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⁽¹⁾ Text with EEA relevance

I

(Acts adopted under the EC Treaty/Euratom Treaty whose publication is obligatory)

REGULATIONS

COMMISSION REGULATION (EC) No 1187/2009

of 27 November 2009

laying down special detailed rules for the application of Council Regulation (EC) No 1234/2007 as regards export licences and export refunds for milk and milk products

(recast)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) ⁽¹⁾, and in particular Articles 161(3), 170 and 171(1) in conjunction with Article 4 thereof,

Whereas:

(1) Regulation (EC) No 1234/2007 lays down, amongst others, general rules for granting export refunds in the milk and milk products sector, in order, in particular, to permit the monitoring of the value and quantity limits for refunds. Detailed rules for the application of those general rules have been laid down in Commission Regulation (EC) No 1282/2006 of 17 August 2006 laying down special detailed rules for the application of Council Regulation (EC) No 1255/1999 as regards export licences and export refunds for milk and milk products ⁽²⁾.

(2) Regulation (EC) No 1282/2006 has been substantially amended several times ⁽³⁾. Since further amendments are to be made, it should be recast in the interest of clarity.

(3) Under the Agriculture Agreement ⁽⁴⁾ concluded during the Uruguay Round of the GATT trade negotiations

and approved by Council Decision 94/800/EC ⁽⁵⁾ (hereinafter referred to as the 'Agriculture Agreement'), export refunds on agricultural products, including milk products, are limited within each 12-month period starting from 1 July 1995 to a maximum quantity and a maximum value. In order to ensure compliance with those limits, the issue of export licences should be monitored and procedures should be adopted for allocating the quantities which may be exported with a refund.

(4) For a refund to be granted the products should meet the relevant requirements of Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs ⁽⁶⁾ 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 ⁽⁷⁾, notably preparation in an approved establishment and compliance with the identification marking requirements specified in Section I of Annex II to Regulation (EC) No 853/2004.

(5) In order to ensure effective controls on limits, there should be no refunds paid on quantities exceeding what is indicated on the licence.

(6) The term of validity of export licences should be fixed.

(7) In order to ensure accurate checking of the products exported and to minimise the risk of speculation, the possibility of changing the product for which a licence has been issued should be restricted.

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 234, 29.8.2006, p. 4.

⁽³⁾ See Annex VII.

⁽⁴⁾ OJ L 336, 23.12.1994, p. 22.

⁽⁵⁾ OJ L 336, 23.12.1994, p. 1.

⁽⁶⁾ OJ L 139, 30.4.2004, p. 1.

⁽⁷⁾ OJ L 139, 30.4.2004, p. 55.

- (8) Article 4(2) of Commission Regulation (EC) No 612/2009 of 7 July 2009 laying down common detailed rules for the application of the system of export refunds on agricultural products ⁽¹⁾ lays down rules for the use of export licences with advance fixing of the refund for the exportation of products with a 12-digit code other than that shown in section 16 of the licence. That provision is applicable in a specific sector only if product categories as referred to in Article 13 of Commission Regulation (EC) No 376/2008 of 23 April 2008 laying down common detailed rules for the application of the system of import and export licences and advance fixing certificates for agricultural products ⁽²⁾ and product groups as referred to in the second indent of the first subparagraph of Article 4(2) of Regulation (EC) No 612/2009 have been defined.
- (9) For the milk and milk products sector, product categories are already defined with reference to the categories provided for in the Agriculture Agreement. In the interest of sound management this use of categories should be retained. With a view to simplification and completeness, the product groups as referred to in the second indent of the first subparagraph of Article 4(2) of Regulation (EC) No 612/2009 should be replaced and based on the Combined Nomenclature codes. If the product actually exported is different from the product shown in box 16 of the licence, the general provisions of Article 4 of Regulation (EC) No 612/2009 should apply. To avoid discriminations between operators exporting under the current regime and those exporting under this Regulation, that provision may be applied retroactively at the request of the licence holder.
- (10) To enable operators to participate in invitations to tender opened by third countries without affecting the restrictions as regards volume, a system of provisional licences should be introduced giving successful tenderers the right to a full licence. To ensure that such licences are correctly used, for certain exports with refunds the country of destination should be defined as compulsory.
- (11) In order to ensure effective monitoring of licences issued, which depends on the notification of information to the Commission by the Member States, a waiting time should be provided for before licences are issued. In order to ensure the smooth operation of the arrangements, and in particular an equitable allocation of the quantities available within the limits laid down by the Agriculture Agreement, various management measures should be laid down and, in particular, provision should be made for the issue of licences to be suspended and for an allocation coefficient to be applied to the quantities applied for, if necessary.
- (12) Exports of the products in the context of food-aid operations should be excluded from certain provisions in regard to issuing of export licences.
- (13) The method for fixing the refund on milk products containing added sugar, the price of which is determined by the price of the ingredients, should be laid down according to the percentage of the ingredients contained therein. However, to facilitate the management of refunds for these products, and particularly measures to ensure compliance with commitments regarding exports in the context of the Agriculture Agreement, a maximum quantity should be fixed for sucrose incorporated for which a refund may be granted. Forty-three percent by weight of whole product should be considered as representative of the sucrose content of such products.
- (14) Article 12(5)(c) of Regulation (EC) No 612/2009 provides that refunds may be granted for ingredients of Community origin in processed cheese manufactured under the inward processing arrangements. Certain special rules are needed to ensure that this specific measure operates properly and can be effectively checked.
- (15) Under the Agreement concluded between the European Community and Canada ⁽³⁾, approved by Council Decision 95/591/EC ⁽⁴⁾, export licences issued by the Community are to be presented for cheese qualifying for preferential terms on import into Canada. The detailed rules for issuing such licences should be laid down.
- (16) The Community has the option of designating which importers may import Community cheese into the United States under the additional quota arising from the Agriculture Agreement. To allow the Community to maximise the value of the quota, a procedure should therefore be laid down for designating importers on the basis of the allocation of export licences for the products concerned.

⁽¹⁾ OJ L 186, 17.7.2009, p. 1.

⁽²⁾ OJ L 114, 26.4.2008, p. 3.

⁽³⁾ OJ L 334, 30.12.1995, p. 33.

⁽⁴⁾ OJ L 334, 30.12.1995, p. 25.

(17) The Economic Partnership Agreement between the Cariforum States, of the one part, and the European Community and its Member States, of the other part ⁽¹⁾, the signature and provisional application of which have been approved by Council Decision 2008/805/EC ⁽²⁾ provides for the Community to manage its share of the tariff quota according to a mechanism of export licences. The procedure for awarding licences should therefore be determined. In order to ensure that products imported into the Dominican Republic are part of the quota and to establish a link between the products imported and those indicated on the export licence, exporters should present, at the time of import, a certified copy of the export declaration, which must contain certain information.

(18) In respect of that quota, Article 30 of Regulation (EC) No 1282/2006 provides for the eligibility criteria applicable to lodge licence applications under the two parts of the quota. Applications under part (b) of the quota can be lodged for a fixed quantity, independent of the trade performance. The number of applicants under part (a) of the quota is increasing steadily and the quantity for which applications may be lodged depends on the export performance in the past years. Given the oversupply of milk powder on the world market in the past years, the quantity imported by the Dominican Republic originating in the Community has decreased, resulting in low performance quantities for which applications can be lodged under part (a). It is therefore appropriate to allow the eligible applicants under part (a) to opt for part (b). However, applications under both parts of the quota should be excluded.

(19) In order to maximise the use of the quota and to alleviate the administrative burden on exporters, the derogation allowing to use the export licence also for a product covered by a 12-digit product code other than that indicated in box 16 of the licence if the same amount of export refund is granted to both products and if both products belong to the same product category, or if both products belong to the same product group, should also apply to exports to the Dominican Republic.

(20) 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:

CHAPTER I

INTRODUCTORY RULES

Article 1

This Regulation lays down:

- (a) the general rules concerning licences and refunds for exports from the Community of the products listed in Part XVI of Annex I to Regulation (EC) No 1234/2007;
- (b) the specific rules concerning exports of the products referred to in point (a) from the Community to certain third countries.

Article 2

Regulations (EC) No 376/2008 and (EC) No 612/2009 shall apply, save as otherwise provided in this Regulation.

CHAPTER II

GENERAL RULES

Article 3

To be granted a refund, the products listed in Part XVI of Annex I to Regulation (EC) No 1234/2007 must meet the relevant requirements of Regulations (EC) No 852/2004 and (EC) No 853/2004, notably preparation in an approved establishment and compliance with the identification marking requirements specified in Section I of Annex II to Regulation (EC) No 853/2004.

Article 4

1. The refund to be paid shall be the rate valid on the day the application for the export licence or, where relevant, the provisional licence, is submitted.

2. Licence applications with advanced fixing of the refund, for the products referred to in Part XVI of Annex I to Regulation (EC) No 1234/2007, which were lodged, within the meaning of Article 16 of Regulation (EC) No 376/2008, on the Wednesday and Thursday following the end of each tendering period as referred to in Article 4(2) of Commission Regulation (EC) No 619/2008 ⁽³⁾ shall be deemed to have been submitted on the working day following that Thursday.

3. Section 7 of licence applications and licences shall show the country of destination and the code of the country or territory of destination, as indicated in the nomenclature of countries and territories for the external trade statistics of the Community and statistics of trade between Member States, laid down by Commission Regulation (EC) No 1833/2006 ⁽⁴⁾.

⁽¹⁾ OJ L 289, 30.10.2008, p. 3.

⁽²⁾ OJ L 289, 30.10.2008, p. 1.

⁽³⁾ OJ L 168, 28.6.2008, p. 20.

⁽⁴⁾ OJ L 354, 14.12.2006, p. 19.

Article 5

1. The product categories as referred to in the Agriculture Agreement concluded during the Uruguay Round of the GATT trade negotiations (hereinafter referred to as the 'Agriculture Agreement') shall be those set out in Annex I to this Regulation.

2. The product groups as referred to in the second indent of the first subparagraph of Article 4(2) of Regulation (EC) No 612/2009 shall be those set out in Annex II to this Regulation.

Article 6

1. Section 16 of licence applications and licences shall show the 12-digit product code of the nomenclature for refunds where a refund is requested or the eight-digit product code of the Combined Nomenclature where no refund is requested. Licences shall be valid for that product alone except in the case specified in paragraphs 2 and 3.

2. By way of derogation from paragraph 1, an export licence shall also be valid for the exportation of a product covered by a 12-digit product code other than that indicated in box 16 of the licence if the same amount of export refund is granted to both products and if both products belong to the same product category as referred to in Annex I.

3. By way of derogation from paragraph 1, an export licence shall also be valid for the exportation of a product covered by a 12-digit product code other than that indicated in box 16 of the licence if both products belong to the same product group as referred to in Annex II.

In such case, refunds shall be calculated in accordance with the second subparagraph of Article 4(2) of Regulation (EC) No 612/2009.

Article 7

Export licences shall be valid from the day of issue, within the meaning of Article 22(1) of Regulation (EC) No 376/2008, until:

- (a) the end of the fourth month following issue in the case of products falling within CN code 0402 10;
- (b) the end of the fourth month following issue in the case of products falling within CN code 0405;
- (c) the end of the fourth month following issue in the case of products falling within CN code 0406;
- (d) the end of the fourth month following issue for the other products referred to in Part XVI of Annex I to Regulation (EC) No 1234/2007;

- (e) the date by which the obligations arising from invitations to tender as referred to in Article 8(1) of this Regulation must be fulfilled and by the end of the eighth month following issue of the full export licence referred to in Article 8(3) of this Regulation at the latest.

Article 8

1. In the case of an invitation to tender issued by a public body in a third country as referred to in Article 47(1) of Regulation (EC) No 376/2008, except for invitations to tender concerning products falling within CN code 0406, operators may apply for a provisional export licence for the quantity covered by their tender subject to the lodging of a security.

The security for provisional licences shall be equal to 75 % of the amount calculated in accordance with Article 9 of this Regulation, with a minimum of EUR 5/100 kg.

Operators shall furnish proof that the body issuing the invitation to tender is public or subject to public law.

2. Provisional licences shall be issued on the fifth working day following that on which the application is lodged, provided that measures as referred to in Article 10(2) have not been adopted.

3. By way of derogation from Article 47(5) of Regulation (EC) No 376/2008, the period for submitting the information referred to in that paragraph shall be 60 days.

Before the end of that period, operators shall apply for the full export licence, which shall be issued on presentation of proof that they have been awarded a contract.

On presentation of proof that the tender has been rejected or that the quantity awarded by the contract is less than that indicated on the provisional licence, the whole or part of the security shall be released as appropriate.

4. Licence applications referred to in paragraphs 2 and 3 shall be submitted in accordance with Article 12 of Regulation (EC) No 376/2008.

5. The provisions of this Chapter, with the exception of Article 10, shall apply to full export licences.

6. The country of destination referred to in Article 4(3) shall be a compulsory destination for the purposes of Article 26(5) of Regulation (EC) No 612/2009 for licences issued in accordance with this Article.

Article 9

The security referred to in Article 14(2) of Regulation (EC) No 376/2008 shall be equal to a percentage of the refund fixed for each product code applicable on the day the export licence application is lodged, as follows:

- (a) 15 % for products covered by CN code 0405;
- (b) 15 % for products covered by CN code 0402 10;
- (c) 15 % for products covered by CN code 0406;
- (d) 15 % for the other products referred to in Part XVI of Annex I to Regulation (EC) No 1234/2007.

The security may not, however, be less than EUR 5/100 kg.

The amount of the refund referred to in the first subparagraph shall be that calculated for the total quantity of the product concerned, except for milk products containing added sugar.

For milk products containing added sugar, the amount of the refund referred to in the first subparagraph shall be equal to the total quantity of the whole product concerned, multiplied by the refund rate applicable per kilogram of milk product.

Article 10

1. Export licences with advanced fixing of the refund shall be issued on the fifth working day following the day on which applications are submitted, provided that the quantities for which licences have been applied for have been communicated in accordance with Article 9(1) of Commission Regulation (EC) No 562/2005 ⁽¹⁾ and that measures referred to in points (a) and (b) of paragraph 2 of this Article have not been adopted.

2. Where the issue of export licences would or might result in the available budgetary amounts being exceeded or in the maximum quantities which may be exported with a refund being exhausted during the 12-month period in question or in a shorter period to be determined pursuant to Article 11 of this Regulation, taking into account Article 169 of Regulation (EC) No 1234/2007, or would not allow exports to continue during the remainder of the period, the Commission

may, without assistance of the Committee referred to in Article 195(1) of that Regulation:

- (a) apply an allocation coefficient to the quantities applied for;
- (b) reject all or part of pending applications for which export licences have not yet been issued;
- (c) suspend the lodging of licence applications for a maximum of five working days; the suspension may be further extended in accordance with the procedure referred to in Article 195(2) of Regulation (EC) No 1234/2007.

Where the coefficient referred to in point (a) of the first subparagraph is less than 0,4, applicants may, within three working days of publication of the decision fixing the coefficient, request the cancellation of their licence application and the release of their security.

In the case referred to in point (c) of the first subparagraph, licence applications submitted during the suspension period shall be invalid.

The measures referred to in the first subparagraph may be implemented or modulated by category of product and by destination or group of destinations.

For the purposes of the first subparagraph, account shall be taken, as regards the product in question, of the seasonal nature of trade, the market situation, and in particular the trend in prices on the market and the export conditions resulting there from.

3. The measures referred to in paragraph 2 may also be adopted where export licence applications relate to quantities which exceed or might exceed the normal available quantities for one destination or group of destinations and issuing the licences requested would entail a risk of speculation, distortion of competition between operators, or disturbance of the trade concerned or the Community market.

4. If applications for licences are rejected or quantities applied for are reduced, the security shall be immediately released for all quantities for which applications have not been accepted.

⁽¹⁾ OJ L 95, 14.4.2005, p. 11.

Article 11

Where the total quantity covered by the licence applications submitted is such that there is a risk of early exhaustion of the maximum quantities which may be exported with refund during the 12-month period in question, it may be decided, in accordance with the procedure referred to in Article 195(2) of Regulation (EC) No 1234/2007, to allocate those maximum quantities over periods to be determined.

Article 12

Where the quantity exported exceeds that shown on the licence, no refund shall be payable on the overrun.

To that end, section 22 of licences shall contain the words: 'Payment of the refund restricted to the quantity shown in sections 17 and 18'.

Article 13

Article 10 shall not apply to the issuing of export licences for food-aid supplies as referred to in Article 10(4) of the Agriculture Agreement.

Article 14

1. For milk products containing added sugar, the refund shall be equal to the sum of the following components:

(a) a component representing the quantity of milk product;

(b) a component representing the quantity of added sucrose, up to a maximum of 43 % by weight of whole product.

2. The component referred to in paragraph 1(a) shall be calculated by multiplying the fixed amount of the refund by the percentage of milk product content of the whole product.

3. The component referred to in paragraph 1(b) shall be calculated by multiplying the sucrose content of the whole product, up to a maximum of 43 %, by the basic amount of the refund applicable on the day the licence application is submitted for the products listed in point (c) of Part III of Annex I to Regulation (EC) No 1234/2007.

Article 15

1. Export licence applications for milk and milk products exported in the form of products falling within CN code 0406 30 as referred to in Article 12(5)(c) of Regulation (EC) No 612/2009 shall be accompanied by a copy of the authorisation to use the relevant customs procedure.

2. Section 20 of licence applications and licences for exports of milk and milk products referred to in paragraph 1 shall contain a reference to this Article.

3. The Member States shall take the necessary steps under the customs procedure referred to in paragraph 1 to identify and check the quality and quantity of the products referred to in that paragraph for which a refund has been applied for and to apply the provisions on entitlement to the refund.

CHAPTER III

SPECIFIC RULES

SECTION 1

Exports to Canada

Article 16

1. An export licence shall be required for exports of cheese to Canada under the quota referred to in the Agreement concluded between the European Community and Canada approved by Decision 95/591/EC.

2. Licence applications shall be admissible only where applicants:

(a) declare in writing that all material falling within Chapter 4 of the Combined Nomenclature and used in the manufacture of products covered by their application has been produced entirely within the Community;

(b) undertake in writing to provide, at the request of the competent authorities, any further substantiation which the latter consider necessary for the issuing of licences and to accept, where applicable, any checks by those authorities on the bookkeeping and manufacturing conditions of the products concerned.

Article 17

Licence applications and licences shall show:

(a) in section 7, the words 'CANADA — CA';

(b) in section 15, the six-digit description of the goods in accordance with the Combined Nomenclature for products falling within CN codes 0406 10, 0406 20, 0406 30 and 0406 40 and the eight-digit description for products falling within CN code 0406 90. Section 15 of applications and licences may contain no more than six products thus described;

(c) in section 16, the eight-figure CN code and the quantity in kilograms for each of the products referred to in section 15. The licence shall be valid only for the products and quantities so designated;

(d) in sections 17 and 18, the total quantity of products referred to in section 16;

(e) in section 20, one of the following entries, as appropriate:

— ‘Cheeses for direct export to Canada. Article 16 of Regulation (EC) No 1187/2009 Quota for ... (year)’;

— ‘Cheeses for export directly/via New York to Canada. Article 16 of Regulation (EC) No 1187/2009 Quota for ... (year)’.

Where cheese is transported to Canada via third countries, such countries must be indicated instead of, or with, a reference to New York;

(f) in section 22, the words ‘without export refund’.

Article 18

1. Licences shall be issued immediately after admissible applications are submitted. At the request of applicants, a certified copy of the licence shall be issued.

2. Licences shall be valid from their date of issue within the meaning of Article 22(1) of Regulation (EC) No 376/2008 until 31 December following that date.

However, licences issued from 20 December to 31 December shall be valid from 1 January until 31 December of the following year. In that case that following year must be indicated in section 20 of licence applications and licences in accordance with Article 17(e) of this Regulation.

Article 19

1. Export licences presented to the competent authority for attribution and endorsement in accordance with Article 23 of Regulation (EC) No 376/2008 may be used for one export declaration only. Licences shall be exhausted once the export declaration has been presented.

2. Export licence holders shall ensure that a certified copy of the export licence is presented to the competent Canadian authority when the import licence is applied for.

3. By way of derogation from Article 8 of Regulation (EC) No 376/2008, licences shall not be transferable.

Article 20

Chapter II shall not apply.

SECTION 2

Exports to the United States

Article 21

It may be decided in accordance with the procedure referred to in Article 195(2) of Regulation (EC) No 1234/2007 to export products falling within CN code 0406 to the United States as part of the following quotas:

(a) the additional quota under the Agriculture Agreement;

(b) the tariff quotas originally resulting from the Tokyo Round and granted to Austria, Finland and Sweden by the United States in Uruguay Round list XX;

(c) the tariff quotas originally resulting from the Uruguay Round and granted to the Czech Republic, Hungary, Poland and Slovakia by the United States in Uruguay Round list XX.

Article 22

1. Exports of cheese to the United States under the quotas referred to in Article 21 shall be subject to presentation of an export licence in accordance with this Section.

Section 16 of licence applications and licences shall show the eight-digit product code of the Combined Nomenclature. However, the licences shall also be valid for any other code falling under CN code 0406.

2. Operators may apply, within a period to be determined in the decision referred to in Article 21, for an export licence for the export of the products referred to in that Article during the following calendar year, subject to the lodging of a security in accordance with Article 9.

3. Applicants for export licences in respect of the product groups and quotas identified by 16-, 22-Tokyo, 16-, 17-, 18-, 20- and 21-, 22-Uruguay, 25-Tokyo and 25-Uruguay in the decision referred to in Article 21 shall provide evidence that they have exported the products of the quota in question to the United States in at least one of the preceding three years and that their designated importer is a subsidiary of the applicant.

The proof of trade as referred to in the first subparagraph shall be furnished in accordance with the second paragraph of Article 5 of Commission Regulation (EC) No 1301/2006 ⁽¹⁾.

⁽¹⁾ OJ L 238, 1.9.2006, p. 13.

4. Applicants for export licences shall indicate in the applications:

- (a) the designation of the product group covered by the United States quota in accordance with Additional Notes 16 to 23 and 25 in Chapter 4 of the Harmonized Tariff Schedule of the United States;
- (b) the product names in accordance with the Harmonized Tariff Schedule of the United States;
- (c) the name and address of the importer in the United States designated by the applicant.

5. Applications for export licences shall be accompanied by a certificate from the designated importer stating that he is eligible under the rules in force in the United States on the issue of import licences for the products referred to in Article 21.

Article 23

1. Where applications for export licences for a product group or a quota referred to in Article 21 exceed the available quantity for the year in question, the Commission shall apply a uniform allocation coefficient to the quantities for which application is made.

The amount resulting from the application of the coefficient shall be rounded down to the nearest kg.

Securities shall be released in whole or in part for rejected applications or for quantities in excess of those allocated.

2. Where the result of applying the allocation coefficient would be to allocate licences for less than 10 tonnes per application, the corresponding quantities available shall be awarded by the Member State concerned drawing lots by quota. The Member State shall draw lots for licences of 10 tonnes each amongst the applicants who would have been allocated less than 10 tonnes as a result of applying the allocation coefficient.

Quantities of less than 10 tonnes remaining when establishing the lots shall be equally distributed over the 10-tonne lots before the lots are drawn.

Where the result of applying the allocation coefficient would be to leave a quantity of less than 10 tonnes, that quantity shall be considered a single lot.

The security for applications which are not successful in the allocation by drawing lots shall be released immediately.

3. Where applications for licences are submitted for quantities of product not exceeding the quotas referred to in Article 21 for the year concerned, the Commission may allocate the remaining quantities to applicants in proportion to the quantities applied for, by application of an allocation coefficient.

In that case, the operators shall inform the competent authority of the supplementary quantity they accept, within a week from the publication of the adjusted allocation coefficient and the security lodged shall be increased accordingly.

Article 24

1. The names of the designated importers referred to in Article 22(4)(c) shall be communicated by the Commission to the competent United States authorities.

2. In the case where an import licence for the quantities concerned is not allocated to the designated importer, in circumstances which do not cast doubt on the good faith of the operator submitting the certificate referred to in Article 22(5), the operator may be authorised by the Member State to designate another importer provided that the latter appears on the list communicated to the competent authorities of the United States in accordance with paragraph 1 of this Article.

The Member State shall inform the Commission as soon as possible of the change of designated importer and the Commission shall notify the change to the competent authorities of the United States.

Article 25

Export licences shall be issued by 15 December of the year preceding the quota year for the quantities for which the licences are allocated.

The licences shall be valid from 1 January to 31 December of the quota year.

The following words shall be entered in section 20 of the licence application and licence:

'For export to the United States of America: Quota for ... (year) — Chapter III, Section 2 of Regulation (EC) No 1187/2009'

Licences issued under this Article shall be valid only for the exports referred to in Article 21.

Securities for export licences shall be released on presentation of the proof referred to in Article 32(2) of Regulation (EC) No 376/2008 together with the transport document referred to in Article 17(3) of Regulation (EC) No 612/2009 mentioning as destination the United States.

Article 26

Chapter II, with the exception of Articles 7 and 10, shall apply.

SECTION 3

Exports to the Dominican Republic

Article 27

1. The presentation to the competent authorities of the Dominican Republic of a certified copy of the export licence issued in accordance with this Section and a duly endorsed copy of the export declaration for each consignment shall be required for exports to the Dominican Republic of milk powder under the quota provided for in Appendix 2 of Annex III to the Economic Partnership Agreement between the Cariforum States and the European Community and its Member States.

2. When export licences are issued, priority shall be given to milk powder falling within the following product codes from the nomenclature for refunds:

— 0402 10 11 9000,

— 0402 10 19 9000,

— 0402 21 11 9900,

— 0402 21 19 9900,

— 0402 21 91 9200,

— 0402 21 99 9200.

Products must have been produced entirely within the Community. At the request of the competent authorities, applicants shall supply any further substantiation which the authorities consider necessary for the issuing of licences and shall accept, where applicable, any checks by those authorities of the bookkeeping and manufacturing conditions of the products concerned.

Article 28

1. The quota referred to in Article 27(1) shall be of 22 400 tonnes per 12-month period commencing on 1 July. The quota shall be divided into two parts:

(a) the first part, equal to 80 % or 17 920 tonnes, shall be distributed among Community exporters who can prove

that they have exported products referred to in Article 27(2) to the Dominican Republic during at least three of the four calendar years prior to the period for submission of applications;

(b) the second part, equal to 20 % or 4 480 tonnes, shall be reserved for applicants other than those referred to in point (a) who can prove, at the time they submit their application, that they have been engaged for at least 12 months in trade with third countries in the milk products listed in Chapter 4 of the Combined Nomenclature and are registered in a Member State for VAT purposes.

The proof of trade as referred to in the first subparagraph shall be furnished in accordance with the second paragraph of Article 5 of Regulation (EC) No 1301/2006.

2. Applications for export licences may not cover more, per applicant, than:

(a) for the part referred to in paragraph 1(a), a quantity equal to 110 % of the total quantity of products referred to in Article 27(2) exported to the Dominican Republic during one of the three calendar years prior to the period for submission of applications;

(b) for the part referred to in paragraph 1(b), a total maximum quantity of 600 tonnes.

However exporters eligible to apply for part (a) may opt to apply under part (b) instead of part (a).

Applications which exceed the ceilings provided for in points (a) and (b) shall be rejected.

3. To be admissible, only one export licence application may be submitted per product code in the nomenclature for refunds and all applications must be lodged at the same time with the competent authority of a single Member State.

Export licence applications shall be admissible only where applicants, at the time they present their applications:

(a) lodge a security in accordance with Article 9;

(b) for the part referred to in paragraph 1(a), indicate the quantity of products referred to in Article 27(2) that they have exported to the Dominican Republic during one of the three calendar years prior to the period referred to in paragraph 1(a) of this Article and are able to prove this to the satisfaction of the competent authority of the Member State concerned. To this end the operator whose name appears on the relevant export declaration shall be regarded as the exporter;

- (c) for the part referred to in paragraph 1(b), are able to prove to the satisfaction of the competent authority of the Member State concerned that they fulfil the conditions laid down therein.

Article 29

Licence applications shall be lodged from 1 to 10 April each year for the quota relating to the period from 1 July to 30 June the following year.

For the purposes of Article 4(1), all applications lodged before the deadline shall be deemed to have been lodged on the first day of the period for submission of licence applications.

Article 30

Licence applications and licences shall contain:

- (a) in section 7, the words 'Dominican Republic — DO';
- (b) in sections 17 and 18, the quantity to which the application or licence relates;
- (c) in section 20, one of the entries listed in Annex III.

Licences issued under this Section shall give rise to an obligation to export to the Dominican Republic.

Article 31

1. Not later than the fifth working day following the expiry of the period for lodging licence applications, Member States shall notify the Commission, using the model form in Annex IV, for each of the two parts of the quota and for each product code of the nomenclature for refunds, of the quantities covered by licence applications or, where applicable, that no applications have been lodged.

Before issuing licences, the Member States shall verify in particular that the information referred to in Article 27(2) and in Article 28(1) and (2) is correct.

If the information provided by an operator to whom a licence has been issued is found to be incorrect, the licence shall be cancelled and the security forfeited.

2. The Commission shall decide as quickly as possible to what extent licences for quantities applied for may be granted and shall inform the Member States of its decision.

If all the quantities covered by licence applications for one of the two parts of the quota exceed the quantities referred to in Article 28(1), the Commission shall fix an allocation coefficient. The amount resulting from the application of the coefficient shall be rounded down to the nearest kg.

If the application of the allocation coefficient results in a quantity per applicant of less than 20 tonnes, applicants may withdraw their applications. In such cases, they shall notify the competent authority within three working days of publication of the Commission's decision. The security shall be released immediately. The competent authority shall notify the Commission, within eight working days of publication of the decision, of the quantities for which applications have been withdrawn and for which the security has been released.

Where the total quantity covered by licence applications is less than the quantity available for the period in question, the Commission shall allocate the quantity remaining, on the basis of objective criteria taking account in particular of licence applications for all the products falling within CN codes 0402 10, 0402 21 and 0402 29.

Article 32

1. Licences shall be issued at the request of the operator, not earlier than 1 June and not later than 15 February of the following year. They shall be issued only to operators whose licence applications were notified in accordance with Article 31(1).

Member States shall communicate to the Commission by the end of February at the latest, using the model form in Annex V, for both parts of the quota, the quantities for which no licences were issued.

2. Export licences issued in accordance with this Section shall be valid from their actual day of issue within the meaning of Article 22(2) of Regulation (EC) No 376/2008 until 30 June of the quota year for which the licence application was made.

3. The security shall be released only in one of the following cases:

(a) on presentation of the proof referred to in Article 32(2) of Regulation (EC) No 376/2008 together with the transport document referred to in Article 17(3) of Regulation (EC) No 612/2009 mentioning as destination the Dominican Republic;

(b) in respect of the quantities covered by applications for which no licence could be issued.

The security relating to the quantity not exported shall be forfeited.

4. By way of derogation from Article 8 of Regulation (EC) No 376/2008, licences shall not be transferable.

5. By 31 August each year at the latest, the competent authority of the Member State shall report to the Commission, using the model form in Annex VI and in respect to the previous 12-month period as referred to in Article 28(1), the following quantities, broken down by product code of the nomenclature for refunds:

- the quantity allocated,
- the quantity for which licences have been issued,
- the quantity exported.

Article 33

1. Chapter II shall apply, with the exception of Articles 7, 9 and 10.

2. The communications by the Member States provided for in this Section shall be made by electronic means as indicated to the Member States by the Commission.

CHAPTER IV

FINAL PROVISIONS

Article 34

1. Regulation (EC) No 1282/2006 is repealed.

However, it shall continue to apply to export licences applied for before 1 January 2010.

2. References to Regulation (EC) No 1282/2006 shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex VIII.

Article 35

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

It shall apply to export licences applied for as from 1 January 2010.

At the request of the interested operator submitted from the date of entry into force of this Regulation and before 1 May 2010, Article 6 shall apply to licences issued since 30 January 2009.

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

Done at Brussels, 27 November 2009.

For the Commission

Mariann FISCHER BOEL

Member of the Commission

ANNEX I

Product categories referred to in Article 5(1)

Number	Description	CN code
I	Butter, other fats and oils derived from milk and spreads	0405 10 0405 20 90 0405 90
II	Skimmed-milk powder	0402 10
III	Cheese and curd	0406
IV	Other milk products	0401 0402 21 0402 29 0402 91 0402 99 0403 10 11 to 0403 10 39 0403 90 11 to 0403 90 69 0404 90 2309 10 15 2309 10 19 2309 10 39 2309 10 59 2309 10 70 2309 90 35 2309 90 39 2309 90 49 2309 90 59 2309 90 70

ANNEX II

Product groups referred to in Article 5(2)

Group No	Combined Nomenclature code
1	0401 30
2	0402 21 0402 29
3	0402 91 0402 99
4	0403 90
5	0404 90
6	0405
7	0406 10
8	0406 20
9	0406 30
10	0406 40
11	0406 90

ANNEX III

Entries referred to in Article 30(c)

— *in Bulgarian*: Глава III, раздел 3 от Регламент (ЕО) № 1187/2009:

тарифна квота за периода 1.7... г. — 30.6... г., за мляко на прах, съгласно допълнение II към приложение III към Споразумението за икономическо партньорство между държавите от КАРИФОРУМ, от една страна, и Европейската общност и нейните държави-членки, от друга страна, чието подписване и временно прилагане е одобрено с Решение 2008/805/ЕО на Съвета.]

— *in Spanish*: Capítulo III, sección 3, del Reglamento (CE) nº 1187/2009:

contingente arancelario de leche en polvo del año 1.7....-30.6...., con arreglo al apéndice 2 del anexo III del Acuerdo de Asociación Económica entre los Estados del CARIFORUM, por una parte, y la Comunidad Europea y sus Estados miembros, por otra, cuya firma y aplicación provisional han sido aprobadas mediante la Decisión 2008/805/CE del Consejo.

— *in Czech*: kapitola III oddíl 3 nařízení (ES) č. 1187/2009:

celní kvóta na období od 1. 7. ... do 30. 6. ... pro sušené mléko podle dodatku 2 přílohy III Dohody o hospodářském partnerství mezi státy CARIFORA na jedné straně a Evropským společenstvím a jeho členskými státy na straně druhé, jejíž podpis a prozatímní uplatňování byly schváleny rozhodnutím Rady 2008/805/ES.

— *in Danish*: Kapitel III, afdeling 3, i forordning (EF) nr. 1187/2009:

toldkontingent for 1.7...-30.6... for mælkepulver i overensstemmelse med bilag III, tillæg 2, til den økonomiske partnerskabsaftale mellem Cariforumlandene på den ene side og Det Europæiske Fællesskab og dets medlemsstater på den anden side, hvis undertegnelse og midlertidige anvendelse blev godkendt ved Rådets afgørelse 2008/805/EF.

— *in German*: Kapitel III Abschnitt 3 der Verordnung (EG) Nr. 1187/2009:

Milchpulverkongingent für den Zeitraum 1.7....—30.6.... gemäß Anhang III Anlage 2 des Wirtschaftspartnerschaftsabkommens zwischen den CARIFORUM-Staaten einerseits und der Europäischen Gemeinschaft und ihren Mitgliedstaaten andererseits, dessen Unterzeichnung und vorläufige Anwendung mit dem Beschluss 2008/805/EG des Rates genehmigt wurde.

— *in Estonian*: määruse (EÜ) nr 1187/2009 III peatüki 3. jagu:

ühelt poolt CARIFORUMi riikide ning teiselt poolt Euroopa Ühenduse ja selle liikmesriikide vahelise majanduspartnerluslepingu (mille allkirjutamine ja esialgne kohaldamine on heaks kiidetud nõukogu otsusega 2008/805/EÜ) III lisa 2. liites on sätestatud piimapulbri tariifikvoot ajavahemikuks 1.7....–30.6....

— *in Greek*: κεφάλαιο III, τμήμα 3 του κανονισμού (ΕΚ) αριθ. 1187/2009:

δαμολογική ποσόστωση 1.7...-30.6..., για το γάλα σε σκόνη σύμφωνα με το προσάρτημα 2 του παραρτήματος III της συμφωνίας οικονομικής εταιρικής σχέσης μεταξύ των κρατών CARIFORUM, αφενός, και της Ευρωπαϊκής Κοινότητας και των κρατών μελών της, αφετέρου, της οποίας η υπογραφή και η προσωρινή εφαρμογή εγκρίθηκε με την απόφαση 2008/805/EK του Συμβουλίου.

— *in English*: Chapter III, Section 3 of Regulation (EC) No 1187/2009:

tariff quota for 1.7...-30.6..., for milk powder according to Appendix 2 of Annex III to the Economic Partnership Agreement between the CARIFORUM States, of the one part, and the European Community and its Member States, of the other part, the signature and provisional application of which has been approved by Council Decision 2008/805/EC.

— *in French*: Chapitre III, Section 3, du règlement (CE) nº 1187/2009:

contingent tarifaire pour la période du 1.7... au 30.6..., pour le lait en poudre conformément à l'appendice 2 de l'annexe III de l'accord de partenariat économique entre les États du Cariforum, d'une part, et la Communauté européenne et ses États membres, d'autre part, dont la signature et l'application provisoire ont été approuvées par la décision 2008/805/CE du Conseil.

— *in Italian*: capo III, sezione 3 del regolamento (CE) n. 1187/2009:

contingente tariffario per l'anno 1.7...-30.6..., per il latte in polvere ai sensi dell'appendice 2 dell'allegato III dell'accordo di partenariato economico tra gli Stati del CARIFORUM, da una parte, e la Comunità europea e i suoi Stati membri, dall'altra, la cui firma e la cui applicazione provvisoria sono state approvate con decisione 2008/805/CE del Consiglio.

— *in Latvian*: Regulas (EK) Nr. 1187/2009 III nodaļas 3. iedaļā –

Tarifa kvota no 1. jūlija līdz 30. jūnijam piena pulverim saskaņā ar III pielikuma 2. papildinājumu Ekonomiskās partnerattiecību nolīgumā starp CARIFORUM valstīm no vienas puses un Eiropas Kopienas un tās dalībvalstīm no otras puses, kura parakstīšana un provizorisks piemērošana apstiprināta ar Padomes Lēmumu 2008/805/EK.

— *in Lithuanian*: Reglamentas (EB) Nr. 1187/2009 III skyriaus 3 skirsnys:

tarifinė kvota nuo ... metų liepos 1 dienos iki ... metų birželio 30 dienos pieno milteliams, numatyta CARIFORUM valstybių ir Europos bendrijos bei jos valstybių narių Ekonominės partnerystės susitarimo, kurio pasirašymas ir laikinas taikymas patvirtinti Tarybos sprendimu 2008/805/EB, III priedo 2 priedėlyje.

— *in Hungarian*: Az 1187/2009/EK rendelet III. fejezetének 3. szakasza:

az egyrészről a CARIFORUM-államok másrészről az Európai Közösség és tagállamai közötti gazdasági partnerségi megállapodás – amelynek aláírását és ideiglenes alkalmazását a 2008/805/EK tanácsi határozat hagyta jóvá – III. mellékletének 2. függeléke szerinti tejporra [...] július 1-től [...] június 30-ig vonatkozó vámkontingens.

— *in Maltese*: Il-Kaptiolu III, it-Taqsimta 3 tar-Regolament (KE) Nru 1187/2009:

kwota tariffarja għal 1.7...-30.6..., għat-trab tal-ħalib skont l-Appendiċi 2 tal-Anness III għall-Ftehim ta' Shubija Ekonomika bejn l-Istati CARIFORUM, minn naħa waħda, u l-Komunità Ewropea u l-Istati Membri tagħha, min-naħa l-oħra, li l-iffirmar u l-applikazzjoni provviżorja tiegħu kienu approvati bid-Deciżjoni tal-Kunsill 2008/805/KE.

— *in Dutch*: hoofdstuk III, afdeling 3 van Verordening (EG) nr. 1187/2009:

tariefcontingent melkpoeder voor het jaar van 1.7.... t/m 30.6.... overeenkomstig aanhangsel 2 van bijlage III bij de economische partnerschapsovereenkomst tussen de CARIFORUM-staten, enerzijds, en de Europese Gemeenschap en haar lidstaten, anderzijds, waarvan de ondertekening en de voorlopige toepassing zijn goedgekeurd bij Besluit 2008/805/EG van de Raad.

— *in Polish*: rozdział III sekcja 3 rozporządzenia (WE) nr 1187/2009:

kontyngent taryfowy na okres od 1.7.... do 30.6.... na mleko w proszku zgodnie z dodatkiem 2 do załącznika III do Umowy o partnerstwie gospodarczym między państwami CARIFORUM z jednej strony, a Wspólnotą Europejską i jej państwami członkowskimi z drugiej strony, której podpisanie i tymczasowe stosowanie zostało zatwierdzone decyzją Rady 2008/805/WE.

— *in Portuguese*: Secção 3 do capítulo III do Regulamento (CE) n.º 1187/2009:

Contingente pautal de leite em pó do ano 1.7....-30.6...., ao abrigo do apêndice 2 do anexo III do Acordo de Parceria Económica entre os Estados do Cariforum, por um lado, e a Comunidade Europeia e os seus Estados-Membros, por outro, cuja assinatura e aplicação a título provisório foram aprovadas pela Decisão 2008/805/CE do Conselho.

— *in Romanian*: capitolul III secțiunea 3 din Regulamentul (CE) nr. 1187/2009:

contingent tarifar pentru anul 1.7....-30.6...., pentru lapte praf în conformitate cu apendicele 2 din anexa III la Acordul de parteneriat economic între statele CARIFORUM, pe de o parte, și Comunitatea Europeană și statele membre ale acesteia, pe de altă parte, ale cărui semnare și aplicare provizorie au fost aprobate prin Decizia 2008/805/CE a Consiliului.

— *in Slovak*: kapitola III oddiel 3 nariadenia (ES) č. 1187/2009:

colná kvóta na obdobie od 1. júla ... do 30. júna ... na sušené mlieko podľa dodatku 2 k prílohe III k Dohode o hospodárskom partnerstve medzi štátmi CARIFORUM-u na jednej strane a Európskym spoločenstvom a jeho členskými štátmi na druhej strane, ktorej podpísanie a predbežné vykonávanie sa schválilo rozhodnutím Rady 2008/805/ES.

— *in Slovenian*: poglavje III, oddelek 3 Uredbe (ES) št. 1187/2009:

Tarifna kvota za obdobje 1.7...–30.6... za mleko v prahu v skladu z Dodatkom 2 k Prilogi III k Sporazumu o gospodárskem partnerstvu med državami CARIFORUMA na eni strani ter Evropsko skupnostjo in njenimi državami članicami na drugi strani, katerega podpis in začasno uporabo je Svet odobril s Sklepom 2008/805/ES.

— *in Finnish*: asetuksen (EY) N:o 1187/2009 III luvun 3 jaksossa:

Euroopan yhteisön ja sen jäsenvaltioiden sekä CARIFORUM-valtioiden talouskumppanuussopimuksen, jonka allekirjoittaminen ja väliaikainen soveltaminen on hyväksytty neuvoston päätöksellä 2008/805/EY, liitteessä III olevan lisäyksen 2 mukainen maitojauheen tariffikiintiö 1.7...–30.6... välisenä aikana.

— *in Swedish*: Kapitel III, avsnitt 3 i förordning (EG) nr 1187/2009:

tullkvot för 1.7...–30.6... för mjölkpulver enligt tillägg 2 till bilaga III till avtalet om ekonomiskt partnerskap mellan Cariforum-staterna, å ena sidan, och Europeiska gemenskapen och dess medlemsstater, å andra sidan, vars under-tecknande och provisoriska tillämpning godkändes genom rådets beslut 2008/805/EG.

ANNEX IV

DOMINICAN REPUBLIC

Information required under Article 31(1)

Member State:

Data relating to the period from 1 July ... to 30 June ...

Quota referred to in Article 28(1)(a)

Name/Address of applicant	Reference data exports to the Dominican Republic			Applications	
(1)	Product code in the refunds nomenclature	Quantities exported (t)	Year of export	Product code in the refunds nomenclature	Quantity maximum = 110 % of (3) (t)
	(2)	(3)	(4)	(5)	(6)
Total			Total		

Quota referred to in Article 28(1)(b)

Name/Address of applicant	Product code in the refunds nomenclature	Quantity applied for (t)
Total		

ANNEX V

DOMINICAN REPUBLIC

Information required under Article 32(1)

Member State:

Data relating to the period from 1 July ... to 30 June ...

Quota referred to in Article 28(1)(a)

Exporter's name and address	Code in the refund nomenclature	Quantities allocated for which licences were not issued (t)
Total		

Quota referred to in Article 28(1)(b)

Exporter's name and address	Code in the refund nomenclature	Quantities allocated for which licences were not issued (t)
Total		

ANNEX VI

DOMINICAN REPUBLIC

Information required under Article 32(5)

Member State:

Data relating to the period from 1 July ... to 30 June ...

Quota referred to in Article 28(1)(a)

Code in the refunds nomenclature	Quantities for which licences were allocated (t)	Quantities for which licences were issued (t)	Quantities exported (t)
Total			

Quota referred to in Article 28(1)(b)

Code in the refunds nomenclature	Quantities for which licences were allocated (t)	Quantities for which licences were issued (t)	Quantities exported (t)
Total			

ANNEX VII

Repealed Regulation with its successive amendments

Commission Regulation (EC) No 1282/2006
(OJ L 234, 29.8.2006, p. 4)

Commission Regulation (EC) No 1919/2006
(OJ L 380, 28.12.2006, p. 1)

Only Article 7 and Annex IX

Commission Regulation (EC) No 532/2007
(OJ L 125, 15.5.2007, p. 7)

Only Article 1

Commission Regulation (EC) No 240/2009
(OJ L 75, 21.3.2009, p. 3)

Commission Regulation (EC) No 433/2009
(OJ L 128, 27.5.2009, p. 5)

Commission Regulation (EC) No 740/2009
(OJ L 290, 13.8.2009, p. 3)

ANNEX VIII

Correlation table

Regulation (EC) No 1282/2006	This Regulation
Article 1	Article 1
Article 2	Article 2
Article 3(2)	Article 3
Article 4(1)	Article 4(1)
Article 4(2)	Article 4(2)
Article 4(3)	Article 4(3)
Article 4(4)	—
Article 6	Article 5
Article 7	Article 6
Article 8	Article 7
Article 9(1) to (6)	Article 8(1) to (6)
Article 9(7)	—
Article 10(1)	Article 9
Article 10(2)	—
Article 11	Article 10
Article 12	Article 11
Article 13(1)	Article 12
Article 13(2)	—
Article 14	Article 13
Article 15	—
Article 16	Article 14
Article 17	Article 15
Article 18	Article 16
Article 19	Article 17
Article 20	Article 18
Article 21(1)	Article 19(1)
Article 21(2)	Article 19(2)
Article 21(3)	Article 19(3)
Article 21(4)	—
Article 22(1)	Article 20
Article 22(2)	—
Article 23	Article 21
Article 24	Article 22
Article 25(1), first subparagraph	Article 23(1), first subparagraph
—	Article 23(1), second subparagraph

Regulation (EC) No 1282/2006	This Regulation
Article 25(1), second subparagraph	Article 23(1), third subparagraph
Article 25(2)	Article 23(2)
Article 25(3)	Article 23(3)
Article 26	Article 24
Article 27	Article 25
Article 28	Article 26
Article 29	Article 27
Article 30(1)	Article 28(1)
Article 30(2), first subparagraph	Article 28(2), first subparagraph
—	Article 28(2), second subparagraph
Article 30(2), second subparagraph	Article 28(2), third subparagraph
Article 30(3)	Article 28(3)
Article 31	Article 29
Article 32	Article 30
Article 33(1)	Article 31(1)
Article 33(2), first subparagraph	Article 31(2), first subparagraph
Article 33(2), second subparagraph, first sentence	Article 31(2), second subparagraph, first sentence
—	Article 31(2), second subparagraph, second sentence
Article 33(2), second subparagraph, second to fifth sentences	Article 31(2), third subparagraph
Article 33(2), third subparagraph	Article 31(2), fourth subparagraph
Article 34	Article 32
Article 35(1)	Article 33(1)
Article 35(2)	—
Article 35(3)	Article 33(2)
Article 36	—
Article 37	—
—	Article 34
—	Article 35
Annex I	Annex I
Annex II	Annex II
Annex III	—
Annex IV	Annex III
Annex V	Annex IV
Annex VI	Annex V
Annex VII	Annex VI
Annex VIII	—
—	Annex VII
—	Annex VIII

DIRECTIVES

COUNCIL DIRECTIVE 2009/143/EC

of 26 November 2009

amending Directive 2000/29/EC as regards the delegation of the tasks of laboratory testing

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 37 thereof,

Having regard to the proposal from the Commission,

Having regard to the Opinion of the European Parliament ⁽¹⁾,

Whereas:

(1) Under Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community ⁽²⁾ the responsible official bodies in the Member States may only delegate the tasks provided for in that Directive, including laboratory testing, to a legal person which under its officially approved constitution is charged exclusively with specific public functions.

(2) The laboratory tests which have to be carried out in the framework of Directive 2000/29/EC are of a highly technical nature and concern different scientific fields. Such tests require a wide range of different and expensive technical facilities and highly specialised laboratory staff capable of adapting to the rapid development of diagnostic methodology. The number of tests to be carried out has been growing over recent years. As a result, it has grown increasingly difficult to find legal persons fulfilling all the necessary requirements.

(3) For these reasons it is appropriate to provide that the numerous and diverse laboratory tests required under Directive 2000/29/EC may, in addition to legal persons which are exclusively charged with specific public functions, be delegated to legal persons not fulfilling this requirement, such as universities, research institutes or private laboratories in any legal form recognised in the Member State in accordance with their national legislation, provided that they satisfy certain conditions.

(4) It is appropriate that the responsible official bodies verify that the legal persons, to which the execution of the

laboratory testing is delegated, can assure quality. They should for example be impartial, free of conflict of interest and able to ensure reliable results and protection of confidential information.

(5) At the same time it is appropriate to allow legal persons carrying out delegated tasks in accordance with Directive 2000/29/EC to use their laboratories for testing activities which do not form part of their specific public functions.

(6) The issue of an appropriate diagnostic infrastructure is one of the issues addressed in the ongoing evaluation of the plant health legislation. However, without prejudice to the outcome of the review, it is appropriate in the short term to modify the requirements on the delegation of laboratory testing to existing needs.

(7) The second subparagraph of Article 2(1)(g) of Directive 2000/29/EC should therefore be amended accordingly.

(8) In accordance with point 34 of the Interinstitutional agreement on better law-making ⁽³⁾, Member States are encouraged to draw up, for themselves and in the interests of the Community, their own tables illustrating, as far as possible, the correlation between this Directive and the transposition measures, and to make them public,

HAS ADOPTED THIS DIRECTIVE:

Article 1

The second subparagraph of Article 2(1)(g) of Directive 2000/29/EC shall be replaced by the following:

‘The responsible official bodies in a Member State may, in accordance with national legislation, delegate the tasks provided for in this Directive to be accomplished under their authority and supervision to a legal person, whether governed by public or private law, provided that such person, and its members, has no personal interest in the outcome of the measure it takes.

⁽¹⁾ Opinion of 20 October 2009 (not yet published in the Official Journal).

⁽²⁾ OJ L 169, 10.7.2000, p. 1.

⁽³⁾ OJ C 321, 31.12.2003, p. 1.

The responsible official bodies in the Member States shall ensure that the legal person referred to in the second subparagraph is, under its officially approved constitution, charged exclusively with specific public functions, with the exception of laboratory testing which such legal person may perform even where the laboratory testing does not form part of its specific public functions.

Notwithstanding the third subparagraph, the responsible official bodies in a Member State may delegate the laboratory testing provided for in this Directive to a legal person which does not comply with that provision.

The laboratory testing may only be delegated if the responsible official body ensures throughout the time of the delegation that the legal person to which it delegates laboratory testing can assure impartiality, quality and protection of confidential information, and that no conflict of interest exists between the exercise of the tasks delegated to it and its other activities.'

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this

Directive before 1 January 2011. They shall forthwith inform the Commission thereof.

When they are adopted by Member States, those measures shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 26 November 2009.

For the Council
The President
J. BJÖRKLUND

II

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

DECISIONS

COMMISSION

COMMISSION DECISION

of 27 November 2009

amending Decision 2002/364/EC on common technical specifications for in vitro diagnostic medical devices

(notified under document C(2009) 9464)

(Text with EEA relevance)

(2009/886/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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⁽¹⁾, and in particular the second subparagraph of Article 5(3) thereof,

Whereas:

- (1) The common technical specifications for in vitro diagnostic medical devices are laid down in Commission Decision 2002/364/EC⁽²⁾.
- (2) In the interest of public health and in order to reflect technical progress including the evolution in the performance and analytical sensitivity of devices, it is appropriate to revise the common technical specifications laid down in Decision 2002/364/EC.
- (3) The definition of rapid test should be refined in order for it to be more precise. For the sake of clarity further definitions should be included.
- (4) To bring the common technical specifications in line with current scientific and technical practices it is necessary to update a number of scientific and technical references.

- (5) The requirements for HIV screening assays should be clarified. In order to ensure that the performance criteria appropriate to today's technology is reflected in the common technical specifications it is necessary to add requirements for HIV antibody/antigen combined tests and further specification of the sample requirements for certain assays.
- (6) The Annex to Decision 2002/364/EC should therefore be amended accordingly and, for the purpose of clarity, be replaced.
- (7) Due to an administrative error, Commission Decision 2009/108/EC of 3 February 2009 amending Decision 2002/364/EC on common technical specifications for *in vitro*-diagnostic medical devices⁽³⁾ was adopted without the European Parliament being given the possibility to exercise its right of scrutiny in accordance with Article 8 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission⁽⁴⁾. Therefore, Decision 2009/108/EC should be replaced by this Decision.
- (8) Manufacturers whose devices are already on the market should be given a transitional period in order to adapt to the new common technical specifications. On the other hand, in the interest of public health, manufacturers who so wish should be able to apply the new common technical specifications before the expiry of the transitional period.
- (9) The measures provided for in this Decision are in accordance with the opinion of the committee set up by Article 6(2) of Council Directive 90/385/EEC⁽⁵⁾,

⁽¹⁾ OJ L 331, 7.12.1998, p. 1.

⁽²⁾ OJ L 131, 16.5.2002, p. 17.

⁽³⁾ OJ L 39, 10.2.2009, p. 34.

⁽⁴⁾ OJ L 184, 17.7.1999, p. 23.

⁽⁵⁾ OJ L 189, 20.7.1990, p. 17.

HAS ADOPTED THIS DECISION:

Article 1

The Annex to Decision 2002/364/EC is replaced by the text in the Annex to this Decision.

Article 2

Decision 2009/108/EC is repealed.

Article 3

This Decision shall apply from 1 December 2010 for those devices first placed on the market prior to 1 December 2009.

It shall apply from 1 December 2009 for all other devices.

However, Member States shall allow manufacturers to apply the requirements set out in the Annex before the dates set out in the first and second paragraphs.

Article 4

This Decision is addressed to the Member States.

Done at Brussels, 27 November 2009.

For the Commission

Günter VERHEUGEN

Vice-President

ANNEX

'ANNEX

COMMON TECHNICAL SPECIFICATIONS (CTS) FOR IN VITRO DIAGNOSTIC MEDICAL DEVICES

1. SCOPE

The common technical specifications set out in this Annex shall apply for the purposes of Annex II List A to Directive 98/79/EC.

2. DEFINITIONS AND TERMS

(Diagnostic) sensitivity

The probability that the device gives a positive result in the presence of the target marker.

True positive

A specimen known to be positive for the target marker and correctly classified by the device.

False negative

A specimen known to be positive for the target marker and misclassified by the device.

(Diagnostic) specificity

The probability that the device gives a negative result in the absence of the target marker.

False positive

A specimen known to be negative for the target marker and misclassified by the device.

True negative

A specimen known to be negative for the target marker and correctly classified by the device.

Analytical sensitivity

Analytical sensitivity may be expressed as the limit of detection, i.e. the smallest amount of the target marker that can be precisely detected.

Analytical specificity

Analytical specificity means the ability of the method to determine solely the target marker.

Nucleic acid amplification techniques (NAT)

The term "NAT" is used for tests for the detection and/or quantification of nucleic acids by either amplification of a target sequence, by amplification of a signal or by hybridisation.

Rapid test

"Rapid test" means qualitative or semi-quantitative *in vitro* diagnostic medical devices, used singly or in a small series, which involve non-automated procedures and have been designed to give a fast result.

Robustness

The robustness of an analytical procedure means the capacity of an analytical procedure to remain unaffected by small but deliberate variations in method parameters and provides an indication of its reliability during normal usage.

Whole system failure rate

The whole system failure rate means the frequency of failures when the entire process is performed as prescribed by the manufacturer.

Confirmation assay

Confirmation assay means an assay used for the confirmation of a reactive result from a screening assay.

Virus typing assay

Virus typing assay means an assay used for typing with already known positive samples, not used for primary diagnosis of infection or for screening.

Sero-conversion HIV samples

Sero-conversion HIV samples mean:

- p24 antigen and/or HIV RNA positive, and
- recognised by all of the antibody screening tests, and
- positive or indeterminate confirmatory assays.

Early sero-conversion HIV samples

Early seroconversion HIV samples mean:

- p24 antigen and/or HIV RNA positive, and
- not recognised by all of the antibody screening tests, and
- indeterminate or negative confirmatory assays.

3. COMMON TECHNICAL SPECIFICATIONS (CTS) FOR PRODUCTS REFERRED TO IN ANNEX II, LIST A OF DIRECTIVE 98/79/EC

3.1. **CTS for performance evaluation of reagents and reagent products for the detection, confirmation and quantification in human specimens of markers of HIV infection (HIV 1 and 2), HTLV I and II, and hepatitis B, C, D**

General principles

- 3.1.1. Devices which detect virus infections placed on the market for use as either screening or diagnostic tests, shall meet the requirements for sensitivity and specificity set out in Table 1. See also principle 3.1.11 for screening assays.
- 3.1.2. Devices intended by the manufacturer for testing body fluids other than serum or plasma, e.g. urine, saliva, etc., shall meet the same CTS requirements for sensitivity and specificity as serum or plasma tests. The performance evaluation shall test samples from the same individuals in both the tests to be approved and in a respective serum or plasma assay.
- 3.1.3. Devices intended by the manufacturer for self-test, i.e. home use, shall meet the same CTS requirements for sensitivity and specificity as respective devices for professional use. Relevant parts of the performance evaluation shall be carried out (or repeated) by appropriate lay users to validate the operation of the device and the instructions for use.
- 3.1.4. All performance evaluations shall be carried out in direct comparison with an established state-of-the-art device. The device used for comparison shall be one bearing CE marking, if on the market at the time of the performance evaluation.
- 3.1.5. If discrepant test results are identified as part of an evaluation, these results shall be resolved as far as possible, for example:
 - by evaluation of the discrepant sample in further test systems,
 - by use of an alternative method or marker,
 - by a review of the clinical status and diagnosis of the patient, and
 - by the testing of follow-up-samples.
- 3.1.6. Performance evaluations shall be performed on a population equivalent to the European population.
- 3.1.7. Positive specimens used in the performance evaluation shall be selected to reflect different stages of the respective disease(s), different antibody patterns, different genotypes, different subtypes, mutants, etc.
- 3.1.8. Sensitivity with true positives and sero-conversion samples shall be evaluated as follows:
 - 3.1.8.1. Diagnostic test sensitivity during sero-conversion has to represent the state of the art. Whether further testing of the same or additional sero-conversion panels is conducted by the notified body or by the manufacturer the results shall confirm the initial performance evaluation data (see Table 1). Sero-conversion panels should start with a negative bleed(s) and should have narrow bleeding intervals.

3.1.8.2. For blood screening devices (with the exception of HBsAg and anti-HBc tests), all true positive samples shall be identified as positive by the device to be CE marked (Table 1). For HBsAg and anti-HBc tests the new device shall have an overall performance at least equivalent to that of the established device (see 3.1.4).

3.1.8.3. Regarding HIV tests:

- all sero-conversion HIV samples shall be identified as positive, and
- at least 40 early sero-conversion HIV samples shall be tested. Results should conform to the state of the art.

3.1.9. Performance evaluation of screening assays shall include 25 positive (if available in the case of rare infections) “same day” fresh serum and/or plasma samples (≤ 1 day after sampling).

3.1.10. Negative specimens used in a performance evaluation shall be defined so as to reflect the target population for which the test is intended, for example blood donors, hospitalised patients, pregnant women, etc.

3.1.11. For performance evaluations for screening assays (Table 1) blood donor populations shall be investigated from at least two blood donation centres and consist of consecutive blood donations, which have not been selected to exclude first time donors.

3.1.12. Devices shall have a specificity of at least 99,5 % on blood donations, unless otherwise indicated in the accompanying tables. Specificity shall be calculated using the frequency of repeatedly reactive (i.e. false positive) results in blood donors negative for the target marker.

3.1.13. Devices shall be evaluated to establish the effect of potential interfering substances, as part of the performance evaluation. The potential interfering substances to be evaluated will depend to some extent on the composition of the reagent and configuration of the assay. Potential interfering substances shall be identified as part of the risk analysis required by the essential requirements for each new device but may include, for example:

- specimens representing “related” infections,
- specimens from multipara, i.e. women who have had more than one pregnancy, or rheumatoid factor positive patients,
- for recombinant antigens, human antibodies to components of the expression system, for example anti-E. coli, or anti-yeast.

3.1.14. For devices intended by the manufacturer to be used with serum and plasma the performance evaluation must demonstrate serum to plasma equivalency. This shall be demonstrated for at least 50 donations (25 positive and 25 negative).

3.1.15. For devices intended for use with plasma the performance evaluation shall verify the performance of the device using all anticoagulants which the manufacturer indicates for use with the device. This shall be demonstrated for at least 50 donations (25 positive and 25 negative).

3.1.16. As part of the required risk analysis the whole system failure rate leading to false-negative results shall be determined in repeat assays on low-positive specimens.

3.1.17. If a new *in vitro* diagnostic medical device belonging to Annex II List A is not specifically covered by the common technical specification, the common technical specification for a related device should be taken into account. Related devices may be identified on different grounds, e.g. by the same or similar intended use or by similar risks.

3.2. Additional requirements for HIV antibody/antigen combined tests

3.2.1. HIV antibody/antigen combined tests intended for anti-HIV and p24 antigen detection which include claims for single p24 antigen detection shall follow Table 1 and Table 5, including criteria for analytical sensitivity for p24 antigen.

3.2.2. HIV antibody/antigen combined tests intended for anti-HIV and p24 detection which do not include claims for single p24 detection shall follow Table 1 and Table 5, excluding criteria for analytical sensitivity for p24.

3.3. Additional requirements for nucleic acid amplification techniques (NAT)

The performance evaluation criteria for NAT assays can be found in Table 2.

3.3.1. For target sequence amplification assays, a functionality control for each test sample (internal control) shall reflect the state of the art. This control shall as far as possible be used throughout the whole process, i.e. extraction, amplification/hybridisation, detection.

- 3.3.2. The analytical sensitivity or detection limit for NAT assays shall be expressed by the 95 % positive cut-off value. This is the analyte concentration where 95 % of test runs give positive results following serial dilutions of an international reference material for example a WHO standard or calibrated reference material.
- 3.3.3. Genotype detection shall be demonstrated by appropriate primer or probe design validation and shall also be validated by testing characterised genotyped samples.
- 3.3.4. Results of quantitative NAT assays shall be traceable to international standards or calibrated reference materials, if available, and be expressed in international units utilised in the specific field of application.
- 3.3.5. NAT assays may be used to detect virus in antibody negative samples, i.e. pre-sero-conversion samples. Viruses within immune-complexes may behave differently in comparison to free viruses, for example during a centrifugation step. It is therefore important that during robustness studies, antibody-negative (pre-sero-conversion) samples are included.
- 3.3.6. For investigation of potential carry-over, at least five runs with alternating high-positive and negative specimens shall be performed during robustness studies. The high positive samples shall comprise samples with naturally occurring high virus titres.
- 3.3.7. The whole system failure rate leading to false-negative results shall be determined by testing low-positive specimens. Low-positive specimens shall contain a virus concentration equivalent to three times the 95 % positive cut-off virus concentration.
- 3.4. **CTS for the manufacturer's release testing of reagents and reagent products for the detection, confirmation and quantification in human specimens of markers of HIV infection (HIV 1 and 2), HTLV I and II, and hepatitis B, C, D (immunological assays only)**
- 3.4.1. The manufacturer's release testing criteria shall ensure that every batch consistently identifies the relevant antigens, epitopes, and antibodies.
- 3.4.2. The manufacturer's batch release testing for screening assays shall include at least 100 specimens negative for the relevant analyte.
- 3.5. **CTS for performance evaluation of reagents and reagent products for determining the following blood group antigens: ABO blood group system ABO1 (A), ABO2 (B), ABO3 (A,B); Rh blood group system RH1 (D), RH2 (C), RH3 (E), RH4 (c), RH5 (e); Kell blood group system KEL1 (K)**
- Criteria for performance evaluation of reagents and reagent products for determining the blood groups antigens: ABO blood group system ABO1 (A), ABO2 (B), ABO3 (A,B); Rh blood group system RH1 (D), RH2 (C), RH3 (E), RH4 (c), RH5 (e); Kell blood group system KEL1 (K) can be found in Table 9.
- 3.5.1. All performance evaluations shall be carried out in direct comparison with an established state-of-the-art device. The device used for comparison shall be one bearing CE marking, if on the market at the time of the performance evaluation.
- 3.5.2. If discrepant test results are identified as part of an evaluation, these results shall be resolved as far as possible, for example:
- by evaluation of the discrepant sample in further test systems,
 - by use of an alternative method,
- 3.5.3. Performance evaluations shall be performed on a population equivalent to the European population.
- 3.5.4. Positive specimens used in the performance evaluation shall be selected to reflect variant and weak antigen expression.
- 3.5.5. Devices shall be evaluated to establish the effect of potential interfering substances, as part of the performance evaluation. The potential interfering substances to be evaluated will depend to some extent on the composition of the reagent and configuration of the assay. Potential interfering substances shall be identified as part of the risk analysis required by the essential requirements for each new device.
- 3.5.6. For devices intended for use with plasma the performance evaluation shall verify the performance of the device using all anticoagulants which the manufacturer indicates for use with the device. This shall be demonstrated for at least 50 donations.
- 3.6. **CTS for the manufacturer's release testing of reagents and reagent products for determining the blood group antigens: ABO blood group system ABO1 (A), ABO2 (B), ABO3 (A,B); Rh blood group system RH1 (D), RH2 (C), RH3 (E), RH4 (c), RH5 (e); Kell blood group system KEL1 (K)**
- 3.6.1. The manufacturer's release testing criteria shall ensure that every batch consistently identifies the relevant antigens, epitopes, and antibodies.
- 3.6.2. Requirements for manufacturers batch release testing are outlined in Table 10.

Table 1

“Screening” assays: anti-HIV 1 and 2, anti-HTLV I and II, anti-HCV, HBsAg, anti-HBc

		Anti-HIV-1/2	Anti-HTLV-I/II	Anti-HCV	HBsAg	Anti-HBc
Diagnostic sensitivity	Positive specimens	400 HIV-1 100 HIV-2 including 40 non-B subtypes, all available HIV/1 subtypes should be represented by at least 3 samples per subtype	300 HTLV-I 100 HTLV-II	400 (positive samples) Including samples from different stages of infection and reflecting different antibody patterns. Genotype 1-4: > 20 samples per genotype (including non-a subtypes of genotype 4); 5: > 5 samples; 6: if available	400 Including subtypeconsideration	400 Including evaluation of other HBV-markers
	Sero-conversion panels	20 panels 10 further panels (at Notified Body or manufacturer)	To be defined when available	20 panels 10 further panels (at Notified Body or manufacturer)	20 panels 10 further panels (at Notified Body or manufacturer)	To be defined when available
Analytical sensitivity	Standards				0,130 IU/ml (Second International Standard for HBsAg, subtype adw2, genotype A, NIBSC code: 00/588)	
Specificity	Unselected donors (including first-time donors)	5 000	5 000	5 000	5 000	5 000
	Hospitalised patients	200	200	200	200	200
	Potentially cross-reacting blood-specimens (RF+, related viruses, pregnant women, etc.)	100	100	100	100	100

Table 2

NAT assays for HIV1, HCV, HBV, HTLV I/II (qualitative and quantitative; not molecular typing)

HIV1			HCV		HBV		HTLV I/II		Acceptance criteria
NAT	qualitative	quantitative	qualitative	quantitative	qualitative	quantitative	qualitative	quantitative	
				As for HIV quantitative		As for HIV quantitative		As for HIV quantitative	
Sensitivity Detection limit Detection of analytical sensitivity (IU/ml; defined on WHO standards or calibrated reference materials)	According to EP validation guideline ⁽¹⁾ : several dilution series into borderline concentration; statistical analysis (e.g. Probit analysis) on the basis of at least 24 replicates; calculation of 95 % cut-off value	Detection limit: as for qualitative tests; Quantification limit: dilutions (half-log10 or less) of calibrated reference preparations, definition of lower, upper quantification limit, precision, accuracy, "linear" measuring range, "dynamic range". Reproducibility at different concentration levels to be shown	According to EP validation guideline ⁽¹⁾ : several dilution series into borderline concentration; statistical analysis (e.g. Probit analysis) on the basis of at least 24 replicates; calculation of 95 % cut-off value		According to EP validation guideline ⁽¹⁾ : several dilution series into borderline concentration; statistical analysis (e.g. Probit analysis) on the basis of at least 24 replicates; calculation of 95 % cut-off value		According to EP validation guideline ⁽¹⁾ : several dilution series into borderline concentration; statistical analysis (e.g. Probit analysis) on the basis of at least 24 replicates; calculation of 95 % cut-off value		
Genotype/subtype detection/ quantification efficiency	At least 10 samples per subtype (as far as available)	Dilution series of all relevant genotypes/ subtypes, preferably of reference materials, as far as available	At least 10 samples per genotype (as far as available)		As far as calibrated genotype reference materials are available		As far as calibrated genotype reference materials are available		

HIV1			HCV		HBV		HTLV I/II		Acceptance criteria
NAT	qualitative	quantitative	qualitative	quantitative	qualitative	quantitative	qualitative	quantitative	
				As for HIV quantitative		As for HIV quantitative		As for HIV quantitative	
	Cell culture supernatants (could substitute for rare HIV-1 subtypes)	Transcripts or plasmids quantified by appropriate methods may be used.							
	According to EP validation guideline ⁽¹⁾ as far as calibrated subtype reference materials are available; <i>in vitro</i> transcripts could be an option		According to EP validation guideline ⁽¹⁾ as far as calibrated subtype reference materials are available; <i>in vitro</i> transcripts could be an option		According to EP validation guideline ⁽¹⁾ as far as calibrated subtype reference materials are available; <i>in vitro</i> transcripts could be an option		According to EP validation guideline ⁽¹⁾ as far as calibrated subtype reference materials are available; <i>in vitro</i> transcripts could be an option		
Diagnostic specificity negative samples	500 blood donors	100 blood donors	500 blood donors		500 blood donors		500 individual blood donations		
Potential cross-reactive markers	By suitable assay design evidence (e.g. sequence comparison) and/or testing of at least 10 human retrovirus (e.g. HTLV)-positive samples	As for qualitative tests	By assays design and/or testing of at least 10 human flavivirus (e.g. HGV, YFV) positive samples		By assays design and/or testing of at least 10 other DNA-virus positive samples		By assay design and/or testing of at least 10 human retrovirus (e.g. HIV-) positive samples		
Robustness		As for qualitative tests							

HIV1			HCV		HBV		HTLV I/II		Acceptance criteria
NAT	qualitative	quantitative	qualitative	quantitative	qualitative	quantitative	qualitative	quantitative	
				As for HIV quantitative		As for HIV quantitative		As for HIV quantitative	
Cross-contamination	At least 5 runs using alternating high positive (known to occur naturally) and negative samples		At least 5 runs using alternating high positive (known to occur naturally) and negative samples		At least 5 runs using alternating high positive (known to occur naturally) and negative samples		At least 5 runs using alternating high positive (known to occur naturally) and negative samples		
Inhibition	Internal control preferably to go through the whole NAT procedure		Internal control preferably to go through the whole NAT procedure		Internal control preferably to go through the whole NAT procedure		Internal control preferably to go through the whole NAT procedure		
Whole system failure rate leading to false-neg results	At least 100 samples virus-spiked with 3 × the 95 % pos cut-off concentration		At least 100 samples virus-spiked with 3 × the 95 % pos cut-off concentration		At least 100 samples virus-spiked with 3 × the 95 % pos cut-off concentration		At least 100 samples virus-spiked with 3 × the 95 % pos cut-off concentration		99/100 assays positive

(¹) European Pharmacopoeia guideline.

Notes: Acceptance criteria for “whole system failure rate leading to false-neg results” is 99/100 assays positive.

For quantitative NATs a study shall be performed on at least 100 positive specimens reflecting the routine conditions of users (e.g. no pre-selection of specimens). Comparative results with another NAT test system shall be generated in parallel.

For qualitative NATs a study on diagnostic sensitivity shall be performed using at least 10 sero-conversion panels. Comparative results with another NAT test system shall be generated in parallel.

Table 3

Rapid tests: anti-HIV 1 and 2, anti-HCV, HBsAg, anti-HBc, anti-HTLV I and II

		Anti-HIV 1/2	Anti-HCV	HBsAg	Anti-HBc	Anti-HTLV I/II	Acceptance criteria
Diagnostic sensitivity	Positive specimens	Same criteria as for screening assays	Same criteria as for screening assays	Same criteria as for screening assays	Same criteria as for screening assays	Same criteria as for screening assays	Same criteria as for screening assays
	Sero-conversion panels	Same criteria as for screening assays	Same criteria as for screening assays	Same criteria as for screening assays	Same criteria as for screening assays	Same criteria as for screening assays	Same criteria as for screening assays
Diagnostic specificity	Negative specimens	1 000 blood donations	1 000 blood donations	1 000 blood donations	1 000 blood donations	1 000 blood donations	≥ 99 % (anti-HBc: ≥ 96 %)
		200 clinical specimens	200 clinical specimens	200 clinical specimens	200 clinical specimens	200 clinical specimens	
		200 samples from pregnant women	200 samples from pregnant women	200 samples from pregnant women		200 samples from pregnant women	
		100 potentially interfering samples	100 potentially interfering samples	100 potentially interfering samples	100 potentially interfering samples	100 potentially interfering samples	

Table 4

Confirmatory/supplementary assays for anti-HIV 1 and 2, anti-HTLV I and II, anti-HCV, HBsAg

		Anti-HIV confirmatory assay	Anti-HTLV confirmatory assay	HCV supplementary assay	HBsAg confirmatory assay	Acceptance criteria
Diagnostic sensitivity	Positive specimens	200 HIV-1 and 100 HIV-2	200 HTLV-I and 100 HTLV-II	300 HCV (positive samples)	300 HBsAg	Correct identification as positive (or indeterminate), not negative
		Including samples from different stages of infection and reflecting different antibody patterns		Including samples from different stages of infection and reflecting different antibody patterns. Genotypes 1 – 4: > 20 samples (including non-a subtypes of genotype 4); 5: > 5 samples; 6: if available	Including samples from different stages of infection 20 “high pos” samples (> 26 IU/ml); 20 samples in the cut-off range	
	Sero-conversion panels	15 sero-conversion panels/ low titre panels		15 sero-conversion panels/ low titre panels	15 sero-conversion panels/ low titre panels	
Analytical sensitivity	Standards				Second International Standard for HBsAg, subtype adw2, genotype A, NIBSC code: 00/588	
Diagnostic specificity	Negative specimens	200 blood donations	200 blood donation	200 blood donations	10 false positives as available from the performance evaluation of the screening assay ⁽¹⁾ .	No false-positive results/ ⁽¹⁾ no neutralisation
		200 clinical samples including pregnant women 50 potentially interfering samples, including samples with indeterminate results in other confirmatory assays	200 clinical samples including pregnant women 50 potentially interfering samples including samples with indeterminate results in other confirmatory assays	200 clinical samples including pregnant women 50 potentially interfering samples including samples with indeterminate results in other supplementary assays	50 potentially interfering samples	

⁽¹⁾ Acceptance criteria no neutralisation for HBsAg confirmatory assay.

Table 5
HIV 1 antigen

		HIV-1 antigen assay	Acceptance criteria
Diagnostic sensitivity	Positive specimens	50 HIV-1 Ag-positive 50 cell culture supernatants including different HIV-1 subtypes and HIV-2	Correct identification (after neutralisation)
	Sero-conversion panels	20 sero-conversion panels/low titre panels	
Analytical sensitivity	Standards	HIV-1 p24 Antigen, First International Reference Reagent, NIBSC code: 90/636	≤ 2 IU/ml
Diagnostic specificity		200 blood donations 200 clinical samples 50 potentially interfering samples	$\geq 99,5$ % after neutralisation

Table 6
Serotyping and genotyping assay: HCV

		HCV serotyping and genotyping assay	Acceptance criteria
Diagnostic sensitivity	Positive specimens	200 (positive samples) Including samples from different stages of infection and reflecting different antibody patterns. Genotypes 1 – 4: > 20 samples (including non-a subtypes of genotype 4); 5: > 5 samples; 6: if available	≥ 95 % agreement between serotyping and genotyping ≥ 95 % agreement between genotyping and sequencing
Diagnostic specificity	Negative specimens	100	

Table 7

HBV markers: anti-HBs, anti HBe IgM, anti-HBe, HBeAg

		Anti-HBs	Anti-HBe IgM	Anti-HBe	HBeAg	Acceptance criteria
Diagnostic sensitivity	Positive specimens	100 vaccinees 100 naturally infected persons	200 Including samples from different stages of infection (acute/chronic, etc.) The acceptance criteria should only be applied on samples from acute infection stage.	200 Including samples from different stages of infection (acute/chronic, etc.)	200 Including samples from different stages of infection (acute/chronic, etc.)	$\geq 98 \%$
	Sero-conversion panels	10 follow-ups or anti-HBs sero-conversions	When available			
Analytical sensitivity	Standards	WHO First International Reference Preparation 1977; NIBSC, United Kingdom			HBe — Referenzantigen 82; PEI Germany	Anti-HBs: < 10 mIU/ml
Diagnostic specificity	Negative specimens	500 Including clinical samples 50 potentially interfering samples	200 blood donations 200 clinical samples 50 potentially interfering samples	200 blood donation 200 clinical samples 50 potentially interfering samples	200 blood donations 200 clinical samples 50 potentially interfering samples	$\geq 98 \%$

Table 8

HDV markers: anti-HDV, anti-HDV IgM, delta antigen

		Anti-HDV	Anti-HDV IgM	Delta antigen	Acceptance criteria
Diagnostic sensitivity	Positive specimens	100 Specifying HBV markers	50 Specifying HBV markers	10 Specifying HBV markers	≥ 98 %
Diagnostic specificity	Negative specimens	200 Including clinical samples 50 potentially interfering samples	200 Including clinical samples 50 potentially interfering samples	200 Including clinical samples 50 potentially interfering samples	≥ 98 %

Table 9

Blood group antigens in the ABO, Rh and Kell blood group systems

	1	2	3
Specificity	Number of tests per recommended method	Total number of samples to be tested for a launch product	Total number of samples to be tested for a new formulation, or use of well-characterised reagents
Anti-ABO1 (anti-A), anti-ABO2 (anti-B), anti-ABO3 (anti-A,B)	500	3 000	1 000
Anti-RH1 (anti-D)	500	3 000	1 000
Anti-RH2 (anti-C), anti-RH4 (anti-c), anti-RH3 (anti-E)	100	1 000	200
Anti-RH5 (anti-e)	100	500	200
Anti-KEL1 (anti-K)	100	500	200

Acceptance criteria:

All of the above reagents shall show comparable test results with established reagents with acceptable performance with regard to claimed reactivity of the device. For established reagents, where the application or use has been changed or extended, further testing should be carried out in accordance with the requirements outlined in column 1 (above).

Performance evaluation of anti-D reagents shall include tests against a range of weak RH1 (D) and partial RH1 (D) samples, depending on the intended use of the product.

Qualifications:

Clinical samples: 10 % of the test population
 Neonatal specimens: > 2 % of the test population
 ABO samples: > 40 % A, B positives
 "weak D": > 2 % of RH1 (D) positives

Table 10

Batch release criteria for reagents and reagent products to determine blood group antigens in the ABO, Rh and Kell blood group systems

Specificity testing requirements on each reagent

1. Test reagents

Blood group reagents	Minimum number of control cells to be tested						
	Positive reactions				Negative reactions		
	A1	A2B	Ax		B	0	
Anti-ABO1 (anti-A)	2	2	2 (*)		2	2	
	B	A1B			A1	0	
Anti-ABO2 (anti-B)	2	2			2	2	
	A1	A2	Ax	B	0		
Anti-ABO3 (anti-A,B)	2	2	2	2	4		
	R1r	R2r	WeakD		r'r	r'r	rr
Anti-RH1 (anti-D)	2	2	2 (*)		1	1	1
	R1R2	R1r	r'r		R2R2	r'r	rr
Anti-RH2 (anti-C)	2	1	1		1	1	1
	R1R2	R1r	r'r		R1R1		
Anti-RH4 (anti-c)	1	2	1		3		
	R1R2	R2r	r'r		R1R1	r'r	rr
Anti-RH 3 (anti-E)	2	1	1		1	1	1
	R1R2	R2r	r'r		R2R2		
Anti-RH5 (anti-e)	2	1	1		3		
	Kk				kk		
Anti-KEL1 (anti-K)	4				3		

(*) Only by recommended techniques where reactivity against these antigens is claimed.

Note: Polyclonal reagents must be tested against a wider panel of cells to confirm specificity and exclude presence of unwanted contaminating antibodies.

Acceptance criteria:

Each batch of reagent must exhibit unequivocal positive or negative results by all recommended techniques in accordance with the results obtained from the performance evaluation data.

2. Control materials (red cells)

The phenotype of red cells used in the control of blood typing reagents listed above should be confirmed using established device.

COMMISSION DECISION

of 30 November 2009

concerning the non-inclusion of bifenthrin in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance

*(notified under document C(2009) 9196)***(Text with EEA relevance)**

(2009/887/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market ⁽¹⁾, and in particular the fourth subparagraph of Article 8(2) thereof,

Whereas:

- (1) Article 8(2) of Directive 91/414/EEC provides that a Member State may, during a period of 12 years following the notification of that Directive, authorise the placing on the market of plant protection products containing active substances not listed in Annex I to that Directive that are already on the market two years after the date of notification, while those substances are gradually being examined within the framework of a programme of work.
- (2) Commission Regulations (EC) No 451/2000 ⁽²⁾ and (EC) No 1490/2002 ⁽³⁾ lay down the detailed rules for the implementation of the third stage of the programme of work referred to in Article 8(2) of Directive 91/414/EEC and establish a list of active substances to be assessed with a view to their possible inclusion in Annex I to Directive 91/414/EEC. That list includes bifenthrin.
- (3) For bifenthrin the effects on human health and the environment have been assessed in accordance with the provisions laid down in Regulations (EC) No 451/2000 and (EC) No 1490/2002 for a range of uses proposed by the notifier. Moreover, those Regulations designate the rapporteur Member States which have to submit the relevant assessment reports and recommendations to the European Food Safety Authority (EFSA) in accordance with Article 10(1) of Regulation (EC) No 1490/2002. For bifenthrin the rapporteur Member State was France and all relevant information was submitted on 15 December 2005.
- (4) The assessment report has been peer reviewed by the Member States and the EFSA within its Working Group Evaluation and presented to the Commission on

30 September 2008 in the format of the EFSA conclusion regarding the peer review of the pesticide risk assessment of the active substance bifenthrin ⁽⁴⁾. This report has been reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and finalised on 12 March 2009 in the format of the Commission review report for bifenthrin.

- (5) During the evaluation of this active substance, a number of concerns have been identified. In particular, based on the data lodged by the notifier within the legal deadlines, it was not possible to assess the potential contamination of groundwater by a major soil degradation product (TFP acid). Furthermore, concerns have been raised as regards a possible underestimation of the risk to consumers, due to the limited number of residue data made available and the lack of investigation on the metabolism pattern of the two isomers constituting bifenthrin. As regards ecotoxicology, the risk to aquatic vertebrates has not shown to generate acceptable uses, while there is a remaining uncertainty as regards the effects of the experienced bioaccumulation in fish of the active substance. Furthermore, high risks have been identified for mammals (long-term risk and secondary poisoning), earthworms (long-term risk) and non-target arthropods (in-field), while the risk to non-target plants and non-target soil macro-organisms has not been sufficiently addressed. Consequently, it was not possible to conclude, on the basis of the information made available within the legal deadlines, that bifenthrin met the criteria for inclusion in Annex I to Directive 91/414/EEC.
- (6) The Commission invited the notifier to submit its comments on the results of the peer review and on its intention or not to further support the substance. The notifier submitted its comments which have been carefully examined. However, despite the arguments put forward by the notifier, the concerns identified could not be eliminated, and assessments made on the basis of the information submitted and evaluated during the EFSA expert meetings have not demonstrated that it may be expected that, under the proposed conditions of use, plant protection products containing bifenthrin satisfy in general the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC.

⁽¹⁾ OJ L 230, 19.8.1991, p. 1.

⁽²⁾ OJ L 55, 29.2.2000, p. 25.

⁽³⁾ OJ L 224, 21.8.2002, p. 23.

⁽⁴⁾ EFSA Scientific Report (2008) 186, Conclusion regarding the peer review of the pesticide risk assessment of the active substance bifenthrin, finalised 30 September 2008.

- (7) Bifenthrin should therefore not be included in Annex I to Directive 91/414/EEC.
- (8) Measures should be taken to ensure that authorisations granted for plant protection products containing bifenthrin are withdrawn within a fixed period of time and are not renewed and that no new authorisations for such products are granted.
- (9) Any period of grace granted by a Member State for the disposal, storage, placing on the market and use of existing stocks of plant protection products containing bifenthrin should be limited to 12 months in order to allow existing stocks to be used in one further growing season, which ensures that plant protection products containing bifenthrin remain available to farmers for 18 months from the adoption of this Decision.
- (10) This Decision does not prejudice the submission of an application for bifenthrin according to the provisions of Article 6(2) of Directive 91/414/EEC, the detailed implementation rules of which have been laid down in Commission Regulation (EC) No 33/2008 of 17 January 2008 laying down detailed rules for the application of Council Directive 91/414/EEC as regards a regular and an accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of that Directive but have not been included into its Annex I ⁽¹⁾, in view of a possible inclusion in its Annex I.
- (11) The Standing Committee on the Food Chain and Animal Health did not deliver an opinion on the measures provided for in this Decision within the time limit laid down by its Chairman and the Commission therefore submitted to the Council a proposal relating to these measures. Since, on the expiry of the period laid down in the second subparagraph of Article 19(2) of Directive 91/414/EEC, the Council had neither adopted the

proposed measures nor indicated its opposition to them, they should be adopted by the Commission,

HAS ADOPTED THIS DECISION:

Article 1

Bifenthrin shall not be included as an active substance in Annex I to Directive 91/414/EEC.

Article 2

Member States shall ensure that:

- (a) authorisations for plant protection products containing bifenthrin are withdrawn by 30 May 2010;
- (b) no authorisations for plant protection products containing bifenthrin are granted or renewed from the date of publication of this Decision.

Article 3

Any period of grace granted by Member States in accordance with the provisions of Article 4(6) of Directive 91/414/EEC, shall be as short as possible and shall expire on 30 May 2011 at the latest.

Article 4

This Decision is addressed to the Member States.

Done at Brussels, 30 November 2009.

For the Commission

Androulla VASSILIOU

Member of the Commission

⁽¹⁾ OJ L 15, 18.1.2008, p. 5.

COMMISSION DECISION

of 30 November 2009

amending Decisions 2002/741/EC, 2002/747/EC, 2003/200/EC, 2005/341/EC, 2005/342/EC, 2005/343/EC, 2005/344/EC, 2005/360/EC, 2006/799/EC, 2007/64/EC, 2007/506/EC and 2007/742/EC in order to prolong the validity of the ecological criteria for the award of the Community Ecolabel to certain products

(notified under document C(2009) 9599)

(Text with EEA relevance)

(2009/888/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 1980/2000 of the European Parliament and of the Council of 17 July 2000 on a revised Community eco-label award scheme⁽¹⁾, and in particular the second subparagraph of Article 6(1) thereof,

After consulting the European Union Eco-Labeling Board,

Whereas:

- (5) Commission Decision 2005/342/EC of 23 March 2005 establishing revised ecological criteria for the award of the Community eco-label to hand dishwashing detergents⁽⁶⁾ expires on 31 December 2010.
- (6) Commission Decision 2005/343/EC of 11 April 2005 establishing ecological criteria and the related assessment and verification requirements for the award of the Community eco-label to portable computers⁽⁷⁾ expires on 31 May 2010.
- (7) Commission Decision 2005/344/EC of 23 March 2005 establishing ecological criteria for the award of the Community eco-label to all purpose cleaners and cleaners for sanitary facilities⁽⁸⁾ expires on 31 December 2010.
- (8) Commission Decision 2005/360/EC of 26 April 2005 establishing ecological criteria and the related assessment and verification requirements for the award of the Community eco-label to lubricants⁽⁹⁾ expires on 31 July 2010.
- (9) Commission Decision 2006/799/EC of 3 November 2006 establishing revised ecological criteria and the related assessment and verification requirements for the award of the Community eco-label to soil improvers⁽¹⁰⁾ expires on 3 November 2010.
- (10) Commission Decision 2007/64/EC of 15 December 2006 establishing revised ecological criteria and the related assessment and verification requirements for the award of the Community eco-label to growing media⁽¹¹⁾ expires on 15 December 2010.
- (11) Commission Decision 2007/506/EC of 21 June 2007 establishing the ecological criteria for the award of the Community eco-label to soaps, shampoos and hair conditioners⁽¹²⁾ expires on 21 June 2010.
- (1) Commission Decision 2002/741/EC of 4 September 2002 establishing revised ecological criteria for the award of the Community eco-label to copying and graphic paper and amending Decision 1999/554/EC⁽²⁾ expires on 31 May 2010.
- (2) Commission Decision 2002/747/EC of 9 September 2002 establishing revised ecological criteria for the award of the Community eco-label to light bulbs and amending Decision 1999/568/EC⁽³⁾ expires on 30 April 2010.
- (3) Commission Decision 2003/200/EC of 14 February 2003 establishing revised ecological criteria for the award of the Community eco-label to laundry detergents and amending Decision 1999/476/EC⁽⁴⁾ expires on 28 February 2010.
- (4) Commission Decision 2005/341/EC of 11 April 2005 establishing ecological criteria and the related assessment and verification requirements for the award of the Community eco-label to personal computers⁽⁵⁾ expires on 31 May 2010.

⁽¹⁾ OJ L 237, 21.9.2000, p. 1.

⁽²⁾ OJ L 237, 5.9.2002, p. 6.

⁽³⁾ OJ L 242, 10.9.2002, p. 44.

⁽⁴⁾ OJ L 76, 22.3.2003, p. 25.

⁽⁵⁾ OJ L 115, 4.5.2005, p. 1.

⁽⁶⁾ OJ L 115, 4.5.2005, p. 9.

⁽⁷⁾ OJ L 115, 4.5.2005, p. 35.

⁽⁸⁾ OJ L 115, 4.5.2005, p. 42.

⁽⁹⁾ OJ L 118, 5.5.2005, p. 26.

⁽¹⁰⁾ OJ L 325, 24.11.2006, p. 28.

⁽¹¹⁾ OJ L 32, 6.2.2007, p. 137.

⁽¹²⁾ OJ L 186, 18.7.2007, p. 36.

- (12) Commission Decision 2007/742/EC of 9 November 2007 establishing the ecological criteria for the award of the Community eco-label to electrically driven, gas driven or gas absorption heat pumps ⁽¹⁾ expires on 9 November 2010.
- (13) Pursuant to Regulation (EC) No 1980/2000 a timely review has been carried out of the ecological criteria, as well as of the related assessment and verification requirements, established by those Decisions.
- (14) Given the different stages of the revision process for those Decisions, it is appropriate to prolong the periods of validity of the ecological criteria and the related assessment and verification requirements which they set out. The period of validity for Decisions 2002/741/EC, 2003/200/EC, 2005/341/EC, 2005/343/EC, and 2002/747/EC should be prolonged until 31 December 2010. The period of validity for Decisions 2005/342/EC, 2005/344/EC and 2005/360/EC should be prolonged until 30 June 2011. The period of validity for Decisions 2006/799/EC, 2007/64/EC, 2007/506/EC and 2007/742/EC should be prolonged until 31 December 2011.
- (15) Decisions 2002/741/EC, 2002/747/EC, 2003/200/EC, 2005/341/EC, 2005/342/EC, 2005/343/EC, 2005/344/EC, 2005/360/EC, 2006/799/EC, 2007/64/EC, 2007/506/EC and 2007/742/EC should therefore be amended accordingly.
- (16) The measures provided for in this Decision are in accordance with the opinion of the Committee instituted by Article 17 of Regulation (EC) No 1980/2000,

HAS ADOPTED THIS DECISION:

Article 1

Article 5 of Decision 2002/741/EC is replaced by the following:

'Article 5

The ecological criteria for the product group "copying and graphic paper", as well as the related assessment and verification requirements, shall be valid until 31 December 2010.'

Article 2

Article 5 of Decision 2002/747/EC is replaced by the following:

⁽¹⁾ OJ L 301, 20.11.2007, p. 14.

'Article 5

The ecological criteria for the product group "light bulbs", as well as the related assessment and verification requirements, shall be valid until 31 December 2010.'

Article 3

Article 5 of Decision 2003/200/EC is replaced by the following:

'Article 5

The ecological criteria for the product group "laundry detergents", as well as the related assessment and verification requirements, shall be valid until 31 December 2010.'

Article 4

Article 3 of Decision 2005/341/EC is replaced by the following:

'Article 3

The ecological criteria for the product group "personal computers", as well as the related assessment and verification requirements, shall be valid until 31 December 2010.'

Article 5

Article 3 of Decision 2005/342/EC is replaced by the following:

'Article 3

The ecological criteria for the product group "hand dish-washing detergents", and the related assessment and verification requirements, shall be valid until 30 June 2011.'

Article 6

Article 3 of Decision 2005/343/EC is replaced by the following:

'Article 3

The ecological criteria for the product group "portable computers", as well as the related assessment and verification requirements, shall be valid until 31 December 2010.'

Article 7

Article 3 of Decision 2005/344/EC is replaced by the following:

'Article 3

The ecological criteria for the product group "all-purpose cleaners and cleaners for sanitary facilities", and the related assessment and verification requirements, shall be valid until 30 June 2011.'

Article 8

Article 4 of Decision 2005/360/EC is replaced by the following:

'Article 4

The ecological criteria for the product group "lubricants", and the related assessment and verification requirements, shall be valid until 30 June 2011.'

Article 9

Article 6 of Decision 2006/799/EC is replaced by the following:

'Article 6

The ecological criteria for the product group "soil improvers", and the related assessment and verification requirements, shall be valid until 31 December 2011.'

Article 10

Article 5 of Decision 2007/64/EC is replaced by the following:

'Article 5

The ecological criteria for the product group "growing media", and the related assessment and verification requirements, shall be valid until 31 December 2011.'

Article 11

Article 4 of Decision 2007/506/EC is replaced by the following:

'Article 4

The ecological criteria for the product group "soaps, shampoos and hair conditioners", and the related assessment and verification requirements, shall be valid until 31 December 2011.'

Article 12

Article 4 of Decision 2007/742/EC is replaced by the following:

'Article 4

The ecological criteria for the product group "electrically driven, gas driven or gas absorption heat pumps", and the related assessment and verification requirements, shall be valid until 31 December 2011.'

Article 13

This Decision is addressed to the Member States.

Done at Brussels, 30 November 2009.

For the Commission

Siim KALLAS

Vice-President

V

(Acts adopted from 1 December 2009 under the Treaty on European Union, the Treaty on the Functioning of the European Union and the Euratom Treaty)

ACTS WHOSE PUBLICATION IS OBLIGATORY

COMMISSION REGULATION (EU) No 1188/2009

of 3 December 2009

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 4 December 2009.

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

Done at Brussels, 3 December 2009.

*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	AL	29,4
	MA	48,4
	MK	52,7
	TR	65,1
	ZZ	48,9
0707 00 05	MA	59,4
	TR	79,2
	ZZ	69,3
0709 90 70	MA	42,9
	TR	98,8
	ZZ	70,9
0805 10 20	MA	56,3
	TR	50,5
	ZA	57,5
	ZZ	54,8
0805 20 10	MA	72,9
	ZZ	72,9
0805 20 30, 0805 20 50, 0805 20 70, 0805 20 90	CN	132,8
	HR	66,8
	TR	75,1
	ZZ	91,6
0805 50 10	MA	61,1
	TR	72,2
	ZZ	66,7
0808 10 80	AU	161,8
	CA	56,5
	CN	88,9
	MK	20,3
	US	94,0
	ZA	106,2
	ZZ	88,0
0808 20 50	CN	63,2
	US	119,8
	ZZ	91,5

⁽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 1189/2009**of 3 December 2009****on the issue of licences for the import of garlic in the subperiod from 1 March 2010 to 31 May 2010**

THE EUROPEAN COMMISSION,

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

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

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

Whereas:

- (1) Commission Regulation (EC) No 341/2007 ⁽³⁾ opens and provides for the administration of tariff quotas and introduces a system of import licences and certificates of origin for garlic and other agricultural products imported from third countries.
- (2) The quantities for which 'A' licence applications have been lodged by traditional importers and by new importers during the first five working days following

the 15th day of November 2009, pursuant to Article 10(1) of Regulation (EC) No 341/2007 exceed the quantities available for products originating in China and all third countries other than China.

- (3) Therefore, in accordance with Article 7(2) of Regulation (EC) No 1301/2006, it is now necessary to establish the extent to which the 'A' licence applications sent to the Commission by the end of November 2009 can be met in accordance with Article 12 of Regulation (EC) No 341/2007,

HAS ADOPTED THIS REGULATION:

Article 1

Applications for 'A' import licences lodged pursuant to Article 10(1) of Regulation (EC) No 341/2007 during the first five working days following the 15th day of November 2009 and sent to the Commission by the end of November 2009 shall be met at a percentage rate of the quantities applied for as set out in the Annex to this Regulation.

Article 2

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

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

Done at Brussels, 3 December 2009.

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

Jean-Luc DEMARTY

*Director-General for Agriculture and
Rural Development*

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 238, 1.9.2006, p. 13.

⁽³⁾ OJ L 90, 30.3.2007, p. 12.

ANNEX

Origin	Order number	Allocation coefficient
Argentina		
— Traditional importers	09.4104	78,646424 %
— New importers	09.4099	1,408063 %
China		
— Traditional importers	09.4105	19,578768 %
— New importers	09.4100	0,426832 %
Other third countries		
— Traditional importers	09.4106	100 %
— New importers	09.4102	6,866417 %

COMMISSION REGULATION (EU) No 1190/2009**of 3 December 2009****fixing the maximum reduction in the duty on maize imported under the invitation to tender issued
in Regulation (EC) No 676/2009**

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 144(1) in conjunction with Article 4 thereof,

Whereas:

- (1) An invitation to tender for the maximum reduction in the duty on maize imported into Spain from third countries was opened by Commission Regulation (EC) No 676/2009 ⁽²⁾.
- (2) Under Article 8 of Commission Regulation (EC) No 1296/2008 of 18 December 2008 laying down detailed rules for the application of tariff quotas for imports of maize and sorghum into Spain and imports of maize into Portugal ⁽³⁾ the Commission, in accordance the procedure laid down in Article 195(2) of Regulation (EC) No 1234/2007, may decide to fix a maximum

reduction in the import duty. In fixing this maximum the criteria provided for in Articles 7 and 8 of Regulation (EC) No 1296/2008 must be taken into account.

- (3) A contract is awarded to any tenderer whose tender is equal to or less than the maximum reduction in the duty.
- (4) 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 tenders lodged from 27 November to 3 December 2009 under the invitation to tender issued in Regulation (EC) No 676/2009, the maximum reduction in the duty on maize imported shall be 17,33 EUR/t for a total maximum quantity of 55 700 t.

Article 2

This Regulation shall enter into force on 4 December 2009.

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

Done at Brussels, 3 December 2009.

*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 196, 28.7.2009, p. 6.

⁽³⁾ OJ L 340, 19.12.2008, p. 57.

COMMISSION REGULATION (EU) No 1191/2009**of 3 December 2009****fixing the maximum reduction in the duty on maize imported under the invitation to tender issued
in Regulation (EC) No 677/2009**

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 144(1) in conjunction with Article 4 thereof,

Whereas:

(1) An invitation to tender for the maximum reduction in the duty on maize imported into Portugal from third countries was opened by Commission Regulation (EC) No 677/2009 ⁽²⁾.

(2) Under Article 8 of Commission Regulation (EC) No 1296/2008 of 18 December 2008 laying down detailed rules for the application of tariff quotas for imports of maize and sorghum into Spain and imports of maize into Portugal ⁽³⁾ the Commission, in accordance the procedure laid down in Article 195(2) of Regulation (EC) No 1234/2007, may decide to fix a maximum

reduction in the import duty. In fixing this maximum the criteria provided for in Articles 7 and 8 of Regulation (EC) No 1296/2008 must be taken into account.

(3) A contract is awarded to any tenderer whose tender is equal to or less than the maximum reduction in the duty.

(4) 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 tenders lodged from 27 November 2009 to 3 December 2009 under the invitation to tender issued in Regulation (EC) No 677/2009, the maximum reduction in the duty on maize imported shall be EUR 16,89/t for a total maximum quantity of 125 300 t.

Article 2

This Regulation shall enter into force on 4 December 2009.

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

Done at Brussels, 3 December 2009.

*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 196, 28.7.2009, p. 7.

⁽³⁾ OJ L 340, 19.12.2008, p. 57.

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