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[1] Text with EEA relevance

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

EN

[1] Text with EEA relevance

(Continued on inside back cover)

II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) No 330/2010

of 20 April 2010

on the application of Article 101(3) of the Treaty on the Functioning of the European Union to categories of vertical agreements and concerted practices

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation No 19/65/EEC of the Council of 2 March 1965 on the application of Article 85(3) of the Treaty to certain categories of agreements and concerted practices [1], and in particular Article 1 thereof,

Having published a draft of this Regulation,

After consulting the Advisory Committee on Restrictive Practices and Dominant Positions,

Whereas:

(1) Regulation No 19/65/EEC empowers the Commission to apply Article 101(3) of the Treaty on the Functioning of the European Union (*) by regulation to certain categories of vertical agreements and corresponding concerted practices falling within Article 101(1) of the Treaty.

(2) Commission Regulation (EC) No 2790/1999 of 22 December 1999 on the application of Article 81(3) of the Treaty to categories of vertical agreements and concerted practices [2] defines a category of vertical agreements which the Commission regarded as normally satisfying the conditions laid down in Article 101(3) of the Treaty. In view of the overall positive experience with the application of that Regulation, which expires on 31 May 2010, and taking into account further experience acquired since its adoption, it is appropriate to adopt a new block exemption regulation.

(3) The category of agreements which can be regarded as normally satisfying the conditions laid down in Article 101(3) of the Treaty includes vertical agreements for the purchase or sale of goods or services where those agreements are concluded between non-competing undertakings, between certain competitors or by certain associations of retailers of goods. It also includes vertical agreements containing ancillary provisions on the assignment or use of intellectual property rights. The term 'vertical agreements' should include the corresponding concerted practices.

(4) For the application of Article 101(3) of the Treaty by regulation, it is not necessary to define those vertical agreements which are capable of falling within Article 101(1) of the Treaty. In the individual assessment of agreements under Article 101(1) of the Treaty, account has to be taken of several factors, and in particular the market structure on the supply and purchase side.

(5) The benefit of the block exemption established by this Regulation should be limited to vertical agreements for which it can be assumed with sufficient certainty that they satisfy the conditions of Article 101(3) of the Treaty.

[1] OJ 36, 6.3.1965, p. 533.

(*) With effect from 1 December 2009, Article 81 of the EC Treaty has become Article 101 of the Treaty on the Functioning of the European Union. The two Articles are, in substance, identical. For the purposes of this Regulation, references to Article 101 of the Treaty on the Functioning of the European Union should be understood as references to Article 81 of the EC Treaty where appropriate.

[2] OJ L 336, 29.12.1999, p. 21.

(6) Certain types of vertical agreements can improve economic efficiency within a chain of production or distribution by facilitating better coordination between the participating undertakings. In particular, they can lead to a reduction in the transaction and distribution costs of the parties and to an optimisation of their sales and investment levels.

(7) The likelihood that such efficiency-enhancing effects will outweigh any anti-competitive effects due to restrictions contained in vertical agreements depends on the degree of market power of the parties to the agreement and, therefore, on the extent to which those undertakings face competition from other suppliers of goods or services regarded by their customers as interchangeable or substitutable for one another, by reason of the products' characteristics, their prices and their intended use.

(8) It can be presumed that, where the market share held by each of the undertakings party to the agreement on the relevant market does not exceed 30 %, vertical agreements which do not contain certain types of severe restrictions of competition generally lead to an improvement in production or distribution and allow consumers a fair share of the resulting benefits.

(9) Above the market share threshold of 30 %, there can be no presumption that vertical agreements falling within the scope of Article 101(1) of the Treaty will usually give rise to objective advantages of such a character and size as to compensate for the disadvantages which they create for competition. At the same time, there is no presumption that those vertical agreements are either caught by Article 101(1) of the Treaty or that they fail to satisfy the conditions of Article 101(3) of the Treaty.

(10) This Regulation should not exempt vertical agreements containing restrictions which are likely to restrict competition and harm consumers or which are not indispensable to the attainment of the efficiency-enhancing effects. In particular, vertical agreements containing certain types of severe restrictions of competition such as minimum and fixed resale-prices, as well as certain types of territorial protection, should be excluded from the benefit of the block exemption established by this Regulation irrespective of the market share of the undertakings concerned.

(11) In order to ensure access to or to prevent collusion on the relevant market, certain conditions should be attached to the block exemption. To this end, the exemption of non-compete obligations should be limited to obligations which do not exceed a defined duration. For the same reasons, any direct or indirect obligation causing the members of a selective distribution system not to sell the brands of particular competing suppliers should be excluded from the benefit of this Regulation.

(12) The market-share limitation, the non-exemption of certain vertical agreements and the conditions provided for in this Regulation normally ensure that the agreements to which the block exemption applies do not enable the participating undertakings to eliminate competition in respect of a substantial part of the products in question.

(13) The Commission may withdraw the benefit of this Regulation, pursuant to Article 29(1) of Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty [1], where it finds in a particular case that an agreement to which the exemption provided for in this Regulation applies nevertheless has effects which are incompatible with Article 101(3) of the Treaty.

(14) The competition authority of a Member State may withdraw the benefit of this Regulation pursuant to Article 29(2) of Regulation (EC) No 1/2003 in respect of the territory of that Member State, or a part thereof where, in a particular case, an agreement to which the exemption provided for in this Regulation applies nevertheless has effects which are incompatible with Article 101(3) of the Treaty in the territory of that Member State, or in a part thereof, and where such territory has all the characteristics of a distinct geographic market.

(15) In determining whether the benefit of this Regulation should be withdrawn pursuant to Article 29 of Regulation (EC) No 1/2003, the anti-competitive effects that may derive from the existence of parallel networks of vertical agreements that have similar effects which significantly restrict access to a relevant market or competition therein are of particular importance. Such cumulative effects may for example arise in the case of selective distribution or non compete obligations.

(16) In order to strengthen supervision of parallel networks of vertical agreements which have similar anti-competitive effects and which cover more than 50 % of a given market, the Commission may by regulation declare this Regulation inapplicable to vertical agreements containing specific restraints relating to the market concerned, thereby restoring the full application of Article 101 of the Treaty to such agreements,

[1] OJ L 1, 4.1.2003, p. 1.

HAS ADOPTED THIS REGULATION:

Article 1

Definitions

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

(a) 'vertical agreement' means an agreement or concerted practice entered into between two or more undertakings each of which operates, for the purposes of the agreement or the concerted practice, at a different level of the production or distribution chain, and relating to the conditions under which the parties may purchase, sell or resell certain goods or services;

(b) 'vertical restraint' means a restriction of competition in a vertical agreement falling within the scope of Article 101(1) of the Treaty;

(c) 'competing undertaking' means an actual or potential competitor; 'actual competitor' means an undertaking that is active on the same relevant market; 'potential competitor' means an undertaking that, in the absence of the vertical agreement, would, on realistic grounds and not just as a mere theoretical possibility, in case of a small but permanent increase in relative prices be likely to undertake, within a short period of time, the necessary additional investments or other necessary switching costs to enter the relevant market;

(d) 'non-compete obligation' means any direct or indirect obligation causing the buyer not to manufacture, purchase, sell or resell goods or services which compete with the contract goods or services, or any direct or indirect obligation on the buyer to purchase from the supplier or from another undertaking designated by the supplier more than 80 % of the buyer's total purchases of the contract goods or services and their substitutes on the relevant market, calculated on the basis of the value or, where such is standard industry practice, the volume of its purchases in the preceding calendar year;

(e) 'selective distribution system' means a distribution system where the supplier undertakes to sell the contract goods or services, either directly or indirectly, only to distributors selected on the basis of specified criteria and where these distributors undertake not to sell such goods or services to unauthorised distributors within the territory reserved by the supplier to operate that system;

(f) 'intellectual property rights' includes industrial property rights, know how, copyright and neighbouring rights;

(g) 'know-how' means a package of non-patented practical information, resulting from experience and testing by the supplier, which is secret, substantial and identified: in this context, 'secret' means that the know-how is not generally known or easily accessible; 'substantial' means that the know-how is significant and useful to the buyer for the use, sale or resale of the contract goods or services; 'identified' means that the know-how is described in a sufficiently comprehensive manner so as to make it possible to verify that it fulfils the criteria of secrecy and substantiality;

(h) 'buyer' includes an undertaking which, under an agreement falling within Article 101(1) of the Treaty, sells goods or services on behalf of another undertaking;

(i) 'customer of the buyer' means an undertaking not party to the agreement which purchases the contract goods or services from a buyer which is party to the agreement.

2. For the purposes of this Regulation, the terms 'undertaking', 'supplier' and 'buyer' shall include their respective connected undertakings.

'Connected undertakings' means:

(a) undertakings in which a party to the agreement, directly or indirectly:

(i) has the power to exercise more than half the voting rights, or

(ii) has the power to appoint more than half the members of the supervisory board, board of management or bodies legally representing the undertaking, or

(iii) has the right to manage the undertaking's affairs;

(b) undertakings which directly or indirectly have, over a party to the agreement, the rights or powers listed in point (a);

(c) undertakings in which an undertaking referred to in point (b) has, directly or indirectly, the rights or powers listed in point (a);

(d) undertakings in which a party to the agreement together with one or more of the undertakings referred to in points (a), (b) or (c), or in which two or more of the latter undertakings, jointly have the rights or powers listed in point (a);

(e) undertakings in which the rights or the powers listed in point (a) are jointly held by:

(i) parties to the agreement or their respective connected undertakings referred to in points (a) to (d), or

(ii) one or more of the parties to the agreement or one or more of their connected undertakings referred to in points (a) to (d) and one or more third parties.

Article 2

Exemption

1. Pursuant to Article 101(3) of the Treaty and subject to the provisions of this Regulation, it is hereby declared that Article 101(1) of the Treaty shall not apply to vertical agreements.

This exemption shall apply to the extent that such agreements contain vertical restraints.

2. The exemption provided for in paragraph 1 shall apply to vertical agreements entered into between an association of undertakings and its members, or between such an association and its suppliers, only if all its members are retailers of goods and if no individual member of the association, together with its connected undertakings, has a total annual turnover exceeding EUR 50 million. Vertical agreements entered into by such associations shall be covered by this Regulation without prejudice to the application of Article 101 of the Treaty to horizontal agreements concluded between the members of the association or decisions adopted by the association.

3. The exemption provided for in paragraph 1 shall apply to vertical agreements containing provisions which relate to the assignment to the buyer or use by the buyer of intellectual property rights, provided that those provisions do not constitute the primary object of such agreements and are directly related to the use, sale or resale of goods or services by the buyer or its customers. The exemption applies on condition that, in relation to the contract goods or services, those provisions do not contain restrictions of competition having the same object as vertical restraints which are not exempted under this Regulation.

4. The exemption provided for in paragraph 1 shall not apply to vertical agreements entered into between competing undertakings. However, it shall apply where competing undertakings enter into a non-reciprocal vertical agreement and:

(a) the supplier is a manufacturer and a distributor of goods, while the buyer is a distributor and not a competing undertaking at the manufacturing level; or

(b) the supplier is a provider of services at several levels of trade, while the buyer provides its goods or services at the retail level and is not a competing undertaking at the level of trade where it purchases the contract services.

5. This Regulation shall not apply to vertical agreements the subject matter of which falls within the scope of any other block exemption regulation, unless otherwise provided for in such a regulation.

Article 3

Market share threshold

1. The exemption provided for in Article 2 shall apply on condition that the market share held by the supplier does not exceed 30 % of the relevant market on which it sells the contract goods or services and the market share held by the buyer does not exceed 30 % of the relevant market on which it purchases the contract goods or services.

2. For the purposes of paragraph 1, where in a multi party agreement an undertaking buys the contract goods or services from one undertaking party to the agreement and sells the contract goods or services to another undertaking party to the agreement, the market share of the first undertaking must respect the market share threshold provided for in that paragraph both as a buyer and a supplier in order for the exemption provided for in Article 2 to apply.

Article 4

Restrictions that remove the benefit of the block exemption — hardcore restrictions

The exemption provided for in Article 2 shall not apply to vertical agreements which, directly or indirectly, in isolation or in combination with other factors under the control of the parties, have as their object:

(a) the restriction of the buyer's ability to determine its sale price, without prejudice to the possibility of the supplier to impose a maximum sale price or recommend a sale price, provided that they do not amount to a fixed or minimum sale price as a result of pressure from, or incentives offered by, any of the parties;

(b) the restriction of the territory into which, or of the customers to whom, a buyer party to the agreement, without prejudice to a restriction on its place of establishment, may sell the contract goods or services, except:

(i) the restriction of active sales into the exclusive territory or to an exclusive customer group reserved to the supplier or allocated by the supplier to another buyer, where such a restriction does not limit sales by the customers of the buyer,

(ii) the restriction of sales to end users by a buyer operating at the wholesale level of trade,

(iii) the restriction of sales by the members of a selective distribution system to unauthorised distributors within the territory reserved by the supplier to operate that system, and

(iv) the restriction of the buyer's ability to sell components, supplied for the purposes of incorporation, to customers who would use them to manufacture the same type of goods as those produced by the supplier;

(c) the restriction of active or passive sales to end users by members of a selective distribution system operating at the retail level of trade, without prejudice to the possibility of prohibiting a member of the system from operating out of an unauthorised place of establishment;

(d) the restriction of cross-supplies between distributors within a selective distribution system, including between distributors operating at different level of trade;

(e) the restriction, agreed between a supplier of components and a buyer who incorporates those components, of the supplier's ability to sell the components as spare parts to end-users or to repairers or other service providers not entrusted by the buyer with the repair or servicing of its goods.

Article 5

Excluded restrictions

1. The exemption provided for in Article 2 shall not apply to the following obligations contained in vertical agreements:

(a) any direct or indirect non-compete obligation, the duration of which is indefinite or exceeds five years;

(b) any direct or indirect obligation causing the buyer, after termination of the agreement, not to manufacture, purchase, sell or resell goods or services;

(c) any direct or indirect obligation causing the members of a selective distribution system not to sell the brands of particular competing suppliers.

For the purposes of point (a) of the first subparagraph, a non-compete obligation which is tacitly renewable beyond a period of five years shall be deemed to have been concluded for an indefinite duration.

2. By way of derogation from paragraph 1(a), the time limitation of five years shall not apply where the contract goods or services are sold by the buyer from premises and land owned by the supplier or leased by the supplier from third parties not connected with the buyer, provided that the duration of the non-compete obligation does not exceed the period of occupancy of the premises and land by the buyer.

3. By way of derogation from paragraph 1(b), the exemption provided for in Article 2 shall apply to any direct or indirect obligation causing the buyer, after termination of the agreement, not to manufacture, purchase, sell or resell goods or services where the following conditions are fulfilled:

(a) the obligation relates to goods or services which compete with the contract goods or services;

(b) the obligation is limited to the premises and land from which the buyer has operated during the contract period;

(c) the obligation is indispensable to protect know-how transferred by the supplier to the buyer;

(d) the duration of the obligation is limited to a period of one year after termination of the agreement.

Paragraph 1(b) is without prejudice to the possibility of imposing a restriction which is unlimited in time on the use and disclosure of know-how which has not entered the public domain.

Article 6

Non-application of this Regulation

Pursuant to Article 1a of Regulation No 19/65/EEC, the Commission may by regulation declare that, where parallel networks of similar vertical restraints cover more than 50 % of a relevant market, this Regulation shall not apply to vertical agreements containing specific restraints relating to that market.

Article 7

Application of the market share threshold

For the purposes of applying the market share thresholds provided for in Article 3 the following rules shall apply:

(a) the market share of the supplier shall be calculated on the basis of market sales value data and the market share of the buyer shall be calculated on the basis of market purchase value data. If market sales value or market purchase value data are not available, estimates based on other reliable market information, including market sales and purchase volumes, may be used to establish the market share of the undertaking concerned;

(b) the market shares shall be calculated on the basis of data relating to the preceding calendar year;

(c) the market share of the supplier shall include any goods or services supplied to vertically integrated distributors for the purposes of sale;

(d) if a market share is initially not more than 30 % but subsequently rises above that level without exceeding 35 %, the exemption provided for in Article 2 shall continue to apply for a period of two consecutive calendar years following the year in which the 30 % market share threshold was first exceeded;

(e) if a market share is initially not more than 30 % but subsequently rises above 35 %, the exemption provided for in Article 2 shall continue to apply for one calendar year following the year in which the level of 35 % was first exceeded;

(f) the benefit of points (d) and (e) may not be combined so as to exceed a period of two calendar years;

(g) the market share held by the undertakings referred to in point (e) of the second subparagraph of Article 1(2) shall be apportioned equally to each undertaking having the rights or the powers listed in point (a) of the second subparagraph of Article 1(2).

Article 8

Application of the turnover threshold

1. For the purpose of calculating total annual turnover within the meaning of Article 2(2), the turnover achieved during the previous financial year by the relevant party to the vertical agreement and the turnover achieved by its connected undertakings in respect of all goods and services, excluding all taxes and other duties, shall be added together. For this purpose, no account shall be taken of dealings between the party to the vertical agreement and its connected undertakings or between its connected undertakings.

2. The exemption provided for in Article 2 shall remain applicable where, for any period of two consecutive financial years, the total annual turnover threshold is exceeded by no more than 10 %.

Article 9

Transitional period

The prohibition laid down in Article 101(1) of the Treaty shall not apply during the period from 1 June 2010 to 31 May 2011 in respect of agreements already in force on 31 May 2010 which do not satisfy the conditions for exemption provided for in this Regulation but which, on 31 May 2010, satisfied the conditions for exemption provided for in Regulation (EC) No 2790/1999.

Article 10

Period of validity

This Regulation shall enter into force on 1 June 2010.

It shall expire on 31 May 2022.

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

Done at Brussels, 20 April 2010.

For the Commission
The President
José Manuel BARROSO

COMMISSION REGULATION (EU) No 331/2010

of 22 April 2010

amending Regulation (EC) No 1580/2007 as regards the trigger levels for additional duties on cucumbers and cherries, other than sour cherries

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], and in particular Article 143(b), in conjunction with Article 4 thereof,

Whereas:

(1) Commission Regulation (EC) No 1580/2007 of 21 December 2007 laying down implementing rules of Council Regulations (EC) No 2200/96, (EC) No 2201/96 and (EC) No 1182/2007 in the fruit and vegetable sector [2] provides for surveillance of imports of the products listed in Annex XVII thereto. That surveillance is to be carried out in accordance with the rules laid down in Article 308d of Commission Regulation (EEC) No 2454/93 of 2 July 1993 laying down provisions for the implementation of Council Regulation (EEC) No 2913/92 establishing the Community Customs Code [3].

(2) For the purposes of applying Article 5(4) of the Agreement on Agriculture [4] concluded as part of the Uruguay Round of multilateral trade negotiations and in the light of the latest data available for 2007, 2008 and 2009, the trigger levels for additional duties on cucumbers and cherries, other than sour cherries, should be adjusted.

(3) Regulation (EC) No 1580/2007 should therefore be amended accordingly.

(4) 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

Annex XVII to Regulation (EC) No 1580/2007 is replaced by the text set out in the Annex to this Regulation.

Article 2

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

It shall apply from 1 May 2010.

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

Done at Brussels, 22 April 2010.

For the Commission
The President
José Manuel BARROSO

[1] OJ L 299, 16.11.2007, p. 1.
[2] OJ L 350, 31.12.2007, p. 1.
[3] OJ L 253, 11.10.1993, p. 1.
[4] OJ L 336, 23.12.1994, p. 22.

ANNEX

'ANNEX XVII

ADDITIONAL IMPORT DUTIES: TITLE IV, CHAPTER II, SECTION 2

Without prejudice to the rules governing the interpretation of the Combined Nomenclature, the description of the products is deemed to be indicative only. The scope of the additional duties for the purposes of this Annex is determined by the scope of the CN codes as they exist at the time of the adoption of this Regulation.

Order number	CN code	Description	Period of application	Trigger level (tonnes)
78.0015	0702 00 00	Tomatoes	From 1 October to 31 May	415 907
78.0020			From 1 June to 30 September	40 107
78.0065	0707 00 05	Cucumbers	From 1 May to 31 October	11 879
78.0075			From 1 November to 30 April	18 611
78.0085	0709 90 80	Artichokes	From 1 November to 30 June	8 866
78.0100	0709 90 70	Courgettes	From 1 January to 31 December	55 369
78.0110	0805 10 20	Oranges	From 1 December to 31 May	355 386
78.0120	0805 20 10	Clementines	From 1 November to end of February	529 006
78.0130	0805 20 30 0805 20 50 0805 20 70 0805 20 90	Mandarins (including tangerines and satsumas); wilkings and similar citrus hybrids	From 1 November to end of February	96 377
78.0155	0805 50 10	Lemons	From 1 June to 31 December	334 680
78.0160			From 1 January to 31 May	62 311
78.0170	0806 10 10	Table grapes	From 21 July to 20 November	89 140
78.0175	0808 10 80	Apples	From 1 January to 31 August	829 840
78.0180			From 1 September to 31 December	884 648
78.0220	0808 20 50	Pears	From 1 January to 30 April	224 927
78.0235			From 1 July to 31 December	38 957
78.0250	0809 10 00	Apricots	From 1 June to 31 July	5 785
78.0265	0809 20 95	Cherries, other than sour cherries	From 21 May to 10 August	90 511
78.0270	0809 30	Peaches, including nectarines	From 11 June to 30 September	131 459
78.0280	0809 40 05	Plums	From 11 June to 30 September	129 925'

COMMISSION REGULATION (EU) No 332/2010

of 22 April 2010

amending Annex I to Regulation (EC) No 798/2008 as regards the entry for Israel in the list of third countries, territories, zones or compartments

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption [1] and in particular the introductory phrase of Article 8, the first paragraph of point 1 of Article 8 and point 4 of Article 8 thereof,

Having regard to Council Directive 2009/158/EC of 30 November 2009 on animal health conditions governing intra-Community trade in, and imports from third countries of, poultry and hatching eggs [2], and in particular Article 24(2) thereof,

Whereas:

(1) Directive 2002/99/EC lays down the general animal health rules governing all stages of the production, processing and distribution within the Union and the introduction from third countries of products of animal origin and products obtained therefrom intended for human consumption. That Directive provides that special import conditions are to be established for each third country or group of third countries, having regard to their animal health situation.

(2) Directive 2009/158/EC lays down the animal health conditions governing trade within the Union and imports from third countries of poultry and hatching eggs. That Directive provides that poultry is to come from third countries free of avian influenza or which, although they are not free from that disease, apply measures to control it which are at least equivalent to those laid down by the relevant Union legislation.

(3) Commission Regulation (EC) No 798/2008 of 8 August 2008 laying down a list of third countries, territories, zones or compartments from which poultry and poultry products may be imported into and transit through the Community and the veterinary certification requirements [3] provides that the commodities covered by it are only to be imported into and transited through the Union from the third countries, territories, zones or compartments listed in the table in Part 1 of Annex I thereto.

(4) Pursuant to that Regulation, where an outbreak of highly pathogenic avian influenza (HPAI) occurs in a third country, territory, zone or compartment previously free of that disease, that third country, territory, zone or compartment is to again be considered as free of HPAI, provided that certain conditions are met; said conditions concern the implementation of a stamping out policy to control the disease, including adequate cleansing and disinfection carried out on all previously infected establishments. In addition, avian influenza surveillance must have been carried out in accordance with Part II of Annex IV to that Regulation during a three-month period following completion of the stamping out policy and cleansing and disinfection.

(5) Israel is currently listed in Part 1 of Annex I to Regulation (EC) No 798/2008 as a third country free from highly pathogenic avian influenza. Imports of poultry commodities to which that Regulation applies are therefore authorised from the whole territory of that third country.

(6) Israel has notified to the Commission an outbreak of highly pathogenic avian influenza of the H5N1 subtype on its territory.

(7) Due to the confirmed outbreak of HPAI, the territory of Israel may no longer be considered as free from that disease and the veterinary authorities of Israel have suspended issuing veterinary certificates for consignments of certain poultry commodities accordingly. Israel has also implemented a stamping out policy in order to control the disease and limit its spread.

(8) The information on the control measures taken has been submitted to the Commission. That information and the epidemiological situation in Israel have been evaluated by the Commission.

[1] OJ L 18, 23.1.2003, p. 11.
[2] OJ L 343, 22.12.2009, p. 74.
[3] OJ L 226, 23.8.2008, p. 1.

(9) The prompt and decisive action taken by Israel to confine the disease and the positive outcome of the evaluation of the epidemiological situation allows limiting the restrictions on imports into the Union for certain poultry commodities to the zones affected by the disease, which the veterinary authorities of Israel have placed under restrictions due to the outbreak of highly pathogenic avian influenza.

(10) In addition, Israel is carrying out surveillance activities for avian influenza which appear to meet the requirements laid down in Part II of Annex IV to Regulation (EC) No 798/2008.

(11) Taking into account the favourable development of the epidemiological situation and related surveillance activities for avian influenza in resolving the outbreak, it is appropriate to limit the time period during which the authorisation for imports into the Union is suspended until 1 May 2010.

(12) Annex I to Regulation (EC) No 798/2008 should therefore be amended accordingly.

(13) In order to implement the zoning requirements and thereby allowing trade to resume as soon as possible this Regulation should enter into force the day after publication.

(14) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Part 1 of Annex I to Regulation (EC) No 798/2008 is replaced by the text in the Annex to this Regulation.

Article 2

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

It shall apply from 26 January 2010.

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

Done at Brussels, 22 April 2010.

For the Commission
The President
José Manuel BARROSO

ANNEX

Part 1 of Annex I to Regulation (EC) No 798/2008 is replaced by the following:

'PART 1

List of third countries, territories, zones or compartments

ISO code and name of third country or territory	Code of third country, territory, zone or compartment	Description of third country, territory, zone or compartment	Veterinary certificate		Specific conditions	Specific conditions		Avian influenza surveillance status	Avian influenza vaccination status	Salmonella control status
			Model(s)	Additional guarantees		Closing date [1]	Opening date [2]			
1	2	3	4	5	6	6A	6B	7	8	9
AL — Albania	AL-0	Whole country	EP, E							S4
AR — Argentina	AR-0	Whole country	SPF							
			POU, RAT, EP, E					A		S4
			WGM	VIII						
AU — Australia	AU-0	Whole country	SPF							
			EP, E							S4
			BPP, DOC, HEP, SRP							S0, ST0
			BPR	I						
			DOR	II						
			HER	III						
			POU	VI						
			RAT	VII						

1	2	3	4	5	6	6A	6B	7	8	9
BR — Brazil	BR-0	Whole country	SPF							
	BR-1	States of: Rio Grande do Sul, Santa Catarina, Paraná, São Paulo and Mato Grosso do Sul	RAT, BPR, DOR, HER, SRA		N			A		
	BR-2	States of: Mato Grosso, Paraná, Rio Grande do Sul, Santa Catarina and São Paulo	BPP, DOC, HEP, SRP		N					S5, ST0
	BR-3	Distrito Federal and States of: Goiás, Minas Gerais, Mato Grosso, Mato Grosso do Sul, Paraná, Rio Grande do Sul, Santa Catarina and São Paulo	WGM	VIII						
			EP, E, POU		N					S4
BW — Botswana	BW-0	Whole country	SPF							
			EP, E							S4
			BPR	I						
			DOR	II						
			HER	III						
			RAT	VII						
BY — Belarus	BY-0	Whole country	EP and E (both “only for transit through the EU”)	IX						
CA — Canada	CA-0	Whole country	SPF							
			EP, E							S4
			BPR, BPP, DOR, HER, SRA, SRP		N			A		S1, ST1
			DOC, HEP		L, N					
			WGM	VIII						
			POU, RAT		N					

1	2	3	4	5	6	6A	6B	7	8	9
CH — Switzerland	CH-0	Whole country	([3])					A		([3])
CL — Chile	CL-0	Whole country	SPF							
			EP, E							S4
			BPR, BPP, DOC, DOR, HEP, HER, SRA, SRP		N			A		S0, ST0
			WGM	VIII						
			POU, RAT		N					
CN — China	CN-0	Whole country	EP							
	CN-1	Province of Shandong	POU, E	VI	P2	6.2.2004	—			S4
GL — Greenland	GL-0	Whole country	SPF							
			EP, WGM							
HK — Hong Kong	HK-0	The whole territory of the Hong Kong Special Administrative Region	EP							
HR — Croatia	HR-0	Whole country	SPF							
			BPR, BPP, DOR, DOC, HEP, HER, SRA, SRP		N			A		S2, ST0
			EP, E, POU, RAT, WGM		N					
IL — Israel	IL-0	Whole country	SPF							
			EP, E							S4
	IL-1	Area of Israel excluding IL-2	BPR, BPP, DOC, DOR, HEP, HER, SRP		N			A		S5, ST1
			WGM	VIII						
			POU, RAT		N					S4

1	2	3	4	5	6	6A	6B	7	8	9
	IL-2	Area of Israel inside the following boundaries: — to the west: road number 4. — to the south: road number 5812 connecting to road number 5815. — to the east: the security fence until road number 6513. — to the north: road number 6513 until the junction with road 65. From this point in a straight line to the entrance of Givat Nili and from there in a straight line to the junction of roads 652 and 4.	BPR, BPP, DOC, DOR, HEP, HER, SRP		N, P2	26.1.2010	1.5.2010	A		S5, ST1
			WGM	VIII	P2	26.1.2010	1.5.2010			
			POU, RAT		N, P2	26.1.2010	1.5.2010			S4
IN — India	IN-0	Whole country	EP							
IS — Iceland	IS-0	Whole country	SPF							
			EP, E							S4
KR — Republic of Korea	KR-0	Whole country	EP, E							S4
ME — Montenegro	ME-O	Whole country	EP							
MG — Madagascar	MG-0	Whole country	SPF							
			EP, E, WGM							S4
MY — Malaysia	MY-0	—	—							
	MY-1	Western Peninsular	EP							
			E		P2	6.2.2004				S4
MK — former Yugoslav Republic of Macedonia [4]	MK-0 [4]	Whole country	EP							

1	2	3	4	5	6	6A	6B	7	8	9
MX — Mexico	MX-0	Whole country	SPF							
			EP							
NA — Namibia	NA-0	Whole country	SPF							
			BPR	I						
			DOR	II						
			HER	III						
			RAT, EP, E	VII						S4
NC — New Caledonia	NC-0	Whole country	EP							
NZ — New Zealand	NZ-0	Whole country	SPF							
			BPR, BPP, DOC, DOR, HEP, HER, SRA, SRP							S0, ST0
			WGM	VIII						
			EP, E, POU, RAT							S4
PM — Saint Pierre and Miquelon	PM-0	Whole territory	SPF							
RS — Serbia [5]	RS-0 [5]	Whole country	EP							
RU — Russia	RU-0	Whole country	EP							
SG — Singapore	SG-0	Whole country	EP							
TH — Thailand	TH-0	Whole country	SPF, EP							
			WGM	VIII	P2	23.1.2004				
			E, POU, RAT		P2	23.1.2004				S4

1	2	3	4	5	6	6A	6B	7	8	9
TN — Tunisia	TN-0	Whole country	SPF							
			DOR, BPR, BPP, HER							S1, ST0
			WGM	VIII						
			EP, E, POU, RAT							S4
TR — Turkey	TR-0	Whole country	SPF							
			EP, E							S4
US — United States	US-0	Whole country	SPF							
			BPR, BPP, DOC, DOR, HEP, HER, SRA, SRP		N			A		S3, ST1
			WGM	VIII						
			EP, E, POU, RAT		N					S4
UY — Uruguay	UY-0	Whole country	SPF							
			EP, E, RAT							S4
ZA — South Africa	ZA-0	Whole country	SPF							
			EP, E							S4
			BPR	I				A		
			DOR	II						
			HER	III						
			RAT	VII						

1	2	3	4	5	6	6A	6B	7	8	9
ZW — Zimbabwe	ZW-0	Whole country	RAT	VII						
			EP, E							S4

([1]) Commodities, including those transported on the high seas, produced before this date may be imported into the Union during a period of 90 days from this date.
([2]) Only commodities produced after this date may be imported into the Union.
([3]) In accordance with the agreement between the European Union and the Swiss Confederation on trade in agricultural products (OJ L 114, 30.4.2002, p. 132).
([4]) The former Yugoslav Republic of Macedonia; provisional code that does not prejudge in any way the definitive nomenclature for this country, which will be agreed following the conclusion of negotiations currently taking place on this subject in the United Nations.
([5]) Not including Kosovo, as defined by United Nations Security Council Resolution 1244 of 10 June 1999.'

COMMISSION REGULATION (EU) No 333/2010

of 22 April 2010

concerning the authorisation of a new use of *Bacillus subtilis* C-3102 (DSM 15544) as a feed additive for weaned piglets (holder of authorisation Calpis Co. Ltd. Japan, represented in the European Union by Calpis Co. Ltd. Europe Representative Office)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ([1]), and in particular Article 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of the preparation set out in the Annex to this Regulation. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of a new use of the preparation of *Bacillus subtilis* C-3102 (DSM 15544) as a feed additive for weaned piglets, to be classified in the additive category 'zootechnical additives'.

(4) The use of that micro-organism preparation has been authorised for chickens for fattening by Commission Regulation (EC) No 1444/2006 ([2]).

(5) New data were submitted in support of the application for authorisation for weaned piglets. The European Food Safety Authority (the Authority) concluded in its opinion of 9 December 2009 ([3]) that *Bacillus subtilis* C-3102 (DSM 15544) does not have an adverse effect on animal health, human health or the environment and that the use of that preparation can improve the performance of the animals. The Authority does not consider that there is a need for specific requirements of post market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Community Reference Laboratory set up by Regulation (EC) No 1831/2003.

(6) The assessment of *Bacillus subtilis* C-3102 (DSM 15544) shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised, as specified in the Annex to this Regulation.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

The preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'gut flora stabilisers', is authorised as an additive in animal nutrition subject to the conditions laid down in that Annex.

Article 2

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

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

Done at Brussels, 22 April 2010.

For the Commission
The President
José Manuel BARROSO

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) OJ L 271, 30.9.2006, p. 19.
([3]) *The EFSA Journal* 2010; 8(1):1426.

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						CFU/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: gut flora stabilisers									
4b1820	Calpis Co. Ltd. Japan, represented in the European Union by Calpis Co. Ltd. Europe Representative Office, France	*Bacillus subtilis* C-3102 (DSM 15544)	Additive composition: *Bacillus subtilis* C-3102 (DSM 15544) with minimum of $1{,}0 \times 10^{10}$ CFU/g Characterisation of the active substance: Viable spores (CFU) of *Bacillus subtilis* C-3102 (DSM 15544) Analytical method (1): Enumeration: spread plate method using tryptone soya agar in all target matrices (EN 15874:2009) Identification: pulsed-field gel electrophoresis (PFGE).	Piglets (weaned)	—	3×10^8	—	1. In the directions for use of the additive, premixture and compound feedingstuff indicate the storage temperature, storage life and stability to pelleting 2. For use in weaned piglets up to approximately 35 kg. 3. For safety: breathing protection, glasses and gloves shall be used during handling.	13 May 2020

(1) Details of the analytical methods are available at the following address of the Community Reference Laboratory: www.irmm.jrc.ec.europa.eu/crl-feed-additives

COMMISSION REGULATION (EU) No 334/2010

of 22 April 2010

amending Regulation (EC) No 721/2008 as regards the composition of feed additives

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition [1], and in particular Article 9(2) thereof,

Whereas:

(1) Commission Regulation (EC) No 721/2008 [2] authorises a preparation of red carotenoid-rich bacterium *Paracoccus carotinifaciens* as a feed additive for salmon and trout until 15 August 2018. That feed additive is classified in the category 'sensory additives', functional group 'a (ii). Colourants; substances which when fed to animals add colours to food of animal origin'.

(2) The Commission received an application requesting a modification of the conditions of the authorisation as regards the composition of the feed additive. That application was accompanied by the relevant supporting data. The Commission forwarded that application to the European Food Safety Authority (the Authority).

(3) The Authority concluded in its opinion of January 2010 that the requested modification would not affect the safety and efficacy of the product [3].

(4) The assessment of the modified preparation shows that it satisfies the conditions for authorisation, provided for in Article 5 of Regulation (EC) No 1831/2003.

(5) Regulation (EC) No 721/2008 should therefore be amended accordingly.

(6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

In the Annex to Regulation (EC) No 721/2008, in the third column, 'Composition, chemical formula, description, analytical method',

the words

'— 10-15 g/kg adonirubin

— 3-5 g/kg canthaxanthin'

are replaced by the words

'— 7-15 g/kg adonirubin

— 1-5 g/kg canthaxanthin'.

Article 2

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

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

Done at Brussels, 22 April 2010.

For the Commission
The President
José Manuel BARROSO

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[1] OJ L 268, 18.10.2003, p. 29.
[2] OJ L 198, 26.7.2008, p. 23.
[3] *The EFSA Journal* (2010); 8(1):1428.

COMMISSION REGULATION (EU) No 335/2010

of 22 April 2010

concerning the authorisation of zinc chelate of hydroxy analogue of methionine as a feed additive for all animal species

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition [1], and in particular Article 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of the preparation set out in the Annex to this Regulation. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of zinc chelate of hydroxy analogue of methionine as a feed additive for all animal species, to be classified in the additive category 'nutritional additives'.

(4) From the opinion of the European Food Safety Authority ('the Authority') adopted on 11 November 2009 [2], read in combination with those of 16 April 2008 [3] and 2 April 2009 [4] it results that zinc chelate of hydroxy analogue of methionine does not have an adverse effect on animal health, human health or the environment. According to the opinion of 16 April 2008, the use of that preparation may be considered as a source of available zinc and fulfils the criteria of a nutritional additive for all animal species. The Authority recommends appropriate measures for user safety. It does not consider that there is a need for specific requirements of post market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Community Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The assessment of that preparation shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised, as specified in the Annex to this Regulation.

(6) By Commission Regulation (EC) No 888/2009 of 25 September 2009 concerning the authorisation of Zinc chelate of hydroxy analogue of methionine as a feed additive for chickens for fattening [5] that preparation was already authorised as a feed additive for chickens for fattening. That Regulation should be repealed.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

The preparation specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'compounds of trace elements', is authorised as an additive in animal nutrition subject to the conditions laid down in that Annex.

Article 2

Regulation (EC) No 888/2009 is repealed.

[1] OJ L 268, 18.10.2003, p. 29.
[2] *The EFSA Journal (2009) 7(11): 1381.*
[3] *The EFSA Journal (2008) 694, 1.*
[4] *The EFSA Journal (2009) 1042:1.*
[5] OJ L 254, 26.9.2009, p. 71.

Article 3

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

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

Done at Brussels, 22 April 2010.

For the Commission
The President
José Manuel BARROSO

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Content of element (Zn) in mg/kg of complete feedingstuff with a moisture content of 12 %			
Category of nutritional additives. Functional group: compounds of trace elements									
3b6.10	—	Zinc chelate of hydroxy analogue of methionine	Characterisation of the additive: Zinc chelate of hydroxy analogue of methionine containing 17,5 %-18 % zinc and 81 % (2-hydroxy-4-methylthio) butanoic acid Mineral oil: ≤ 1 % Analytical method (1): Inductively coupled plasma atomic emission spectrometry (ICP-AES) according to EN 15510:2007	All species	—		Pets: 250 (total) Fish: 200 (total) Other species: 150 (total) Complete and complementary milk replacers: 200 (total)	1. The additive shall be incorporated into feed in the form of a premixture. 2. For user safety: breathing protection, safety glasses and gloves shall be worn during handling.	13 May 2020

(1) Details of the analytical methods are available at the following address of the Community Reference Laboratory: http://irmm.jrc.ec.europa.eu/crl-feed-additives

COMMISSION REGULATION (EU) No 336/2010

of 21 April 2010

concerning the classification of certain goods in the Combined Nomenclature

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff [1], and in particular Article 9(1)(a) thereof,

Whereas:

(1) In order to ensure uniform application of the Combined Nomenclature annexed to Regulation (EEC) No 2658/87, it is necessary to adopt measures concerning the classification of the goods referred to in the Annex to this Regulation.

(2) Regulation (EEC) No 2658/87 has laid down the general rules for the interpretation of the Combined Nomenclature. Those rules apply also to any other nomenclature which is wholly or partly based on it or which adds any additional subdivision to it and which is established by specific provisions of the Union, with a view to the application of tariff and other measures relating to trade in goods.

(3) Pursuant to those general rules, the goods described in column 1 of the table set out in the Annex should be classified under the CN codes indicated in column 2, by virtue of the reasons set out in column 3 of that table.

(4) It is appropriate to provide that binding tariff information which has been issued by the customs authorities of Member States in respect of the classification of goods in the Combined Nomenclature but which is not in accordance with this Regulation can, for a period of three months, continue to be invoked by the holder, under Article 12(6) of Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code [2].

(5) The measures provided for in this Regulation are in accordance with the opinion of the Customs Code Committee,

HAS ADOPTED THIS REGULATION:

Article 1

The goods described in column 1 of the table set out in the Annex shall be classified within the Combined Nomenclature under the CN codes indicated in column 2 of that table.

Article 2

Binding tariff information issued by the customs authorities of Member States, which is not in accordance with this Regulation, can continue to be invoked for a period of three months under Article 12(6) of Regulation (EEC) No 2913/92.

Article 3

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

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

Done at Brussels, 21 April 2010.

For the Commission,
On behalf of the President,
Algirdas ŠEMETA
Member of the Commission

[1] OJ L 256, 7.9.1987, p. 1.

[2] OJ L 302, 19.10.1992, p. 1.

ANNEX

Description of the goods	Classification (CN code)	Reasons
(1)	(2)	(3)
1. A disc of a diameter of approximately 580 mm and a thickness of approximately 3 mm, consisting of 2 layers made of polyurethane, one of which has machined grooves, whereas the other has an adhesive coating protected by a detachable plastic sheet (so-called 'polymeric pad'). The article is used with machines for the manufacture of silicon and semiconductor wafers. It is fitted on the carrier head of an interchangeable tool of such machines and is used to planarise/flatten and polish the wafers.	3919 90 00	Classification is determined by General Rules 1 and 6 for the interpretation of the Combined Nomenclature and by the wording of CN codes 3919 and 3919 90 00. Classification under heading 8486 as a part or an accessory of a machine of a kind used solely or principally for the manufacture of semiconductor wafers is excluded, as the article does not have the characteristics to be considered as a part or an accessory of such a machine. As the article constitutes consumable goods, it is to be classified according to its constituent material under CN code 3919 90 00 as a self-adhesive plate or sheet of plastics.
2. A disc of a diameter of approximately 580 mm and a thickness of approximately 2 mm, consisting of 2 layers of synthetic felt, one of them being impregnated with a polymeric binder (polyurethane) (so-called 'poromeric pad'). The other layer has an adhesive coating protected by a detachable plastic sheet. The article is used with machines for the manufacture of silicon and semiconductor wafers. It is fitted on the carrier head of an interchangeable tool of such machines and is used to planarise/flatten and polish the wafers.	5911 90 90	Classification is determined by General Rules 1 and 6 for the interpretation of the Combined Nomenclature, Note 7(a) to Section XI, Note 1(e) to Section XVI, Note 7(b) to Chapter 59 and by the wording of CN codes 5911, 5911 90 and 5911 90 90. Classification under heading 8486 as a part or an accessory of a machine of a kind used solely or principally for the manufacture of semiconductor wafers is excluded as the article does not have the characteristics to be considered as a part or an accessory of such a machine. The product constitutes an article for technical use within the meaning of Note 1(e) to Section XVI, as it is used with machines for the manufacture of silicon and semiconductor wafers to planarise/flatten and polish the wafers. It is therefore to be classified under CN code 5911 90 90 as a textile article (constituent material) used for technical purposes (see Note 7(b) to Chapter 59).

COMMISSION REGULATION (EU) No 337/2010

of 22 April 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 23 April 2010.

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

Done at Brussels, 22 April 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	JO	94,2
	MA	90,1
	TN	106,8
	TR	99,1
	ZZ	97,6
0707 00 05	MA	45,9
	TR	111,1
	ZZ	78,5
0709 90 70	MA	86,8
	TR	91,8
	ZZ	89,3
0805 10 20	EG	45,1
	IL	54,0
	MA	52,3
	TN	48,9
	TR	57,7
	ZZ	51,6
0805 50 10	EG	65,6
	IL	58,2
	TR	63,3
	ZA	63,4
	ZZ	62,6
0808 10 80	AR	94,2
	BR	79,8
	CA	113,4
	CL	86,0
	CN	78,5
	MK	24,7
	NZ	120,7
	US	134,1
	UY	78,3
	ZA	82,2
	ZZ	89,2
0808 20 50	AR	95,6
	CL	102,2
	CN	76,1
	NZ	167,4
	ZA	93,8
	ZZ	107,0

(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 338/2010

of 22 April 2010

fixing the export refunds on beef and veal

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 [1], and in particular Article 164(2), final subparagraph, and Article 170 thereof,

Whereas:

(1) Article 162(1) of Regulation (EC) No 1234/2007 provides that the difference between prices on the world market for the products listed in Part XV of Annex I to that Regulation and prices for those products on the Community market may be covered by an export refund.

(2) Given the present situation on the market in beef and veal, export refunds should therefore be set in accordance with the rules and criteria provided for in Articles 162 to 164 and 167 to 170 of Regulation (EC) No 1234/2007.

(3) Article 164(1) of Regulation (EC) No 1234/2007 provides that the refund may vary according to destination, especially where the world market situation, the specific requirements of certain markets, or obligations resulting from agreements concluded in accordance with Article 300 of the Treaty make this necessary.

(4) Refunds should be granted only on products that are allowed to move freely in the Community and that bear the health mark as provided for in Article 5(1)(a) of Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin [2]. Those products must also satisfy the requirements laid down in Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs [3] and Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption [4].

(5) The conditions laid down in the third subparagraph of Article 7(2) of Commission Regulation (EC) No 1359/2007 of 21 November 2007 laying down the conditions for granting special export refunds on certain cuts of boned meat of bovine animals [5] provide for a reduction of the special refund if the quantity of cuts of boned meat to be exported amounts to less than 95 %, but not less than 85 %, of the total weight of cuts produced by boning.

(6) Commission Regulation (EC) No 62/2010 [6] should therefore be repealed and replaced by a new regulation.

(7) 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

1. Export refunds as provided for in Article 164 of Regulation (EC) No 1234/2007 shall be granted on the products and for the amounts set out in the Annex to this Regulation subject to the conditions provided for in paragraph 2 of this Article.

2. The products eligible for a refund under paragraph 1 must meet the relevant requirements of Regulations (EC) Nos 852/2004 and 853/2004, notably preparation in an approved establishment and compliance with the health marking requirements laid down in Annex I, Section I, Chapter III to Regulation (EC) No 854/2004.

Article 2

In the case referred to in the third subparagraph of Article 7(2) of Regulation (EC) No 1359/2007, the rate of the refund on products falling within product code 0201 30 00 9100 shall be reduced by EUR 7/100 kg.

Article 3

Regulation (EC) No 62/2010 is hereby repealed.

[1] OJ L 299, 16.11.2007, p. 1.
[2] OJ L 139, 30.4.2004, p. 55
[3] OJ L 139, 30.4.2004, p. 1.
[4] OJ L 139, 30.4.2004, p. 206.
[5] OJ L 304, 22.11.2007, p. 21.
[6] OJ L 17, 22.1.2010, p. 33.

Article 4

This Regulation shall enter into force on 23 April 2010.

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

Done at Brussels, 22 April 2010.

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

ANNEX

Export refunds on beef and veal applicable from 23 April 2010

Product code	Destination	Unit of measurement	Refunds
0102 10 10 9140	B00	EUR/100 kg live weight	25,9
0102 10 30 9140	B00	EUR/100 kg live weight	25,9
0201 10 00 9110 (1)	B02	EUR/100 kg net weight	36,6
	B03	EUR/100 kg net weight	21,5
0201 10 00 9130 (1)	B02	EUR/100 kg net weight	48,8
	B03	EUR/100 kg net weight	28,7
0201 20 20 9110 (1)	B02	EUR/100 kg net weight	48,8
	B03	EUR/100 kg net weight	28,7
0201 20 30 9110 (1)	B02	EUR/100 kg net weight	36,6
	B03	EUR/100 kg net weight	21,5
0201 20 50 9110 (1)	B02	EUR/100 kg net weight	61,0
	B03	EUR/100 kg net weight	35,9
0201 20 50 9130 (1)	B02	EUR/100 kg net weight	36,6
	B03	EUR/100 kg net weight	21,5
0201 30 00 9050	US (3)	EUR/100 kg net weight	6,5
	CA (4)	EUR/100 kg net weight	6,5
0201 30 00 9060 (6)	B02	EUR/100 kg net weight	22,6
	B03	EUR/100 kg net weight	7,5
0201 30 00 9100 (2) (6)	B04	EUR/100 kg net weight	84,7
	B03	EUR/100 kg net weight	49,8
	EG	EUR/100 kg net weight	103,4
0201 30 00 9120 (2) (6)	B04	EUR/100 kg net weight	50,8
	B03	EUR/100 kg net weight	29,9
	EG	EUR/100 kg net weight	62,0
0202 10 00 9100	B02	EUR/100 kg net weight	16,3
	B03	EUR/100 kg net weight	5,4
0202 20 30 9000	B02	EUR/100 kg net weight	16,3
	B03	EUR/100 kg net weight	5,4
0202 20 50 9900	B02	EUR/100 kg net weight	16,3
	B03	EUR/100 kg net weight	5,4
0202 20 90 9100	B02	EUR/100 kg net weight	16,3
	B03	EUR/100 kg net weight	5,4
0202 30 90 9100	US (3)	EUR/100 kg net weight	6,5
	CA (4)	EUR/100 kg net weight	6,5

Product code	Destination	Unit of measurement	Refunds
0202 30 90 9200 (6)	B02	EUR/100 kg net weight	22,6
	B03	EUR/100 kg net weight	7,5
1602 50 31 9125 (5)	B00	EUR/100 kg net weight	23,3
1602 50 31 9325 (5)	B00	EUR/100 kg net weight	20,7
1602 50 95 9125 (5)	B00	EUR/100 kg net weight	23,3
1602 50 95 9325 (5)	B00	EUR/100 kg net weight	20,7

N.B.: The product codes and the 'A' series destination codes are set out in the Commission Regulation (EEC) No 3846/87 (OJ L 366, 24.12.1987, p. 1).

The destination codes are set out in Commission Regulation (EC) No 1833/2006 (OJ L 354, 14.12.2006, p. 19).

The other destinations are defined as follows:

B00: all destinations (third countries, other territories, victualling and destinations treated as exports from the Community).

B02: B04 and destination EG.

B03: Albania, Croatia, Bosnia-Herzegovina, Serbia, Kosovo (*), Montenegro, former Yugoslav Republic of Macedonia, stores and provisions (destinations referred to in Articles 33 and 42, and if appropriate in Article 41, of Commission Regulation (EC) No 612/2009 (OJ L 186, 17.7.2009, p. 1).

B04: Turkey, Ukraine, Belarus, Moldova, Russia, Georgia, Armenia, Azerbaijan, Kazakhstan, Turkmenistan, Uzbekistan, Tajikistan, Kyrgyzstan, Morocco, Algeria, Tunisia, Libya, Lebanon, Syria, Iraq, Iran, Israel, West Bank/Gaza Strip, Jordan, Saudi Arabia, Kuwait, Bahrain, Qatar, United Arab Emirates, Oman, Yemen, Pakistan, Sri Lanka, Myanmar (Burma), Thailand, Vietnam, Indonesia, Philippines, China, North Korea, Hong Kong, Sudan, Mauritania, Mali, Burkina Faso, Niger, Chad, Cape Verde, Senegal, Gambia, Guinea-Bissau, Guinea, Sierra Leone, Liberia, Côte-d'Ivoire, Ghana, Togo, Benin, Nigeria, Cameroun, Central African Republic, Equatorial Guinea, Sao Tome Principe, Gabon, Congo, Congo (Democratic Republic), Rwanda, Burundi, Saint Helena and dependencies, Angola, Ethiopia, Eritrea, Djibouti, Somalia, Uganda, Tanzania, Seychelles and dependencies, British Indian Ocean Territory, Mozambique, Mauritius, Comoros, Mayotte, Zambia, Malawi, South Africa, Lesotho.

(*) As defined by United Nations Security Council Resolution 1244 of 10 June 1999.

(1) Entry under this subheading is subject to the submission of the certificate appearing in the Annex to Commission Regulation (EC) No 433/2007 (OJ L 104, 21.4.2007, p. 3).

(2) The refund is granted subject to compliance with the conditions laid down in amended Commission Regulation (EC) No 1359/2007 (OJ L 304, 22.11.2007, p. 21), and, if applicable, in Commission Regulation (EC) No 1741/2006 (OJ L 329, 25.11.2006, p. 7).

(3) Carried out in accordance with Commission Regulation (EC) No 1643/2006 (OJ L 308, 8.11.2006, p. 7).

(4) Carried out in accordance with Commission Regulation (EC) No 1041/2008 (OJ L 281, 24.10.2008, p. 3).

(5) The refund is granted subject to compliance with the conditions laid down in Commission Regulation (EC) No 1731/2006 (OJ L 325, 24.11.2006, p. 12).

(6) The lean bovine meat content excluding fat is determined in accordance with the procedure described in the Annex to Commission Regulation (EEC) No 2429/86 (OJ L 210, 1.8.1986, p. 39).

The term 'average content' refers to the sample quantity as defined in Article 2(1) of Commission Regulation (EC) No 765/2002 (OJ L 117, 4.5.2002, p. 6). The sample is to be taken from that part of the consignment presenting the highest risk.

COMMISSION REGULATION (EU) No 339/2010

of 22 April 2010

granting no export refund for butter in the framework of the standing invitation to tender provided for in Regulation (EC) No 619/2008

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], and in particular Article 164(2), in conjunction with Article 4, thereof,

Whereas:

(1) Commission Regulation (EC) No 619/2008 of 27 June 2008 opening a standing invitation to tender for export refunds concerning certain milk products [2] provides for a permanent tender.

(2) Pursuant to Article 6 of Commission Regulation (EC) No 1454/2007 of 10 December 2007 laying down common rules for establishing a tender procedure for fixing export refunds for certain agricultural products [3] and following an examination of the tenders submitted in response to the invitation to tender, it is appropriate not to grant any refund for the tendering period ending on 20 April 2010.

(3) The Management Committee for the Common Organisation of Agricultural Markets has not delivered an opinion within the time limit set by its Chair,

HAS ADOPTED THIS REGULATION:

Article 1

For the standing invitation to tender opened by Regulation (EC) No 619/2008, for the tendering period ending on 20 April 2010, no export refund shall be granted for the products and destinations referred to in points (a) and (b) of Article 1 and in Article 2 of that Regulation.

Article 2

This Regulation shall enter into force on 23 April 2010.

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

Done at Brussels, 22 April 2010.

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

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[1] OJ L 299, 16.11.2007, p. 1.
[2] OJ L 168, 28.6.2008, p. 20.
[3] OJ L 325, 11.12.2007, p. 69.

COMMISSION REGULATION (EU) No 340/2010

of 22 April 2010

granting no export refund for skimmed milk powder in the framework of the standing invitation to tender provided for in Regulation (EC) No 619/2008

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], and in particular Article 164(2), in conjunction with Article 4, thereof,

Whereas:

(1) Commission Regulation (EC) No 619/2008 of 27 June 2008 opening a standing invitation to tender for export refunds concerning certain milk products [2] provides for a standing invitation to tender procedure.

(2) Pursuant to Article 6 of Commission Regulation (EC) No 1454/2007 of 10 December 2007 laying down common rules for establishing a tender procedure for fixing export refunds for certain agricultural products [3] and following an examination of the tenders submitted in response to the invitation to tender, it is appropriate not to grant any refund for the tendering period ending on 20 April 2010.

(3) The Management Committee for the Common Organisation of Agricultural Markets has not delivered an opinion within the time limit set by its Chair,

HAS ADOPTED THIS REGULATION:

Article 1

For the standing invitation to tender opened by Regulation (EC) No 619/2008, for the tendering period ending on 20 April 2010, no export refund shall be granted for the product and destinations referred to in point (c) of Article 1 and in Article 2 respectively of that Regulation.

Article 2

This Regulation shall enter into force on 23 April 2010.

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

Done at Brussels, 22 April 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 168, 28.6.2008, p. 20.
[3] OJ L 325, 11.12.2007, p. 69.

COMMISSION REGULATION (EU) No 341/2010

of 22 April 2010

fixing the export refunds on eggs

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 [1], and in particular Article 164(2), last subparagraph, and Article 170 thereof,

Whereas:

(1) Article 162(1) of Regulation (EC) No 1234/2007 provides that the difference between prices on the world market for the products referred to in Part XIX of Annex I to that Regulation and prices in the Community for those products may be covered by an export refund.

(2) In view of the current situation on the market in eggs, export refunds should be fixed in accordance with the rules and certain criteria provided for in Articles 162 to 164, 167, 169 and 170 of Regulation (EC) No 1234/2007.

(3) Article 164(1) of Regulation (EC) No 1234/2007 provides that refunds may vary according to destination, especially where the world market situation, the specific requirements of certain markets, or obligations resulting from agreements concluded in accordance with Article 300 of the Treaty make this necessary.

(4) Refunds should be granted only on products which are authorised to move freely within the Community and comply with requirements under Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs [2] and of Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin [3], as well as marking requirements under point A of Annex XIV to Regulation (EC) No 1234/2007.

(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

1. The products on which the export refunds provided for in Article 164 of Regulation (EC) No 1234/2007 may be paid, subject to the conditions laid down in paragraph 2 of this Article, and the amounts of those refunds are specified in the Annex to this Regulation.

2. The products on which a refund may be paid under paragraph 1 shall meet the requirements under Regulations (EC) Nos 852/2004 and 853/2004 and, in particular, shall be prepared in an approved establishment and comply with the marking conditions laid down in Section I of Annex II to Regulation (EC) No 853/2004 and those defined in point A of Annex XIV to Regulation (EC) No 1234/2007.

Article 2

This Regulation shall enter into force on 23 April 2010.

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

Done at Brussels, 22 April 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 139, 30.4.2004, p. 1.

[3] OJ L 139, 30.4.2004, p. 55.

ANNEX

Export refunds on eggs applicable from 23 April 2010

Product code	Destination	Unit of measurement	Amount of refund
0407 00 11 9000	A02	EUR/100 pcs	0,39
0407 00 19 9000	A02	EUR/100 pcs	0,20
0407 00 30 9000	E09	EUR/100 kg	0,00
	E10	EUR/100 kg	22,00
	E19	EUR/100 kg	0,00
0408 11 80 9100	A03	EUR/100 kg	84,72
0408 19 81 9100	A03	EUR/100 kg	42,53
0408 19 89 9100	A03	EUR/100 kg	42,53
0408 91 80 9100	A03	EUR/100 kg	53,67
0408 99 80 9100	A03	EUR/100 kg	9,00

NB: The product codes and the 'A' series destination codes are set out in Commission Regulation (EEC) No 3846/87 (OJ L 366, 24.12.1987, p. 1), as amended.
The other destinations are defined as follows:
E09: Kuwait, Bahrain, Oman, Qatar, the United Arab Emirates, Yemen, Hong Kong SAR, Russia and Turkey.
E10: South Korea, Japan, Malaysia, Thailand, Taiwan and the Philippines.
E19: all destinations except Switzerland and those of E09 and E10.

COMMISSION REGULATION (EU) No 342/2010

of 22 April 2010

fixing the export refunds on poultrymeat

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 [1], and in particular Article 164(2), last subparagraph, and Article 170 thereof,

Whereas:

(1) Article 162(1) of Regulation (EC) No 1234/2007 provides that the difference between prices on the world market for the products referred to in Part XX of Annex I to that Regulation and prices in the Community for those products may be covered by an export refund.

(2) In view of the current situation on the market in poultrymeat, export refunds should be fixed in accordance with the rules and criteria provided for in Articles 162 to 164, 167, 169 and 170 of Regulation (EC) No 1234/2007.

(3) Article 164(1) of Regulation (EC) No 1234/2007 provides that refunds may vary according to destination, especially where the world market situation, the specific requirements of certain markets, or obligations resulting from agreements concluded in accordance with Article 300 of the Treaty make this necessary.

(4) Refunds should be granted only on products which are authorised to move freely in the Community and bear the identification mark provided for in Article 5(1)(b) of Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin [2]. Those products should also comply with the requirements of Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs [3].

(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

1. The products on which the export refunds provided for in Article 164 of Regulation (EC) No 1234/2007 may be paid, subject to the conditions laid down in paragraph 2 of this Article, and the amounts of those refunds are specified in the Annex to this Regulation.

2. The products on which a refund may be paid under paragraph 1 shall meet the requirements under Regulations (EC) Nos 852/2004 and 853/2004 and, in particular, shall be prepared in an approved establishment and comply with the identification marking conditions laid down in Section I of Annex II to Regulation (EC) No 853/2004.

Article 2

This Regulation shall enter into force on 23 April 2010.

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

Done at Brussels, 22 April 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 139, 30.4.2004, p. 55.

[3] OJ L 139, 30.4.2004, p. 1.

ANNEX

Export refunds on poultrymeat applicable from 23 April 2010

Product code	Destination	Unit of measurement	Amount of refund
0105 11 11 9000	A02	EUR/100 pcs	0,24
0105 11 19 9000	A02	EUR/100 pcs	0,24
0105 11 91 9000	A02	EUR/100 pcs	0,24
0105 11 99 9000	A02	EUR/100 pcs	0,24
0105 12 00 9000	A02	EUR/100 pcs	0,47
0105 19 20 9000	A02	EUR/100 pcs	0,47
0207 12 10 9900	V03	EUR/100 kg	40,00
0207 12 90 9190	V03	EUR/100 kg	40,00
0207 12 90 9990	V03	EUR/100 kg	40,00

NB: The product codes and the 'A' series destination codes are set out in Commission Regulation (EEC) No 3846/87 (OJ L 366, 24.12.1987, p. 1), as amended.

The other destinations are defined as follows:
V03: A24, Angola, Saudi Arabia, Kuwait, Bahrain, Qatar, Oman, United Arab Emirates, Jordan, Yemen, Lebanon, Iraq and Iran.

COMMISSION REGULATION (EU) No 343/2010

of 22 April 2010

fixing the export refunds on pigmeat

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], and in particular Article 164(2), final subparagraph, and Article 170 thereof,

Whereas:

(1) Article 162(1) of Regulation (EC) No 1234/2007 provides that the difference between prices on the world market for the products listed in Part XVII of Annex I to that Regulation and prices for those products on the Community market may be covered by an export refund.

(2) Given the present situation on the market in pigmeat, export refunds should therefore be fixed in accordance with the rules and criteria provided for in Articles 162 to 164, 167, 169 and 170 of Regulation (EC) No 1234/2007.

(3) Article 164(1) of Regulation (EC) No 1234/2007 provides that the refund may vary according to destination, especially where the world market situation, the specific requirements of certain markets, or obligations resulting from agreements concluded in accordance with Article 300 of the Treaty make this necessary.

(4) Refunds should be granted only on products that are allowed to move freely in the Community and that bear the health mark as provided for in Article 5(1)(a) of Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin [2]. Those products must also satisfy the requirements laid down in Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs [3] and Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption [4].

(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

1. Export refunds as provided for in Article 164 of Regulation (EC) No 1234/2007 shall be granted on the products and for the amounts set out in the Annex to this Regulation subject to the condition provided for in paragraph 2 of this Article.

2. The products eligible for a refund under paragraph 1 must meet the relevant requirements of Regulations (EC) Nos 852/2004 and 853/2004, notably preparation in an approved establishment and compliance with the health marking requirements laid down in Annex I, Section I, Chapter III to Regulation (EC) No 854/2004.

Article 2

This Regulation shall enter into force on 23 April 2010.

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

Done at Brussels, 22 April 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 139, 30.4.2004, p. 55.

[3] OJ L 139, 30.4.2004, p. 1.

[4] OJ L 139, 30.4.2004, p. 206.

ANNEX

Export refunds on pigmeat applicable from 23 April 2010

Product code	Destination	Unit of measurement	Amount of refund
0210 11 31 9110	A00	EUR/100 kg	54,20
0210 11 31 9910	A00	EUR/100 kg	54,20
0210 19 81 9100	A00	EUR/100 kg	54,20
0210 19 81 9300	A00	EUR/100 kg	54,20
1601 00 91 9120	A00	EUR/100 kg	19,50
1601 00 99 9110	A00	EUR/100 kg	15,20
1602 41 10 9110	A00	EUR/100 kg	29,00
1602 41 10 9130	A00	EUR/100 kg	17,10
1602 42 10 9110	A00	EUR/100 kg	22,80
1602 42 10 9130	A00	EUR/100 kg	17,10
1602 49 19 9130	A00	EUR/100 kg	17,10

NB: The product codes and the 'A' series destination codes are set out in Commission Regulation (EEC) No 3846/87 (OJ L 366, 24.12.1987, p. 1) as amended.

COMMISSION REGULATION (EU) No 344/2010

of 22 April 2010

fixing representative prices in the poultrymeat and egg sectors and for egg albumin, and amending Regulation (EC) No 1484/95

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of 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 143 thereof,

Having regard to Council Regulation (EC) No 614/2009 of 7 July 2009 on the common system of trade for ovalbumin and lactalbumin [2], and in particular Article 3(4) thereof,

Whereas:

(1) Commission Regulation (EC) No 1484/95 [3] lays down detailed rules for implementing the system of additional import duties and fixes representative prices for poultrymeat and egg products and for egg albumin.

(2) Regular monitoring of the data used to determine representative prices for poultrymeat and egg products and for egg albumin shows that the representative import prices for certain products should be amended to take account of variations in price according to origin. The representative prices should therefore be published.

(3) In view of the situation on the market, this amendment should be applied as soon as possible.

(4) 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

Annex I to Regulation (EC) No 1484/95 is replaced by the Annex to this Regulation.

Article 2

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

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

Done at Brussels, 22 April 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 181, 14.7.2009, p. 8.
[3] OJ L 145, 29.6.1995, p. 47.

ANNEX

to the Commission Regulation of 22 April 2010 fixing representative prices in the poultrymeat and egg sectors and for egg albumin, and amending Regulation (EC) No 1484/95

'ANNEX I

CN code	Description of goods	Representative price (EUR/100 kg)	Security under Article 3(3) (EUR/100 kg)	Origin (1)
0207 12 10	Fowls of the species *Gallus domesticus*, not cut in pieces, presented as "70 % chickens", frozen	114,5	0	AR
0207 12 90	Fowls of the species *Gallus domesticus*, not cut in pieces, presented as "65 % chickens", frozen	124,2	0	BR
		108,7	3	AR
0207 14 10	Fowls of the species *Gallus domesticus*, boneless cuts, frozen	217,9	25	BR
		223,1	23	AR
		291,5	3	CL
0207 14 50	Fowls of the species *Gallus domesticus*, breasts, frozen	190,1	7	BR
0207 14 60	Fowl of the species *Gallus domesticus*, legs, frozen	110,3	10	BR
0207 25 10	Turkeys, not cut in pieces, presented as "80 % turkeys", frozen	146,0	4	BR
0207 27 10	Turkeys, boneless cuts, frozen	262,6	10	BR
		286,8	3	CL
0408 11 80	Egg yolks	318,2	0	AR
0408 91 80	Eggs, not in shell, dried	325,9	0	AR
1602 32 11	Preparations of fowls of the species Gallus domesticus, uncooked	300,8	0	BR
		311,4	0	TH
3502 11 90	Egg albumin, dried	531,4	0	AR

(1) Nomenclature of countries laid down by Commission Regulation (EC) No 1833/2006 (OJ L 354, 14.12.2006, p. 19). The code "ZZ" represents "other origins".'

COMMISSION REGULATION (EU) No 345/2010

of 22 April 2010

fixing the rates of the refunds applicable to eggs and egg yolks exported in the form of goods not covered by Annex I to the Treaty

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 market and on specific provisions for certain agricultural products (single CMO Regulation) [1], and in particular Article 164(2) thereof,

Whereas:

(1) Article 162(1)b of Regulation (EC) No 1234/2007 provides that the difference between prices in international trade for the products referred to in Article 1(1)(s) and listed in Part XIX of Annex 1 to of that Regulation and prices within the Community may be covered by an export refund where these goods are exported in the form of goods listed Part V of the Annex XX to that Regulation.

(2) Commission Regulation (EC) No 1043/2005 of 30 June 2005 implementing Council Regulation (EC) No 3448/93 as regards the system of granting export refunds on certain agricultural products exported in the form of goods not covered by Annex I to the Treaty, and the criteria for fixing the amount of such refunds [2], specifies the products for which a rate of refund is to be fixed, to be applied where these products are exported in the form of goods listed in Part V of Annex XX to Regulation (EC) No 1234/2007.

(3) In accordance with paragraph 2(b) of Article 14 of Regulation (EC) No 1043/2005, the rate of the refund per 100 kilograms for each of the basic products in question is to be fixed for a period of the same duration as that for which refunds are fixed for the same products exported unprocessed.

(4) Article 11 of the Agreement on Agriculture concluded under the Uruguay Round lays down that the export refund for a product contained in a good may not exceed the refund applicable to that product when exported without further processing.

(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

The rates of the refunds applicable to the basic products listed in Annex I to Regulation (EC) No 1043/2005 and in Article 1(1)(s) of Regulation (EC) No 1234/2007, and exported in the form of goods listed in Part V of Annex XX to Regulation (EC) No 1234/2007, shall be fixed as set out in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on 23 April 2010.

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

Done at Brussels, 22 April 2010.

For the Commission,
On behalf of the President,
Heinz ZOUREK
Director-General Enterprise and Industry

[1] OJ L 299, 16.11.2007, p. 1.
[2] OJ L 172, 5.7.2005, p. 24.

ANNEX

Rates of the refunds applicable from 23 April 2010 to eggs and egg yolks exported in the form of goods not covered by Annex I to the Treaty

(EUR/100 kg)

CN code	Description	Destination (1)	Rate of refund
0407 00	Birds' eggs, in shell, fresh, preserved or cooked:		
	– Of poultry:		
0407 00 30	– – Other:		
	(a) On exportation of ovalbumin of CN codes 3502 11 90 and 3502 19 90	02	0,00
		03	22,00
		04	0,00
	(b) On exportation of other goods	01	0,00
0408	Birds' eggs, not in shell and egg yolks, fresh, dried, cooked by steaming or by boiling in water, moulded, frozen or otherwise preserved, whether or not containing added sugar or other sweetening matter:		
	– Egg yolks:		
0408 11	– – Dried:		
ex 0408 11 80	– – – Suitable for human consumption:		
	not sweetened	01	84,72
0408 19	– – Other:		
	– – – Suitable for human consumption:		
ex 0408 19 81	– – – – Liquid:		
	not sweetened	01	42,53
ex 0408 19 89	– – – – Frozen:		
	not sweetened	01	42,53
	– Other:		
0408 91	– – Dried:		
ex 0408 91 80	– – – Suitable for human consumption:		
	not sweetened	01	53,67
0408 99	– – Other:		
ex 0408 99 80	– – – Suitable for human consumption:		
	not sweetened	01	9,00

(1) The destinations are as follows:
01 Third countries. For Switzerland and Liechtenstein these rates are not applicable to the goods listed in Tables I and II to Protocol No 2 to the Agreement between the European Community and the Swiss Confederation of 22 July 1972,
02 Kuwait, Bahrain, Oman, Qatar, United Arab Emirates, Yemen, Turkey, Hong Kong SAR and Russia,
03 South Korea, Japan, Malaysia, Thailand, Taiwan and the Philippines,
04 all destinations except Switzerland and those of 02 and 03.

DECISIONS

COMMISSION DECISION

of 19 April 2010

on the European Databank on Medical Devices (Eudamed)

(notified under document C(2010) 2363)

(Text with EEA relevance)

(2010/227/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices [1], and in particular Article 10b(3) thereof,

Having regard to Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [2], and in particular Article 14a(3) thereof,

Having regard to Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices [3], and in particular Article 12(3) thereof,

Whereas:

(1) Directives 90/385/EEC, 93/42/EEC and 98/79/EC contain provisions on a European databank for medical devices which require the establishment of that databank.

(2) The aim of the European databank for medical devices is to strengthen market surveillance by providing competent authorities with fast access to information on manufacturers and authorised representatives, devices and certificates and to vigilance data, to share information on clinical investigation data, as well as to contribute to a uniform application of those Directives, in particular in relation to registration requirements.

(3) The databank should therefore contain the data required by Directives 90/385/EEC, 93/42/EEC and 98/79/EC, in particular on registration of manufacturers and devices, data relating to certificates issued or renewed, modified, supplemented, suspended, withdrawn or refused, data obtained in accordance with the vigilance procedure and data on clinical investigations.

(4) Such a databank has been developed by the European Commission in cooperation with the Member States under the name 'European Databank for Medical Devices (Eudamed)' and is being used by numerous Member States on a voluntary basis.

(5) The data should be entered into the databank using prescribed data transfer methods.

(6) It is appropriate to use an internationally recognised nomenclature for medical devices when entering data into Eudamed in order to allow a uniform description of the devices concerned and efficient use of that databank. Given that data can be entered in all official languages of the Community, a numeric code should be used so that devices can be easily searched.

(7) The Global Medical Device Nomenclature that has been developed based on EN ISO 15225:2000 *Nomenclature — Specification for a nomenclature system for medical devices for the purpose of regulatory data exchange* is such an internationally recognised nomenclature. The need to establish and maintain Eudamed and to start implementing the Global Medical Device Nomenclature as a basis for that databank was recalled in the Council Conclusions of 2 December 2003 on Medical Devices [4].

[1] OJ L 189, 20.7.1990, p. 17.
[2] OJ L 169, 12.7.1993, p. 1.
[3] OJ L 331, 7.12.1998, p. 1.
[4] OJ C 20, 24.1.2004, p. 1.

(8) An appropriate transitional period is necessary to allow Member States to prepare for the mandatory use of Eudamed and to take account of the changes introduced by Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market [1].

(9) Member States should only be required to enter data existing before 1 May 2011 to the extent required for the future functioning of Eudamed. It is necessary for the completeness of Eudamed to enter data existing before 1 May 2011 on the manufacturer, the authorised representative and on device registration, which are required by Directives 93/42/EEC and 98/79/EC, in the form in which such data are available at national level.

(10) The measures provided for in this Decision are in accordance with the opinion of the Committee on Medical Devices,

HAS ADOPTED THIS DECISION:

Article 1

This Decision establishes the European Databank on Medical Devices (Eudamed) as databank for the purposes of Article 10b(3) of Directive 90/385/EEC, Article 14a(3) of Directive 93/42/EEC and Article 12(3) of Directive 98/79/EC.

Article 2

Member States shall ensure that the data referred to in points (a) and (b) of Article 10b(1) of Directive 90/385/EEC, points (a), (b) and (c) of Article 14a(1) of Directive 93/42/EEC and points (a), (b) and (c) of Article 12(1) of Directive 98/79/EC, are entered into Eudamed in accordance with the Annex to this Decision.

For clinical investigations Member States shall ensure that an extract of the notifications referred to in Article 10(1) of Directive 90/385/EEC and in Article 15(1) of Directive 93/42/EEC, as well as the information referred to in Article 10(3) and (4) of Directive 90/385/EEC and in Article 15(6) and (7) of Directive 93/42/EEC are entered into Eudamed in accordance with the Annex to this Decision.

Article 3

Eudamed shall use the Hypertext Transfer Protocol Secure (HTTPS) and the Extensible Mark-up Language (XML).

Article 4

When entering data in Eudamed, Member States may choose between on-line data entry and up-loading of XML files.

Member States shall ensure that when entering data into Eudamed medical devices are described using a code from an internationally recognised nomenclature for medical devices.

Article 5

As concerns data existing before the date referred to in Article 6, Member States shall ensure that the data on registration of manufacturers, authorised representatives and devices are entered into Eudamed in accordance with Article 14a(1)(a) of Directive 93/42/EEC and Article 12(1)(a) of Directive 98/79/EC.

That data shall be entered by 30 April 2012 at the latest.

Article 6

Member States shall apply this Decision from 1 May 2011.

Article 7

This Decision is addressed to the Member States.

Done at Brussels, 19 April 2010.

For the Commission
John DALLI
Member of the Commission

[1] OJ L 247, 21.9.2007, p. 21.

ANNEX

Table detailing the mandatory data fields in the respective module in the Eudamed databank according to the obligations arising from Directives 93/42/EEC, 90/385/EEC and 98/79/EC

Directive 93/42/EEC	Minimum data required for Eudamed data entry
Article 14a(1)(a) and Article 14(1) and (2)	1. Actor (manufacturer/authorised representative): (a) Name; (b) Street; (c) Locality; (d) Postcode; (e) Country; (f) Phone or E-mail; (g) Role. 2. Device: (a) Internationally recognised nomenclature code (for data generated after 1 May 2011); (b) Device Name/Make or, where not available, generic name.
Article 14a(1)(b)	3. Certificate: (a) Certificate number; (b) Certificate type; (c) Date of Issue; (d) Expiration Date; (e) Manufacturer and, if applicable, authorised representative (see fields under 1. Actor); (f) Notified Body (selected from system); (g) General Scope description and, where applicable, details on device (see fields under 2. Device); (h) Status and, where applicable, reasons for decision of Notified Body.
Article 14a(1)(c) and Article 10(3)	4. Incident (National Competent Authority Report): (a) Competent Authority reference; (b) Manufacturer, where applicable authorised representative (see fields under 1. Actor); (c) Manufacturer contact; (d) Manufacturer reference/Field Safety Corrective Action (FSCA) nr.; (e) Device (see fields under 2. Device), plus where applicable lot number, serial number, software version; (f) Notified Body (selected from system); (g) Device known to be in the market in; (h) Confidential; (i) Complete investigation; (j) Background Information (Description); (k) Conclusion; (l) Recommendation; (m) Action and action description.

Article 14a(1)(d) and Article 15(1), (6) and (7)	5. Clinical Investigation: (a) Manufacturer, where applicable authorised representative (see fields under 1. Actor); (b) Device (see fields under 2. Device); (c) Title of investigation; (d) Protocol number; (e) Primary objective; (f) Competent Authority Contact for this Clinical Investigation; (g) Decisions taken by Competent Authority pursuant to Article 15(6), date of decision and grounds; (h) Early termination on safety grounds pursuant to Article 15(7), date of decision and grounds.
Directive 90/385/EEC	Minimum data required for Eudamed data entry
Article 10b(1)(a)	6. Certificate (see fields under 3. Certificate)
Article 10b(1)(b) and Article 8(3)	7. Incident (see fields under 4. Incident)
Article 10b(1)(c) and Article 10(1), (3) and (4)	8. Clinical Investigation (see fields under 5. Clinical Investigation, (a) to (f)): (a) Decisions taken by Competent Authority pursuant to Article 10(3), date of decision and grounds; (b) Early termination on safety grounds pursuant to Article 10(4), date of decision and grounds.
Directive 98/79/EC	Minimum data required for Eudamed data entry
Article 12(1)(a) and Article 10(1), (3) and (4) and Annex VIII (4)	9. Actor (for all *in vitro* diagnostic medical devices (IVD's): Address of manufacturer, respectively authorised representative (see fields under 1. Actor). 10. Device: For all IVD's (a) Device (see fields under Device 2.); (b) Information on whether device is 'new'; (c) Discontinuation of placing on the market. In addition for Annex II and self-testing (d) Outcome of performance evaluation, where applicable; (e) Certificates (see fields under 3. Certificate); (f) Conformity with Common Technical Specifications, where applicable; (g) Identification of device.
Article 12(1)(b)	11. Certificate (see fields under 3. Certificate)
Article 12(1)(c) and Article 11(3)	12. Incident (see fields under 4. Incident)

COMMISSION DECISION

of 21 April 2010

authorising the placing on the market of puree and concentrate of the fruits of *Morinda citrifolia* as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council

(notified under document C(2010) 2397)

(Only the English text is authentic)

(2010/228/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients [1], and in particular Article 7 thereof,

Whereas:

(1) On 20 April 2006 Tahitian Noni International Inc. made a request to the competent authorities of Belgium to place puree and concentrate of the fruits of *Morinda citrifolia* on the market as a novel food ingredient.

(2) On 28 February 2007 the competent food assessment body of Belgium issued its initial assessment report. In that report it came to the conclusion that the use of the puree and concentrate of the fruits of *Morinda citrifolia* as a food ingredient was acceptable.

(3) The Commission forwarded the initial assessment report to all Member States on 28 March 2007.

(4) Within the 60-day period laid down in Article 6(4) of Regulation (EC) No 258/97 reasoned objections to the marketing of the product were raised in accordance with that provision.

(5) Therefore the European Food Safety Authority (EFSA) was consulted on 7 November 2007.

(6) On 13 March 2009, EFSA in the 'Scientific opinion of the Panel on Dietetic Products Nutrition and Allergies' on a request from the European Commission on the safety of '*Morinda citrifolia* (Noni) fruit puree and concentrate' as a novel food ingredient came to the conclusion that the Noni fruit puree and concentrate was safe for the general population.

(7) On the basis of the scientific assessment, it is established that the fruit puree and concentrate from *Morinda citrifolia* (Noni) complies with the criteria laid down in Article 3(1) of Regulation (EC) No 258/97.

(8) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

Morinda citrifolia (Noni) fruit puree and concentrate as specified in Annex I may be placed on the market in the Union as a novel food ingredient for the uses listed in Annex II.

Article 2

The designation of the *Morinda citrifolia* fruit puree authorised by this Decision on the labelling of the foodstuff containing it shall be '*Morinda citrifolia* fruit puree' or 'Noni fruit puree'.

The designation of the *Morinda citrifolia* fruit concentrate authorised by this Decision on the labelling of the foodstuff containing it shall be '*Morinda citrifolia* fruit concentrate' or 'Noni fruit concentrate'.

Article 3

This Decision is addressed to Tahitian Noni International Inc., 333 West River Park Drive, Provo, Utah 84604, USA.

Done at Brussels, 21 April 2010.

For the Commission

John DALLI

Member of the Commission

[1] OJ L 43, 14.2.1997, p. 1.

ANNEX I

Specifications of *Morinda citrifolia* fruit puree and concentrate

Description:

The fruits of *Morinda citrifolia* are harvested by hand. Seeds and skin are separated mechanically from the pureed fruits. After pasteurisation, the puree is packaged in aseptic containers and stored under cold conditions.

Morinda citrifolia concentrate is prepared from *M. citrifolia* puree by treatment with pectinolytic enzymes (50-60 °C for 1-2 h). Then the puree is heated to inactivate the pectinases and then immediately cooled. The juice is separated in a decanter centrifuge. Afterwards the juice is collected and pasteurised, prior to being concentrated in a vacuum evaporator from a brix of 6 to 8 to a brix of 49 to 51 in the final concentrate.

Composition of *Morinda citrifolia* fruit puree and concentrate

Moisture	89 – 93 %	48 – 53 %
Protein	< 0,6 g/100 g	3 – 3,5 g/100 g
Fat	< 0,2 g/100 g	< 0,04 g/100 g
Ash	< 1 g/100 g	4,5 – 5 g/100 g
Total carbohydrates	5 – 10 g/100 g	37 – 45 g/100 g
Fructose	0,5 – 2 g/100 g	9 – 11 g/100 g
Glucose	0,5 – 2 g/100 g	9 – 11 g/100 g
Dietary fibre	1,5 – 3 g/100 g	1,5 – 5 g/100 g
5,15-dimethylmorindol (*)	0,19 – 0,20 µg/mL	0,11 – 0,77 µg/mL
Lucidin (*)	Not detectable	Not detectable
Alizarin (*)	Not detectable	Not detectable
Rubiadin (*)	Not detectable	Not detectable

(*) By an HPLC-UV method developed and validated by the applicant for the analysis of anthraquinones in *Morinda citrifolia* puree and concentrate.
Limits of detection: 2,5 ng/mL (5,15 dimethylmorindol); 50,0 ng/mL (lucidin); 6,3 ng/mL (alizarin) and 62,5 ng/mL (rubiadin).

ANNEX II

Uses of *Morinda citrifolia* fruit puree and concentrate

Use group	Maximum use level of *Morinda citrifolia* fruit	
	puree	concentrate
Candy/Confectionery	45 g/100 g	10 g/100 g
Cereal bars	53 g/100 g	12 g/100 g
Powdered nutritional drink mixes (dry weight)	53 g/100 g	12 g/100 g
Carbonated beverages	11 g/100 g	3 g/100 g
Ice cream & sorbet	31 g/100 g	7 g/100 g
Yogurt	12 g/100 g	3 g/100 g
Biscuits	53 g/100 g	12 g/100 g
Buns, cakes & pastries	53 g/100 g	12 g/100 g
Breakfast cereal (whole grain)	88 g/100 g	20 g/100 g
Jams and jellies (fruit preserves)	(*) 133 g/100 g	30 g/100 g
Sweet spreads, fillings and icings	31 g/100 g	7 g/100 g
Savoury sauces, pickles, gravies, and condiments	88 g/100 g	20 g/100 g
Food supplements (in accordance with Directive 2002/46/EC of the European Parliament and of the Council [1])	26 g per daily dose as recommended by the manufacturer	6 g per daily dose as recommended by the manufacturer

(*) Based on pre-processing quantity to produce final 100 g product.
[1] OJ L 183, 12.7.2002, p. 51.

COMMISSION DECISION

of 22 April 2010

concerning the draft Decree from Italy setting out standards governing the labelling of shelf-stable milk, UHT milk, micro-filtered pasteurised milk and high-temperature pasteurised milk, as well as milk products

(notified under document C(2010) 2436)

(Only the Italian text is authentic)

(Text with EEA relevance)

(2010/229/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs [1], and in particular Article 19 thereof,

Whereas:

(1) In accordance with the procedure provided for in the second paragraph of Article 19 of Directive 2000/13/EC, the Italian authorities notified the Commission on 25 August 2009 of the draft Decree setting out standards governing the labelling of shelf-stable milk, UHT milk, micro-filtered pasteurised milk and high-temperature pasteurised milk, as well as milk products.

(2) According to Article 1 of the notified Decree, this applies to shelf-stable milk, UHT milk, micro-filtered pasteurised milk and high-temperature pasteurised milk as well as milk products.

(3) Article 2 of the notified Decree requires that the labels of sterilised shelf-stable milk, UHT milk, micro-filtered pasteurised milk and high-temperature pasteurised milk must indicate the place of origin of the milk which has undergone the treatments in question.

(4) Article 3(1) of the notified Decree provides that the labels of milk products must indicate the place of origin of the milk used in the preparation of such products.

(5) Article 3(3) of the notified Decree provides that the labels of cheeses, including cottage cheeses, containing substances obtained from processing milk or milk products must include those substances in the list of ingredients with a reference to the place of origin of the milk used for processing those substances.

(6) Article 4 of the notified Decree provides that the labels of cheeses obtained from curd must indicate the place of origin of the milk used in the curd.

(7) Directive 2000/13/EC harmonises the rules governing the labelling of foodstuffs by making provision for, on the one hand, harmonisation of certain national provisions and, secondly, arrangements for non-harmonised national provisions. The scope of harmonisation is defined in Article 3(1) of that Directive, which lists all the particulars that are compulsory on the labelling of foodstuffs in accordance with Articles 4 to 17 and subject to the exceptions contained therein.

(8) In particular, in accordance with Article 3(1)(8) of Directive 2000/13/EC the indication of the place of origin or provenance is mandatory where failure to give such a particular might mislead the consumer to a material degree as to the true origin or provenance of the foodstuff. This provision puts in place an appropriate mechanism to counter the risk of consumers being misled in cases where some elements could imply that a given food comes from an origin or provenance different from the true one.

(9) Furthermore, Article 4(2) of Directive 2000/13/EC provides that other particulars in addition to those listed in Article 3(1) of that Directive may be required, in the case of specified foodstuffs, by Union provisions or, in their absence, by national provisions.

(10) Article 18(2) of Directive 2000/13/EC allows the adoption of non-harmonised national provisions if they are justified on one of the grounds listed therein, including, inter alia, the prevention of fraud and the protection of public health, and provided they are not of such a nature as to impede application of the definitions and rules laid down by Directive 2000/13/EC. Therefore, where draft national labelling provisions have been proposed in a Member State, it is necessary to examine their compatibility with the above-mentioned requirements and the provisions of the Treaty.

[1] OJ L 109, 6.5.2000, p. 29.

(11) The Italian authorities maintain that the notified Decree is necessary to define and regulate the traceability system for sterilised shelf-stable milk, UHT milk, micro-filtered pasteurised milk and high-temperature pasteurised milk and milk products. They also state that the notified Decree is necessary to regulate the labelling of the foods listed in Article 1 thereof in order to ensure that the interests of the consumer are protected to the greatest extent.

(12) With regard to the traceability of the products listed in Article 1 of the notified Decree, Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [1] requests that, at all stages of production, processing and distribution, a comprehensive system of traceability should be established by food businesses so that targeted and accurate withdrawals can be undertaken or information given to consumers or control officials. In particular, pursuant to Article 18 thereof, food business operators shall be able to identify any person from whom they have been supplied with a food, and the other businesses to which their products have been supplied. Moreover, Article 19 of that Regulation foresees specific obligations for food business operators. The mandatory indication of origin on the label of the finished products in question is not necessary information for the purpose of meeting those traceability requirements.

(13) In addition, apart from a generic reference to the need of protecting the interests of the consumer, the Italian authorities did not provide any justification allowing to conclude that, as regards the products listed in Article 1 of the notified Decree, the mandatory indication of the origin, beyond the obligation laid down in Article 3(1)(8) of Directive 2000/13/EC, is necessary.

(14) Therefore, the Italian authorities failed to demonstrate that the indication of origin as provided by the notified Decree is necessary to attain one of the objectives listed in Article 18(2) of Directive 2000/13/EC.

(15) In light of these observations, the Commission has delivered a negative opinion on the above-mentioned provisions of the notified Decree, pursuant to the third paragraph of Article 19 of Directive 2000/13/EC.

(16) The Italian authorities should accordingly be requested not to adopt the provisions of notified Decree in question.

(17) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

Italy shall not adopt Article 2, 3(1) and (3) and Article 4 (as far as the obligation to indicate the place of origin of the milk used in the curd is concerned) of the notified Decree setting out standards governing the labelling of shelf-stable milk, UHT milk, micro-filtered pasteurised milk and high-temperature pasteurised milk, as well as milk products.

Article 2

This Decision is addressed to the Italian Republic.

Done at Brussels, 22 April 2010.

For the Commission

John DALLI

Member of the Commission

[1] OJ L 31, 1.2.2002, p. 1.

DECISIONS

EN

([1]) Text with EEA relevance

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