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II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) No 38/2010

of 15 January 2010

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) ⁽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 16 January 2010.

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

Done at Brussels, 15 January 2010.

*For the Commission,
On behalf of the President,*

Jean-Luc DEMARTY

*Director-General for Agriculture and
Rural Development*

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 350, 31.12.2007, p. 1.

ANNEX

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

(EUR/100 kg)

CN code	Third country code ⁽¹⁾	Standard import value
0702 00 00	IL	122,3
	JO	64,0
	MA	64,3
	TN	112,1
	TR	86,4
	ZZ	89,8
0707 00 05	EG	174,9
	JO	106,0
	MA	76,9
	TR	119,6
	ZZ	119,4
0709 90 70	MA	167,4
	TR	115,0
	ZZ	141,2
0709 90 80	EG	225,1
	ZZ	225,1
0805 10 20	EG	51,6
	IL	57,7
	MA	53,2
	TN	68,6
	TR	54,6
	ZZ	57,1
0805 20 10	MA	91,6
	ZZ	91,6
0805 20 30, 0805 20 50, 0805 20 70, 0805 20 90	CN	51,9
	EG	67,7
	HR	59,0
	IL	70,2
	JM	106,6
	MA	83,8
	TR	67,6
	ZZ	72,4
	ZZ	72,4
0805 50 10	EG	72,2
	IL	88,6
	TR	71,9
	US	87,7
	ZZ	80,1
0808 10 80	CA	91,9
	CL	60,1
	CN	88,6
	MK	24,7
	US	117,9
	ZZ	76,6
0808 20 50	CN	51,0
	US	101,3
	ZZ	76,2

⁽¹⁾ 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 (EU) No 39/2010**of 15 January 2010****fixing the import duties in the cereals sector applicable from 16 January 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) ⁽¹⁾,Having regard to Commission Regulation (EC) No 1249/96 of 28 June 1996 laying down detailed rules for the application of Council Regulation (EEC) No 1766/92 in respect of import duties in the cereals sector ⁽²⁾, and in particular Article 2(1) thereof,

Whereas:

(1) Article 136(1) of Regulation (EC) No 1234/2007 states that the import duty on products falling within CN codes 1001 10 00, 1001 90 91, ex 1001 90 99 (high quality common wheat), 1002, ex 1005 other than hybrid seed, and ex 1007 other than hybrids for sowing, is to be equal to the intervention price valid for such products on importation increased by 55 %, minus the cif import price applicable to the consignment in question. However, that duty may not exceed the rate of duty in the Common Customs Tariff.

(2) Article 136(2) of Regulation (EC) No 1234/2007 lays down that, for the purposes of calculating the import duty referred to in paragraph 1 of that Article, representative cif import prices are to be established on a regular basis for the products in question.

(3) Under Article 2(2) of Regulation (EC) No 1249/96, the price to be used for the calculation of the import duty on products of CN codes 1001 10 00, 1001 90 91, ex 1001 90 99 (high quality common wheat), 1002 00, 1005 10 90, 1005 90 00 and 1007 00 90 is the daily cif representative import price determined as specified in Article 4 of that Regulation.

(4) Import duties should be fixed for the period from 16 January 2010 and should apply until new import duties are fixed and enter into force,

HAS ADOPTED THIS REGULATION:

Article 1

From 16 January 2010, the import duties in the cereals sector referred to in Article 136(1) of Regulation (EC) No 1234/2007 shall be those fixed in Annex I to this Regulation on the basis of the information contained in Annex II.

Article 2

This Regulation shall enter into force on 16 January 2010.

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

Done at Brussels, 15 January 2010.

*For the Commission,
on behalf of the President,*

Jean-Luc DEMARTY

*Director-General for Agriculture and
Rural Development*

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 161, 29.6.1996, p. 125.

ANNEX I

Import duties on the products referred to in Article 136(1) of Regulation (EC) No 1234/2007 applicable from 16 January 2010

CN code	Description	Import duties ⁽¹⁾ (EUR/t)
1001 10 00	Durum wheat, high quality	0,00
	medium quality	0,00
	low quality	0,00
1001 90 91	Common wheat seed	0,00
ex 1001 90 99	High quality common wheat, other than for sowing	0,00
1002 00 00	Rye	36,92
1005 10 90	Maize seed other than hybrid	11,99
1005 90 00	Maize, other than seed ⁽²⁾	11,99
1007 00 90	Grain sorghum other than hybrids for sowing	36,92

⁽¹⁾ For goods arriving in the Community via the Atlantic Ocean or via the Suez Canal the importer may benefit, under Article 2(4) of Regulation (EC) No 1249/96, from a reduction in the duty of:

- 3 EUR/t, where the port of unloading is on the Mediterranean Sea, or
- 2 EUR/t, where the port of unloading is in Denmark, Estonia, Ireland, Latvia, Lithuania, Poland, Finland, Sweden, the United Kingdom or the Atlantic coast of the Iberian peninsula.

⁽²⁾ The importer may benefit from a flatrate reduction of EUR 24 per tonne where the conditions laid down in Article 2(5) of Regulation (EC) No 1249/96 are met.

ANNEX II

Factors for calculating the duties laid down in Annex I

31.12.2009-14.1.2010

1. Averages over the reference period referred to in Article 2(2) of Regulation (EC) No 1249/96:

	(EUR/t)					
	Common wheat ⁽¹⁾	Maize	Durum wheat, high quality	Durum wheat, medium quality ⁽²⁾	Durum wheat, low quality ⁽³⁾	Barley
Exchange	Minnéapolis	Chicago	—	—	—	—
Quotation	155,97	111,78	—	—	—	—
Fob price USA	—	—	165,85	155,85	135,85	98,98
Gulf of Mexico premium	41,51	12,14	—	—	—	—
Great Lakes premium	—	—	—	—	—	—

⁽¹⁾ Premium of 14 EUR/t incorporated (Article 4(3) of Regulation (EC) No 1249/96).⁽²⁾ Discount of 10 EUR/t (Article 4(3) of Regulation (EC) No 1249/96).⁽³⁾ Discount of 30 EUR/t (Article 4(3) of Regulation (EC) No 1249/96).

2. Averages over the reference period referred to in Article 2(2) of Regulation (EC) No 1249/96:

Freight costs: Gulf of Mexico–Rotterdam: 23,26 EUR/t

Freight costs: Great Lakes–Rotterdam: — EUR/t

COMMISSION REGULATION (EU) No 40/2010
of 15 January 2010

fixing the allocation coefficient to be applied to applications for import licences for olive oil lodged from 11 to 12 January 2010 under the Tunisian tariff quota and suspending the issue of import licences for the month of January 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) ⁽¹⁾,

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 ⁽²⁾, and in particular Article 7(2) thereof,

Whereas:

- (1) Article 3(1) and (2) of Protocol No 1 ⁽³⁾ 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 ⁽⁴⁾, 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 Community, 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 ⁽⁵⁾ 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 January 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 January 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 11 and 12 January 2010 under Article 3(1) of Regulation (EC) No 1918/2006 shall be multiplied by an allocation coefficient of 90,575916 %.

The issue of import licences in respect of amounts applied for as from 18 January 2010 shall be suspended for January 2010.

Article 2

This Regulation shall enter into force on 16 January 2010.

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

Done at Brussels, 15 January 2010.

For the Commission,
On behalf of the President,
Jean-Luc DEMARTY
Director-General for Agriculture and
Rural Development

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 238, 1.9.2006, p. 13.

⁽³⁾ OJ L 97, 30.3.1998, p. 57.

⁽⁴⁾ OJ L 97, 30.3.1998, p. 2.

⁽⁵⁾ OJ L 365, 21.12.2006, p. 84.

IV

(Acts adopted before 1 December 2009 under the EC Treaty, the EU Treaty and the Euratom Treaty)

COMMISSION DECISION

of 17 June 2009

on the scheme for consolidating the onerous debts of agriculture cooperatives and holdings implemented in Lazio Region (Italy) pursuant to Regional Law No 52/1994 and refinanced by Article 257 of Regional Law No 10 of 10 May 2001

(notified under document C(2009) 4525)

(Only the Italian text is authentic)

(2010/27/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community and in particular the first paragraph of Article 88(2) thereof,

Having called on interested parties to submit their comments pursuant to that Article,

Whereas:

I. PROCEDURE

(1) By letter dated 11 September 2001, registered on 13 September 2001, the Permanent Representation of Italy to the European Union notified the Commission, pursuant to Article 88(3) of the EC Treaty, of the text of Article 257 of Regional Law No 10 of 10 May 2001, amending Article 2 of Regional Law No 52 of 31 October 1994.

(2) By letter dated 19 April 2002, registered on 22 April 2002, the Permanent Representation of Italy to the European Union sent the Commission the additional information it had requested from the Italian authorities concerning the above provisions by letter dated 9 November 2001.

(3) After examining this information, the Commission asked the Italian authorities, by letter dated 17 June 2002, to send further information within four weeks.

(4) As it had not received any reply by the deadline set in the letter of 17 June 2002, the Commission sent a new letter dated 19 August 2003 urgently asking for the information that had previously been requested.

(5) By letter dated 23 October 2003, registered on 29 October 2003, the Permanent Representation of Italy to the European Union sent the Commission the additional information requested from the Italian authorities in the letter of 17 June 2002.

(6) By letter dated 11 December 2003, the Commission informed Italy of its decision to initiate the procedure provided for by Article 88(2) of the EC Treaty in relation the provisions of Article 257 of Regional Law No 10 of 10 May 2001 (hereinafter 'Law No 10/01') and the aid paid between 1 January 1998 and 20 May 2001 (the date of entry into force of Law No 10/01) under the aid scheme that was to have been refinanced by the budget allocation provided for in that article ⁽¹⁾.

(7) The Commission's decision to initiate the procedure was published in the *Official Journal of the European Union* ⁽²⁾. The Commission invited interested parties to submit comments.

(8) The Commission did not receive any comments from interested parties. Nevertheless, the Italian authorities met Commission staff to make clarifications in relation to the comments made by the Commission after the procedure under Article 88(2) of the EC Treaty was initiated.

(9) By e-mail dated 3 April 2009, the Permanent Representation of Italy to the European Union sent the Commission a letter from the Italian authorities summarising the discussions that took place at the meeting referred to in the previous paragraph.

⁽¹⁾ Letter SG (2003) D/233340.

⁽²⁾ OJ C 15, 21.1.2004, p. 28.

II. DESCRIPTION

The notified measure

(10) Article 257 of Law No 10/01 provides for an additional allocation of ITL 400 million (EUR 206 583) as an interest-rate subsidy on 15-year loans intended to consolidate the onerous debts of agricultural cooperatives, groupings thereof and agricultural holdings pursuant to Regional Law No 52 of 31 October 1994 (hereinafter 'Law No 52/94'), as amended by Law No 13 of 29 April 1996 (hereinafter 'Law No 13/96'). It also modifies Article 2 of Law No 52/94 by extending the possibility of receiving the aid provided for by that law to onerous debts existing as at 31 December 2000. Lastly, it includes a clause under which the aid provided for can be implemented only after publication, in the *Bollettino ufficiale della Regione Lazio* [Official Bulletin of Lazio Region] of the positive outcome of the examination carried out by the Commission pursuant to Articles 87 and 88 of the EC Treaty.

Legal basis changed by the notified measure

(11) Law No 52/94, which constitutes the legal basis for the consolidation, provided for the following:

(a) aid to cooperatives and groupings thereof in the form of an interest-rate subsidy on 15-year loans intended to consolidate onerous debts resulting from loans not covered by public subsidies (Article 1(1));

(b) aid to agricultural holdings in the form of an interest-rate subsidy on 15-year loans intended to consolidate onerous debts resulting from investments that had already been made (Article 1(2));

(c) aid in the form of grants to cooperatives and groupings thereof in the event of merger or absorption by another cooperative body, covering up to 50 % of the liabilities in the balance sheet of the aforementioned cooperatives or groupings thereof, for the purposes of discharging such liabilities (Article 4);

(d) onerous debts were defined as those resulting from short-, medium- and long-term bank loans obtained without public aid and existing as at the date of entry into force of the law.

(12) The Commission launched the investigation procedure under paragraph 2 of Article 88 (formerly Article 93) of the EC Treaty in relation to the aid provided for by the law in question⁽³⁾, since it was not certain that this aid complied with the criteria used at the time as the basis for its analysis.

(13) According to these criteria, the Commission considered this type of grant to be operating aid, which, in principle, could be considered compatible with the common market only if the following three conditions were satisfied:

(a) such aid had to concern onerous debts resulting from loans taken out to finance investments that had already been made;

(b) the aggregate amount of any aid granted when the loan was taken out and the aid in question could not exceed the percentage generally authorised by the Commission, i.e.:

— for investments in the primary agricultural sector: 35 % or 75 % in less-favoured areas within the meaning of Council Directive 75/268/EEC⁽⁴⁾;

— for investments in the sector of processing and marketing of agricultural products: 55 % (or 75 % in Objective 1 regions) for projects complying with the sectoral programmes or one of the objectives of Article 1 of Council Regulation (EEC) No 866/90⁽⁵⁾ and 35 % (or 50 % in Objective 1 regions) for other products not excluded on the basis of the selection criteria under point 2 of the Annex to Commission Decision 90/342/EEC⁽⁶⁾ (or Commission Decision 94/173/EEC⁽⁷⁾);

(c) the aid in question could be paid only following changes in the rates for the new loans taken out, so as to take account of variations in the cost of money (in such cases, the amount of aid had to be less than or equal to the cost of such changes) or had to concern agricultural holdings providing guarantees of viability, particularly in the event that the financial burdens resulting from the existing loans were such as to be detrimental to the holdings or lead them to bankruptcy.

(14) After the procedure had been initiated, the Italian authorities amended Law No 52/94 by means of Law No 13/96, on the basis of which the Commission was able to close the procedure by declaring the aid, as modified by that law, to be compatible with the common market⁽⁸⁾.

⁽⁴⁾ OJ L 128, 19.5.1975, p. 1.

⁽⁵⁾ OJ L 91, 6.4.1990, p. 1.

⁽⁶⁾ OJ L 163, 29.6.1990, p. 71.

⁽⁷⁾ OJ L 222, 20.9.1995, p. 19.

⁽⁸⁾ Letter SG (96) D/3465¹ of 29 March 1996.

⁽³⁾ Case No C 43/95 (ex NN 73/94) (OJ C 327, 7.12.1995, p. 9).

(15) The changes made to the scheme by Law No 13/96 were as follows:

- (a) the aid of up to 50 % of the liabilities entered in the balance sheet of cooperatives in the event of merger or absorption was cancelled;
- (b) the aid for the consolidation of the onerous debts of cooperatives and groupings thereof (Article 1(1) of Law No 52/94) and aid for holdings (Article 1(2)) may be granted only to consolidate debts resulting from the carrying out of investments;
- (c) this aid may concern only a part (share) of the investment, namely 80 % for cooperatives and 65 % for agricultural holdings;
- (d) the aid must be granted within the limits of the rates generally authorised by the Commission, as regards the aggregate amount of any aid granted when the loan was taken out and the aid in question, i.e. 35 % (75 % in less-favoured areas within the meaning of Directive 75/268/EEC) for investments in the primary agricultural sector and 55 % for investments in the sector of processing and marketing of agricultural products;
- (e) the aid in question may concern only agricultural holdings or cooperatives providing guarantees of viability, particularly in the event that the financial burdens resulting from the existing loans are such as to be detrimental to the holdings or lead them to bankruptcy.

(16) The aid scheme, which was approved in the light of these changes, remained unchanged until the Commission decided to initiate the procedure provided for by Article 88(2) of the EC Treaty in relation to the provisions of Article 257 of Law No 10/01.

III. INITIATION OF THE PROCEDURE UNDER ARTICLE 88(2) OF THE EC TREATY

(17) The Commission launched the procedure provided for by Article 88(2) of the EC Treaty in relation to the provisions of Article 257 of Law No 10/01 and the aid paid between 1 January 1998 and 20 May 2001 (the date of entry into force of Law No 10/01) under the aid scheme that was to have been refinanced by the budget allocation provided for in that article, since it had doubts as to the compatibility with the common market of the aid in question, particularly as regards the following aspects:

- (a) the allocation under Article 257 of Law No 10/01 was to have served to fund an aid scheme for the consolidation of the onerous debts of agricultural holdings and cooperatives, as approved by the Commission in 1996 on the basis of special conditions concerning the rescue and restructuring of firms in difficulty which could be applied to the agricultural sector instead of the provisions of the 1994 Community guidelines on State aid for rescuing and restructuring firms in difficulty⁽⁹⁾ (hereinafter 'the 1994 Guidelines'), as expressly provided for in the latter;
- (b) the 1994 Guidelines were replaced by the 1997 Community guidelines on State aid for rescuing and restructuring firms in difficulty⁽¹⁰⁾ (hereinafter 'the 1997 Guidelines'), which laid down new conditions applicable to the agricultural sector. The scheme should have been brought into line with these new conditions with effect from 1 January 1998 but none of the information available made it possible to establish whether this had taken place;
- (c) the 1997 Guidelines were in turn replaced by the 1999 Community guidelines on State aid for rescuing and restructuring firms in difficulty (hereinafter 'the 1999 Guidelines'), to which the scheme in question should similarly have been brought into line;
- (d) none of the information in question made it possible to establish whether the scheme in question had been brought into line with the conditions of the 1999 Guidelines;
- (e) in this context, the compatibility with the common market of the aid granted between 1 January 1998 and 20 May 2001 (date of entry into force of Law No 10/01) and the manner of use of the allocation provided for by Article 257 of Law No 10/01 appeared doubtful.

IV. COMMENTS FROM THE ITALIAN AUTHORITIES

(18) By letter dated 2 July 2004, registered on 7 July 2004, the Permanent Representation of Italy to the European Union sent the Commission the comments made by the Italian authorities following initiation of the procedure under Article 88(2) of the EC Treaty in relation to the provisions of Article 257 of Law No 10/01 and the aid paid between 1 January 1998 and 20 May 2001 (the date of entry into force of that Regional Law) under the aid scheme that was to have been refinanced by the budget allocation provided for in that article.

⁽⁹⁾ OJ C 368, 23.12.1994, p. 12.

⁽¹⁰⁾ OJ C 283, 19.9.1997, p. 2.

- (19) In that letter, the Italian authorities first announced the withdrawal of the notification of Article 257 of Law No 10/01 and the launching of the procedure to repeal it, while stating that no implementing measures had been adopted and no aid had been paid pursuant to that article.
- (20) The Italian authorities also stressed that, in the letter approving Law No 52/94, the Commission had stated that the aid in question complied with the criteria applicable thereto and could thus benefit from the exemption under paragraph 3(c) of Article 92 (now Article 87) of the EC Treaty, as they were measures intended to facilitate the development of certain economic activities or of certain economic areas, without adversely affecting trading conditions to an extent contrary to the common interest, and had not made reference to the Community guidelines on State aid for rescuing and restructuring firms in difficulty.
- (21) In their opinion, as emerges from the correspondence with the Commission between 1994 and 1996, it was clear that the objective of Law No 52/94 was to avoid situations whereby, when making investments, agricultural holdings were faced with interest rates much higher than market rates as a result of fluctuations in the cost of money, thereby placing them in difficulty. Furthermore, Lazio regional authority always guaranteed that the viability of the beneficiary holdings would be checked, with particular reference to the recovery plans that the latter were required to submit pursuant to Law No 52/94 and amendments thereto.
- (22) In this context, the Italian authorities asserted that the aid under Law No 52/94 could benefit from the exemption under Article 87(3)(c) of the EC Treaty.
- (23) In the letter of 2 July 2004, the Italian authorities also asked whether, in the case in point, as regards the rescue and restructuring of firms in difficulty, it would be possible for the aid paid between 1998 and 2000⁽¹¹⁾ for loans in place as at 5 December 1994 to be covered by point 2.5 of the 1997 Guidelines, according to which 'the guidelines are also without prejudice to the application of aid schemes authorized for other purposes than rescues or restructuring, such as regional development [and] the development of SMEs', given that the measures provided for by Law No 52/94 had been approved as measures intended to facilitate the development of certain economic activities or of certain economic areas, without adversely affecting trading conditions to an extent contrary to the common interest.
- (24) Finally, in reply to point 29 of the letter of 11 December 2003 (see footnote 1), in which the Commission asked the Italian authorities to send it a series of Decisions of Lazio Regional Authority and extracts of all the Finance Laws adopted with effect from 1 January 1998, so as to enable it to establish the exact value of the allocations earmarked each year to fund the scheme in question, the Italian authorities explained that:
- (a) the only funding laid down for Law No 52/94 was that provided for in the law itself and reproduced in the 1995 regional budget⁽¹²⁾;
 - (b) the expenditure commitments became effective only in 1996, after the law had been approved by the Commission;
 - (c) subsequently, the aid to undertakings that satisfied the conditions of Law No 52/94 were financed through funds that had been freed up thanks to savings resulting from the reduction in interest rates and the rigorous implementation of the law, without there being any need to have recourse to supplementary budgetary appropriations;
 - (d) the aid from Lazio Region to agricultural holdings concerned only bank loans that were linked to the making of investments and were in place as at 5 December 1994, bearing in mind that, in 1994, as in previous years, Italy had one of the highest interest rates among the Member States of the Union.
- (25) In the letter sent to the Commission on 3 April 2009, the Italian authorities clarified that all the aid applications under the scheme had been submitted prior to 1 January 1998.

V. ASSESSMENT

- (26) According to Article 87(1) of the EC Treaty, any aid granted by a Member State or through State resources in any form whatsoever which distorts or threatens to distort competition by favouring certain undertakings or the production of certain goods is, in so far as it affects trade between Member States, incompatible with the common market.
- (27) The measure in question meets this definition, insofar as it favours certain undertakings (those with onerous debts in the agricultural sector) and can affect trade, given Italy's position in the agricultural production sector (by way of example, in 2006 Italy was the third-largest beef and veal producer and the largest tomato producer in the Union).

⁽¹¹⁾ The Italian authorities referred to 2000 and not to 2001 since no aid was granted after 2000.

⁽¹²⁾ This figure was ITL 4 000 000 000 (EUR 2 061 856). Between 1998 and 2000 the total value of the aid granted was ITL 1 400 000 000 (EUR 721 650).

- (28) However, in the cases provided for in Article 87(2) and (3) of the EC Treaty, such measures may, by derogation, be considered compatible with the common market.
- (29) In the present case, given the type of scheme in question, the only derogation that may be invoked is that laid down in Article 87(3)(c) of the EC Treaty, according to which aid may be considered compatible with the common market if it is intended to facilitate the development of certain economic activities or of certain economic areas, provided that it does not adversely affect trading conditions to an extent contrary to the common interest.
- (30) Before examining the applicability of that derogation, the Commission would point out that, in their letter of 2 July 2004 following initiation of the procedure under Article 88(2) of the EC Treaty, the Italian authorities stated that the procedure to repeal Article 257 of Law No 10/01 had been launched and that no aid had been paid out pursuant to that article. By telex dated 20 September 2005, the Commission asked the Italian authorities to supply proof that Article 257 of Law No 10/01 had been repealed.
- (31) The Commission received a reply to that telex by letter dated 16 July 2008 confirming the repeal, by means of Article 27(2) of Regional Law No 4 of 28 April 2006, of the disputed provisions contained in Article 257 of Law No 10/01, the application of which had in any case been on hold since the procedure under Article 88(2) of the EC Treaty had been initiated. Moreover, the Italian authorities announced the withdrawal of the notification of the aforementioned Article 257 in their letter of 2 July 2004.
- (32) In view of the foregoing, the Commission has no reason to continue its investigations into the provisions of Article 257 of Law No 10/01 and can close its examination procedure.
- (33) As regards the applicability of the derogation under Article 87(3)(c) of the EC Treaty in relation to the aid granted between 1 January 1998 and 31 December 2000 (see footnote 11), the Commission notes that, in the comments made after the procedure under Article 88(2) of the EC Treaty was initiated and during the subsequent meeting, the Italian authorities clarified that the aid in question was funded exclusively from the sums entered in the budget for scheme C 43/95, which was approved by the Commission (see recital 24). It is also inferred from the letter of 3 April 2009

from the Italian authorities that all the aid applications were submitted prior to 1 January 1998 (see recital 25).

- (34) Since these clarifications demonstrate that the sums used between 1998 and 2000 were already covered by a Commission decision and that no applications were submitted subsequent to the date after which any new application had to be in line with the new provisions on aid for rescuing and restructuring firms in difficulty (see recital 17), the Commission no longer has any reason to take a new decision, in the light of these provisions, on the applicability of the derogation under Article 87(3)(c) of the EC Treaty to the aid granted between 1998 and 2000, which, in practice, is the continuation of the funding resulting from aid applications submitted prior to 1 January 1998 that complied with the conditions referred to in recital 15, and that were already approved by the Commission (see recital 14). The procedure initiated in relation to the aid granted between 1998 and 2000 may thus also be closed,

HAS ADOPTED THIS DECISION:

Article 1

The procedure under Article 88(2) of the EC Treaty that was launched by letter dated 11 December 2003⁽¹³⁾ in relation to the abovementioned scheme is hereby closed owing to having become redundant, since Italy withdrew the notification on 2 July 2004 and has not pursued the proposed aid.

Article 2

The procedure under Article 88(2) of the EC Treaty that was launched in relation to the aid granted by Italy (Lazio Region) between 1998 and 2000 under the scheme based on the provisions of Law No 52/94, as amended by Law No 13/96, and which has become redundant, is hereby closed.

Article 3

This Decision is addressed to the Italian Republic.

Done at Brussels, 17 June 2009.

For the Commission
Mariann FISCHER BOEL
Member of the Commission

⁽¹³⁾ See footnote 2.

COMMISSION DECISION**of 28 July 2009****amending the list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products**

(notified under document C(2009) 5804)

(Text with EEA relevance)

(2010/28/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use ⁽¹⁾, and in particular Article 16(f) thereof,

Having regard to the opinions of the European Medicines Agency, formulated on 10 January 2008 and 6 March 2008 by the Committee for Herbal Medicinal Products,

Whereas:

- (1) *Calendula officinalis* L and *Pimpinella anisum* L comply with the requirements set out in Directive 2001/83/EC. *Calendula officinalis* L and *Pimpinella anisum* L can be considered as herbal substances, herbal preparations or combinations thereof.
- (2) It is therefore appropriate to include *Calendula officinalis* L and *Pimpinella anisum* L in the list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products established in Annex I to Commission Decision 2008/911/EC ⁽²⁾.
- (3) Decision 2008/911/EC should therefore be amended accordingly.

- (4) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

HAS ADOPTED THIS DECISION:

Article 1

Decision 2008/911/EC is amended as follows:

1. Annex I is amended in accordance with Annex I to this Decision.
2. Annex II is amended in accordance with Annex II to this Decision.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 28 July 2009.

For the Commission

Günter VERHEUGEN

Vice-President⁽¹⁾ OJ L 311, 28.11.2001, p. 67.⁽²⁾ OJ L 328, 6.12.2008, p. 42.

ANNEX I

In Annex I to Decision 2008/911/EC, the following is inserted:

- '*Calendula officinalis* L' is inserted before *Foeniculum vulgare* Miller subsp. *vulgare* var. *vulgare* (Bitter fennel, fruit),
 - '*Pimpinella anisum* L' is inserted after *Foeniculum vulgare* Miller subsp. *vulgare* var. *dulce* (Miller) Thellung (Sweet fennel, fruit).
-

ANNEX II

In Annex II to Decision 2008/911/EC, the following is inserted:

— '*Calendula officinalis* L' is inserted before *Foeniculum vulgare* Miller subsp. *vulgare* var. *vulgare* (Bitter fennel, fruit)

'COMMUNITY LIST ENTRY ON CALENDULA OFFICINALIS L**Scientific name of the plant**

Calendula officinalis L.

Botanical family

Asteraceae

Herbal substance

Calendula flower

Common name in all EU official languages of herbal substance

BG (bългарski): Невен, цвят	LT (lietuvių kalba): Medetkų žiedai
CS (čeština): Měsíčkový květ	LV (latviešu valoda): Kliņģerītes ziedi
DA (dansk): Morgenfrueblomst	MT (malti): Fjura calendula
DE (Deutsch): Ringelblumenblüten	NL (nederlands): Goudsbloem
EL (elliniká): Άνθος καλέντουλας	PL (polski): Kwiat nagietka
EN (English): Calendula flower	PT (português): Flor de calêndula
ES (español): Flor de calêndula	RO (română): Floare de gălbenele (calendula)
ET (eesti keel): Saialilleõisik	SK (slovenčina): Nechtíkový kvet
FI (suomi): Tarhakehäkukan kukka	SL (slovenščina): Cvet vrtnega ognjiča
FR (français): Souci	SV (svenska): Ringblomma, blomma
HU (magyar): A körömvirág virága	IS (íslenska): Morgunfrú, blóm
IT (italiano): Calendula fiore	NO (norsk): Ringblomst

Herbal preparation(s)

- Liquid extract (DER 1:1), extraction solvent ethanol 40-50 % (v/v).
- Liquid extract (DER 1:1,8-2,2), extraction solvent ethanol 40-50 % (v/v).
- Tincture (DER 1:5), extraction solvent ethanol 70-90 % (v/v).

European Pharmacopoeia monograph reference

Calendula flower – *Calendulae flos* (01/2005:1297)

Indication(s)

- Traditional herbal medicinal product for the symptomatic treatment of minor inflammations of the skin (such as sunburn) and as an aid in healing of minor wounds.
- Traditional herbal medicinal product for the symptomatic treatment of minor inflammations in the mouth or the throat.

The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.

Type of tradition

European

Specified strength

Please see "Specified posology".

Specified posology

Herbal preparations:

A. Liquid extract (DER 1:1)

In semi-solid dosage forms: amount equivalent to 2-10 % herbal substance.

B. Liquid extract (DER 1:1,8-2,2)

In semi-solid dosage forms: amount equivalent to 2-5 % herbal substance.

C. Tincture (DER 1:5)

In compresses diluted at least 1:3 with freshly boiled water.

In semi-solid dosage forms: amount equivalent to 2-10 % herbal substance.

As a gargle or mouth rinse in a 2 % solution.

2 to 4 times daily

Indication (a)

The use is not recommended in children under 6 years of age (see below "Special warnings and precautions for use").

Indication (b)

The use in children under 12 years of age is not recommended because there is no experience available (see below "Special warnings and precautions for use").

Route of administration

Cutaneous and oromucosal use.

Duration of use or any restrictions on the duration of use

Compresses: remove after 30-60 minutes

All herbal preparations: If the symptoms persist after 1 week during the use of the medicinal product a doctor or a qualified health care practitioner should be consulted.

Any other information necessary for the safe use*Contraindications*

Hypersensitivity to members of the *Asteraceae* (*Compositae*) family.

Special warnings and precautions for use

Indication (a)

The use in children under 6 years of age is not recommended because there is no experience available.

Indication (b)

The use in children under 12 years of age is not recommended because there is no experience available.

If signs of skin infection are observed, a doctor or a qualified health care practitioner should be consulted.

Interactions with other medicinal products and other forms of interaction

None reported.

Pregnancy and lactation

Safety during pregnancy and lactation has not been established.

In the absence of sufficient data, the use during pregnancy and lactation is not recommended.

Effects on ability to drive and use machines

Not relevant.

Undesirable effects

Skin sensitisation. The frequency is not known.

If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.

Overdose

None reported.

- *Pimpinella anisum* L' is inserted after *Foeniculum vulgare* Miller subsp. *vulgare* var. *dulce* (Miller) Thellung (Sweet fennel, fruit)

'COMMUNITY LIST ENTRY ON PIMPINELLA ANISUM L**Scientific name of the plant**

Pimpinella anisum L.

Botanical family

Apiaceae

Herbal substance

Aniseed

Common name in all EU official languages of herbal substance

BG (bългарski): Анасон, плод	LT (lietuvių kalba): Anyžių sėklos
CS (čeština): Anýzový plod	LV (latviešu valoda): Anīsa sēklas
DA (dansk): Anisfrø	MT (malti): Frotta tal-Anisi
DE (Deutsch): Anis	NL (nederlands): Anijsvrucht
EL (elliniká): Γλυκάνισο	PL (polski): Owoc anyżu
EN (English): Aniseed	PT (português): Anis
ES (español): Fruto de anís	RO (română): Fruct de anason
ET (eesti keel): Aniis	SK (slovenčina): Anízový plod
FI (suomi): Anis	SL (slovenščina): Plod vrtnega janeža
FR (français): Anis (fruit d)	SV (svenska): Anis
HU (magyar): Ánizsmag	IS (íslenska): Anís
IT (italiano): Anice (Anice verde), frutto	NO (norsk): Anis

Herbal preparation(s)

Dried aniseed, comminuted or crushed

European Pharmacopoeia monograph reference

Anisi fructus (01/2005:0262)

Indication(s)

- (a) Traditional herbal medicinal product for symptomatic treatment of mild, spasmodic gastro-intestinal complaints including bloating and flatulence.
- (b) Traditional herbal medicinal product used as an expectorant in cough associated with cold.

The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.

Type of tradition

European

Specified strength

Please see "Specified posology"

Specified posology

Adolescents over 12 years of age, adults, elderly:

Indications (a) and (b)

1 to 3,5 g of whole or (freshly (*)) comminuted or crushed aniseed in 150 ml of boiling water as a herbal tea
3 times daily

The use in children under 12 years is not recommended of age (see below "Special warnings and precautions for use").

Route of administration

Oral use

Duration of use or any restrictions on the duration of use

Not to be taken for more than 2 weeks.

If the symptoms persist during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.

Any other information necessary for the safe use*Contraindications*

Hypersensitivity to the active substance or to *Apiaceae* (*Umbelliferae*) (caraway, celery, coriander, dill and fennel) or to anethole.

Special warnings and precautions for use

The use is not recommended in children under 12 years of age due to the lack of adequate data for safety assessment.

Interactions with other medicinal products and other forms of interaction

None reported.

Pregnancy and lactation

There are no data from the use of aniseed in pregnant patients.

It is unknown if aniseed constituents are excreted in human breast milk.

In the absence of sufficient data, the use during pregnancy and lactation is not recommended.

Effects on ability to drive and use machines

No studies on the effect on the ability to drive and use machines have been performed.

Undesirable effects

Allergic reactions to aniseed affecting the skin or the respiratory system may occur. The frequency is not known.

If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.

Overdose

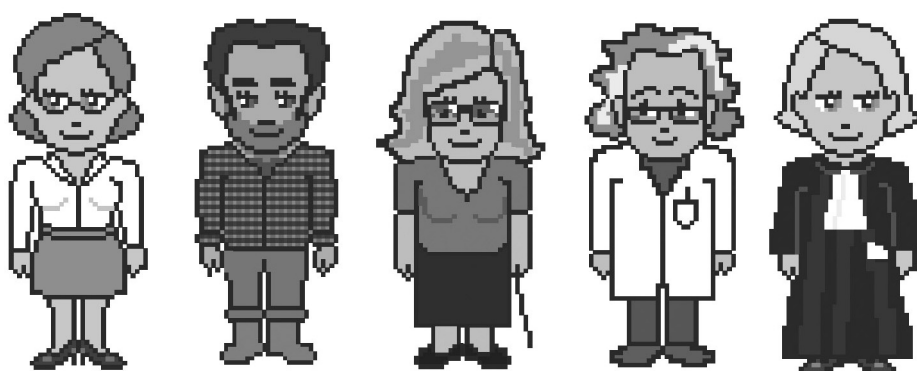
No case of overdose has been reported.

(*) For commercial preparations of comminuted or crushed aniseed the applicant must carry out appropriate stability testing related to the content of essential oil components.'

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