct air conditioners, shall correspond to requirements as indicated in Annex I, point 2(b) and points 3(a), 3(b), 3(c);
- (b) single ducts and double ducts shall correspond to requirements as indicated in Annex I, points 3(a), 3(b), 3(d);
- (c) comfort fans shall correspond to requirements as indicated in Annex I, points 3(a), 3(b), 3(e).

From 1 January 2014:

- (a) air conditioners shall correspond to ecodesign requirements as indicated in Annex I, point 2(c);
  - (b) single duct and double duct air conditioners shall correspond to requirements as indicated in Annex I, point 2(d).
3. Compliance with ecodesign requirements shall be measured and calculated in accordance with requirements set out in Annex II.

#### Article 4

##### Conformity assessment

1. The conformity assessment procedure referred to in Article 8 of Directive 2009/125/EC shall be the internal design control set out in Annex IV to that Directive or the management system set out in Annex V to that Directive.
2. For the purposes of conformity assessment pursuant to Article 8 of Directive 2009/125/EC, the technical documentation file shall contain the results of the calculation set out in Annex II to this Regulation.

#### Article 5

##### Verification procedure for market surveillance purposes

Member States shall apply the verification procedure described in Annex III to this Regulation when performing the market surveillance checks referred to in Article 3(2) of Directive 2009/125/EC for compliance with requirements set out in Annex I to this Regulation.

#### Article 6

##### Benchmarks

The indicative benchmarks for best-performing air conditioners available on the market at the time of entry into force of this Regulation are set out in Annex IV.

*Article 7***Revision**

The Commission shall review this Regulation in the light of technological progress and present the result of this review to the Ecodesign Consultation Forum no later than 5 years from the date of the entry into force of this Regulation. The review shall in particular assess the efficiency and sound power level requirements, the approach to promote the use of low-global warming potential (GWP) refrigerants and the scope of the Regulation for air conditioners and possible changes in market share of types of appliances, including air conditioners above 12 kW rated output power. The review shall also assess the appropriateness of the standby and off mode requirements,

seasonal calculation and measurement method, including considerations on the development of a possible seasonal calculation and measurement method for all air conditioners in the scope for cooling and heating seasons.

*Article 8***Entry into force and application**

1. This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.
2. It shall apply from 1 January 2013.

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

Done at Brussels, 6 March 2012.

For the Commission  
The President  
José Manuel BARROSO

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## ANNEX I

## Ecodesign requirements

## 1. DEFINITIONS APPLICABLE FOR THE PURPOSES OF THE ANNEXES

- (1) '*reversible air conditioner*' means an air conditioner capable of both cooling and heating;
- (2) '*standard rating conditions*' means the combination of indoor ( $T_{in}$ ) and outdoor temperatures ( $T_j$ ) that describe the operating conditions while establishing the sound power level, rated capacity, rated air flow rate, rated energy efficiency ratio ( $EER_{rated}$ ) and/or rated coefficient of performance ( $COP_{rated}$ ), as set out in Annex II, Table 2;
- (3) '*indoor temperature*' ( $T_{in}$ ) means the dry bulb indoor air temperature [°C] (with the relative humidity indicated by the corresponding wet bulb temperature);
- (4) '*outdoor temperature*' ( $T_j$ ) means the dry bulb outdoor air temperature [°C] (with the relative humidity indicated by the corresponding wet bulb temperature);
- (5) '*rated energy efficiency ratio*' ( $EER_{rated}$ ) means the *declared capacity* for cooling [kW] divided by the *rated power input for cooling* [kW] of a unit when providing cooling at *standard rating conditions*;
- (6) '*rated coefficient of performance*' ( $COP_{rated}$ ) means the *declared capacity* for heating [kW] divided by the *rated power input for heating* [kW] of a unit when providing heating at *standard rating conditions*;
- (7) '*global warming potential*' (GWP) means the measure of how much 1 kg of the refrigerant applied in the vapour compression cycle is estimated to contribute to global warming, expressed in kg CO<sub>2</sub> equivalents over a 100-year time horizon;

GWP values considered will be those set out in Annex I to Regulation (EC) No 842/2006;

for fluorinated refrigerants, the GWP values shall be those published in the Third Assessment Report (TAR), adopted by the Intergovernmental Panel on Climate Change <sup>(1)</sup> (2001 IPCC GWP values for a 100-year period);

for non-fluorinated gases, the GWP values are those published in the first IPCC assessment <sup>(2)</sup> over a 100-year period;

GWP values for mixtures of refrigerants shall be based on the formula stated in Annex I to Regulation (EC) No 842/2006;

for refrigerants not included in the above references, the IPCC UNEP 2010 report on Refrigeration, Air Conditioning and Heat Pumps, dated February 2011, or newer, shall be used as a reference;

- (8) '*off mode*' is a condition in which the air conditioner or comfort fan is connected to the mains power source and is not providing any function. Also considered as off mode are conditions providing only an indication of off mode condition, as well as conditions providing only functionalities intended to ensure electromagnetic compatibility pursuant to Directive 2004/108/EC of the European Parliament and of the Council <sup>(3)</sup>;
- (9) '*standby mode*' means a condition where the equipment (air conditioner or comfort fan) is connected to the mains power source, depends on energy input from the mains power source to work as intended and provides only the following functions, which may persist for an indefinite time: reactivation function, or reactivation function and only an indication of enabled reactivation function, and/or information or status display;
- (10) '*reactivation function*' means a function facilitating the activation of other modes, including active mode, by remote switch including remote control, internal sensor, timer to a condition providing additional functions, including the main function;
- (11) '*information or status display*' is a continuous function providing information or indicating the status of the equipment on a display, including clocks;
- (12) '*sound power level*' means the A-weighted sound power level [dB(A)] indoors and/or outdoors measured at *standard rating conditions* for cooling (or heating, if the product has no cooling function);

<sup>(1)</sup> IPCC Third Assessment Climate Change 2001. A Report of the Intergovernmental Panel on Climate Change: [http://www.ipcc.ch/publications\\_and\\_data/publications\\_and\\_data\\_reports.shtml](http://www.ipcc.ch/publications_and_data/publications_and_data_reports.shtml)

<sup>(2)</sup> Climate Change, The IPCC Scientific Assessment, J.T. Houghton, G.J. Jenkins, J.J. Ephraums (ed.) Cambridge University Press, Cambridge (UK) 1990.

<sup>(3)</sup> OJ L 390, 31.12.2004, p. 24.

- (13) 'reference design conditions' means the combination of requirements for the reference design temperature, the maximum bivalent temperature and the maximum operation limit temperature, as set out in Annex II, Table 3;
- (14) 'reference design temperature' means the outdoor temperature [ $^{\circ}\text{C}$ ] for either cooling ( $T_{\text{designc}}$ ) or heating ( $T_{\text{designh}}$ ) as described in Annex II, Table 3, at which the part load ratio shall be equal to 1, and which varies according to the designated cooling or heating season;
- (15) 'part load ratio' ( $pl(T_j)$ ) means the outdoor temperature minus  $16^{\circ}\text{C}$ , divided by the reference design temperature minus  $16^{\circ}\text{C}$ , for either cooling or heating;
- (16) 'season' means one of the four sets of operating conditions (available for four seasons: one cooling season, three heating seasons: average/colder/warmer) describing per bin the combination of outdoor temperatures and the number of hours these temperatures occur per season for which the unit is declared fit for purpose;
- (17) 'bin' (with index  $j$ ) means a combination of an outdoor temperature ( $T_j$ ) and bin hours ( $h_j$ ), as set out in Annex II, Table 1;
- (18) 'bin hours' means the hours per season ( $h_j$ ) the outdoor temperature occurs for each bin, as set out in Annex II, Table 1;
- (19) 'seasonal energy efficiency ratio' (SEER) is the overall energy efficiency ratio of the unit, representative for the whole cooling season, calculated as the Reference annual cooling demand divided by the annual electricity consumption for cooling;
- (20) 'reference annual cooling demand' ( $Q_C$ ) means the reference cooling demand [ $\text{kWh/a}$ ] to be used as basis for calculation of SEER and calculated as the product of the design load for cooling ( $P_{\text{designc}}$ ) and the equivalent active mode hours for cooling ( $H_{\text{CE}}$ );
- (21) 'equivalent active mode hours for cooling' ( $H_{\text{CE}}$ ) means the assumed annual number of hours [ $\text{h/a}$ ] the unit must provide the design load for cooling ( $P_{\text{designc}}$ ) in order to satisfy the reference annual cooling demand, as set out in Annex II, Table 4;
- (22) 'annual electricity consumption for cooling' ( $Q_{\text{CE}}$ ) means the electricity consumption [ $\text{kWh/a}$ ] required to meet the reference annual cooling demand and is calculated as the reference annual cooling demand divided by the active mode seasonal energy efficiency ratio (SEER<sub>on</sub>), and the electricity consumption of the unit for thermostat off-, standby-, off- and crankcase heater-mode during the cooling season;
- (23) 'active mode seasonal energy efficiency ratio' (SEER<sub>on</sub>) means the average energy efficiency ratio of the unit in active mode for the cooling function, constructed from part load and bin-specific energy efficiency ratio's ( $EER_{\text{bin}}(T_j)$ ) and weighted by the bin hours the bin condition occurs;
- (24) 'part load' means the cooling load ( $P_c(T_j)$ ) or the heating load ( $P_h(T_j)$ ) [ $\text{kW}$ ] at a specific outdoor temperature  $T_j$ , calculated as the design load multiplied by the part load ratio;
- (25) 'bin-specific energy efficiency ratio' ( $EER_{\text{bin}}(T_j)$ ) means the energy efficiency ratio specific for every bin  $j$  with outdoor temperature  $T_j$  in a season, derived from the part load, declared capacity and declared energy efficiency ratio ( $EER_d(T_j)$ ) for specified bins ( $j$ ) and calculated for other bins through inter/extrapolation, when necessary corrected by the degradation coefficient;
- (26) 'seasonal coefficient of performance' (SCOP) is the overall coefficient of performance of the unit, representative for the whole designated heating season (the value of SCOP pertains to a designated heating season), calculated as the reference annual heating demand divided by the annual electricity consumption for heating;
- (27) 'reference annual heating demand' ( $Q_H$ ) means the reference heating demand [ $\text{kWh/a}$ ], pertaining to a designated heating season, to be used as basis for calculation of SCOP and calculated as the product of the design load for heating ( $P_{\text{designh}}$ ) and the seasonal equivalent active mode hours for heating ( $H_{\text{HE}}$ );
- (28) 'equivalent active mode hours for heating' ( $H_{\text{HE}}$ ) means the assumed annual number of hours [ $\text{h/a}$ ] the unit must provide the design load for heating ( $P_{\text{designh}}$ ) in order to satisfy the reference annual heating demand, as set out in Annex II, Table 4;

- (29) 'annual electricity consumption for heating' ( $Q_{HE}$ ) means the electricity consumption [kWh/a] required to meet the indicated *reference annual heating demand* and which pertains to a designated heating season; and is calculated as the *reference annual heating demand* divided by the *active mode seasonal coefficient of performance* (SCOP<sub>on</sub>), and the electricity consumption of the unit for *thermostat off-, standby-, off- and crankcase heater-mode* during the heating season;
- (30) 'active mode seasonal coefficient of performance' (SCOP<sub>on</sub>) means the average coefficient of performance of the unit in active mode for the designated heating season, constructed from the *part load, electric back up heating capacity* (where required) and *bin-specific coefficients of performance* (COP<sub>bin</sub>(T<sub>j</sub>)) and weighted by the *bin hours* the *bin condition* occurs;
- (31) 'electric back-up heater capacity' (elbu(T<sub>j</sub>)) is the heating capacity [kW] of a real or assumed electric back-up heater with COP of 1 that supplements the *declared capacity for heating* (P<sub>dh</sub>(T<sub>j</sub>)) in order to meet the *part load* for heating (Ph(T<sub>j</sub>)) in case P<sub>dh</sub>(T<sub>j</sub>) is less than Ph(T<sub>j</sub>), for the *outdoor temperature* (T<sub>j</sub>);
- (32) 'bin-specific coefficient of performance' (COP<sub>bin</sub>(T<sub>j</sub>)) means the coefficient of performance specific for every *bin j* with *outdoor temperature* T<sub>j</sub> in a season, derived from the *part load, declared capacity* and *declared coefficient of performance* (COP<sub>d</sub>(T<sub>j</sub>)) for specified *bins (j)* and calculated for other *bins* through inter/extrapolation, when necessary corrected by the *degradation coefficient*;
- (33) 'declared capacity' [kW] is the capacity of the vapour compression cycle of the unit for cooling (P<sub>dc</sub>(T<sub>j</sub>)) or heating (P<sub>dh</sub>(T<sub>j</sub>)), pertaining to an *outdoor temperature* T<sub>j</sub> and *indoor temperature* (T<sub>in</sub>), as declared by the manufacturer;
- (34) 'service value' (SV) [(m<sup>3</sup>/min)/W] means for comfort fans the ratio of the *maximum fan flow rate* [m<sup>3</sup>/min] and the *fan power input* [W];
- (35) 'capacity control' means the ability of the unit to change its capacity by changing the volumetric flow rate. Units are to be indicated as 'fixed' if the unit can not change its volumetric flow rate, 'staged' if the volumetric flow rate is changed or varied in series of not more than two steps, or 'variable' if the volumetric flow rate is changed or varied in series of three or more steps;
- (36) 'function' means the indication of whether the unit is capable of indoor air cooling, indoor air heating or both;
- (37) 'design load' means the declared cooling load (P<sub>designc</sub>) and/or declared heating load (P<sub>designh</sub>) [kW] at the *reference design temperature*, whereby  
for cooling mode, P<sub>designc</sub> is equal to the *declared capacity* for cooling at T<sub>j</sub> equal to T<sub>designc</sub>;  
for heating mode, P<sub>designh</sub> is equal to the *part load* at T<sub>j</sub> equal to T<sub>designh</sub>;
- (38) 'declared energy efficiency ratio' (EER<sub>d</sub>(T<sub>j</sub>)) means the energy efficiency ratio at a limited number of specified *bins (j)* with *outdoor temperature* (T<sub>j</sub>), as declared by the manufacturer;
- (39) 'declared coefficient of performance' (COP<sub>d</sub>(T<sub>j</sub>)) means the coefficient of performance at a limited number of specified *bins (j)* with *outdoor temperature* (T<sub>j</sub>), as declared by the manufacturer;
- (40) 'bivalent temperature' (T<sub>biv</sub>) means the *outdoor temperature* (T<sub>j</sub>) [°C] declared by the manufacturer for heating at which the *declared capacity* equals the *part load* and below which the *declared capacity* must be supplemented with *electric back up heater capacity* in order to meet the *part load* for heating;
- (41) 'operation limit temperature' (T<sub>ol</sub>) means the *outdoor temperature* [°C] declared by the manufacturer for heating, below which air conditioner will not be able to deliver any heating capacity. Below this temperature, the *declared capacity* is equal to zero;
- (42) 'cycling interval capacity' [kW] is the (time-weighted) average of the *declared capacity* over the cycling test interval for cooling (P<sub>cycc</sub>) or heating (P<sub>cych</sub>);
- (43) 'cycling interval efficiency for cooling' (EER<sub>cycc</sub>) is the average energy efficiency ratio over the cycling test interval (compressor switching on and off), calculated as the integrated cooling capacity over the interval [kWh] divided by the integrated electric power input over that same interval [kWh];
- (44) 'cycling interval efficiency for heating' (COP<sub>cycc</sub>) is the average coefficient of performance over the cycling test interval (compressor switching on and off), calculated as the integrated heating capacity over the interval [kWh] divided by the integrated electric power input over that same interval [kWh];
- (45) 'degradation coefficient' is the measure of efficiency loss due to cycling (compressor switching on/off in *active mode*) established for cooling (C<sub>dc</sub>), heating (C<sub>dh</sub>) or chosen as default value 0,25;

- (46) 'active mode' means the mode corresponding to the hours with a cooling or heating load of the building and whereby the cooling or heating function of the unit is activated. This condition may involve on/off-cycling of the unit in order to reach or maintain a required indoor air temperature;
- (47) 'thermostat-off mode' means a mode corresponding to the hours with no cooling or heating load whereby the cooling or heating function of the unit is switched on but the unit is not operational as there is no cooling or heating load. This condition is therefore related to outdoor temperatures and not to indoor loads. Cycling on/off in active mode is not considered as thermostat off;
- (48) 'crankcase heater operation mode' means a condition where the unit has activated a heating device to avoid the refrigerant migrating to the compressor in order to limit the refrigerant concentration in oil at compressor start;
- (49) 'thermostat-off mode power consumption' ( $P_{TO}$ ) means the power consumption of the unit [kW] while in *thermostat-off mode*;
- (50) 'standby mode power consumption' ( $P_{SB}$ ) means the power consumption of the unit [kW] while in *standby mode*;
- (51) 'off-mode power consumption' ( $P_{OFF}$ ) means the power consumption of the unit [kW] while in *off-mode*;
- (52) 'crankcase heater mode power consumption' ( $P_{CK}$ ) means the power consumption of the unit [kW] while in *crankcase heater operation mode*;
- (53) 'thermostat-off mode operating hours' ( $H_{TO}$ ) means the annual number of hours [h/a] the unit is considered to be in *thermostat-off mode*, the value of which depends on the designated season and function;
- (54) 'standby mode operating hours' ( $H_{SB}$ ) means the annual number of hours [h/a] the unit is considered to be in *standby mode*, the value of which depends on the designated season and function;
- (55) 'off-mode operating hours' ( $H_{OFF}$ ) means the annual number of hours [h/a] the unit is considered to be in *off-mode*, the value of which depends on the designated season and function;
- (56) 'crankcase heater mode operating hours' ( $H_{CK}$ ) means the annual number of hours [h/a] the unit is considered to be in *crankcase heater operation mode*, the value of which depends on the designated season and function;
- (57) 'nominal air flow rate' means the air flow rate [ $m^3/h$ ] measured at the air outlet of indoor and/or outdoor units (if applicable) of air conditioners at *standard rating conditions* for cooling (or heating, if the product has no cooling function);
- (58) 'rated power input for cooling' ( $P_{EER}$ ) means the electric power input [kW] of a unit when providing cooling at *standard rating conditions*;
- (59) 'rated power input for heating' ( $P_{COP}$ ) means the electric power input [kW] of a unit when providing heating at *standard rating conditions*;
- (60) 'electricity consumption of single and double ducts' ( $Q_{SD}$  respectively  $Q_{DD}$ ) means the electricity consumption of single or double duct air conditioners for the cooling and/or heating mode (whichever applies) [single duct in kWh/h, double duct in kWh/a];
- (61) 'capacity ratio' means the ratio of the total declared cooling or heating capacity of all operating indoor units to the declared cooling or heating capacity of the outdoor unit at *standard rating conditions*;
- (62) 'maximum fan flow rate' ( $F$ ) means the air flow rate of the comfort fan at its maximum setting [ $m^3/min$ ], measured at the fan outlet with the *oscillating mechanism* (if applicable) turned off;
- (63) 'oscillating mechanism' means the capability of the comfort fan to automatically vary the direction of the air flow while the fan is operating;
- (64) 'fan sound power level' means the A-weighted sound power level of the comfort fan while providing the *maximum fan flow rate*, measured at the outlet side;
- (65) 'fan active mode hours' ( $H_{CF}$ ) means the number of hours [h/a] the comfort fan is assumed to provide the *maximum fan flow rate*, as described in Annex II, Table 4.



2. REQUIREMENTS FOR MINIMUM ENERGY EFFICIENCY, MAXIMUM POWER CONSUMPTION IN OFF-MODE AND STANDBY MODE AND FOR MAXIMUM SOUND POWER LEVEL

- (a) From 1 January 2013, single duct and double duct air conditioners shall correspond to requirements as indicated in Tables 1, 2 and 3 below, calculated in accordance with Annex II. Single duct and double duct air conditioners and comfort fans shall fulfil the requirements on standby and off mode as indicated in Table 2 below. The requirements on minimum energy efficiency and maximum sound power shall relate to the standard rating conditions specified in Annex II, Table 2.

Table 1

**Requirements for minimum energy efficiency**

	Double duct air conditioners		Single duct air conditioners	
	EER <sub>rated</sub>	COP <sub>rated</sub>	EER <sub>rated</sub>	COP <sub>rated</sub>
If GWP of refrigerant > 150	2,40	2,36	2,40	1,80
If GWP of refrigerant ≤ 150	2,16	2,12	2,16	1,62

Table 2

**Requirements for maximum power consumption in off-mode and standby mode for single duct and double duct air conditioners and comfort fans**

Off mode	Power consumption of equipment in any off-mode condition shall not exceed 1,00 W.
Standby mode	The power consumption of equipment in any condition providing only a reactivation function, or providing only a reactivation function and a mere indication of enabled reactivation function, shall not exceed 1,00 W.
	The power consumption of equipment in any condition providing only information or status display, or providing only a combination of reactivation function and information or status display, shall not exceed 2,00 W.
Availability of standby and/or off mode	Equipment shall, except where this is inappropriate for the intended use, provide off mode and/or standby mode, and/or another condition which does not exceed the applicable power consumption requirements for off mode and/or standby mode when the equipment is connected to the mains power source.

Table 3

**Requirements for maximum sound power level**

Indoor sound power level in dB(A)
65

- (b) From 1 January 2013, air conditioners, except single and double duct air conditioners, shall correspond to minimum energy efficiency and maximum sound power level requirements as indicated in Tables 4 and 5 below, calculated in accordance with Annex II. The requirements on energy efficiency shall take into account the reference design conditions specified in Annex II, Table 3 using the 'Average' heating season where applicable. The requirements on sound power shall relate to the standard rating conditions specified in Annex II, Table 2

Table 4

**Requirements for minimum energy efficiency**

	SEER	SCOP (Average heating season)
If GWP of refrigerant > 150	3,60	3,40
If GWP of refrigerant ≤ 150	3,24	3,06

Table 5

**Requirements for maximum sound power level**

Rated capacity ≤ 6 kW		6 < Rated capacity ≤ 12 kW	
Indoor sound power level in dB(A)	Outdoor sound power level in dB(A)	Indoor sound power level in dB(A)	Outdoor sound power level in dB(A)
60	65	65	70

- (c) From 1 January 2014, air conditioners shall correspond to requirements as indicated in the table below, calculated in accordance with Annex II. The requirements on energy efficiency for air conditioners, excluding single and double duct air conditioners, shall relate to the reference design conditions specified in Annex II, Table 3 using the 'Average' heating season where applicable. The requirements on energy efficiency for single and double duct air conditioners shall relate to the standard rating conditions specified in Annex II, Table 2.

Table 6

**Requirements for minimum energy efficiency**

	Air conditioners, except double and single duct air conditioners		Double duct air conditioners		Single duct air conditioners	
	SEER	SCOP (heating season: Average)	EER <sub>rated</sub>	COP <sub>rated</sub>	EER <sub>rated</sub>	COP <sub>rated</sub>
If GWP of refrigerant > 150 for < 6 kW	4,60	3,80	2,60	2,60	2,60	2,04
If GWP of refrigerant ≤ 150 for < 6 kW	4,14	3,42	2,34	2,34	2,34	1,84
If GWP of refrigerant > 150 for 6-12 kW	4,30	3,80	2,60	2,60	2,60	2,04
If GWP of refrigerant ≤ 150 for 6-12 kW	3,87	3,42	2,34	2,34	2,34	1,84

- (d) From 1 January 2014, single duct and double duct air conditioners and comfort fans shall correspond to requirements as indicated in Table 7 below, calculated in accordance with Annex II.

Table 7

**Requirements for maximum power consumption in off-mode and standby mode**

Off mode	Power consumption of equipment in any off-mode condition shall not exceed 0,50 W.
Standby mode	The power consumption of equipment in any condition providing only a reactivation function, or providing only a reactivation function and a mere indication of enabled reactivation function, shall not exceed 0,50 W.
	The power consumption of equipment in any condition providing only information or status display, or providing only a combination of reactivation function and information or status display shall not exceed 1,00 W.
Availability of standby and/or off mode	Equipment shall, except where this is inappropriate for the intended use, provide off mode and/or standby mode, and/or another condition which does not exceed the applicable power consumption requirements for off mode and/or standby mode when the equipment is connected to the mains power source.

Power management	<p>When equipment is not providing the main function, or when other energy-using product(s) are not dependent on its functions, equipment shall, unless inappropriate for the intended use, offer a power management function, or a similar function, that switches equipment after the shortest possible period of time appropriate for the intended use of the equipment, automatically into:</p> <ul style="list-style-type: none"> <li>— standby mode, or</li> <li>— off mode, or</li> <li>— another condition which does not exceed the applicable power consumption requirements for off mode and/or standby mode when the equipment is connected to the mains power source. The power management function shall be activated before delivery.</li> </ul>
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### 3. PRODUCT INFORMATION REQUIREMENTS

- (a) From 1 January 2013, as regards air conditioners and comfort fans, the information set out in points below and calculated in accordance with Annex II shall be provided on:
- (i) the technical documentation of the product;
  - (ii) free access websites of manufacturers of air conditioners and comfort fans;
- (b) The manufacturer of air conditioners and comfort fans shall provide laboratories performing market surveillance checks, upon request, the necessary information on the setting of the unit as applied for the establishment of *declared capacities*, *SEER/EER*, *SCOP/COP* values and *service values* and provide contact information for obtaining such information.
- (c) Information requirements for air conditioners, except double duct and single duct air conditioners.

Table 1

#### Information requirements <sup>(1)</sup>

(the number of decimals in the box indicates the precision of reporting)

Information to identify the model(s) to which the information relates to:

Function (indicate if present)				If function includes heating: Indicate the heating season the information relates to. Indicated values should relate to one heating season at a time. Include at least the heating season 'Average'.			
cooling	Y/N			Average (mandatory)	Y/N		
heating	Y/N			Warmer (if designated)	Y/N		
				Colder (if designated)	Y/N		
Item	symbol	value	unit	Item	symbol	value	unit
Design load				Seasonal efficiency			
cooling	P <sub>designc</sub>	x,x	kW	cooling	SEER	x,x	—
heating/Average	P <sub>designh</sub>	x,x	kW	heating/Average	SCOP/A	x,x	—
heating/Warmer	P <sub>designh</sub>	x,x	kW	heating/Warmer	SCOP/W	x,x	—
heating/Colder	P <sub>designh</sub>	x,x	kW	heating/Colder	SCOP/C	x,x	—
Declared capacity (*) for cooling, at indoor temperature 27(19) °C and outdoor temperature T <sub>j</sub>				Declared energy efficiency ratio (*), at indoor temperature 27(19) °C and outdoor temperature T <sub>j</sub>			

<sup>(1)</sup> For multisplit appliances, data shall be provided at capacity ratio of 1.

Function (indicate if present)				If function includes heating: Indicate the heating season the information relates to. Indicated values should relate to one heating season at a time. Include at least the heating season 'Average'.			
cooling	Y/N			Average (mandatory)	Y/N		
heating	Y/N			Warmer (if designated)	Y/N		
				Colder (if designated)	Y/N		
Item	symbol	value	unit	Item	symbol	value	unit
Tj = 35 °C	Pdc	x,x	kW	Tj = 35 °C	EERd	x,x	—
Tj = 30 °C	Pdc	x,x	kW	Tj = 30 °C	EERd	x,x	—
Tj = 25 °C	Pdc	x,x	kW	Tj = 25 °C	EERd	x,x	—
Tj = 20 °C	Pdc	x,x	kW	Tj = 20 °C	EERd	x,x	—
Declared capacity (*) for heating/Average season, at indoor temperature 20 °C and outdoor temperature Tj				Declared coefficient of performance (*)/Average season, at indoor temperature 20 °C and outdoor temperature Tj			
Tj = - 7 °C	Pdh	x,x	kW	Tj = - 7 °C	COPd	x,x	—
Tj = 2 °C	Pdh	x,x	kW	Tj = 2 °C	COPd	x,x	—
Tj = 7 °C	Pdh	x,x	kW	Tj = 7 °C	COPd	x,x	—
Tj = 12 °C	Pdh	x,x	kW	Tj = 12 °C	COPd	x,x	—
Tj = bivalent temperature	Pdh	x,x	kW	Tj = bivalent temperature	COPd	x,x	—
Tj = operating limit	Pdh	x,x	kW	Tj = operating limit	COPd	x,x	—
Declared capacity (*) for heating/Warmer season, at indoor temperature 20 °C and outdoor temperature Tj				Declared coefficient of performance (*)/Warmer season, at indoor temperature 20 °C and outdoor temperature Tj			
Tj = 2 °C	Pdh	x,x	kW	Tj = 2 °C	COPd	x,x	—
Tj = 7 °C	Pdh	x,x	kW	Tj = 7 °C	COPd	x,x	—
Tj = 12 °C	Pdh	x,x	kW	Tj = 12 °C	COPd	x,x	—
Tj = bivalent temperature	Pdh	x,x	kW	Tj = bivalent temperature	COPd	x,x	—
Tj = operating limit	Pdh	x,x	kW	Tj = operating limit	COPd	x,x	—
Declared capacity (*) for heating/Colder season, at indoor temperature 20 °C and outdoor temperature Tj				Declared coefficient of performance (*)/Colder season, at indoor temperature 20 °C and outdoor temperature Tj			
Tj = - 7 °C	Pdh	x,x	kW	Tj = - 7 °C	COPd	x,x	—
Tj = 2 °C	Pdh	x,x	kW	Tj = 2 °C	COPd	x,x	—

Function (indicate if present)				If function includes heating: Indicate the heating season the information relates to. Indicated values should relate to one heating season at a time. Include at least the heating season 'Average'.			
cooling	Y/N			Average (mandatory)	Y/N		
heating	Y/N			Warmer (if designated)	Y/N		
				Colder (if designated)	Y/N		
Item	symbol	value	unit	Item	symbol	value	unit
Tj = 7 °C	Pdh	x,x	kW	Tj = 7 °C	COPd	x,x	—
Tj = 12 °C	Pdh	x,x	kW	Tj = 12 °C	COPd	x,x	—
Tj = bivalent temperature	Pdh	x,x	kW	Tj = bivalent temperature	COPd	x,x	—
Tj = operating limit	Pdh	x,x	kW	Tj = operating limit	COPd	x,x	—
Tj = - 15 °C	Pdh	x,x	kW	Tj = - 15 °C	COPd	x,x	—
Bivalent temperature				Operating limit temperature			
heating/Average	Tbiv	x	°C	heating/Average	Tol	x	°C
heating/Warmer	Tbiv	x	°C	heating/Warmer	Tol	x	°C
heating/Colder	Tbiv	x	°C	heating/Colder	Tol	x	°C
Cycling interval capacity				Cycling interval efficiency			
for cooling	Pcycc	x,x	kW	for cooling	EERcyc	x,x	—
for heating	Pcyh	x,x	kW	for heating	COPcyc	x,x	—
Degradation co-efficient cooling (**)	Cdc	x,x	—	Degradation co-efficient heating (**)	Cdh	x,x	—
Electric power input in power modes other than 'active mode'				Annual electricity consumption			
off mode	P <sub>OFF</sub>	x,x	kW	cooling	Q <sub>CE</sub>	x	kWh/a
standby mode	P <sub>SB</sub>	x,x	kW	heating/Average	Q <sub>HE</sub>	x	kWh/a
thermostat-off mode	P <sub>TO</sub>	x,x	kW	heating/Warmer	Q <sub>HE</sub>	x	kWh/a
crankcase heater mode	P <sub>CK</sub>	x,x	kW	heating/Colder	Q <sub>HE</sub>	x	kWh/a
Capacity control (indicate one of three options)				Other items			

Function (indicate if present)				If function includes heating: Indicate the heating season the information relates to. Indicated values should relate to one heating season at a time. Include at least the heating season 'Average'.			
cooling	Y/N			Average (mandatory)	Y/N		
heating	Y/N			Warmer (if designated)	Y/N		
				Colder (if designated)	Y/N		
Item	symbol	value	unit	Item	symbol	value	unit
fixed	Y/N			Sound power level (indoor/outdoor)	$L_{WA}$	x,x/x,x	dB(A)
staged	Y/N			Global warming potential	GWP	x	kgCO <sub>2</sub> eq.
variable	Y/N			Rated air flow (indoor/outdoor)	—	x/x	m <sup>3</sup> /h
Contact details for obtaining more information	Name and address of the manufacturer or of its authorised representative.						

(\*) For staged capacity units, two values divided by a slash (/) will be declared in each box in the section 'Declared capacity of the unit' and 'declared EER/COP' of the unit.

(\*\*) If default Cd = 0,25 is chosen then (results from) cycling tests are not required. Otherwise either the heating or cooling cycling test value is required.

In as much as is relevant in view of the functionality, the manufacturer shall supply the information as requested in the above Table 1 in the technical documentation of the product. For units with *capacity control* marked 'staged', two values for the highest and lowest, noted 'hi/lo' divided by a slash (/) will be declared in each box under 'Declared capacity'.

(d) Information requirements for single duct and double duct air conditioners.

Single duct air conditioners shall be named 'local air conditioners' in packaging, product documentation and in any advertisement material, whether electronic or in paper.

Manufacturer shall provide information as detailed in the table below.

Table 2

**Information requirements**

Information to identify the model(s) to which the information relates to [fill in as necessary]			
Description	Symbol	Value	Unit
Rated capacity for cooling	$P_{rated}$ for cooling	[x,x]	kW
Rated capacity for heating	$P_{rated}$ for heating	[x,x]	kW
Rated power input for cooling	$P_{EER}$	[x,x]	kW
Rated power input for heating	$P_{COP}$	[x,x]	kW
Rated Energy efficiency ratio	$EERd$	[x,x]	—
Rated Coefficient of performance	$COPd$	[x,x]	—

Information to identify the model(s) to which the information relates to <i>[fill in as necessary]</i>			
Description	Symbol	Value	Unit
Power consumption in thermostat-off mode	$P_{TO}$	[x,x]	W
Power consumption in standby mode	$P_{SB}$	[x,x]	W
Electricity consumption of single/double duct appliances (indicate for cooling and heating separately)	DD: $Q_{DD}$ SD: $Q_{SD}$	DD: [x] SD: [x,x]	DD: kWh/a SD: kWh/h
Sound power level	$L_{WA}$	[x]	dB(A)
Global warming potential	GWP	[x]	kgCO <sub>2</sub> eq.
Contact details for obtaining more information	Name and address of the manufacturer or of its authorised representative.		

## (e) Information requirements for comfort fans.

Manufacturer shall provide information as detailed in the table below.

Table 3

**Information requirements**

Information to identify the model(s) to which the information relates to <i>[fill in as necessary]</i>			
Description	Symbol	Value	Unit
Maximum fan flow rate	$F$	[x,x]	m <sup>3</sup> /min
Fan power input	$P$	[x,x]	W
Service value	SV	[x,x]	(m <sup>3</sup> /min)/W
Standby power consumption	$P_{SB}$	[x,x]	W
Fan sound power level	$L_{WA}$	[x]	dB(A)
Maximum air velocity	$c$	[x,x]	meters/sec
Measurement standard for service value	[state here the reference to measurement standard used]		
Contact details for obtaining more information	Name and address of the manufacturer or of its authorised representative.		

## ANNEX II

**Measurements and calculations**

1. For the purposes of compliance and verification of compliance with the requirements of this Regulation, measurements and calculations shall be made using harmonised standards the reference numbers of which have been published in the *Official Journal of European Union*, or other reliable, accurate and reproducible method, which takes into account the generally recognised state of the art methods, and whose results are deemed to be of low uncertainty. They shall fulfil all of the following technical parameters.
2. The determination of the seasonal energy consumption and efficiency for seasonal energy efficiency ratio (SEER) and seasonal coefficient of performance (SCOP) shall take into account:
  - (a) European cooling and heating season(s), as defined in Table 1 below;
  - (b) reference design conditions, as defined in Table 3 below;
  - (c) electric energy consumption for all relevant modes of operation, using time periods as defined in Table 4 below;
  - (d) effects of the degradation of the energy efficiency caused by on/off cycling (if applicable) depending on the type of control of the cooling and/or heating capacity;
  - (e) corrections on the seasonal coefficients of performance in conditions where the heating load can not be met by the heating capacity;
  - (f) the contribution of a back-up heater (if applicable) in the calculation of the seasonal efficiency of a unit in heating mode.
3. Where the information relating to a specific model, being a combination of indoor and outdoor unit(s), has been obtained by calculation on the basis of design, and/or extrapolation from other combinations, the documentation should include details of such calculations and/or extrapolations, and of tests undertaken to verify the accuracy of the calculations undertaken (including details of the mathematical model for calculating performance of such combinations, and of measurements taken to verify this model).
4. The rated energy efficiency ratio ( $EER_{rated}$ ) and, when applicable, rated coefficient of performance ( $COP_{rated}$ ) for single and double duct air conditioners shall be established at the standard rating conditions as defined in Table 2 below.
5. The calculation of seasonal electricity consumption for cooling (and/or heating) shall take into account electric energy consumption of all relevant modes of operation, as defined in Table 3 below, using operational hours, as defined in Table 4 below.
6. The comfort fan efficiency shall be determined on the basis of the nominal air flow rate of the unit divided by the nominal electric power input of the unit.



Table 1

Cooling and heating season bins ( $j$  = bin index,  $T_j$  = outdoor temperature,  $h_j$  = hours per annum per bin) where 'db' = dry bulb temperature

COOLING SEASON			HEATING SEASON				
j #	$T_j$ °C db	$h_j$ h/annum	j #	$T_j$ °C db	$h_j$ h/annum		
					Average	Warmer	Colder
1	17	205	1 to 8	- 30 to - 23	0	0	0
2	18	227	9	- 22	0	0	1
3	19	225	10	- 21	0	0	6
4	20	225	11	- 20	0	0	13
5	21	216	12	- 19	0	0	17
6	22	215	13	- 18	0	0	19
7	23	218	14	- 17	0	0	26
8	24	197	15	- 16	0	0	39
9	25	178	16	- 15	0	0	41
10	26	158	17	- 14	0	0	35
11	27	137	18	- 13	0	0	52
12	28	109	19	- 12	0	0	37
13	29	88	20	- 11	0	0	41
14	30	63	21	- 10	1	0	43
15	31	39	22	- 9	25	0	54
16	32	31	23	- 8	23	0	90
17	33	24	24	- 7	24	0	125
18	34	17	25	- 6	27	0	169
19	35	13	26	- 5	68	0	195
20	36	9	27	- 4	91	0	278
21	37	4	28	- 3	89	0	306
22	38	3	29	- 2	165	0	454
23	39	1	30	- 1	173	0	385
24	40	0	31	0	240	0	490
			32	1	280	0	533
			33	2	320	3	380
			34	3	357	22	228
			35	4	356	63	261
			36	5	303	63	279
			37	6	330	175	229
			38	7	326	162	269
			39	8	348	259	233
			40	9	335	360	230
			41	10	315	428	243
			42	11	215	430	191
			43	12	169	503	146
			44	13	151	444	150
			45	14	105	384	97
			46	15	74	294	61
<b>Total h.</b>		<b>2 602</b>	<b>Total h.</b>		<b>4 910</b>	<b>3 590</b>	<b>6 446</b>

Table 2

**Standard rating conditions, temperatures in 'dry bulb' air temperature**

('wet bulb' indicated in brackets)

Appliance	Function	Indoor air temperature (°C)	Outdoor air temperature (°C)
air conditioners, excluding single duct air conditioners	cooling	27 (19)	35 (24)
	heating	20 (max. 15)	7(6)
single duct air conditioner	cooling	35 (24)	35 (24) (*)
	heating	20 (12)	20 (12) (*)

(\*) In case of single duct air conditioners the condenser (evaporator) when cooling (heating) is not supplied with outdoor air, but indoor air.

Table 3

**Reference design conditions, temperatures in 'dry bulb' air temperature**

('wet bulb' indicated in brackets)

Function/season	Indoor air temperature (°C)	Outdoor air temperature (°C)	Bivalent temperature (°C)	Operating limit temperature (°C)
	$T_{in}$	$T_{designc}/T_{designh}$	$T_{biv}$	$T_{ol}$
cooling	27 (19)	$T_{designc} = 35 (24)$	n.a.	n.a.
heating/Average	20 (15)	$T_{designh} = - 10 (- 11)$	max. 2	max. - 7
heating/Warmer		$T_{designh} = 2 (1)$	max. 7	max. 2
heating/Colder		$T_{designh} = - 22 (- 23)$	max. - 7	max. - 15

Table 4

**Operational hours per type of appliance per functional mode to be used for calculation of electricity consumption**

Type of appliance/functionality (if applicable)	Unit	Heating season	On mode	Thermostat-off mode	Standby mode	Off mode	Crankcase heater mode
			cooling: $H_{CE}$ heating: $H_{HE}$	$H_{TO}$	$H_{SB}$	$H_{OFF}$	$H_{CK}$

**Air conditioners, except single and double duct air conditioner**

Cooling mode, if appliance offers cooling only	h/annum		350	221	2 142	5 088	7 760	
Cooling and heating modes, if appliance offers both modes	Cooling mode	h/annum		350	221	2 142	0	2 672
	Heating mode	h/annum	Average	1 400	179	0	0	179
			Warmer	1 400	755	0	0	755
			Colder	2 100	131	0	0	131

Type of appliance/functionality (if applicable)	Unit	Heating season	On mode	Thermostat-off mode	Standby mode	Off mode	Crankcase heater mode
			cooling: $H_{CE}$ heating: $H_{HE}$	$H_{TO}$	$H_{SB}$	$H_{OFF}$	$H_{CK}$
Heating mode, if appliance offers heating only	h/annum	Average	1 400	179	0	3 672	3 851
		Warmer	1 400	755	0	4 345	4 476
		Colder	2 100	131	0	2 189	2 944

**Double duct air conditioner**

Cooling mode, if appliance offers cooling only		h/60 min		1	n/a	n/a	n/a	n/a
Cooling and heating modes, if appliance offers both modes	Cooling mode	h/60 min		1	n/a	n/a	n/a	n/a
	Heating mode	h/60 min		1	n/a	n/a	n/a	n/a
Heating mode, if appliance offers heating only		h/60 min		1	n/a	n/a	n/a	n/a

**Single duct air conditioner**

Cooling mode		h/60 min		1	n/a	n/a	n/a	n/a
Heating mode		h/60 min		1	n/a	n/a	n/a	n/a

## ANNEX III

**Verification procedure for market surveillance purposes**

When performing the market surveillance checks referred to in Article 3(2) of Directive 2009/125/EC, the authorities of the Member States shall apply the following verification procedure for the requirements set out in Annex I.

1. The authorities of the Member State shall test one single unit.
2. The air conditioner model, except single and double duct air conditioners, shall be considered to comply with the requirements set out in Annex I, as applicable, to this Regulation, if its seasonal energy efficiency ratio (SEER), or seasonal coefficient for performance (SCOP), if applicable, is not less than the declared value minus 8 % at the declared capacity of the unit. The SEER and SCOP values shall be established in accordance with Annex II.

The model of a single and double duct air conditioner shall be considered to comply with the requirements set out in Annex I, as applicable, to this Regulation, if the results for off-mode and standby-mode conditions do not exceed the limit values by more than 10 %, and if the energy efficiency ratio ( $EER_{rated}$ ), or coefficient for performance ( $COP_{rated}$ ), if applicable, is not less than the declared value minus 10 %. The EER and COP values shall be established in accordance with Annex II.

The air conditioner model shall be considered to comply with the requirements set out in this Regulation, as applicable, if the maximum sound power level does not exceed more than 2 dB(A) of the declared value.

3. If the result referred to in point 2 is not achieved, the market surveillance authority shall randomly select three additional units of the same model for testing.
4. The air conditioner model, except single and double duct air conditioners, shall be considered to comply with the requirements set out in Annex I, as applicable, to this Regulation, if the average of the three units for the seasonal energy efficiency ratio (SEER), or seasonal coefficient of performance (SCOP), if applicable, is not less than the declared value minus 8 % at the declared capacity of the unit. The SEER and SCOP values shall be established in accordance with Annex II.

The model of a single and double duct air conditioner shall be considered to comply with the requirements set out in Annex I, as applicable, to this Regulation, if the average of the results of the three units for off-mode and standby-mode conditions do not exceed the limit values by more than 10 %, and if the average of the energy efficiency ratio ( $EER_{rated}$ ), or coefficient of performance ( $COP_{rated}$ ), if applicable, is not less than the declared value minus 10 %. The EER and COP values shall be established in accordance with Annex II.

The air conditioner model shall be considered to comply with the requirements set out in this Regulation, as applicable, if the average of the maximum sound power level does not exceed more than 2 dB(A) of the declared value.

5. If the results referred to in point 4 are not achieved, the model shall be considered not to comply with this Regulation.

For the purposes of checking conformity with the requirements of this Regulation, Member States shall apply the procedures referred to in Annex II, and harmonised standards the reference numbers of which have been published in the *Official Journal of the European Union*, or other reliable, accurate and reproducible calculation and measurement methods, which take into account the generally recognised state-of-the-art.

## ANNEX IV

**Benchmarks**

At the time of entry into force of this Regulation, the best available technology on the market for air conditioners in terms of their energy performance was identified as follows:

**Benchmarks for air conditioners**

Air conditioners, excluding double duct and single duct air conditioners		Double duct air conditioner		Single duct air conditioner	
SEER	SCOP	EER	COP	EER	COP
8,50	5,10	3,00 (*)	3,15	3,15 (*)	2,60

Benchmark for the level of GWP of the refrigerant used in the air conditioner is  $GWP \leq 20$ .

(\*) Based on efficiency of evaporatively cooled single duct air conditioners.

**COMMISSION REGULATION (EU) No 207/2012**  
**of 9 March 2012**  
**on electronic instructions for use of medical devices**  
 (Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices <sup>(1)</sup>, and in particular Article 9(10) thereof,

Having regard to Council Directive 93/42/EEC of 14 June 1993 concerning medical devices <sup>(2)</sup>, and in particular Article 11(14) thereof,

Whereas:

- (1) For some medical devices the provision of instructions for use in electronic form instead of in paper form can be beneficial for professional users. It can reduce the environmental burden and improve the competitiveness of the medical devices industry by reducing costs, while maintaining or improving the level of safety.
- (2) Such possibility of providing instructions for use in electronic form instead of in paper form should be limited to certain medical devices and accessories intended to be used in specific conditions. In any case, for reasons of safety and efficiency users should always have the possibility to obtain those instructions for use in paper form on request.
- (3) In order to reduce potential risks as far as possible, the appropriateness of the provision of instructions for use in electronic form should be subject to a specific risk assessment by the manufacturer.
- (4) In order to ensure that users have access to the instructions for use, appropriate information about access to those instructions for use in electronic form and about the right to request the instructions for use in paper form, should be provided.
- (5) To ensure unconditional access to the instructions for use in electronic form and to facilitate the communication of updates and of product alerts, the instructions for use in electronic form should also be available through a website.
- (6) Regardless of the language obligations imposed on manufacturers by the law of the Member States, manufacturers who provide instructions for use in electronic form should indicate on their website in which Union languages those instructions are available.
- (7) Except for medical devices of Class I, as defined in Annex IX to Directive 93/42/EEC, the fulfilment of the

obligations laid down in this Regulation should be reviewed by a notified body during the procedure applicable for conformity assessment based on a specific sampling method.

- (8) As the protection of the right to privacy of natural persons with respect to the processing of personal data should be ensured by manufacturers and notified bodies as well, it is appropriate to provide that websites containing instructions for use of a medical device fulfil the requirements of Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data <sup>(3)</sup>.
- (9) In order to ensure safety and consistency, instructions for use in electronic form which are provided in addition to complete instructions for use in paper form should be covered by this Regulation as regards limited requirements in relation to their contents and websites.
- (10) It is appropriate to provide for a deferred application of this Regulation so as to facilitate the smooth transition to the new system and to allow all operators and Member States time to adapt to it.
- (11) The measures provided for in this Regulation are in accordance with the opinion of the Committee set up by Article 6(2) of Directive 90/385/EEC,

HAS ADOPTED THIS REGULATION:

*Article 1*

This Regulation establishes the conditions under which the instructions for use of medical devices referred to in point 15 of Annex 1 to Directive 90/385/EEC and in point 13 of Annex I to Directive 93/42/EEC may be provided in electronic form instead of in paper form.

It also establishes certain requirements concerning instructions for use in electronic form which are provided in addition to complete instructions for use in paper form relating to their contents and websites.

*Article 2*

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

- (a) 'instructions for use' means information provided by the manufacturer to inform the user of the device of its safe and proper use, of its expected performances and of any

<sup>(1)</sup> OJ L 189, 20.7.1990, p. 17.

<sup>(2)</sup> OJ L 169, 12.7.1993, p. 1.

<sup>(3)</sup> OJ L 281, 23.11.1995, p. 31.

precautions to be taken as outlined in the relevant parts of point 15 of Annex 1 to Directive 90/385/EEC and of point 13 of Annex I to Directive 93/42/EEC;

- (b) 'instructions for use in electronic form' means instructions for use displayed in electronic form by the device, contained in portable electronic storage media supplied by the manufacturer together with the device, or instructions for use available through a website;
- (c) 'professional users' means persons using the medical device in the course of their work and in the framework of a professional healthcare activity;
- (d) 'fixed installed medical devices' means devices and their accessories which are intended to be installed, fastened or otherwise secured at a specific location in a healthcare facility so that they cannot be moved from this location or detached without using tools or apparatus, and which are not specifically intended to be used within a mobile healthcare facility.

#### Article 3

1. Subject to the conditions set out in paragraph 2, manufacturers may provide instructions for use in electronic form instead of in paper form where those instructions relate to any of the following devices:

- (a) active implantable medical devices and their accessories covered by Directive 90/385/EEC intended to be used exclusively for the implantation or programming of a defined active implantable medical device;
- (b) implantable medical devices and their accessories covered by Directive 93/42/EEC intended to be used exclusively for the implantation of a defined implantable medical device;
- (c) fixed installed medical devices covered by Directive 93/42/EEC;
- (d) medical devices and their accessories covered by Directives 90/385/EEC and 93/42/EEC fitted with a built-in system visually displaying the instructions for use;
- (e) stand-alone software covered by Directive 93/42/EEC.

2. Manufacturers may provide instructions for use in electronic form instead of in paper form for the devices listed in paragraph 1 under the following conditions:

- (a) the devices and accessories are intended for exclusive use by professional users;
- (b) the use by other persons is not reasonably foreseeable.

#### Article 4

1. Manufacturers of devices referred to in Article 3 that provide instructions for use in electronic form instead of in paper form shall undertake a documented risk assessment which shall cover at least the following elements:

- (a) knowledge and experience of the intended users in particular regarding the use of the device and user needs;
- (b) characteristics of the environment in which the device will be used;
- (c) knowledge and experience of the intended user of the hardware and software needed to display the instructions for use in electronic form;
- (d) access of the user to the reasonably foreseeable electronic resources needed at the time of use;
- (e) performance of safeguards to ensure that the electronic data and content are protected from tampering;
- (f) safety and back-up mechanisms in the event of a hardware or software fault, particularly if the instructions for use in electronic form are integrated within the device;
- (g) foreseeable medical emergency situations requiring the provision of information in paper form;
- (h) impact caused by the temporary unavailability of the specific website or of the Internet in general, or of their access in the healthcare facility as well as the safety measures available to cope with such a situation;
- (i) evaluation of the time period within which the instructions for use shall be provided in paper form at the users request.

2. The risk assessment for the provision of the instructions for use in electronic form shall be updated in view of the experience gained in the post-marketing phase.

#### Article 5

Manufacturers of devices referred to in Article 3 may provide instructions for use in electronic form instead of in paper form under the following conditions:

- (1) the risk assessment referred to in Article 4 shall demonstrate that providing instructions for use in electronic form maintains or improves the level of safety obtained by providing the instructions for use in paper form;
- (2) they shall provide instructions for use in electronic form in all Member States where the product is made available or put into service, unless duly justified in the risk assessment referred to in Article 4;

- (3) they shall have a system in place to provide the instructions for use in printed paper form at no additional cost for the user, within the time period set out in the risk assessment referred to in Article 4 and at the latest within 7 calendar days of receiving a request from the user or at the time of delivery of the device if so requested at the time of order;
- (4) they shall provide, on the device or on a leaflet, information on foreseeable medical emergency situations and, for devices fitted with a built-in system visually displaying the instructions for use, information on how to start the device;
- (5) they shall ensure the proper design and functioning of the instructions for use in electronic form and provide verification and validation evidence to this effect;
- (6) for medical devices fitted with a built-in system visually displaying the instructions for use, they shall ensure that displaying the instructions for use does not impede the safe use of the device, in particular life-monitoring or life-supporting functions;
- (7) they shall provide, in their catalogue or in other appropriate device information support, information on software and hardware requirements needed to display the instructions for use;
- (8) they shall have a system in place to clearly indicate when the instructions for use have been revised and to inform each user of the device thereof if the revision was necessary for safety reasons;
- (9) for devices with a defined expiry date, except implantable devices, they shall keep the instructions for use available for the users in electronic form for at least 2 years after the end of the expiry date of the last produced device;
- (10) for devices without a defined expiry date and for implantable devices, they shall keep the instructions for use available for the users in electronic form for a period of 15 years after the last device has been manufactured.

#### Article 6

1. Manufacturers shall clearly indicate that the instructions for use of the device are supplied in electronic form instead of in paper form.

That information shall be provided on the packaging for each unit or, where appropriate, on the sales packaging. In the case of fixed installed medical devices, that information shall also be provided on the device itself.

2. Manufacturers shall provide information on how to access the instructions for use in electronic form.

That information shall be provided as set out in the second subparagraph of paragraph 1 or, if not practicable, in a paper document supplied with each device.

3. The information on how to access the instructions for use in electronic form shall contain the following:

- (a) any information needed to view the instructions for use;
- (b) a unique reference, giving direct access, and any other information needed by the user to identify and access the appropriate instructions for use;
- (c) relevant manufacturer contact details;
- (d) where, how and within which time instructions for use in paper form can be requested and shall be obtained at no additional cost in conformity with Article 5.

4. Where a part of the instructions for use is intended to be provided to the patient, that part shall not be provided in electronic form.

5. The instructions for use in electronic form shall be available entirely as text which may contain symbols and graphics with at least the same information as the instructions for use in paper form. Video or audio files may be offered in addition to the text.

#### Article 7

1. Where manufacturers provide the instructions for use in electronic form on an electronic storage medium together with the device or where the device itself is fitted with a built-in system visually displaying the instructions for use, the instructions for use in electronic form shall also be made accessible to the users through a website.

2. Any website containing instructions for use of a device which are provided in electronic form instead of in paper form shall comply with the following requirements:

- (a) the instructions for use shall be provided in a commonly used format that can be read with freely available software;
- (b) it shall be protected against hardware and software intrusion;
- (c) it shall be provided in such a way that the server downtime and display errors are reduced as far as possible;
- (d) it shall mention in which Union languages the manufacturer provides the instructions for use in electronic form;
- (e) it shall fulfil the requirements of Directive 95/46/EC;



- (f) the Internet address as displayed in accordance with Article 6(2) shall be stable and directly accessible during the periods set out in points (9) and (10) of Article 5;
- (g) all previous versions of the instructions for use issued in electronic form and their date of publication shall be available on the website.

*Article 8*

Except for medical devices of Class I, as defined in Annex IX to Directive 93/42/EEC, the fulfilment of the obligations laid down in Articles 4 to 7 of this Regulation shall be reviewed by a notified body during the procedure applicable for conformity assessment as referred to in Article 9 of Directive 90/385/EEC or Article 11 of Directive 93/42/EEC. The review shall be based on a specific sampling method adapted to the class and the complexity of the product.

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

Done at Brussels, 9 March 2012.

*Article 9*

Instructions for use in electronic form which are provided in addition to complete instructions for use in paper form shall be consistent with the content of the instructions for use in paper form.

Where such instructions for use are provided through a website, this website shall fulfil the requirements set out in points (b), (e) and (g) of paragraph 2 of Article 7.

*Article 10*

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

It shall apply from 1 March 2013.

*For the Commission*  
*The President*  
José Manuel BARROSO

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## COMMISSION IMPLEMENTING REGULATION (EU) No 208/2012

of 9 March 2012

**amending Implementing Regulation (EU) No 562/2011 adopting the plan allocating to the Member States resources to be charged to the 2012 budget year for the supply of food from intervention stocks for the benefit of the most deprived persons in the European Union and derogating from certain provisions of Regulation (EU) No 807/2010**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) <sup>(1)</sup>, and in particular points (f) and (g) of Article 43, in conjunction with Article 4 thereof,

Having regard to Council Regulation (EC) No 2799/98 of 15 December 1998 establishing agrimonetary arrangements for the euro <sup>(2)</sup>, and in particular Article 3(2) thereof,

Whereas:

- (1) Article 27 of Regulation (EC) No 1234/2007 as amended by Regulation (EU) No 121/2012 of the European Parliament and of the Council <sup>(3)</sup> has established a scheme whereby food products may be distributed to the most deprived persons in the Union. For that purpose, products in intervention stocks may be made available or, where intervention stocks suitable for the food distribution scheme are not available, food products may be purchased on the market. For 2012 and 2013, that scheme is included in the list of measures eligible for financing by the European Agricultural Guarantee Fund (EAGF) set out in Council Regulation (EC) No 1290/2005 of 21 June 2005 on the financing of the common agricultural policy <sup>(4)</sup>, within an annual ceiling of EUR 500 million.
- (2) In accordance with Article 27(3) of Regulation (EC) No 1234/2007 the Commission has to adopt annual plans. The annual distribution plan for 2012 was adopted on 10 June 2011 by Commission Implementing Regulation (EU) No 562/2011 <sup>(5)</sup> solely on the basis of products available in intervention stocks. The additional resources made available on the 2012 budget year for the distribution of food products to the most deprived persons in the Union, as a result of the amendment of Article 27 of Regulation (EC) No 1234/2007 by Regulation (EU) No 121/2012, should be allocated to the Member States.
- (3) In order to enforce the annual budgetary ceiling, the intra-Union transfer costs, where relevant, should be included into the total financial allocation made

available for each Member State to implement the 2012 distribution plan. Moreover, the deadlines fixed by Article 9 of Commission Regulation (EU) No 807/2010 of 14 September 2010 laying down detailed rules for the supply of food from intervention stocks for the benefit of the most deprived persons in the Union <sup>(6)</sup> for the requests for payment and the execution of payments by the competent authorities should be adjusted, in order to ensure that the resources allocated within the 2012 distribution plan are only eligible for Union support if those payments are made in the 2012 budget year.

- (4) Taking into account the shortened time-frame left to the Member States for the implementation of the 2012 distribution plan as a consequence of the date of entry into force of Regulation (EU) No 121/2012, it is appropriate to grant an extension of the deadlines provided for in Article 3(1) and (3) of Regulation (EU) No 807/2010 as regards the implementation period of the annual plan and the completion of the payment operations for products mobilised on the market.
- (5) That revision of the distribution plan for 2012 being made at a time when national administrative arrangements for the implementation of the plan should be approaching completion, the quantities of products available in intervention stocks which are reallocated following the decision of Finland to renounce to a part of its allocation of skimmed milk powder or to reassessment of the exact quantities in intervention storage should not be taken into account for calculating whether Member States have respected the obligation laid down in the second and third subparagraphs of Article 3(2) of Regulation (EU) No 807/2010 to have withdrawn 70 % of cereals and skimmed milk powder by the deadlines fixed in that Article.
- (6) In view of the fact that the implementation period of the 2012 distribution plan is already advanced and to allow Member States as much time as possible to proceed to the actions needed for the implementation of the amended plan, this Regulation should enter into force on the day of its publication.
- (7) Implementing Regulation (EU) No 562/2011 should therefore be amended accordingly.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for the Common Organisation of Agricultural Markets,

<sup>(1)</sup> OJ L 299, 16.11.2007, p. 1.

<sup>(2)</sup> OJ L 349, 24.12.1998, p. 1.

<sup>(3)</sup> OJ L 44, 16.2.2012, p. 1.

<sup>(4)</sup> OJ L 209, 11.8.2005, p. 1.

<sup>(5)</sup> OJ L 152, 11.6.2011, p. 24.

<sup>(6)</sup> OJ L 242, 15.9.2010, p. 9.

HAS ADOPTED THIS REGULATION:

*Article 1*

Implementing Regulation (EU) No 562/2011 is amended as follows:

(1) Articles 1 and 2 are replaced by the following:

*'Article 1*

1. In 2012, the distribution of food to the most deprived persons in the Union under Article 27 of Regulation (EC) No 1234/2007 shall be implemented in accordance with the annual distribution plan set out in Annex I to this Regulation.

Financial resources available to implement the 2012 plan can be used by Member States within the limits set out in point (a) of Annex I.

The quantities of each type of product to be withdrawn from intervention stocks are set out in point (b) of that Annex.

Indicative allocations to Member States for the purchase of food products on the Union market are set out in point (c) of that Annex.

2. The use of cereals as payment for mobilising rice products on the market is authorised, as referred to in Article 4(2) of Regulation (EU) No 807/2010.

*Article 2*

The intra-Union transfer of products listed in Annex II to this Regulation shall be authorised, subject to the conditions laid down in Article 8 of Regulation (EU) No 807/2010. Indicative allocations to Member States for the reimbursement of the cost of intra-Union transfers, as required under the annual distribution plan referred to in Article 1, are set out in point (d) of Annex I.;

(2) the following Articles 2a to 2d are inserted:

*'Article 2a*

By way of derogation from Article 3(1) of Regulation (EU) No 807/2010, the implementation period of the 2012 distribution plan shall end on 28 February 2013.

*Article 2b*

By way of derogation from Article 3(3) of Regulation (EU) No 807/2010, for the 2012 distribution plan, payment operations for products to be supplied by the operator shall, in case of products to be mobilised on the market under Article 2(3)(a)(iii) and (iv) of Regulation (EU) No 807/2010, be effected before 15 October 2012.

*Article 2c*

For the 2012 distribution plan, the first sentence of the second subparagraph and the third subparagraph of Article 3(2) of Regulation (EU) No 807/2010, where relevant, shall not apply to the following quantities of intervention stocks:

- (a) 5,46 tonnes of cereals stored in the United Kingdom and allocated to Bulgaria;
- (b) 0,651 tonne of cereals stored in Finland and allocated to Bulgaria;
- (c) 249,04 tonnes of cereals stored in France and allocated to France;
- (d) 635,325 tonnes of skimmed milk powder stored in Estonia and allocated to Estonia.

*Article 2d*

By way of derogation from Article 9 of Regulation (EU) No 807/2010, for the 2012 distribution plan, requests for payment shall be submitted to the competent authorities of each Member State by 30 September 2012. Except in cases of *force majeure*, requests submitted after that date shall not be accepted.

Expenditure, within the limits set out in point (a) of Annex I, shall only be eligible for Union financing if it has been paid by the Member State to the beneficiary by 15 October 2012 at the latest.;

(3) Annexes I and II are replaced by the text set out in the Annex to this Regulation.

*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 be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 9 March 2012.

For the Commission  
The President  
José Manuel BARROSO

## ANNEX

## ANNEX I

## ANNUAL DISTRIBUTION PLAN FOR 2012

(a) Total amounts of financial resources broken down per Member State:

(EUR)	
Member State	Amount
Belgium	11 710 463
Bulgaria	21 439 346
Czech Republic	135 972
Estonia	2 359 486
Ireland	2 594 467
Greece	21 651 199
Spain	80 401 345
France	70 563 823
Italy	95 641 425
Latvia	5 558 220
Lithuania	7 491 644
Luxembourg	171 704
Hungary	13 715 022
Malta	721 992
Poland	75 296 812
Portugal	19 332 607
Romania	60 689 367
Slovenia	2 533 778
Slovakia	5 098 384
Finland	2 892 944
Total	500 000 000

(b) Quantity of each type of product to be withdrawn from Union intervention stocks for distribution per Member State within the limits set out in point (a) of this Annex:

(tonnes)		
Member State	Cereals	Skimmed milk powder
Belgium		1 560,275
Bulgaria	39 150,874	
Czech Republic	450,000	

(tonnes)

Member State	Cereals	Skimmed milk powder
Estonia		635,325
Ireland		727,900
Greece		2 682,575
Spain		10 093,975
France	249,040	8 858,925
Italy		12 337,975
Latvia		870,050
Lithuania		1 032,575
Hungary		1 807,425
Malta	1 230,373	
Poland		9 662,825
Portugal		2 524,725
Romania	112 527,069	
Slovenia		287,750
Slovakia	8 976,092	
Finland		489,300
Total	162 583,448	53 571,600

- (c) Indicative allocations to Member States for the purchase of food products on the Union market within the limits set out in point (a) of this Annex:

(EUR)

Member State	Amount
Belgium	8 346 393
Bulgaria	14 004 438
Czech Republic	70 619
Estonia	1 136 698
Ireland	1 200 145
Greece	15 656 380
Spain	57 977 800
France	51 172 604
Italy	68 479 620

(EUR)

Member State	Amount
Latvia	3 736 468
Lithuania	5 281 095
Luxembourg	161 225
Hungary	9 751 550
Malta	493 784
Poland	54 100 415
Portugal	13 763 634
Romania	39 979 504
Slovenia	1 883 893
Slovakia	3 590 632
Finland	1 871 094
Total	352 657 991

- (d) Indicative allocations to Member States for the reimbursement of intra-Union transfer costs within the limits set out in point (a) of this Annex:

(EUR)

Member State	Amount
Bulgaria	2 300 431
Czech Republic	12 211
Greece	126 066
Spain	401 345
France	17 915
Italy	399 005
Latvia	5 509
Hungary	61 128
Malta	63 361
Poland	205 907
Portugal	108 700
Romania	5 970 071
Slovenia	7 073
Slovakia	305 884
Finland	15 394
Total	10 000 000

## ANNEX II

(a) Intra-Union transfers of cereals authorised under the distribution plan for the 2012 budget year:

	Quantity (in tonnes)	Holder	Recipient
1	33 989,414	Agency for Rural Affairs, Finland	Държавен фонд "Земеделие" — Разплащателна агенция, Bulgaria
2	5 161,460	RPA, United Kingdom	Държавен фонд "Земеделие" — Разплащателна агенция, Bulgaria
3	450,000	SJV, Sweden	SZIF, Czech Republic
4	1 230,373	SJV, Sweden	Ministry for Resources and Rural Affairs Paying Agency, Malta
5	16 856,043	BLE, Germany	Agenția de Plăți și Intervenție pentru Agricultură, Romania
6	41 360,295	Agency for Rural Affairs, Finland	Agenția de Plăți și Intervenție pentru Agricultură, Romania
7	54 310,731	SJV, Sweden	Agenția de Plăți și Intervenție pentru Agricultură, Romania
8	147,000	FranceAgriMer, France	Pôdohospodárska platobná agentúra, Slovakia
9	8 829,092	SJV, Sweden	Pôdohospodárska platobná agentúra, Slovakia

(b) Intra-Union transfers of skimmed milk powder authorised under the distribution plan for the 2012 budget year:

	Quantity (in tonnes)	Holder	Recipient
1	2 682,575	BLE, Germany	ΟΡΕΚΕΡΕ, Greece
2	330,350	SZIF, Czech Republic	FEGA, Spain
3	6 308,425	OFI, Ireland	FEGA, Spain
4	3 455,200	RPA, United Kingdom	FEGA, Spain
5	2 118,875	RPA, United Kingdom	FranceAgriMer, France
6	7 904,825	BIRB, Belgium	AGEA, Italy
7	1 476,375	OFI, Ireland	AGEA, Italy
8	2 749,625	Dienst Regelingen Roermond, Netherlands	AGEA, Italy
9	207,150	SJV, Sweden	AGEA, Italy
10	870,050	Lietuvos žemės ūkio ir maisto produktų rinkos reguliavimo agentūra, Lithuania	Rural Support Service, Latvia
11	1 807,425	RPA, United Kingdom	Mezőgazdasági és Vidékfejlesztési Hivatal, Hungary
12	3 294,150	BLE, Germany	ARR, Poland

	Quantity (in tonnes)	Holder	Recipient
13	1 675,025	Lietuvos žemės ūkio ir maisto produktų rinkos reguliavimo agentūra, Lithuania	ARR, Poland
14	4 692,825	RPA, United Kingdom	ARR, Poland
15	2 524,275	RPA, United Kingdom	IFAP I.P. Portugal
16	287,750	Dienst Regelingen Roermond, Netherlands	Agencija Republike Slovenije za kmetijske trge in razvoj podeželja, Slovenia
17	489,300	Dienst Regelingen Roermond, Netherlands	Agency for Rural Affairs, Finland'



**COMMISSION IMPLEMENTING REGULATION (EU) No 209/2012****of 9 March 2012****establishing the standard import values for determining the entry price of certain fruit and vegetables**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) <sup>(1)</sup>,

Having regard to Commission Implementing Regulation (EU) No 543/2011 of 7 June 2011 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 in respect of the fruit and vegetables and processed fruit and vegetables sectors <sup>(2)</sup>, and in particular Article 136(1) thereof,

Whereas:

- (1) Implementing Regulation (EU) No 543/2011 lays down, pursuant to the outcome of the Uruguay Round multi-lateral trade negotiations, the criteria whereby the

Commission fixes the standard values for imports from third countries, in respect of the products and periods stipulated in Annex XVI, Part A thereto.

- (2) The standard import value is calculated each working day, in accordance with Article 136(1) of Implementing Regulation (EU) No 543/2011, taking into account variable daily data. Therefore this Regulation should enter into force on the day of its publication in the *Official Journal of the European Union*,

HAS ADOPTED THIS REGULATION:

*Article 1*

The standard import values referred to in Article 136 of Implementing Regulation (EU) No 543/2011 are fixed in the Annex to this Regulation.

*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 be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 9 March 2012.

*For the Commission,  
On behalf of the President,  
José Manuel SILVA RODRÍGUEZ  
Director-General for Agriculture and  
Rural Development*

<sup>(1)</sup> OJ L 299, 16.11.2007, p. 1.

<sup>(2)</sup> OJ L 157, 15.6.2011, p. 1.

## ANNEX

**Standard import values for determining the entry price of certain fruit and vegetables**

(EUR/100 kg)		
CN code	Third country code <sup>(1)</sup>	Standard import value
0702 00 00	IL	103,0
	JO	78,3
	MA	68,2
	SN	207,5
	TN	80,7
	TR	95,1
	ZZ	105,5
0707 00 05	JO	183,3
	TR	172,1
	ZZ	177,7
0709 91 00	EG	85,9
	ZZ	85,9
0709 93 10	MA	55,8
	TR	134,6
	ZZ	95,2
0805 10 20	EG	48,8
	IL	68,4
	MA	56,6
	TN	58,6
	TR	72,2
	ZZ	60,9
0805 50 10	BR	43,7
	EG	41,7
	MA	69,1
	TR	50,4
	ZZ	51,2
0808 10 80	BR	83,3
	CA	117,2
	CL	103,0
	CN	110,7
	MK	31,8
	US	159,7
	ZZ	101,0
0808 30 90	AR	92,3
	CL	106,5
	CN	44,8
	ZA	94,2
	ZZ	84,5

<sup>(1)</sup> Nomenclature of countries laid down by Commission Regulation (EC) No 1833/2006 (OJ L 354, 14.12.2006, p. 19). Code 'ZZ' stands for 'of other origin'.

## COMMISSION IMPLEMENTING REGULATION (EU) No 210/2012

of 9 March 2012

fixing the allocation coefficient to be applied to applications for import licences for olive oil lodged from 5 to 6 March 2012 under the Tunisian tariff quota and suspending the issue of import licences for the month of March 2012

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) <sup>(1)</sup>,

Having regard to Commission Regulation (EC) No 1301/2006 of 31 August 2006 laying down common rules for the administration of import tariff quotas for agricultural products managed by a system of import licences <sup>(2)</sup>, and in particular Article 7(2) thereof,

Whereas:

- (1) Article 3(1) and (2) of Protocol No 1 <sup>(3)</sup> to the Euro-Mediterranean Agreement establishing an association between the European Communities and their Member States, of the one part, and the Republic of Tunisia, of the other part <sup>(4)</sup>, opens a tariff quota at a zero rate of duty for imports of untreated olive oil falling within CN codes 1509 10 10 and 1509 10 90, wholly obtained in Tunisia and transported direct from that country to the European Union, up to the limit laid down for each year.
- (2) Article 2(2) of Commission Regulation (EC) No 1918/2006 of 20 December 2006 opening and providing for the administration of tariff quota for

olive oil originating in Tunisia <sup>(5)</sup> lays down monthly quantitative limits for the issue of import licences.

- (3) Import licence applications have been submitted to the competent authorities under Article 3(1) of Regulation (EC) No 1918/2006 in respect of a total quantity exceeding the limit laid down for the month of March in Article 2(2) of that Regulation.
- (4) In these circumstances, the Commission must set an allocation coefficient allowing import licences to be issued in proportion to the quantity available.
- (5) Since the limit for the month of March has been reached, no more import licences can be issued for that month,

HAS ADOPTED THIS REGULATION:

*Article 1*

The quantities for which import licence applications were lodged for 5 and 6 March 2012 under Article 3(1) of Regulation (EC) No 1918/2006 shall be multiplied by an allocation coefficient of 57,099350 %.

The issue of import licences in respect of amounts applied for as from 12 March 2012 shall be suspended for March 2012.

*Article 2*

This Regulation shall enter into force on 10 March 2012.

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

Done at Brussels, 9 March 2012.

For the Commission,  
On behalf of the President,  
José Manuel SILVA RODRÍGUEZ  
Director-General for Agriculture and  
Rural Development

<sup>(1)</sup> OJ L 299, 16.11.2007, p. 1.

<sup>(2)</sup> OJ L 238, 1.9.2006, p. 13.

<sup>(3)</sup> OJ L 97, 30.3.1998, p. 57.

<sup>(4)</sup> OJ L 97, 30.3.1998, p. 2.

<sup>(5)</sup> OJ L 365, 21.12.2006, p. 84.









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