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#### REGULATIONS

#### COMMISSION REGULATION (EC) No 497/2009

#### of 12 June 2009

establishing the standard import values for determining the entry price of certain fruit and vegetables

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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) (1),

Having regard to Commission Regulation (EC) No 1580/2007 of 21 December 2007 laying down implementing rules for Council Regulations (EC) No 2200/96, (EC) No 2201/96 and (EC) No 1182/2007 in the fruit and vegetable sector (²), and in particular Article 138(1) thereof,

Whereas:

Regulation (EC) No 1580/2007 lays down, pursuant to the outcome of the Uruguay Round multilateral 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 XV, Part A thereto,

HAS ADOPTED THIS REGULATION:

Article 1

The standard import values referred to in Article 138 of Regulation (EC) No 1580/2007 are fixed in the Annex hereto.

Article 2

This Regulation shall enter into force on 13 June 2009.

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

Done at Brussels, 12 June 2009.

For the Commission

Jean-Luc DEMARTY

Director-General for Agriculture and
Rural Development

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

<sup>(2)</sup> OJ L 350, 31.12.2007, p. 1.

 $\label{eq:annex} ANNEX$  Standard import values for determining the entry price of certain fruit and vegetables

(EUR/100 kg)

ay 1	mt · t · · · · t · (t)	(EUR/100 Rg)
CN code	Third country code (1)	Standard import value
0702 00 00	MA	37,3
	MK	35,9
	TR	41,3
	ZA	28,0
	ZZ	35,6
0707 00 05	JO	162,3
	MK	31,4
	TR	162,3
	ZZ	118,7
0709 90 70	TR	85,9
	ZZ	85,9
0805 50 10	AR	54,7
	TR	87,8
	ZA	65,6
	ZZ	69,4
0808 10 80	AR	82,8
	BR	76,6
	CL	79,2
	CN	99,5
	NZ	100,2
	US	117,5
	ZA	78,8
	ZZ	90,7
0809 10 00	TN	146,2
	TR	168,7
	ZZ	157,5
0809 20 95	TR	505,0
	ZZ	505,0
0809 30	TR	133,0
5557,35	US	340,6
	ZZ	236,8
0809 40 05	CL	118,9
	ZZ	118,9

<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 REGULATION (EC) No 498/2009

#### of 12 June 2009

amending Regulation (EC) No 639/2003 laying down detailed rules pursuant to Council Regulation (EC) No 1254/1999 as regards requirements for the granting of export refunds related to the welfare of live bovine animals during transport

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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) (1), and in particular Article 170 in conjunction with Article 4 thereof,

#### Whereas:

- Article 1 of Commission Regulation (EC) No 639/2003 (2) refers to the compliance with Community legislation concerning the protection of animals during transport as a condition for the payment of export refunds.
- (2) Following the judgments of the Court of Justice of the European Communities of 17 January 2008 in Joined Cases C-37/06 and C-58/06 and of 13 March 2008 in Case C-96/06 the link should be clarified between Regulation (EC) No 639/2003 and Council Regulation (EC) No 1/2005 of 22 December 2004 on the protection of animals during transport and related operations and amending Directives 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/97 (3).
- (3) The animal welfare rules of Regulation (EC) No 1/2005 which are addressed to the operators and which trigger, in any case of violation of these rules, the loss of the refund related to the violation concerned, should be clearly set out. In that context, Articles 2 and 3 and Articles 4 to 9 of Regulation (EC) No 1/2005 and the Annexes mentioned therein aim to specify provisions addressed to the operators which are in direct connection with the objective of the protection of animals whilst other provisions of that Regulation concern administrative rules.
- (4) Article 168 of Regulation (EC) No 1234/2007 and Regulation (EC) No 639/2003 provide that the respect of the animal welfare rules is a condition for the payment of export refunds. Therefore, it should be clearly set out that, without prejudice to cases of *force majeure* recognised by the case law of the Court of Justice, a violation of these animal welfare provisions does not

trigger a reduction but the loss of the export refund, related to the number of animals for which the welfare requirements were not respected. It equally results from these provisions as well as from the animal welfare rules contained in Articles 2 and 3 and Articles 4 to 9 of Regulation (EC) No 1/2005 and the Annexes mentioned therein that the refund shall be lost for the animals for which these welfare rules were not respected, irrespective of the concrete physical conditions of the animals.

(5) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for the Common Organisation of Agricultural Markets,

HAS ADOPTED THIS REGULATION:

#### Article 1

Regulation (EC) No 639/2003 is amended as follows:

1. the first subparagraph of Article 1 is replaced by the following:

Payment of export refunds for live bovine animals falling within CN code 0102 (hereinafter referred to as the animals), pursuant to Article 168 of Regulation (EC) No 1234/2007, shall be subject to compliance, during the transport of the animals to the first place of unloading in the third country of final destination, with the provisions of Articles 2 and 3 and Articles 4 to 9 of Council Regulation (EC) No 1/2005 (\*) and the Annexes mentioned therein, and with the provisions of this Regulation.

2. the first subparagraph of paragraph 1 of Article 5 is replaced by the following:

The total sum of the export refund per animal calculated in accordance with the second subparagraph shall not be paid for:

(a) animals which have died during transport, except as provided in paragraph 2;

<sup>(\*)</sup> OJ L 3, 5.1.2005, p. 1.';

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

<sup>(2)</sup> OJ L 93, 10.4.2003, p. 10.

<sup>(3)</sup> OJ L 3, 5.1.2005, p. 1.

- (b) animals which have given birth or aborted during transport before their first unloading in the third country of final destination;
- (c) animals for which, in the light of the documents referred to in Article 4(2) and/or all other elements at its disposal concerning compliance with this Regulation, the competent authority considers that Articles 2 and 3 and Articles 4 to 9 of Regulation (EC) No 1/2005 and the Annexes mentioned therein have not been complied with.'

#### Article 2

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

It shall apply to export declarations accepted after the date of entry into force of this Regulation.

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

Done at Brussels, 12 June 2009.

For the Commission

Mariann FISCHER BOEL

Member of the Commission

#### **DIRECTIVES**

#### **COMMISSION DIRECTIVE 2009/56/EC**

#### of 12 June 2009

correcting Directive 2008/126/EC amending Directive 2006/87/EC of the European Parliament and of the Council laying down technical requirements for inland waterway vessels, as regards its date of transposition

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 2006/87/EC of the European Parliament and of the Council of 12 December 2006 laying down technical requirements for inland waterway vessels and repealing Council Directive 82/714/EEC (¹), and in particular Article 20(1) thereof,

#### Whereas:

- (1) According to Article 2 of Commission Directive 2008/126/EC of 19 December 2008 amending Directive 2006/87/EC of the European Parliament and of the Council laying down technical requirements for inland waterway vessels (²), Member States are to transpose Directive 2008/126/EC with effect from 30 December 2008.
- (2) For technical reasons, Directive 2008/126/EC was not published in the Official Journal of the European Union before that date. Directive 2008/126/EC should therefore be corrected as regards its date of transposition.
- (3) In order to avoid distortions of competition as well as different levels of safety, the amendments to Directive 2006/87/EC should be implemented as quickly as

possible. Following the publication of Directive 2008/126/EC on 31 January 2009, a reasonable deadline must however be given for the transposition of that Directive.

(4) The measure provided for in this Directive is in accordance with the opinion of the Committee referred to in Article 7 of Council Directive 91/672/EEC of 16 December 1991 on the reciprocal recognition of national boatmasters' certificates for the carriage of goods and passengers by inland waterway (3),

HAS ADOPTED THIS DIRECTIVE:

#### Article 1

In the first paragraph of Article 2 of Directive 2008/126/EC, '30 December 2008' is replaced by '30 June 2009'.

#### Article 2

This Directive is addressed to the Member States which have inland waterways as referred to in Article 1(1) of Directive 2006/87/EC.

Done at Brussels, 12 June 2009.

For the Commission Antonio TAJANI Vice-President

<sup>(1)</sup> OJ L 389, 30.12.2006, p. 1.

<sup>(2)</sup> OJ L 32, 31.1.2009, p. 1.

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(Acts adopted under the EC Treaty/Euratom Treaty whose publication is not obligatory)

#### **DECISIONS**

#### **COUNCIL**

#### **COUNCIL DECISION**

of 6 May 2009

#### granting mutual assistance for Romania

(2009/458/EC)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 119 thereof,

Having regard to the recommendation from the Commission made after consulting the Economic and Financial Committee,

Whereas:

- (1) Romanian capital and financial markets have recently come under pressure, reflecting the global economic downturn and rising concerns about the Romanian economy, given its wide external deficit, and the rapidly increasing public deficit. Pressures on the exchange rate have also increased and entail a risk to the wider banking sector stability.
- In response, the government and the National Bank of (2) Romania (NBR) have developed a comprehensive strategy to firmly anchor macroeconomic policies and reduce financial market stress and outlined this strategy in a letter of intent received by the Commission on 27 April 2009. A cornerstone of the economic programme is the reduction of the fiscal deficit from 5,4% of GDP in 2008 to 5,1% of GDP in 2009 and to below 3 % of GDP by 2011. In order to help a sustainable achievement of lower budgetary deficits, measures will be taken to improve the budgetary strategy and process. This economic programme and in particular the fiscal targets will be reflected in the Government budget as well as in the convergence programme.

- (3) The Council is reviewing on a regular basis the economic policies implemented by Romania, in particular in the context of the annual reviews of Romania's update of the convergence programme and implementation of the National Reform Programme and the regular review of progress made by Romania in the context of the Convergence Report and of the Annual Progress Report.
- External financing is expected to remain under significant (4)pressure as the persistent, although declining, current account deficit, together with the need to roll over sizeable short-term and longer-term foreign currencydenominated debt, are likely not to be covered fully by Foreign Direct Investment (FDI) and other financial and capital account inflows in 2009-2011. External financing needs are estimated at around EUR 20 billion in the period until the first quarter of 2011. Foreign banks' rollover rate of their exposures to Romania is assumed at 100 % once the mutual assistance is awarded, consistent with the required commitment of main foreign banks to maintain their exposure to Romania (as confirmed in their joint statement of 26 March 2009), whereas the rollover rate for corporate external debt to parent institutions and for external debt of Romanian banks is assumed at 50 % in 2009. For 2010 and 2011, all maturing foreign liabilities are assumed to be rolled over at 100 % in line with the expected financial market stabilisation and start of the recovery in Romania's major export markets. Apart from sufficiently high foreign exchange reserve target (of more than 100 % of short-term external debt at remaining maturity) conservative assumptions were made about other capital outflows such as non-resident deposit outflows, decreases in trade credits and portfolio outflows in order to incorporate additional buffers into the calculations.

- (5) The authorities of Romania have requested substantial financial assistance from the EU and other international financial institutions to support balance of payments sustainability and to bring international currency reserves to a prudent level.
- (6) There is a serious threat to the Romanian balance of payments which justifies the urgent granting of mutual assistance by the Community. In addition, in view of the urgency of the matter, it is imperative to grant an exception to the six-week period referred to in paragraph I(3) of the Protocol on the role of national Parliaments in the European Union, annexed to the Treaty on European Union and to the Treaties establishing the European Communities,

HAS ADOPTED THIS DECISION:

Article 1

The Community shall grant mutual assistance to Romania.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 6 May 2009.

For the Council
The President
J. KOHOUT

#### **COUNCIL DECISION**

#### of 6 May 2009

#### providing Community medium-term financial assistance for Romania

(2009/459/EC)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 332/2002 of 18 February 2002 establishing a facility providing mediumterm financial assistance for Member States' balance of payments (1) and in particular Article 3(2) thereof,

Having regard to the proposal from the Commission made after consulting the Economic and Financial Committee (EFC),

#### Whereas:

- (1) By Decision 2009/458/EC (2) the Council has decided to grant mutual assistance to Romania.
- (2) Despite the expected improvement in the current account, Romania's external financing needs in the period until the first quarter of 2011 are estimated by the Commission, the International Monetary Fund (IMF) and the authorities of Romania at EUR 20 billion in March 2009; in view of the recent financial market developments the capital and financial account could substantially deteriorate.
- (3) It is appropriate to provide Community support to Romania of up to EUR 5 billion under the Facility providing medium-term financial assistance for Member States' balance of payments established by Regulation (EC) No 332/2002. That assistance should be provided in conjunction with a loan from the IMF of SDR 11,443 billion (around EUR 12,95 billion) under a Stand-by arrangement expected to be approved on 6 May 2009. The World Bank has also agreed to provide a loan to Romania of EUR 1 billion and the European Investment Bank (EIB) and the European Bank for Reconstruction and Development (EBRD) will provide a total EUR 1 billion of additional support.
- (4) The Community assistance should be managed by the Commission. The specific economic policy conditions agreed with the authorities of Romania after consultation of the EFC should be laid down in a Memorandum of Understanding. The detailed financial terms should be laid down by the Commission in the Loan Agreement.

- (5) The Commission should verify at regular intervals that the economic policy conditions attached to the assistance are fulfilled through missions and regular reporting by the authorities of Romania.
- (6) Throughout the implementation of the programme, the Commission will provide additional policy advice and technical assistance in specific areas.
- (7) Without prejudice to Article 27 of the Protocol on the Statute of the European System of Central Banks and of the European Central Bank, the European Court of Auditors shall have the right to carry out any financial controls or audits that it considers necessary in relation to the management of this assistance. The Commission, including the European Anti-Fraud Office, shall have the right to send its own officials or duly authorised representatives to carry out technical or financial controls or audits that it considers necessary in relation to the management of the Community medium-term financial assistance.
- (8) Independently of the lifetime and the framework of the assistance programme, the Commission will also, applying the existing relevant procedures, including the Cooperation and Verification Mechanism, continue to monitor progress in the areas contributing to transparent and effective public spending, in particular in the field of justice and implementation of structural funds in order to facilitate Romania to reinforce the impact of the Community assistance.
- (9) The assistance should be provided with a view to supporting the balance of payments sustainability in Romania and, in this way, contributing to the successful implementation of the Government's economic policy programme,

HAS ADOPTED THIS DECISION:

#### Article 1

- 1. The Community shall make available to Romania a medium-term loan amounting to a maximum of EUR 5 billion, with a maximum average maturity of seven years.
- 2. The Community financial assistance shall be made available during three years starting from the first day after the date when this Decision becomes effective.

<sup>(1)</sup> OJ L 53, 23.2.2002, p. 1.

<sup>(2)</sup> See page 6 of this Official Journal.

#### Article 2

- 1. The assistance shall be managed by the Commission in a manner consistent with Romania's undertakings and recommendations by the Council, in particular the Country Specific Recommendations in the context of the implementation of the National Reform Programme as well as of the convergence programme.
- 2. The Commission shall agree with the authorities of Romania, after consulting the EFC, the specific economic policy conditions attached to the financial assistance as laid down in Article 3(5). Those conditions shall be laid down in a Memorandum of Understanding consistent with the undertakings and recommendations referred to in paragraph 1. The detailed financial terms shall be laid down by the Commission in the Loan Agreement.
- 3. The Commission shall verify at regular intervals in collaboration with the EFC that the economic policy conditions attached to the assistance are fulfilled. To this end, the authorities of Romania shall place all the necessary information at the disposal of the Commission and cooperate in full with the latter. The EFC shall be kept informed by the Commission of possible refinancing of the borrowings or restructuring of the financial conditions.
- 4. Romania shall be ready to adopt and implement additional consolidation measures to ensure macro-financial stability, in case such measures will be necessary during the assistance programme. The authorities of Romania shall consult the Commission in advance of the adoption of any such additional measures.

#### Article 3

- 1. The Community financial assistance shall be made available by the Commission to Romania in a maximum of five instalments, the size of which will be laid down in the Memorandum of Understanding.
- 2. The first instalment shall be released subject to the entry into force of the Loan Agreement and Memorandum of Understanding.
- 3. If required in order to finance the loan, the prudent use of interest rate swaps with counterparties of the highest credit quality shall be permitted.
- 4. The Commission shall decide on the release of further instalments after having obtained the opinion of the EFC.
- 5. The disbursement of each further instalment shall be made on the basis of a satisfactory implementation of the new economic programme of the Government of Romania to be included in the Convergence Programme of Romania, in the National Reform Programme and, more particularly, the specific economic policy conditions laid down in the Memorandum of Understanding. These shall include, inter alia,

- (a) adopting a clearly-set medium-term fiscal programme designed to lower by 2011 the general government deficit to not more than the Treaty reference level of 3 % of GDP;
- (b) adopting and executing an amended budget for 2009 (by the second quarter of 2009), targeting a general government deficit of no higher than 5,1 % of GDP in ESA 95 terms;
- (c) reducing the public sector wage bill in nominal terms compared to the 2008 outcome by foregoing public sector wage increases (totalling 5 % in nominal terms) scheduled for 2009 (or equivalent further cuts in employment) and by reducing public employment, including by replacing only one of seven departing employees;
- (d) additional reductions in spending on goods and services and in subsidies to public enterprises;
- (e) improving the budgetary management by the adoption and implementation of a binding medium-term fiscal framework, establishing limits on budget revisions during the year, including fiscal rules and creating a fiscal council to provide independent and expert scrutiny;
- (f) reforming the public compensation system, including by unifying and simplifying the pay scales and reforming the bonus system;
- (g) reforming key parameters of the pension system by moving towards indexation of pensions to consumer prices rather than wages, gradually adjusting retirement age beyond the currently agreed plans, especially for women, and phasing in pension contributions of groups of public employees currently excluded from such contributions;
- (h) amending banking and winding-up laws to be able to respond in a timely and effective fashion in the event of bank distress. A key objective of the amendments will be to strengthen powers of the administrators of banks placed under special administration. Beyond bank resolution, the remedial powers of the National Bank of Romania (NBR) should be strengthened with provisions allowing it to request that significant shareholders increase their share capital and financially support the bank. Financial supervision will be strengthened in line with the relevant EU legislation. In addition, more detailed reporting requirements on liquidity will be introduced. Furthermore, procedures for the activation of deposit insurance should be modified to simplify and accelerate payouts. Under modified legislation, deposit insurance will be activated upon the NBR's determination within the 20-day period. Finally, in order to guarantee sufficient liquidity provision, the NBR is committed to widening the range of assets acceptable as collateral. Considering the particular circumstances, the regulatory minimum level of the capital adequacy ratio should increase from 8 % to 10 % at an appropriate time;

- (i) Structural reform measures in the areas of the Country Specific Recommendations issued in the context of the Lisbon strategy. These will include measures towards improving the efficiency and effectiveness of public administration, enhancing the quality of public expenditure, sound use and increased absorption of EU funds, reducing administrative, fiscal and legal burdens on business and tackling undeclared work, thereby broadening the tax base.
- 6. In order to ensure the smooth implementation of the programme conditionality and to help restoring imbalances in a sustainable way, the Commission will provide continued advice and guidance on fiscal, financial market and structural reforms.
- 7. Romania shall open a special account with the NBR for the management of the Community medium-term financial assistance.

Article 4

This Decision is addressed to Romania.

Article 5

This Decision shall be published in the Official Journal of the European Union.

Done at Brussels, 6 May 2009.

For the Council The President J. KOHOUT

#### **COMMISSION**

#### **COMMISSION DECISION**

of 5 June 2009

on the adoption of a common safety method for assessment of achievement of safety targets, as referred to in Article 6 of Directive 2004/49/EC of the European Parliament and of the Council

(notified under document number C(2009) 4246)

(Text with EEA relevance)

(2009/460/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 2004/49/EC of the European Parliament and of the Council of 29 April 2004 on safety on the Community's railways and amending Council Directive 95/18/EC on the licensing of railway undertakings and Directive 2001/14/EC on the allocation of railway infrastructure capacity and the levying of charges for the use of railway infrastructure and safety certification (Railway Safety Directive) (¹) and in particular Article 6(1) thereof,

Having regard to the recommendation of the European Railway Agency on the common safety methods for calculation, assessment and enforcement to be used in the framework of the first set of common safety targets, delivered to the Commission on 29 April 2008,

#### Whereas:

- (1) In accordance with Directive 2004/49/EC, common safety targets (CSTs) and common safety methods (CSMs) should be gradually introduced to ensure that a high level of safety is maintained and, when and where necessary and reasonably practicable, improved.
- (2) Pursuant to Article 6(1) of Directive 2004/49/EC, the European Commission should adopt CSMs. These should describe, amongst others and in accordance with Article 6(3) of Directive 2004/49/EC, how the safety level and achievement of CSTs are assessed.
- (3) In order to ensure that the current safety performance of the railway system is not reduced in any Member State,

the first set of CSTs should be introduced. It should be based on an examination of existing targets and safety performance of railway systems in the Member States.

- (4) Furthermore, in order to maintain the current safety performance of the railway system, a harmonisation, in terms of risk acceptance criteria, of safety levels for the whole national railway systems is necessary. The compliance with safety levels should be monitored in the different Member States.
- (5) In order to establish the first set of CSTs in compliance with Article 7(3) of Directive 2004/49/EC, it is necessary to quantitatively identify the current safety performance of railway systems in Member States by means of national reference values (NRVs), to be calculated and utilised by the European Railway Agency (the Agency) and the Commission. These NRVs should be calculated only in 2009, with a view to developing the first set of CSTs, and in 2011, with a view to developing the second set of CSTs.
- (6) In order to ensure consistency of the NRVs and to avoid undue burden, light rail systems, functionally separate networks, privately owned railway infrastructures solely used by the owner, heritage, museum and tourist railways should be exempted from this Decision.
- (7) Due to the lack of harmonised and reliable data on safety performance of parts of the railway system referred to in Article 7(4) of Directive 2004/49/EC, it has been ascertained that the development of the first set of CSTs, expressed in risk acceptance criteria for specified categories of individuals and for society as a whole, is at the moment feasible only for the railway system in its entirety and not for its parts.

<sup>(1)</sup> OJ L 164, 30.4.2004, p. 44; corrected by OJ L 220, 21.6.2004, p. 16.

- (8) Following the progressive harmonisation of national statistical data on accidents and related consequences, in compliance with Regulation (EC) No 91/2003 of the European Parliament and of the Council of 16 December 2002 on rail transport statistics (¹) and Directive 2004/49/EC, the development of common methods for monitoring and targeting safety performance of railway systems in Member States should take account of statistical uncertainties and the need for an element of judgement in deciding whether a Member State's safety performance is maintained.
- (9) To allow a fair and transparent comparison of railway safety performance amongst Member States, Member States should perform their own assessments on the basis of a common approach for identifying the safety targets of the railway system and for demonstrating compliance with them.
- (10) The measures provided for in this Decision are in accordance with the opinion of the Committee established in compliance with Article 27(1) of Directive 2004/49/EC,

HAS ADOPTED THIS DECISION:

#### Article 1

#### Subject matter

This Decision establishes a common safety method to be used by the European Railway Agency (hereafter 'the Agency') for calculating and assessing the achievement of common safety targets (CSTs), in application of Article 6(1) of Directive 2004/49/EC.

#### Article 2

#### Scope

This Decision shall apply to the whole railway system within each of the Member States. However it shall not apply to:

- (a) metros, trams and other light rail systems;
- (b) networks that are functionally separate from the rest of the railway system and intended only for the operation of local, urban or suburban passenger services, as well as railway undertakings operating solely on these networks;
- (c) privately owned railway infrastructure that exists solely for use by the infrastructure owner for its own freight operations;
- (1) OJ L 14, 21.1.2003, p. 1.

- (d) heritage vehicles that run on national networks providing that they comply with national safety rules and regulations with a view to ensuring safe circulation of such vehicles;
- (e) heritage, museum and tourist railways that operate on their own network, including workshops, vehicles and staff.

#### Article 3

#### **Definitions**

For the purposes of this Decision, definitions of Directive 2004/49/EC and Regulation (EC) No 91/2003 shall apply.

In addition, the following definitions shall apply:

- (a) 'national reference value (NRV)' means a reference measure indicating, for the Member State concerned, the maximum tolerable level for a railway risk category;
- (b) 'risk category' means one of the railway risk categories specified by Article 7(4)(a) and (b) of Directive 2004/49/EC;
- (c) 'safety enhancement plan' means a schedule to implement the organisational structure, responsibilities, procedures, activities, capabilities and resources required to reduce the risk for one or more risk categories;
- (d) 'fatalities and weighted serious injuries (FWSIs)' means a measurement of the consequences of significant accidents combining fatalities and serious injuries, where 1 serious injury is considered statistically equivalent to 0,1 fatalities;
- (e) 'level crossing users' means all persons using a level crossing to cross the railway line by any means of transportation or by foot;
- (f) 'staff or 'employees including the staff of contractors' means any persons whose employment is in connection with a railway and is at work at the moment of the accident; it includes the crew of the train and persons handling rolling stock and infrastructure installations;
- (g) 'unauthorised persons on railway premises' means any persons present on railway premises where such presence is forbidden, with the exception of level crossing users;
- (h) 'others (third parties)' means all persons not defined as 'passengers', 'employees including the staff of contractors', 'level crossing users' or 'unauthorised persons on railway premises';

- (i) 'risk to the society as a whole' means the collective risk to all categories of persons listed in Article 7(4)(a) of Directive 2004/49/EC;
- (j) 'passenger train-km' means the unit of measure representing the movement of a passenger train over one kilometre; only the distance on the national territory of the reporting country shall be taken into account;
- (k) 'track-km' means the length measured in kilometres of the railway network in Member States where each track of a multiple track railway line is to be counted.

#### Article 4

## Methodologies to calculate NRVs and CSTs and to assess their achievement

- 1. The methodology described in the Annex shall apply for calculating and assessing the achievements of NRVs and CSTs.
- 2. The Agency shall propose to the Commission NRVs calculated in accordance with section 2.1 of the Annex and CSTs derived from the NRVs, in accordance with the methodology set out in section 2.2 of the Annex. After adoption of NRVs and CSTs by the Commission, the Agency shall assess their achievement by Member States in compliance with chapter 3 of the Annex.
- 3. The assessment of the estimated costs and benefits of CSTs referred to in Article 7(3) of Directive 2004/49/EC shall be limited to those Member States whose NRVs, for any of the risk categories, are found to be higher than the corresponding CSTs.

#### Article 5

#### **Enforcement actions**

In accordance with the different final results of the assessment of achievement, referred to in point 3.1.5 of the Annex, the following enforcement actions shall be taken:

- (a) in case of 'possible deterioration of safety performance': the Member State/s concerned shall send to the Commission a report explaining the likely causes of the results obtained;
- (b) in case of 'probable deterioration of safety performance': the Member State/s concerned shall send to the Commission a report explaining the likely causes of the results obtained and submit, if appropriate, a safety enhancement plan.

In order to evaluate any information and evidences provided by Member States in accordance with the process referred to in points (a) and (b), the Commission may ask the Agency to provide technical opinions.

#### Article 6

#### Addressees

This Decision is addressed to the Member States.

Done at Brussels, 5 June 2009.

For the Commission Antonio TAJANI Vice-President

#### **ANNEX**

#### 1. Statistical sources and measurement units for calculating NRVs and CSTs

#### 1.1. Statistical sources

- 1.1.1. The NRVs and the CSTs shall be calculated on the basis of data on railway accidents and related consequences, reported according to Annex H to Regulation (EC) No 91/2003 and according to provisions of Articles 5, 18 and Annex I to Directive 2004/49/EC.
- 1.1.2. Within the framework of determining the first set of CSTs, in case of inconsistencies between data coming from the two sources referred to in point 1.1.1, data reported according to Annex H to Regulation (EC) No 91/2003 shall have precedence.
- 1.1.3. The time series of data which will be used for attributing values to NRVs and CSTs shall include the four most recent reported years. No later than 31 January 2011 the Agency shall propose to the Commission the adoption of updated values for NRVs and CSTs, calculated from data for the six most recent reported years.

#### 1.2. Measurement units for NRVs

- 1.2.1. The measurement units for NRVs shall be expressed in compliance with the mathematical definition of risk. The consequences of accidents which shall be considered for each of the risk categories are the FWSIs.
- 1.2.2. The measurement units which shall be used for quantifying NRVs for each of the risk categories are laid down in Appendix 1 and result from the application of the principles and definitions referred to in point 1.2.1 and, where relevant, point 1.2.3. The measurement units include the scaling bases listed in Appendix 1, for the normalisation of NRVs.
- 1.2.3. For each of the risk categories 'passengers' and 'level crossing users' two different NRVs shall be set, expressed with the two different measurement units referred to in Appendix 1. For the purposes of the assessment of achievement referred to in chapter 3, compliance with at least one of these NRVs shall be considered sufficient.

#### 1.3. Measurement units for CSTs

1.3.1. The measurement units to be used for quantifying CSTs for each of the risk categories shall be the same as the ones described for NRVs in section 1.2.

#### 2. Methodology for calculating NRVs and for deriving CSTs

- 2.1. Methodology for calculating NRVs
- 2.1.1. For each Member State and for each of the risk categories the NRV shall be calculated by applying in sequential order the following process:
  - (a) calculation of the values returned by the corresponding measurement units listed in Appendix 1, by considering the data and provisions referred to in section 1.1;
  - (b) analysis of the results of the process described in point (a), to check presence and recurrence of zero values for the FWSIs in the observed safety performances for the years concerned;
  - (c) if the zero values referred to in point (b) are no more than two, the calculation is made of the weighted average of the values referred to in point (a), as described in section 2.3, and the returned value is taken as the NRV.
  - (d) if the zero values referred to in point (b) are more than two, the Agency shall attribute to the NRV a discretional value to be identified by consulting the Member State concerned.

#### 2.2. Methodology for deriving CSTs from NRVs

- 2.2.1. For each of the risk categories, once the NRV has been calculated for each Member State according to the procedure laid down by section 2.1, the corresponding CST shall be assigned a value equal to the lower of:
  - (a) the value of the NRV which is the highest amongst the Member States;
  - (b) the value equal to 10 times the European average value of the risk to which the considered NRV refers.

- 2.2.2. The European average referred to in point 2.2.1(b) shall be calculated by cumulating the relevant data for all the Member States and by using the corresponding measurement units listed in Appendix 1, as well as the weighted average described in section 2.3.
- 2.3. Weighted averaging process for the calculation of NRVs
- 2.3.1. For each Member State and for each of the risk categories to which the weighted averaging can be applied according to point 2.1.1(c), the following steps shall be applied for calculating, during year Y (where Y = 2009 and 2011), the NRV<sub>Y</sub>:
  - (a) calculation of the annual observations  $OBS_i$  (where i is the considered year of observation) returned by the corresponding measurement units listed in Appendix 1, after providing as input the data for the most recent reported n years as referred to in point 2.1.1(a) [initially n = 4; from 2011 onwards n = 6];
  - (b) calculation of the arithmetic n-year average (AV) of annual observations OBS;
  - (c) calculation of the absolute value of the difference ABSDIFF<sub>i</sub> between each annual observation OBS<sub>i</sub> and the AV. If ABSDIFF<sub>i</sub> < 0,01 \* AV, to ABSDIFF<sub>i</sub> is attributed a constant value equal to 0,01 \* AV;
  - (d) calculation of the weight (Wi) for each single year i, by taking the inverse of ABSDIFFi;
  - (e) calculation of the NRV<sub>Y</sub> in the form of weighted average, as follows:

$$NRV_{Y} = \frac{\sum_{i=x}^{N} W_{i} \times OBS_{i}}{\sum_{i=x}^{N} W_{i}};$$

where i is a natural number and

$$\begin{cases} if Y = 2009; x = Y - 5; N = Y - 2 \\ if Y = 2011; x = Y - 7; N = Y - 2 \end{cases}$$

- 3. Framework model for the assessment of achievement of NRVs and CSTs
- 3.1. Methodology for assessing achievement of NRVs and CSTs
- 3.1.1. The following principles shall apply for assessing achievement of NRVs and CSTs:
  - (a) for each Member State and for each of the risk categories whose respective NRV is equal to or lower than the corresponding CST, the achievement of the NRV will also automatically imply the achievement of the CST. The assessment of achievement of the NRV shall be carried out according to the procedure described in section 3.2 and the NRV shall represent the maximum tolerable level of the risk to which it refers, without prejudice to the provisions on the range of tolerance laid down in point 3.2.3;
  - (b) for each Member State and for each of the risk categories whose respective NRV is higher than the corresponding CST, the CST shall represent the maximum tolerable level of the risk to which it refers. The assessment of achievement of the CST shall be carried out in compliance with the requirements deriving from the impact assessment and, where applicable, the timetable for gradual implementation of the CST, according to Article 7(3) of Directive 2004/49/EC.
- 3.1.2. For each Member State, and for each of the risk categories, the assessment of achievement of the NRV and CST shall be carried out annually by the Agency, taking into consideration the most recent four preceding reported years.
- 3.1.3. No later than 31 March each year the Agency shall report to the Commission on the overall results of the assessment of achievement of NRVs and CSTs.
- 3.1.4. Taking into account the provisions laid down in point 1.1.3, from 2012 onwards the assessment of achievement of the NRVs and CSTs shall be carried out annually by the Agency taking into consideration the most recent five preceding reported years.
- 3.1.5. The outcome of the assessment of achievement referred to in point 3.1.1 shall be classified as follows:
  - (a) acceptable safety performance;

- (b) possible deterioration of safety performance;
- (c) probable deterioration of safety performance.
- 3.2. Stepwise description of the procedure referred to in point 3.1.1(a)
- 3.2.1. The procedure for the assessment of achievement of NRVs is composed of four different steps as described in the following points. The overall decisional flowchart of the procedure is shown in Appendix 2, where positive and negative decisional arrows correspond respectively to a 'passed' and a 'failed' result of the different assessment steps.
- 3.2.2. The first assessment step shall verify whether the observed safety performance is complying with the NRV or not. The observed safety performance shall be measured by using the measurement units listed in Appendix 1 and the data referred to in section 1.1, with time series which shall include the most recent years of observations as specified in section 3.1. The observed safety performance shall be expressed in terms of:
  - (a) safety performance observed in the single most recent reported year;
  - (b) moving weighted average (MWA), as specified in section 3.3.

The values returned by applying points (a) and (b) shall then be compared with the NRV, and if one of these values does not exceed the NRV the safety performance shall be considered acceptable. If this is not the case, the procedure shall continue with the second assessment step.

3.2.3. The second assessment step shall consider the safety performance as acceptable if the MWA does not exceed the NRV plus a 20 % range of tolerance. If this condition is not satisfied, the Agency shall ask the safety authority of the Member State concerned to provide the specifics of the single highest-consequence accident (in terms of FWSIs) in the most recent years of observation as referred to in section 3.1, excluding the years used to set the NRV.

If this single accident is more severe, in terms of consequences, than the most severe single accident included in the data used for setting the NRV, it shall be excluded from the statistics. The MWA is then recalculated to check whether it lies within the abovementioned range of tolerance. If this is the case, the safety performance shall be considered acceptable. If this is not the case, the procedure shall continue with the third assessment step.

- 3.2.4. The third assessment step shall verify whether it is the first time in the last 3 years that the second assessment step did not return evidence of acceptable safety performance. If this is the case, the outcome of the third assessment step shall be classified as 'passed'. The procedure shall continue with the fourth step, whatever the outcome of the third step may be.
- 3.2.5. The fourth assessment step shall verify whether the number of significant accidents per train-km, with respect to the previous years, remained stable (or decreased). The criteria for this appraisal shall be whether there has been a statistically significant increase in the number of relevant significant accidents per train-km. This shall be evaluated by using an upper Poisson tolerance bound which will determine the acceptable variability based on the number of accidents that occurred in the different Member States.

If the number of significant accidents per train-km does not exceed the abovementioned tolerance bound, it is assumed that there has not been a statistically significant increase, and the outcome of this assessment step shall be classified as 'passed'.

Depending on the risk category to which the different NRVs under assessment of achievement refer, the significant accidents to be considered for carrying out this assessment step are as follows:

- (a) risks to passengers: all relevant significant accidents;
- (b) risks to staff or employees, including the staff of contractors: all relevant significant accidents;
- (c) risks to level crossing users: all relevant significant accidents included in the category 'accidents involving level crossings';
- (d) risks to unauthorised persons on railway premises: all relevant significant accidents included in the category 'accidents to persons caused by rolling stock in motion';

- (e) risks to others: all relevant significant accidents;
- (f) risk to society as a whole: all significant accidents.
- 3.3. Moving weighted averaging process for the annual assessment of achievement of NRVs
- 3.3.1. For each Member State and for each of the risk categories to which the Moving Weighted Averaging (MWA) is applied for carrying out, in each year Y (starting from Y = 2010 onwards), the assessment steps described in section 3.2, the following phases shall be applied for calculating the MWA<sub>Y</sub>:
  - (a) calculation of the annual observations OBS<sub>i</sub> returned by the corresponding indicators listed in Appendix 1, after providing as input the data available from the sources referred to in section 1.1 for the relevant years (the index *i* takes the values as defined in the formula below);
  - (b) calculation of the arithmetic n-year average (AV) of annual observations  $OBS_i$  [initially n=4; from 2012 onwards n=5];
  - (c) calculation of the absolute value of the difference ABSDIFF<sub>i</sub> between each annual observation OBS<sub>i</sub> and the AV. If ABSDIFF<sub>i</sub> < 0,01 \* AV, to ABSDIFF<sub>i</sub> is attributed a constant value equal to 0,01 \* AV;
  - (d) calculation of the weight Wi, by taking the inverse of ABSDIFFi;
  - (e) calculation of the  $\mbox{MWA}_{\mbox{\scriptsize Y}}$  as follows:

$$MWA_{Y} = \frac{\sum_{i=x}^{N} W_{i} \times OBS_{i}}{\sum_{i=x}^{N} W_{i}};$$

where i is a natural number and

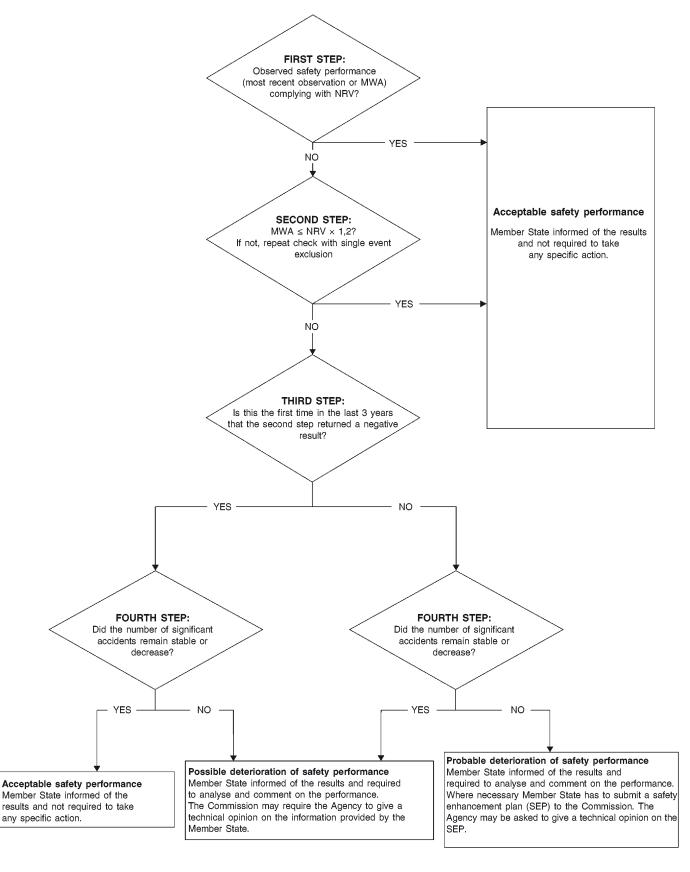
$$\begin{cases} \text{if } Y = 2010 \text{ or } 2011\text{: } x = Y - 5\text{; } N = Y - 2\\ \text{if } Y \geq 2012\text{: } x = Y - 6\text{; } N = Y - 2 \end{cases}$$

#### APPENDIX 1

#### Measurement units for NRVs and CSTs

Risk category	Measurement units	Scaling bases	
1. Passengers	1.1 Number of passenger FWSIs per year arising from significant accidents/Number of passenger train-km per year	Passenger train-km per year	
	1.2 Number of passenger FWSIs per year arising from significant accidents/Number of passenger-km per year	Passenger-km per year	
2. Employees	Number of employee FWSIs per year arising from significant accidents/Number of train-km per year	Train-km per year	
3. Level crossing users	3.1 Number of level-crossing user FWSIs per year arising from significant accidents/Number of train-km per year	Train-km per year	
	3.2 Number of level-crossing user FWSIs per year arising from significant accidents/[(Number of Train-km per year * Number of level crossings)/Track-km)]	(Train-km per year * Number of level crossings)/Track-km	
4. Others	Yearly number of FWSIs to persons belonging to the category 'others' arising from significant accidents/Number of train-km per year	Train-km per year	
5. Unauthorised persons on railway premises	Number of FWSIs to unauthorised persons on railway premises per year arising from significant accidents/ Number of train-km per year	Train-km per year	
6. Whole society	Total number of FWSIs per year arising from significant accidents/Number of train-km per year	Train-km per year	

 $\label{eq:appendix2} \mbox{ APPENDIX 2}$  Decision flowchart for the procedure referred to in point 3.1.1(a) of the Annex



#### **COMMISSION DECISION**

#### of 12 June 2009

## appointing a Commission representative to the Management Board of the European Medicines Agency

(2009/461/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (1), and in particular Article 65 thereof,

#### Whereas:

- (1) Pursuant to Article 65 of Regulation (EC) No 726/2004, the Management Board of the European Medicine Agency (hereinafter 'the Agency') is to include two representatives of the Commission.
- (2) Due to the expiry on 2 June 2009 of the current mandate of the Commission representative and alternate from the Directorate-General for Enterprise and Industry, it is necessary to appoint a member of the Management Board of the Agency from the Directorate-General for Enterprise and Industry and an alternate who will replace the member in his/her absence and vote on his/her behalf,

HAS DECIDED AS FOLLOWS:

#### Article 1

The representative of the Commission to the Management Board of the European Medicines Agency shall be the person occupying the following position and exercising the following functions: (a) Director-General of the Directorate-General for Enterprise and Industry.

The alternate representative shall be the person occupying the following position and exercising the following functions:

(b) Director heading the Directorate which is responsible for the authorisation of medicinal products on the basis of the work program of the Directorate-General for Enterprise and Industry.

#### Article 2

This Decision shall apply to the persons occupying, including on a temporary basis, the positions referred to in Article 1 at the date of adoption of this Decision, or to any successor of those persons in those positions.

#### Article 3

The Director-General of the Directorate-General for Enterprise and Industry shall inform the Executive Director of the European Medicines Agency of the names of the persons occupying the positions referred to in Article 1, and any changes thereof.

Done at Brussels, 12 June 2009.

For the Commission Günter VERHEUGEN Vice-President

#### COMMISSION DECISION

#### of 12 June 2009

derogating from point 1(d) of the Annex to Decision 2006/133/EC, as amended by Decision 2009/420/EC, as regards the date of application in relation to susceptible wood originating outside the demarcated areas

(notified under document number C(2009) 4515)

(2009/462/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community (¹), and in particular the fourth sentence of Article 16(3) thereof,

#### Whereas:

- On 28 May 2009, the Commission adopted Decision (1) 2009/420/EC amending Decision 2006/133/EC requiring Member States temporarily to take additional measures against the dissemination of Bursaphelenchus xylophilus (Steiner et Buhrer) Nickle et al. (the pine wood nematode) as regards areas in Portugal, other than those in which it is known not to occur (2). That Decision introduced in Commission Decision 2006/133/EC (3), as from 16 June 2009, the obligation that susceptible wood packaging material not originating from the demarcated areas undergoes one of the approved treatments specified in Annex I to FAO International Standard for Phytosanitary measures No 15 and is marked according to Annex II to the said Standard before being moved from the demarcated areas to other areas in Member States or in third countries as well as from part of the demarcated area in which the pine wood nematode is known to occur to the part of the demarcated area designated as a buffer zone.
- (2) Wood packaging material is required for the transport of many goods of all kinds. However, until now the production and use of susceptible wood packaging material treated and marked in accordance with the Annexes I and II to FAO International Standard for Phytosanitary measures No 15 is not generalised in the Community. It appears in particular that not enough

- wood packaging material complying with the FAO International Standard for Phytosanitary measures No 15 can be made available at short time to cover the needs of the economic operators trading goods from Portugal to other Member States or third countries.
- (3) To avoid risks of disproportionate disruption of trade, it appears necessary to provide for a derogation as regards the date of application of the requirements set out in Decision 2006/133/EC, as amended by Decision 2009/420/EC, which refer to the obligation to treat and mark in accordance with Annexes I and II to FAO International Standard for Phytosanitary measures No 15 susceptible wood packaging material not originating from demarcated areas before moving it from the demarcated areas in Portugal to other areas.
- (4) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plant Health,

HAS ADOPTED THIS DECISION:

#### Article 1

Point 1(d) of the Annex to Decision 2006/133/EC, as amended by Decision 2009/420/EC, shall not apply to susceptible wood originating outside the demarcated areas.

#### Article 2

This Decision shall apply from 16 June 2009 until 31 December 2009.

#### Article 3

This Decision is addressed to the Member States.

Done at Brussels, 12 June 2009.

For the Commission Androulla VASSILIOU Member of the Commission

<sup>(1)</sup> OJ L 169, 10.7.2000, p. 1.

<sup>(2)</sup> OJ L 135, 30.5.2009, p. 29.

<sup>(3)</sup> OJ L 52, 23.2.2006, p. 34.

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