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<sup>(1)</sup> Text with EEA relevance

**NOTE TO THE READER**

The institutions have decided no longer to quote in their texts the last amendment to cited acts.

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## I

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

## REGULATIONS

## COMMISSION REGULATION (EC) No 1230/2008

of 11 December 2008

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

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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

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 <sup>(2)</sup>, 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 12 December 2008.

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

Done at Brussels, 11 December 2008.

*For the Commission*

Jean-Luc DEMARTY

*Director-General for Agriculture and  
Rural Development*

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

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

## ANNEX

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

(EUR/100 kg)

CN code	Third country code <sup>(1)</sup>	Standard import value
0702 00 00	MA	81,5
	TR	71,9
	ZZ	76,7
0707 00 05	JO	167,2
	MA	51,4
	TR	85,6
	ZZ	101,4
0709 90 70	MA	105,7
	TR	133,9
	ZZ	119,8
0805 10 20	AR	18,1
	BR	56,0
	CL	50,9
	EG	30,5
	MA	91,7
	TR	68,8
	ZA	51,8
	ZW	43,9
	ZZ	51,5
0805 20 10	MA	68,8
	TR	73,0
	ZZ	70,9
0805 20 30, 0805 20 50, 0805 20 70, 0805 20 90	CN	54,6
	HR	54,2
	IL	70,8
	TR	55,8
	ZZ	58,9
0805 50 10	MA	78,3
	TR	66,6
	ZZ	72,5
0808 10 80	CA	89,2
	CL	43,7
	CN	77,8
	MK	35,3
	US	117,4
	ZA	123,2
	ZZ	81,1
0808 20 50	CN	49,6
	TR	97,0
	US	131,4
	ZZ	92,7

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

**COMMISSION REGULATION (EC) No 1231/2008****of 11 December 2008****fixing representative prices in the poultrymeat and egg sectors and for egg albumin, and amending Regulation (EC) No 1484/95**

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) <sup>(1)</sup>, and in particular Article 143 thereof,

Having regard to Regulation (EEC) No 2783/75 of the Council of 29 October 1975 on the common system of trade for ovalbumin and lactalbumin, and in particular Article 3(4) thereof,

Whereas:

- (1) Commission Regulation (EC) No 1484/95 <sup>(2)</sup> lays down detailed rules for implementing the system of additional import duties and fixes representative prices for poultrymeat and egg products and for egg albumin.
- (2) Regular monitoring of the data used to determine representative prices for poultrymeat and egg products and

for egg albumin shows that the representative import prices for certain products should be amended to take account of variations in price according to origin. The representative prices should therefore be published.

- (3) In view of the situation on the market, this amendment should be applied as soon as possible.
- (4) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for the Common Organisation of Agricultural Markets,

HAS ADOPTED THIS REGULATION:

*Article 1*

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

*Article 2*

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

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

Done at Brussels, 11 December 2008.

*For the Commission*

Jean-Luc DEMARTY

*Director-General for Agriculture and  
Rural Development*

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

<sup>(2)</sup> OJ L 145, 29.6.1995, p. 47.

## ANNEX

**to the Commission Regulation of 11 December 2008 fixing representative prices in the poultrymeat and egg sectors and for egg albumin, and amending Regulation (EC) No 1484/95**

## ‘ANNEX I

CN code	Description of goods	Representative price (EUR/100 kg)	Security under Article 3(3) (EUR/100 kg)	Origin <sup>(1)</sup>
0207 12 10	Fowls of the species <i>Gallus domesticus</i> , not cut in pieces, presented as “70 % chickens”, frozen	150,4	0	AR
0207 12 90	Fowls of the species <i>Gallus domesticus</i> , not cut in pieces, presented as “65 % chickens”, frozen	155,8	0	BR
		145,9	0	AR
0207 14 10	Fowls of the species <i>Gallus domesticus</i> , boneless cuts, frozen	234,1	20	BR
		279,5	6	AR
		298,3	1	CL
0207 14 50	Fowls of the species <i>Gallus domesticus</i> , breasts, frozen	200,6	3	BR
0207 14 60	Fowl of the species <i>Gallus domesticus</i> , legs, frozen	123,1	6	BR
0207 25 10	Turkeys, not cut in pieces, presented as “80 % turkeys”, frozen	202,9	0	BR
0207 27 10	Turkeys, boneless cuts, frozen	307,8	0	BR
		327,4	0	CL
0408 11 80	Egg yolks	452,7	0	AR
0408 91 80	Eggs, not in shell, dried	436,2	0	AR
1602 32 11	Preparations of fowls of the species <i>Gallus domesticus</i> , uncooked	220,4	20	BR
3502 11 90	Egg albumin, dried	604,0	0	AR

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

**COMMISSION REGULATION (EC) No 1232/2008****of 11 December 2008****granting no export refund for butter in the framework of the standing invitation to tender provided for in Regulation (EC) No 619/2008**

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) <sup>(1)</sup>, and in particular Article 164(2), in conjunction with Article 4, thereof,

Whereas:

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

(2) Pursuant to Article 6 of Commission Regulation (EC) No 1454/2007 of 10 December 2007 laying down common rules for establishing a tender procedure for fixing export refunds for certain agricultural products <sup>(3)</sup> and following

an examination of the tenders submitted in response to the invitation to tender, it is appropriate not to grant any refund for the tendering period ending on 9 December 2008.

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

HAS ADOPTED THIS REGULATION:

*Article 1*

For the standing invitation to tender opened by Regulation (EC) No 619/2008, for the tendering period ending on 9 December 2008, no export refund shall be granted for the products and destinations referred to in points (a) and (b) of Article 1 and in Article 2 of that Regulation.

*Article 2*

This Regulation shall enter into force on 12 December 2008.

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

Done at Brussels, 11 December 2008.

*For the Commission*

Jean-Luc DEMARTY

*Director-General for Agriculture and  
Rural Development*

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

<sup>(2)</sup> OJ L 168, 28.6.2008, p. 20.

<sup>(3)</sup> OJ L 325, 11.12.2007, p. 69.

**COMMISSION REGULATION (EC) No 1233/2008****of 11 December 2008****granting no export refund for skimmed milk powder in the framework of the standing invitation to tender provided for in Regulation (EC) No 619/2008**

THE 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) <sup>(1)</sup>, and in particular Article 164(2), in conjunction with Article 4, thereof,

Whereas:

- (1) Commission Regulation (EC) No 619/2008 of 27 June 2008 opening a standing invitation to tender for export refunds concerning certain milk products <sup>(2)</sup> provides for a standing invitation to tender procedure.
- (2) Pursuant to Article 6 of Commission Regulation (EC) No 1454/2007 of 10 December 2007 laying down common rules for establishing a tender procedure for

fixing export refunds for certain agricultural products <sup>(3)</sup> and following an examination of the tenders submitted in response to the invitation to tender, it is appropriate not to grant any refund for the tendering period ending on 9 December 2008.

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

HAS ADOPTED THIS REGULATION:

*Article 1*

For the standing invitation to tender opened by Regulation (EC) No 619/2008, for the tendering period ending on 9 December 2008, no export refund shall be granted for the product and destinations referred to in point (c) of Article 1 and in Article 2 respectively of that Regulation.

*Article 2*

This Regulation shall enter into force on 12 December 2008.

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

Done at Brussels, 11 December 2008.

*For the Commission*

Jean-Luc DEMARTY

*Director-General for Agriculture and  
Rural Development*

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

<sup>(2)</sup> OJ L 168, 28.6.2008, p. 20.

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<sup>(3)</sup> OJ L 325, 11.12.2007, p. 69.

**COMMISSION REGULATION (EC) No 1234/2008****of 24 November 2008****concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products****(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

establish a simpler, clearer and more flexible legal framework, while guaranteeing the same level of public and animal health protection.

Having regard to the Treaty establishing the European Community,

Having regard to Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products <sup>(1)</sup>, and in particular Article 39(1) thereof,

- (2) The procedures laid down in Regulations (EC) No 1084/2003 and (EC) No 1085/2003 should therefore be adjusted, without departing from the general principles on which those procedures are based. For reasons of proportionality, homeopathic and traditional herbal medicinal products which have not been granted a marketing authorisation but are subject to a simplified registration procedure should remain excluded from the scope of the Regulation.

Having regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use <sup>(2)</sup>, and in particular Article 35(1) thereof,

- (3) Variations to medicinal products can be classified in different categories, depending on the level of risk to public or animal health and the impact on the quality, safety and efficacy of the medicinal product concerned. Definitions for each of those categories should therefore be laid down. In order to bring further predictability, guidelines on the details of the various categories of variations should be established and regularly updated in the light of scientific and technical progress, taking in particular account of developments regarding international harmonisation. The European Medicines Agency (hereinafter the Agency) and the Member States should also be empowered to give recommendations on the classification of unforeseen variations.

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency <sup>(3)</sup>, and in particular of Article 16(4) and Article 41(6) thereof,

Whereas:

- (1) The Community legal framework regarding variations to the terms of marketing authorisations is laid down in Commission Regulation (EC) No 1084/2003 of 3 June 2003 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products granted by a competent authority of a Member State <sup>(4)</sup> and Commission Regulation (EC) No 1085/2003 of 3 June 2003 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products falling within the scope of Council Regulation (EEC) No 2309/93 <sup>(5)</sup>. In the light of practical experience in the application of those two Regulations, it is appropriate to proceed to their review in order to

- (4) It should be clarified that certain changes which have the highest potential impact on the quality, safety or efficacy of medicinal products require a complete scientific assessment, in the same way as for the evaluation of new marketing authorisation applications.
- (5) In order to further reduce the overall number of variations procedures and to enable competent authorities to focus on those variations that have a genuine impact on quality, safety or efficacy, an annual reporting system should be introduced for certain minor variations. Such variations should not require any prior approval and should be notified within 12 months following implementation. However, other types of minor variations whose immediate reporting is necessary for the continuous supervision of the medicinal product concerned should not be subject to the annual reporting system.

<sup>(1)</sup> OJ L 311, 28.11.2001, p. 1.

<sup>(2)</sup> OJ L 311, 28.11.2001, p. 67.

<sup>(3)</sup> OJ L 136, 30.4.2004, p. 1.

<sup>(4)</sup> OJ L 159, 27.6.2003, p. 1.

<sup>(5)</sup> OJ L 159, 27.6.2003, p. 24.

- (6) Each variation should require a separate submission. Grouping of variations should nevertheless be allowed in certain cases, in order to facilitate the review of the variations and reduce the administrative burden. Grouping of variations to the terms of several marketing authorisations from the same marketing authorisation holder should be allowed only insofar as all concerned marketing authorisations are affected by the exact same group of variations.
- (7) In order to avoid duplication of work in the evaluation of variations to the terms of several marketing authorisations, a worksharing procedure should be established under which one authority, chosen amongst the competent authorities of the Member States and the Agency, should examine the variation on behalf of the other concerned authorities.
- (8) Provisions should be established reflecting those laid down in Directive 2001/82/EC and Directive 2001/83/EC as regards the role of the coordination groups established under Article 31 of Directive 2001/82/EC and Article 27 of Directive 2001/83/EC, to increase cooperation between Member States and allow for the settlement of disagreements in the evaluation of certain variations.
- (9) This Regulation should clarify when the holder of a marketing authorisation is allowed to implement a given variation as such clarification is essential for economic operators.
- (10) A transitional period should be established in order to give all interested parties, in particular Member States authorities and the industry, time to adapt to the new legal framework.
- (11) The measures provided for in this Regulation are in accordance with the opinions of the Standing Committee on Medicinal Products for Human Use and the Standing Committee on Veterinary Medicinal Products,

HAS ADOPTED THIS REGULATION:

## CHAPTER I

### GENERAL PROVISIONS

#### Article 1

#### Subject matter and scope

1. This Regulation lays down provisions concerning the examination of variations to the terms of the following

marketing authorisations for medicinal products for human use and veterinary medicinal products:

(a) authorisations granted in accordance with Council Directive 87/22/EEC <sup>(1)</sup>, Articles 32 and 33 of Directive 2001/82/EC, Articles 28 and 29 of Directive 2001/83/EC and Regulation (EC) No 726/2004;

(b) authorisations granted following a referral, as provided for in Articles 36, 37 and 38 of Directive 2001/82/EC or Articles 32, 33 and 34 of Directive 2001/83/EC, which has led to complete harmonisation.

2. This Regulation shall not apply to transfers of a marketing authorisation from one marketing authorisation holder (hereinafter holder) to another.

3. Chapter II shall apply only to variations to the terms of marketing authorisations granted in accordance with Directive 87/22/EEC, Chapter 4 of Directive 2001/82/EC or Chapter 4 of Directive 2001/83/EC.

4. Chapter III shall apply only to variations to the terms of marketing authorisations granted in accordance with Regulation (EC) No 726/2004 (hereinafter centralised marketing authorisations).

#### Article 2

#### Definitions

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

1. 'Variation to the terms of a marketing authorisation' or 'variation' means an amendment to the contents of the particulars and documents referred to in:

(a) Articles 12(3), 13, 13a, 13b, 13c, 13d and 14 of Directive 2001/82/EC and Annex I thereto, and Article 31(2) of Regulation (EC) No 726/2004 in the case of veterinary medicinal products;

(b) Articles 8(3), 9, 10, 10a, 10b, 10c and 11 of Directive 2001/83/EC and Annex I thereto, Article 6(2) of Regulation (EC) No 726/2004, point (a) of Article 7(1) and Article 34(1) of Regulation (EC) No 1901/2006 of the European Parliament and of the Council <sup>(2)</sup> and Articles 7 and 14(1) of Regulation (EC) No 1394/2007 of the European Parliament and of the Council <sup>(3)</sup> in the case of medicinal products for human use;

<sup>(1)</sup> OJ L 15, 17.1.1987, p. 38.

<sup>(2)</sup> OJ L 378, 27.12.2006, p. 1.

<sup>(3)</sup> OJ L 324, 10.12.2007, p. 121.

2. 'Minor variation of type IA' means a variation which has only a minimal impact, or no impact at all, on the quality, safety or efficacy of the medicinal product concerned;
3. 'Major variation of type II' means a variation which is not an extension and which may have a significant impact on the quality, safety or efficacy of the medicinal product concerned;
4. 'Extension of a marketing authorisation' or 'extension' means a variation which is listed in Annex I and fulfils the conditions laid down therein;
5. 'Minor variation of type IB' means a variation which is neither a minor variation of type IA nor a major variation of type II nor an extension;
6. 'Member State concerned' means a Member State whose competent authority has granted a marketing authorisation for the medicinal product in question;
7. 'Relevant authority' means:
- (a) the competent authority of each Member State concerned;
- (b) in the case of centralised marketing authorisations, the Agency;
8. 'Urgent safety restriction' means an interim change to the product information due to new information having a bearing on the safe use of the medicinal product, concerning in particular one or more of the following items in the summary of product characteristics: therapeutic indications, posology, contra-indications, warnings, target species and withdrawal periods.

#### Article 3

##### Classification of variations

1. In relation to any variation which is not an extension the classification laid down in Annex II shall apply.
2. A variation which is not an extension and whose classification is undetermined after application of the rules provided for in this Regulation, taking into account the guidelines

referred to in point (a) of Article 4(1) and, where relevant, any recommendations delivered pursuant to Article 5, shall by default be considered a minor variation of type IB.

3. By way of derogation from paragraph 2, a variation which is not an extension and whose classification is undetermined after application of the rules provided for in this Regulation shall be considered a major variation of type II in the following cases:

- (a) upon request from the holder when submitting the variation;
- (b) where the competent authority of the reference Member State as referred to in Article 32 of Directive 2001/82/EC and Article 28 of Directive 2001/83/EC (hereinafter the reference Member State), in consultation with the other Member States concerned or, in the case of a centralised marketing authorisation, the Agency concludes, following the assessment of validity of a notification in accordance with Article 9(1) or Article 15(1) and taking into account the recommendations delivered pursuant to Article 5, that the variation may have a significant impact on the quality, safety or efficacy of the medicinal product concerned.

#### Article 4

##### Guidelines

1. The Commission shall, after consulting the Member States, the Agency and interested parties, draw up:
- (a) guidelines on the details of the various categories of variations;
- (b) guidelines on the operation of the procedures laid down in Chapters II, III and IV of this Regulation as well as on the documentation to be submitted pursuant to these procedures.

2. Guidelines referred to in point (a) of paragraph 1 shall be drawn up by the date referred to in the second subparagraph of Article 28 and shall be regularly updated, taking into account the recommendations delivered in accordance with Article 5 as well as scientific and technical progress.

*Article 5***Recommendation on unforeseen variations**

1. Prior to submission or examination of a variation whose classification is not provided for in this Regulation, a holder or a competent authority of a Member State may request the coordination group referred to in Article 31 of Directive 2001/82/EC or in Article 27 of Directive 2001/83/EC (hereinafter the coordination group) or, in the case of a variation to the terms of a centralised marketing authorisation, the Agency to provide a recommendation on the classification of the variation.

The recommendation referred to in the first subparagraph shall be consistent with the guidelines referred to in point (a) of Article 4(1). It shall be delivered within 45 days following receipt of the request and sent to the holder, the Agency and the competent authorities of all Member States.

2. The Agency and the two coordination groups referred to in paragraph 1 shall cooperate to ensure the coherence of the recommendations delivered in accordance with that paragraph and publish those recommendations after deletion of all information of commercial confidential nature.

*Article 6***Variations leading to the revision of product information**

Where a variation leads to the revision of the summary of product characteristics, labelling or package leaflet, this revision shall be considered as part of that variation.

*Article 7***Grouping of variations**

1. Where several variations are notified or applied for, a separate notification or application as laid down in Chapters II, III and IV shall be submitted in respect of each variation sought.

2. By way of derogation from paragraph 1, the following shall apply:

(a) where the same minor variations of type IA to the terms of one or several marketing authorisations owned by the same holder are notified at the same time to the same relevant authority, a single notification as referred to in Articles 8 and 14 may cover all such variations;

(b) where several variations to the terms of the same marketing authorisation are submitted at the same time, a single submission may cover all such variations provided that the variations concerned fall within one of the cases listed in Annex III or, if they do not fall within one of those cases, provided that the competent authority of the reference Member State in consultation with the other Member States concerned or, in the case of a centralised marketing authorisation, the Agency agrees to subject those variations to the same procedure.

The submission referred to in point (b) of the first subparagraph shall be made by means of the following:

- a single notification as referred to in Articles 9 and 15 where at least one of the variations is a minor variation of type IB and all variations are minor variations;
- a single application as referred to in Articles 10 and 16 where at least one of the variations is a major variation of type II and none of the variations is an extension;
- a single application as referred to in Article 19 where at least one of the variations is an extension.

## CHAPTER II

**VARIATIONS TO MARKETING AUTHORISATIONS GRANTED IN ACCORDANCE WITH DIRECTIVE 87/22/EEC, CHAPTER 4 OF DIRECTIVE 2001/82/EC OR CHAPTER 4 OF DIRECTIVE 2001/83/EC***Article 8***Notification procedure for minor variations of type IA**

1. Where a minor variation of type IA is made, the holder shall submit simultaneously to all relevant authorities a notification containing the elements listed in Annex IV. This notification shall be submitted within 12 months following the implementation of the variation.

However, the notification shall be submitted immediately after the implementation of the variation in the case of minor variations requiring immediate notification for the continuous supervision of the medicinal product concerned.

2. Within 30 days following receipt of the notification, the measures provided for in Article 11 shall be taken.

*Article 9***Notification procedure for minor variations of type IB**

1. The holder shall submit simultaneously to all relevant authorities a notification containing the elements listed in Annex IV.

If the notification fulfils the requirement laid down in the first subparagraph, the competent authority of the reference Member State shall, after consulting the other Member States concerned, acknowledge receipt of a valid notification.

2. If within 30 days following the acknowledgement of receipt of a valid notification, the competent authority of the reference Member State has not sent the holder an unfavourable opinion, the notification shall be deemed accepted by all relevant authorities.

Where the notification is accepted by the competent authority of the reference Member State, the measures provided for in Article 11 shall be taken.

3. Where the competent authority of the reference Member State is of the opinion that the notification cannot be accepted, it shall inform the holder and the other relevant authorities, stating the grounds on which its unfavourable opinion is based.

Within 30 days following the receipt of the unfavourable opinion, the holder may submit to all relevant authorities an amended notification in order to take due account of the grounds laid down in that opinion.

If the holder does not amend the notification in accordance with the second subparagraph, the notification shall be deemed rejected by all relevant authorities and the measures provided for in Article 11 shall be taken.

4. Where an amended notification has been submitted, the competent authority of the reference Member State shall assess it within 30 days following its receipt and the measures provided for in Article 11 shall be taken.

*Article 10***'Prior Approval' procedure for major variations of type II**

1. The holder shall submit simultaneously to all relevant authorities an application containing the elements listed in Annex IV.

If the application fulfils the requirements laid down in the first subparagraph, the competent authority of the reference Member State shall acknowledge receipt of a valid application and inform the holder and the other relevant authorities that the procedure starts from the date of such acknowledgement.

2. Within 60 days following the acknowledgement of receipt of a valid application, the competent authority of the reference Member State shall prepare an assessment report and a decision on the application, which shall be communicated to the other relevant authorities.

The competent authority of the reference Member State may reduce the period referred to in the first subparagraph, having regard to the urgency of the matter, or extend it to 90 days for variations listed in Part 1 of Annex V.

The period referred to in the first subparagraph shall be 90 days for variations listed in Part 2 of Annex V.

3. Within the period referred to in paragraph 2, the competent authority of the reference Member State may request the holder to provide supplementary information within a time limit set by that competent authority. In this case:

- (a) the competent authority of the reference Member State shall inform the other competent authorities concerned of its request for supplementary information;
- (b) the procedure shall be suspended until such supplementary information has been provided;
- (c) the competent authority of the reference Member State may extend the period referred to in paragraph 2.

4. Without prejudice to Article 13 and within 30 days following receipt of the decision and of the assessment report referred to in paragraph 2, the relevant authorities shall recognise the decision and inform the competent authority of the reference Member State accordingly.

If, within the period referred to in the first subparagraph, a relevant authority has not expressed its disagreement in accordance with Article 13, the decision shall be deemed recognised by that relevant authority.

5. Where the decision referred to in paragraph 2 has been recognised by all relevant authorities in accordance with paragraph 4, the measures provided for in Article 11 shall be taken.

#### Article 11

##### Measures to close the procedures of Articles 8 to 10

1. Where reference is made to this Article, the competent authority of the reference Member State shall take the following measures:

- (a) it shall inform the holder and the other relevant authorities as to whether the variation is accepted or rejected;
- (b) where the variation is rejected, it shall inform the holder and the other relevant authorities of the grounds for the rejection;
- (c) it shall inform the holder and the other relevant authorities as to whether the variation requires any amendment to the decision granting the marketing authorisation.

2. Where reference is made to this Article, each relevant authority shall, where necessary and within the time limit laid down in paragraph 1 of Article 23, amend the decision granting the marketing authorisation in accordance with the accepted variation.

#### Article 12

##### Human influenza vaccines

1. By way of derogation from Article 10, the procedure laid down in paragraphs 2 to 6 shall apply to the examination of variations concerning changes to the active substance for the purposes of the annual update of a human influenza vaccine.

2. The holder shall submit simultaneously to all relevant authorities an application containing the elements listed in Annex IV.

If the application fulfils the requirements laid down in the first subparagraph, the competent authority of the reference Member State shall acknowledge receipt of a valid application and inform the holder and the other relevant authorities that the procedure starts from the date of such acknowledgement.

3. Within 30 days following the acknowledgement of receipt of a valid application, the competent authority of the reference

Member State shall prepare an assessment report and a decision on the application, which shall be communicated to the other relevant authorities.

4. Within the period referred to in paragraph 3, the competent authority of the reference Member State may request the holder to provide supplementary information. It shall inform the other relevant authorities accordingly.

5. Within 12 days from the date of receipt of the decision and of the assessment report referred to in paragraph 3, the relevant authorities shall recognise the decision and inform the competent authority of the reference Member State accordingly.

6. Where requested by the competent authority of the reference Member State, the clinical data and data concerning the stability of the medicinal product shall be submitted by the holder to all relevant authorities within 12 days from the expiry of the period referred to in paragraph 5.

The competent authority of the reference Member State shall evaluate the data referred to in the first subparagraph and draft a final decision within seven days following receipt of the data. The other relevant authorities shall, within seven days following its receipt, recognise that final decision and adopt a decision in accordance with the final decision.

#### Article 13

##### Coordination group and arbitration

1. Where recognition of a decision in accordance with Article 10(4) or approval of an opinion in accordance with point (b) of Article 20(8) is not possible on grounds of a potential serious risk to public health in the case of medicinal products for human use or, in the case of veterinary medicinal products, on grounds of a potential serious risk to human or animal health or to the environment, a relevant authority shall request that the matter of disagreement be forthwith referred to the coordination group.

The party in disagreement shall give a detailed statement of the reasons for its position to all Member States concerned and to the applicant.

2. Article 33(3), (4) and (5) of Directive 2001/82/EC or Article 29(3), (4) and (5) of Directive 2001/83/EC shall apply to the matter of disagreement referred to in paragraph 1.

## CHAPTER III

VARIATIONS TO CENTRALISED MARKETING  
AUTHORISATIONS

## Article 14

**Notification procedure for minor variations of type IA**

1. Where a minor variation of type IA is made, the holder shall submit to the Agency a notification containing the elements listed in Annex IV. This notification shall be submitted within 12 months following implementation of the variation.

However, the notification shall be submitted immediately after the implementation of the variation in the case of minor variations requiring immediate notification for the continuous supervision of the medicinal product concerned.

2. Within 30 days following receipt of the notification, the measures provided for in Article 17 shall be taken.

## Article 15

**Notification procedure for minor variations of type IB**

1. The holder shall submit to the Agency a notification containing the elements listed in Annex IV.

If the notification fulfils the requirement laid down in the first subparagraph, the Agency shall acknowledge receipt of a valid notification.

2. If within 30 days following the acknowledgement of receipt of a valid notification the Agency has not sent the holder an unfavourable opinion, its opinion shall be deemed favourable.

Where the opinion of the Agency on the notification is favourable, the measures provided for in Article 17 shall be taken.

3. Where the Agency is of the opinion that the notification cannot be accepted, it shall inform the holder, stating the grounds on which its unfavourable opinion is based.

Within 30 days of receipt of the unfavourable opinion, the holder may submit to the Agency an amended notification in

order to take due account of the grounds laid down in that opinion.

If the holder does not amend the notification in accordance with the second subparagraph, the notification shall be deemed rejected and the measures provided for in Article 17 shall be taken.

4. Where an amended notification has been submitted, the Agency shall assess it within 30 days following its receipt and the measures provided for in Article 17 shall be taken.

## Article 16

**'Prior Approval' procedure for major variations of type II**

1. The holder shall submit to the Agency an application containing the elements listed in Annex IV.

If the application fulfils the requirements laid down in the first subparagraph, the Agency shall acknowledge receipt of a valid application.

2. The Agency shall issue an opinion on the valid application referred to in paragraph 1 within 60 days following its receipt.

The Agency may reduce the period referred to in the first subparagraph, having regard to the urgency of the matter, or extend it to 90 days for variations listed in Part 1 of Annex V.

The period referred to in the first subparagraph shall be 90 days for variations listed in Part 2 of Annex V.

3. Within the period referred to in paragraph 2, the Agency may request the holder to provide supplementary information within a time limit set by the Agency. The procedure shall be suspended until such time as the supplementary information has been provided. In this case the Agency may extend the period referred to in paragraph 2.

4. Article 9(1) and (2) and Article 34(1) and (2) of Regulation (EC) No 726/2004 shall apply to the opinion on the valid application.

Within 15 days from the adoption of the final opinion on the valid application, the measures provided for in Article 17 shall be taken.

*Article 17***Measures to close the procedures of Articles 14 to 16**

1. Where reference is made to this Article, the Agency shall take the following measures:

- (a) it shall inform the holder and the Commission as to whether its opinion on the variation is favourable or unfavourable;
- (b) where its opinion on the variation is unfavourable, it shall inform the holder and the Commission of the grounds for that opinion;
- (c) it shall inform the holder and the Commission as to whether the variation requires any amendment to the decision granting the marketing authorisation.

2. Where reference is made to this Article, the Commission shall, where necessary, based on a proposal from the Agency and within the time limit laid down in paragraph 1 of Article 23, amend the decision granting the marketing authorisation and update the Community Register of Medicinal Products provided for in Article 13(1) and Article 38(1) of Regulation (EC) No 726/2004 accordingly.

*Article 18***Human influenza vaccines**

1. By way of derogation from Article 16, the procedure laid down in paragraphs 2 to 7 shall apply to the examination of variations concerning changes to the active substance for the purposes of the annual update of a human influenza vaccine.

2. The holder shall submit to the Agency an application containing the elements listed in Annex IV.

If the application fulfils the requirements laid down in the first subparagraph, the Agency shall acknowledge receipt of a valid application and inform the holder that the procedure starts from the date of such acknowledgement.

3. Within 45 days following the acknowledgement of receipt of a valid application, the Agency shall give its opinion on the application.

4. Within the period referred to in paragraph 3, the Agency may request the holder to provide supplementary information.

5. The Agency shall submit forthwith its opinion to the Commission.

The Commission shall, where necessary and on the basis of that opinion, adopt a decision on the variation to the terms of the marketing authorisation and inform the holder accordingly.

6. Where requested, the holder shall submit the clinical data and the data concerning the stability of the medicinal product to the Agency within 12 days from the expiry of the period referred to in paragraph 3.

The Agency shall evaluate the data referred to in the first subparagraph and shall give its final opinion within 10 days following receipt of the data. The Agency shall communicate its final opinion to the Commission and to the holder within three days from the date of issue of its final opinion.

7. Where necessary and based on the final opinion of the Agency, the Commission shall amend the decision granting the marketing authorisation and update the Community Register of Medicinal Products provided for in Article 13(1) of Regulation (EC) No 726/2004 accordingly.

## CHAPTER IV

## SECTION 1

**Special procedures***Article 19***Extensions of marketing authorisations**

1. An application for an extension of a marketing authorisation shall be evaluated in accordance with the same procedure as for the initial marketing authorisation to which it relates.

2. An extension shall either be granted a marketing authorisation in accordance with the same procedure as for the granting of the initial marketing authorisation to which it relates or be included in that marketing authorisation.

*Article 20***Worksharing procedure**

1. By way of derogation from Article 7(1) and Articles 9, 10, 15 and 16, where a minor variation of type IB, a major variation of type II or a group of variations in the cases of point (b) of Article 7(2) which does not contain any extension relates to several marketing authorisations owned by the same holder, the holder of such authorisations may follow the procedure laid down in paragraphs 3 to 9 of this Article.

2. For the purposes of paragraphs 3 to 9, 'reference authority' shall mean one of the following:

- (a) the Agency where at least one of the marketing authorisations referred to in paragraph 1 is a centralised marketing authorisation;
- (b) the competent authority of a Member State concerned chosen by the coordination group, taking into account a recommendation of the holder, in the other cases.

3. The holder shall submit to all relevant authorities an application containing the elements listed in Annex IV, with an indication of the recommended reference authority.

If the application fulfils the requirements laid down in the first subparagraph, the coordination group shall choose a reference authority and that reference authority shall acknowledge receipt of a valid application.

Where the chosen reference authority is the competent authority of a Member State which has not granted a marketing authorisation for all the medicinal products affected by the application, the coordination group may request another relevant authority to assist the reference authority in the evaluation of that application.

4. The reference authority shall issue an opinion on the valid application referred to in paragraph 3 within one of the following periods:

- (a) a period of 60 days following acknowledgement of receipt of a valid application in the case of minor variations of type IB or major variations of type II;
- (b) a period of 90 days following acknowledgement of receipt of a valid application in the case of variations listed in Part 2 of Annex V.

5. The reference authority may reduce the period referred to in point (a) of paragraph 4, having regard to the urgency of the matter, or extend it to 90 days for variations listed in Part 1 of Annex V.

6. Within the period referred to in paragraph 4, the reference authority may request the holder to provide supplementary information within a time limit set by the reference authority. In this case:

- (a) the reference authority shall inform the other relevant authorities of its request for supplementary information;
- (b) the procedure shall be suspended until such supplementary information has been provided;
- (c) the reference authority may extend the period referred to in point (a) of paragraph 4.

7. Where the reference authority is the Agency, Article 9(1), (2) and (3) and Article 34(1), (2) and (3) of Regulation (EC) No 726/2004 shall apply to the opinion on a valid application referred to in paragraph 4.

Where the opinion on a valid application is favourable:

- (a) the Commission shall, within 30 days following receipt of the final opinion and on the basis of a proposal from the Agency, amend where necessary the concerned centralised marketing authorisations and update the Community Register of Medicinal Products provided for in Article 13(1) and Article 38(1) of Regulation (EC) No 726/2004 accordingly;
- (b) the Member States concerned shall, within 30 days following receipt of the final opinion of the Agency, approve that final opinion, inform the Agency thereof and amend where necessary the concerned marketing authorisations accordingly, unless a referral procedure in accordance with Article 35 of Directive 2001/82/EC or Article 31 of Directive 2001/83/EC is initiated within 30 days following receipt of the final opinion.

8. Where the reference authority is the competent authority of a Member State:

- (a) it shall send its opinion on the valid application to the holder and to all relevant authorities;

(b) without prejudice to Article 13 and within 30 days following receipt of the opinion, the relevant authorities shall approve that opinion, inform the reference authority and amend the concerned marketing authorisations accordingly.

9. Upon request from the reference authority, the Member States concerned shall provide information related to the marketing authorisations affected by the variation for the purpose of verifying the validity of the application and of issuing the opinion on the valid application.

#### Article 21

##### **Pandemic situation with respect to human influenza**

1. By way of derogation from Articles 12, 18 and 19, where a pandemic situation with respect to human influenza is duly recognised by the World Health Organisation or by the Community in the framework of Decision 2119/98/EC of the European Parliament and of the Council <sup>(1)</sup>, the relevant authorities or, in the case of centralised marketing authorisations, the Commission may exceptionally and temporarily accept a variation to the terms of a marketing authorisation for a human influenza vaccine, where certain non-clinical or clinical data are missing.

2. Where a variation is accepted pursuant to paragraph 1, the holder shall submit the missing non-clinical and clinical data within a time limit set by the relevant authority.

#### Article 22

##### **Urgent safety restrictions**

1. Where, in the event of a risk to public health in the case of medicinal products for human use or, in the case of veterinary medicinal products, in the event of a risk to human or animal health or to the environment, the holder takes urgent safety restrictions on its own initiative, it shall forthwith inform all relevant authorities and, in the case of a centralised marketing authorisation, the Commission.

If no relevant authority or, in the case of a centralised marketing authorisation, the Commission has raised objections within 24 hours following receipt of that information, the urgent safety restrictions shall be deemed accepted.

2. In the event of a risk to public health in the case of medicinal products for human use or, in the case of veterinary medicinal products, in the event of a risk to human or animal health or to the environment, relevant authorities or, in the case of centralised marketing authorisations, the Commission may impose urgent safety restrictions on the holder.

3. Where an urgent safety restriction is taken by the holder or imposed by a relevant authority or the Commission, the holder shall submit the corresponding application for variation within 15 days following the initiation of that restriction.

#### SECTION 2

##### **Amendments to the decision granting the marketing authorisation and implementation**

#### Article 23

##### **Amendments to the decision granting the marketing authorisation**

1. The amendment to the decision granting the marketing authorisation resulting from the procedures laid down in Chapters II and III shall be made:

(a) within 30 days following receipt of the information referred to in Article 11(1)(c) and Article 17(1)(c), where the concerned variation leads to a six-month extension of the period referred to in Article 13(1) and (2) of Council Regulation (EEC) No 1768/92 <sup>(2)</sup>, in accordance with Article 36 of Regulation (EC) No 1901/2006;

(b) within two months following receipt of the information referred to in Article 11(1)(c) and Article 17(1)(c), in the case of major variations of type II and minor variations of type IA which do not require immediate notification for the continuous supervision of the medicinal product concerned;

(c) within six months following receipt of the information referred to in Article 11(1)(c) and Article 17(1)(c), in the other cases.

2. Where the decision granting a marketing authorisation is amended as a result of one of the procedures laid down in Chapters II, III and IV, the relevant authority or, in the case of centralised marketing authorisations, the Commission shall notify the amended decision without delay to the holder.

<sup>(1)</sup> OJ L 268, 3.10.1998, p. 1.

<sup>(2)</sup> OJ L 182, 2.7.1992, p. 1.

*Article 24***Implementation of variations**

1. A minor variation of type IA may be implemented any time before completion of the procedures laid down in Articles 8 and 14.

Where a notification concerning one or several minor variations of type IA is rejected, the holder shall cease to apply the concerned variation(s) immediately after receipt of the information referred to in Articles 11(1)(a) and 17(1)(a).

2. Minor variations of type IB may only be implemented in the following cases:

(a) after the competent authority of the reference Member State has informed the holder that it has accepted the notification pursuant to Article 9, or after the notification is deemed accepted pursuant to Article 9(2);

(b) after the Agency has informed the holder that its opinion referred to in Article 15 is favourable, or after that opinion is deemed favourable pursuant to Article 15(2);

(c) after the reference authority referred to in Article 20 has informed the holder that its opinion is favourable.

3. Major variations of type II may only be implemented in the following cases:

(a) 30 days after the competent authority of the reference Member State has informed the holder that it has accepted the variation pursuant to Article 10, under the condition that the documents necessary for the amendment to the marketing authorisation have been provided to the Member States concerned;

(b) after the Commission has amended the decision granting the marketing authorisation in accordance with the accepted variation and notified the holder accordingly;

(c) 30 days after the reference authority referred to in Article 20 has informed the holder that its final opinion is favourable, unless an arbitration procedure in accordance with Article 13 or a referral procedure in accordance with Article 35 of Directive 2001/82/EC or Article 31 of Directive 2001/83/EC has been initiated.

4. An extension may only be implemented after the relevant authority or, in the case of extensions to a centralised marketing authorisation, the Commission has amended the decision granting the marketing authorisation in accordance with the approved extension and notified the holder accordingly.

5. Urgent safety restrictions and variations which are related to safety issues shall be implemented within a time frame agreed by the holder and the relevant authority and, in the case of a centralised marketing authorisation, the Commission.

By way of derogation from the first subparagraph, urgent safety restrictions and variations related to safety issues which concern marketing authorisations granted in accordance with Chapter 4 of Directive 2001/82/EC or Chapter 4 of Directive 2001/83/EC shall be implemented within a time frame agreed by the holder and the competent authority of the reference Member State, in consultation with the other relevant authorities.

## CHAPTER V

## FINAL PROVISIONS

*Article 25***Continuous monitoring**

Where requested by a relevant authority, the holder shall supply without delay any information related to the implementation of a given variation.

*Article 26***Review**

By two years from the date referred to in the second subparagraph of Article 28, the Commission services shall assess the application of this Regulation as regards the classification of variations, with a view to proposing any necessary amendments to adapt Annexes I, II and V to take account of scientific and technical progress.

*Article 27***Repeal and transitional provision**

1. Regulations (EC) No 1084/2003 and (EC) No 1085/2003 are hereby repealed.

References to the repealed Regulations shall be construed as references to this Regulation.

2. By way of derogation from paragraph 1, Regulations (EC) Nos 1084/2003 and 1085/2003 shall continue to apply to valid notifications or applications for variations which are pending at the date referred to in the second subparagraph of Article 28.

*Article 28***Entry into force**

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

It shall apply from 1 January 2010.

By way of derogation from the second subparagraph, the recommendations on unforeseen variations provided for in Article 5 may be requested, delivered and published from the date of entry into force referred to in the first subparagraph.

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

Done at Brussels, 24 November 2008.

*For the Commission*  
Günter VERHEUGEN  
*Vice-President*

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## ANNEX I

**Extensions of marketing authorisations**

1. Changes to the active substance(s):
  - (a) replacement of a chemical active substance by a different salt/ester complex/derivative, with the same therapeutic moiety, where the efficacy/safety characteristics are not significantly different;
  - (b) replacement by a different isomer, a different mixture of isomers, of a mixture by an isolated isomer (e.g. racemate by a single enantiomer), where the efficacy/safety characteristics are not significantly different;
  - (c) replacement of a biological active substance with one of a slightly different molecular structure where the efficacy/safety characteristics are not significantly different, with the exception of:
    - changes to the active substance of a seasonal, pre-pandemic or pandemic vaccine against human influenza;
    - replacement or addition of a serotype, strain, antigen or combination of serotypes, strains or antigens for a veterinary vaccine against avian influenza, foot-and-mouth disease or bluetongue;
    - replacement of a strain for a veterinary vaccine against equine influenza;
  - (d) modification of the vector used to produce the antigen or the source material, including a new master cell bank from a different source, where the efficacy/safety characteristics are not significantly different;
  - (e) a new ligand or coupling mechanism for a radiopharmaceutical, where the efficacy/safety characteristics are not significantly different;
  - (f) change to the extraction solvent or the ratio of herbal drug to herbal drug preparation where the efficacy/safety characteristics are not significantly different.
2. Changes to strength, pharmaceutical form and route of administration:
  - (a) change of bioavailability;
  - (b) change of pharmacokinetics e.g. change in rate of release;
  - (c) change or addition of a new strength/potency;
  - (d) change or addition of a new pharmaceutical form;
  - (e) change or addition of a new route of administration <sup>(1)</sup>.
3. Other changes specific to veterinary medicinal products to be administered to food-producing animals: change or addition of target species.

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<sup>(1)</sup> For parenteral administration, it is necessary to distinguish between intra-arterial, intravenous, intramuscular, subcutaneous and other routes. For administration to poultry, respiratory, oral and ocular (nebulisation) routes used for vaccination are considered to be equivalent routes of administration.

## ANNEX II

**Classification of variations**

1. The following variations shall be classified as minor variations of type IA:
  - (a) variations of purely administrative nature that are related to the identity and contact details of:
    - the holder;
    - the manufacturer or supplier of any starting material, reagent, intermediate, active substance used in the manufacturing process or finished product;
  - (b) variations related to the deletion of any manufacturing site, including for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place;
  - (c) variations related to minor changes to an approved physico-chemical test procedure, where the updated procedure is demonstrated to be at least equivalent to the former test procedure, appropriate validation studies have been performed and the results show that the updated test procedure is at least equivalent to the former;
  - (d) variations related to changes made to the specifications of the active substance or of an excipient in order to comply with an update of the relevant monograph of the European Pharmacopoeia or of the national pharmacopoeia of a Member State, where the change is made exclusively to comply with the pharmacopoeia and the specifications for product specific properties are unchanged;
  - (e) variations related to changes in the packaging material not in contact with the finished product, which do not affect the delivery, use, safety or stability of the medicinal product;
  - (f) variations related to the tightening of specification limits, where the change is not a consequence of any commitment from previous assessment to review specification limits and does not result from unexpected events arising during manufacture.
2. The following variations shall be classified as major variations of type II:
  - (a) variations related to the addition of a new therapeutic indication or to the modification of an existing one;
  - (b) variations related to significant modifications of the summary of product characteristics due in particular to new quality, pre-clinical, clinical or pharmacovigilance findings;
  - (c) variations related to changes outside the range of approved specifications, limits or acceptance criteria;
  - (d) variations related to substantial changes to the manufacturing process, formulation, specifications or impurity profile of the active substance or finished medicinal product which may have a significant impact on the quality, safety or efficacy of the medicinal product;
  - (e) variations related to modifications in the manufacturing process or sites of the active substance for a biological medicinal product;
  - (f) variations related to the introduction of a new design space or the extension of an approved one, where the design space has been developed in accordance with the relevant European and international scientific guidelines;
  - (g) variations concerning a change to or addition of a non-food producing target species;

- (h) variations concerning the replacement or addition of a serotype, strain, antigen or combination of serotypes, strains or antigens for a veterinary vaccine against avian influenza, foot-and-mouth disease or bluetongue;
  - (i) variations concerning the replacement of a strain for a veterinary vaccine against equine influenza;
  - (j) variations related to changes to the active substance of a seasonal, pre-pandemic or pandemic vaccine against human influenza;
  - (k) variations related to changes to the withdrawal period for a veterinary medicinal product.
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## ANNEX III

**Cases for grouping variations referred to in Article 7(2)(b)**

1. One of the variations in the group is an extension of the marketing authorisation.
  2. One of the variations in the group is a major variation of type II; all other variations in the group are variations which are consequential to this major variation of type II.
  3. One of the variations in the group is a minor variation of type IB; all other variations in the group are minor variations which are consequential to this minor variation of type IB.
  4. All variations in the group relate solely to changes of administrative nature to the summary of product characteristics, labelling and package leaflet or insert.
  5. All variations in the group are changes to an Active Substance Master File, Vaccine Antigen Master File or Plasma Master File.
  6. All variations in the group relate to a project intended to improve the manufacturing process and the quality of the medicinal product concerned or its active substance(s).
  7. All variations in the group are changes affecting the quality of a human pandemic influenza vaccine.
  8. All variations in the group are changes to the pharmacovigilance system referred to in points (ia) and (n) of Article 8(3) of Directive 2001/83/EC or points (k) and (o) of Article 12(3) of Directive 2001/82/EC.
  9. All variations in the group are consequential to a given urgent safety restriction and submitted in accordance with Article 22.
  10. All variations in the group relate to the implementation of a given class labelling.
  11. All variations in the group are consequential to the assessment of a given periodic safety update report.
  12. All variations in the group are consequential to a given post-authorisation study conducted under the supervision of the holder.
  13. All variations in the group are consequential to a specific obligation carried out pursuant to Article 14(7) of Regulation (EC) No 726/2004.
  14. All variations in the group are consequential to a specific procedure or condition carried out pursuant to Articles 14(8) or 39(7) of Regulation (EC) No 726/2004, Article 22 of Directive 2001/83/EC or Article 26(3) of Directive 2001/82/EC.
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## ANNEX IV

**Elements to be submitted**

1. A list of all the marketing authorisations affected by the notification or application.
2. A description of all the variations submitted, including:
  - (a) in the case of minor variations of type IA, the date of implementation for each variation described;
  - (b) in the case of minor variations of type IA which do not require immediate notification, a description of all minor variations of type IA made in the last 12 months to the terms of the concerned marketing authorisation(s) and which have not been already notified.
3. All necessary documents as listed in the guidelines referred to in point (b) of Article 4(1).
4. Where a variation leads to or is the consequence of other variations to the terms of the same marketing authorisation, a description of the relation between these variations.
5. In the case of variations to centralised marketing authorisations, the relevant fee provided for in Council Regulation (EC) No 297/95 <sup>(1)</sup>.
6. In the case of variations to marketing authorisations granted by the competent authorities of Member States:
  - (a) a list of those Member States with an indication of the reference Member State if applicable;
  - (b) the relevant fees provided for in the applicable national rules in the Member States concerned.

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<sup>(1)</sup> OJ L 35, 15.2.1995, p. 1.

## ANNEX V

## PART 1

Variations concerning a change to or addition of therapeutic indications.

## PART 2

1. Variations concerning a change to or addition of a non-food producing target species.
  2. Variations concerning the replacement or addition of a serotype, strain, antigen or combination of serotypes, strains or antigens for a veterinary vaccine against avian influenza, foot-and-mouth disease or bluetongue.
  3. Variations concerning the replacement of a strain for a veterinary vaccine against equine influenza.
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**COMMISSION REGULATION (EC) No 1235/2008****of 8 December 2008****laying down detailed rules for implementation of Council Regulation (EC) No 834/2007 as regards the arrangements for imports of organic products from third countries**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91 <sup>(1)</sup>, and in particular Article 33(2), Article 38(d) and Article 40 thereof,

Whereas:

- (1) Articles 32 and 33 of Regulation (EC) No 834/2007 lay down general provisions for import of organic products. With a view to guarantee that these provisions will be applied in a correct and uniform way, detailed rules and procedures for the application of those provisions should be laid down.
- (2) As substantial experience has been built up since 1992 with the import of products providing equivalent guarantees, a relatively short period should be given to control bodies and control authorities to request their inclusion in the list for the purpose of equivalence in accordance with Article 33 of Regulation (EC) No 834/2007. However, as there is no experience with the direct application of Community rules on organic production and labelling of organic products outside the territory of the Community, more time should be given to control bodies and control authorities wishing to request their inclusion in the list for the purpose of compliance in accordance with Article 32 of Regulation (EC) No 834/2007. Therefore a longer period should be provided for sending in the requests and for examining them.
- (3) For products imported according to Article 32 of Regulation (EC) No 834/2007, the operators concerned should be able to provide documentary evidence. It is necessary to establish a model for this documentary evidence. Products imported according to Article 33 of Regulation (EC) No 834/2007 should be covered by a certificate of inspection. It is necessary to lay down detailed rules with regard to the issuing of this certificate. Moreover, a procedure in order to coordinate at Community level certain controls on products imported

from third countries which are intended to be marketed in the Community as organic should be laid down.

- (4) Argentina, Australia, Costa Rica, India, Israel, New Zealand and Switzerland were previously listed as third countries from which imported products could be marketed in the Community as organic, under Commission Regulation (EC) No 345/2008 of 17 April 2008 laying down detailed rules for implementing the arrangements for imports from third countries provided for in Council Regulation (EEC) No 2092/91 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs <sup>(2)</sup>. The Commission has re-examined the situation of those countries according to the criteria set out in Regulation (EC) No 834/2007, taking into consideration the production rules applied and the experience gained with the import of organic products from these third countries as previously listed under Article 11(1) of Council Regulation (EEC) No 2092/2091. On this basis it is concluded that the conditions for inclusion of Argentina, Australia, Costa Rica, India, Israel, and New Zealand in the list of third countries for equivalency according to Article 33(1) of Regulation (EC) No 834/2007 are fulfilled.
- (5) The European Community and the Swiss Confederation have concluded an Agreement on trade in agricultural products <sup>(3)</sup> approved by Decision 2002/309/EC of the Council and of the Commission <sup>(4)</sup>. Annex 9 to that Agreement covers organically produced agricultural products and foodstuffs and sets out that the Parties must take the necessary measures so that organic products complying with each other's laws and regulations can be imported and placed on the market. For the sake of clarity, Switzerland should also be listed in the list of third countries for equivalency according to Article 33(1) of Regulation (EC) No 834/2007.
- (6) Member States' authorities have acquired substantial experience and expertise in the field of granting access for organic imported goods into the territory of the Community. To establish and maintain the lists of third countries and control bodies and control authorities, this experience should be used and the Commission should be able to take account of reports from Member States and other experts. The tasks involved should be divided in a just and proportionate way.

<sup>(1)</sup> OJ L 189, 20.7.2007, p. 1.

<sup>(2)</sup> OJ L 108, 18.4.2008, p. 8.

<sup>(3)</sup> OJ L 114, 30.4.2002, p. 132.

<sup>(4)</sup> OJ L 114, 30.4.2002, p. 1.

- (7) Provision should also be made for transitional measures applicable to third country applications received by the Commission before 1 January 2009, the date from which Regulation (EC) No 834/2007 applies.
- (8) In order not to disrupt international trade, and to facilitate the transition between the rules established by Regulation (EEC) No 2092/2091 and those established by Regulation (EC) No 834/2007, it is necessary to extend the possibility of Member States to continue to grant authorisations to importers on a case by case basis for placing on the Community market of products until the measures necessary for the functioning of the new import rules have been put in place, in particular as regards the recognition of control bodies and control authorities referred to in Article 33(3) of Regulation (EC) No 834/2007. This possibility should be gradually phased out as the list of control bodies referred to in that Article is being established.
- (9) In order to improve transparency and guarantee the application of this Regulation, an electronic system for exchange of information between the Commission, the Member States, the third countries, and the control bodies and control authorities should be foreseen.
- (10) The detailed rules laid down in this Regulation replace those laid down in Commission Regulation (EC) No 345/2008 and in Commission Regulation (EC) No 605/2008 of 20 June 2008 laying down detailed rules for implementing the provisions concerning the certificate of inspection for imports from third countries under Article 11 of Council Regulation (EEC) No 2092/91 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs<sup>(1)</sup>. Those Regulations should therefore be repealed and replaced by a new Regulation.
- (11) The measures provided for in this Regulation are in accordance with the opinion of the regulatory Committee on organic production,

HAS ADOPTED THIS REGULATION:

#### TITLE I

### INTRODUCTORY PROVISIONS

#### Article 1

#### Subject matter

This Regulation lays down the detailed rules for the import of compliant products and the import of products providing

equivalent guarantees as provided for in Articles 32 and 33 of Regulation (EC) No 834/2007.

#### Article 2

#### Definitions

For the purposes of this Regulation:

1. 'certificate of inspection': means the certificate of inspection referred to in Article 33(1)(d) of Regulation (EC) No 834/2007 covering one consignment;
2. 'documentary evidence': means the document referred to in Article 68 of Commission Regulation (EC) No 889/2008<sup>(2)</sup> and in Article 6 of this Regulation, for which the model is set out in Annex II to this Regulation;
3. 'consignment': means a quantity of products under one or more Combined Nomenclature codes, covered by a single certificate of inspection, conveyed by the same means of transport and imported from the same third country;
4. 'first consignee': means the natural or legal person as defined in Article 2(d) of Regulation (EC) No 889/2008;
5. 'verification of the consignment': means the verification by the relevant Member States' authorities of the certificate of inspection to satisfy Article 13 of this Regulation, and, where these authorities consider appropriate, of the products, in relation to the requirements of Regulation (EC) No 834/2007, of Regulation (EC) No 889/2008 and of this Regulation;
6. 'relevant Member States authorities': means the customs authorities or other authorities, designated by the Member States;
7. 'assessment report': means the assessment report referred to in Articles 32(2) and 33(3) of Regulation (EC) No 834/2007 drawn up by an independent third party fulfilling the requirements of ISO Standard 17011 or by a relevant competent authority, which includes information on document reviews, including the descriptions referred to in Articles 4(3)(b) and 11(3)(b) of this Regulation, on office audits, including critical locations and on risk-oriented witness audits conducted in representative third countries.

<sup>(1)</sup> OJ L 166, 27.6.2008, p. 3.

<sup>(2)</sup> OJ L 250, 18.9.2008, p. 1.

## TITLE II

## IMPORT OF COMPLIANT PRODUCTS

## CHAPTER 1

**List of recognised control bodies and control authorities for the purpose of compliance**

## Article 3

**Compilation and content of the list of recognised control bodies and control authorities for the purpose of compliance**

1. The Commission shall draw up a list of control bodies and control authorities, recognised for the purpose of compliance in accordance with Article 32(2) of Regulation (EC) No 834/2007. The list shall be published in Annex I to this Regulation. The procedures for drawing up and amending the list are defined in Articles 4, 16 and 17 of this Regulation. The list shall be made available to the public on the Internet in accordance with Articles 16(4) and 17 of this Regulation.

2. The list shall contain all the information necessary in respect of each control body or control authority to allow verifying whether products placed on the Community market have been controlled by a control body or authority recognised in accordance with Article 32(2) of Regulation (EC) No 834/2007 and in particular:

- (a) the name and address of the control body or control authority, including e-mail and Internet address and their code number;
- (b) the third countries concerned and in which the products have their origin;
- (c) the product categories concerned for each third country;
- (d) the duration of the inclusion in the list;
- (e) the Internet address where the list of operators subject to the control system can be found, including their certification status and the product categories concerned, as well as suspended and decertified operators and products.

## Article 4

**Procedure for requesting inclusion in the list of recognised control bodies and control authorities for the purpose of compliance**

1. The Commission shall consider whether to recognise and include a control body or control authority in the list provided for in Article 3 upon receipt of a request for inclusion in this

list from the representative of the control body or control authority concerned. Only complete requests that have been received before 31 October 2011 shall be considered, on the basis of the model of application made available by the Commission in accordance with Article 17(2), for the drawing up of the first list. For the following calendar years, only complete requests that have been received before 31 October of each year shall be considered.

2. The request can be introduced by control bodies and control authorities established in the Community or in a third country.

3. The request shall consist of a technical dossier, which shall comprise all the information needed for the Commission to ensure that the conditions set out in Article 32(1) and (2) of Regulation (EC) No 834/2007 are met for all organic products intended for export to the Community, namely:

- (a) an overview of the activities of the control body or control authority in the third country or third countries concerned, including an estimate of the number of operators involved and an indication of the expected nature and quantities of agricultural products and foodstuffs originated from the third country or third countries concerned and intended for export to the Community under the rules set out in Article 32(1) and (2) of Regulation (EC) No 834/2007;
- (b) a detailed description of how Titles II, III and IV of Regulation (EC) No 834/2007 as well as the provisions of Regulation (EC) No 889/2008 have been implemented in the third country or in each of the third countries concerned;
- (c) a copy of the assessment report as set out in the fourth subparagraph of Article 32(2) of Regulation (EC) No 834/2007:
  - (i) proving that the control body or control authority has been satisfactorily assessed on its ability to meet the conditions set out in Article 32(1) and (2) of Regulation (EC) No 834/2007;
  - (ii) giving guarantees on the elements referred to in Article 27(2), (3), (5), (6) and (12) of Regulation (EC) No 834/2007;
  - (iii) ensuring that the control body or control authority meets the control requirements and precautionary measures set out in Title IV of Regulation (EC) No 889/2008; and

- (iv) confirming that it has effectively implemented its control activities according to these conditions and requirements;
- (d) proof that the control body or authority has notified its activities to the authorities of the third country concerned and its undertaking to respect the legal requirements imposed on it by the authorities of the third country concerned;
- (e) the website address where the list of operators subject to the control system can be found, as well as a contact point where information is readily available on their certification status, the product categories concerned, as well as suspended and decertified operators and products;
- (f) an undertaking to comply with the provisions of Article 5 of this Regulation;
- (g) any other information deemed relevant by the control body or control authority or by the Commission.
4. When examining a request for inclusion in the list of control body or control authority, and also any time after its inclusion, the Commission may request any further information, including the presentation of one or more on-the-spot examination reports established by independent experts. Furthermore, the Commission may, based on risk-assessment and in case of suspected irregularities, organise an on-the-spot examination by experts it designates.
5. The Commission shall assess whether the technical dossier referred to in paragraph 3 and the information referred to in paragraph 4 are satisfactory and may subsequently decide to recognise and include a control body or control authority in the list. The decision shall be taken in accordance with the procedure referred to in Article 37(2) of Regulation (EC) No 834/2007.

#### Article 5

### **Management and review of the list of recognised control bodies and control authorities for the purpose of compliance**

1. A control body or control authority may only be included in the list referred to in Article 3 when it fulfils the following obligations:

- (a) if, after the control body or control authority has been included in the list, any changes are made to the measures applied by the control body or control authority, that control body or control authority shall notify the Commission thereof; requests to amend the infor-

mation in respect of a control body or control authority referred to in Article 3(2) shall also be notified to the Commission;

- (b) a control body or control authority included in the list shall keep available and communicate at first request all information related to its control activities in the third country; it shall give access to its offices and facilities to experts designated by the Commission;
- (c) by 31 March every year, the control body or control authority shall send a concise annual report to the Commission; the annual report shall update the information of the technical dossier referred to in Article 4(3); it shall describe in particular the control activities carried out by the control body or control authority in the third countries during the previous year, the results obtained, the irregularities and infringements observed and the corrective measures taken; it shall furthermore contain the most recent assessment report or update of such report, which shall contain the results of the regular on-the-spot evaluation, surveillance and multiannual reassessment as referred to in Article 32(2) of Regulation (EC) No 834/2007; the Commission may request any other information deemed necessary;
- (d) in the light of any information received, the Commission may at any time amend the specifications relating to the control body or control authority and may suspend the entry of that body or authority in the list referred to in Article 3; a similar decision may also be made where a control body or authority has not supplied information required or where it has not agreed to an on-the-spot examination;
- (e) the control body or control authority shall make available to interested parties, on an Internet website, a continuously updated list of operators and products certified as organic.

2. If a control body or a control authority does not send the annual report, referred to in paragraph 1(c), does not keep available or does not communicate all information related to its technical dossier, control system or updated list of operators and products certified as organic, or does not agree to an on-the-spot examination, after request by the Commission within a period which the Commission shall determine according to the severity of the problem and which generally may not be less than 30 days, that control body or control authority may be withdrawn from the list of control bodies and control authorities, in accordance with the procedure referred to in Article 37(2) of Regulation (EC) No 834/2007.

If a control body or a control authority fails to take appropriate and timely remedial action, the Commission shall withdraw it from the list without delay.

## CHAPTER 2

**Documentary evidence required for import of compliant products**

## Article 6

**Documentary evidence**

1. The documentary evidence required for import of compliant products referred to in Article 32(1)(c) of Regulation (EC) No 834/2007, shall, in accordance with Article 17(2) of this Regulation, be established on the basis of the model set out in Annex II to this Regulation and contain at least all the elements that are part of that model.

2. The original documentary evidence shall be established by a control authority or the control body which has been recognised for issuing that documentary by a decision as referred to in Article 4.

3. The authority or body issuing the documentary evidence shall follow the rules established in accordance with Article 17(2) and in the model, notes and guidelines made available by the Commission via the computer system enabling electronic exchange of documents referred to in Article 17(1).

## TITLE III

**IMPORT OF PRODUCTS PROVIDING EQUIVALENT GUARANTEES**

## CHAPTER 1

**List of recognised third countries**

## Article 7

**Compilation and content of the list of third countries**

1. The Commission shall establish a list of recognised third countries in accordance with Article 33(2) of Regulation (EC) No 834/2007. The list of recognised countries is set out in Annex III to this Regulation. The procedures for drawing up and amending the list are defined in Articles 8 and 16 of this Regulation. Amendments to the list shall be made available to the public on the Internet in accordance with Articles 16(4) and 17 of this Regulation.

2. The list shall contain all the information necessary in respect of each third country to allow verifying whether products placed on the Community market have been subject to the control system of the third country recognised in accordance with Article 33(2) of Regulation (EC) No 834/2007 and in particular:

- (a) the product categories concerned;
- (b) the origin of the products;
- (c) a reference to the production standards applied in the third country;

(d) the competent authority in the third country responsible for the control system, its address, including e-mail and Internet addresses;

(e) the control authority or authorities in the third country and/or the control body or bodies recognised by the said competent authority to carry out controls, their addresses, including, when appropriate, e-mail and Internet addresses;

(f) the authority or authorities or the control body or bodies responsible in the third country for issuing certificates with a view to importing into the Community, their addresses and their code numbers and, when appropriate, their e-mail and Internet addresses;

(g) the duration of the inclusion in the list.

## Article 8

**Procedure for requesting inclusion in the list of third countries**

1. The Commission shall consider whether to include a third country in the list provided for in Article 7 upon receipt of a request for inclusion, from the representative of the third country concerned.

2. The Commission shall only be required to consider a request for inclusion which meets the following preconditions.

The request for inclusion shall be completed by a technical dossier, which shall comprise all the information needed for the Commission to ensure that the conditions set out in Article 33(1) of Regulation (EC) No 834/2007 are met for products intended for export to the Community, namely:

- (a) general information on the development of organic production in the third country, the products produced, the area in cultivation, the production regions, the number of producers, the food processing taking place;
- (b) an indication of the expected nature and quantities of organic agricultural products and foodstuffs intended for export to the Community;
- (c) the production standards applied in the third country as well as an assessment of their equivalence to the standards applied in the Community;
- (d) the control system applied in the third country, including the monitoring and supervisory activities carried out by the competent authorities in the third country, as well as an assessment of its equivalent effectiveness when compared to the control system applied in the Community;

- (e) the Internet or other address where the list of operators subject to the control system can be found, as well as a contact point where information is readily available on their certification status and the product categories concerned;
- (f) the information the third country proposes to include in the list as referred to in Article 7;
- (g) an undertaking to comply with the provisions of Article 9;
- (h) any other information deemed relevant by the third country or by the Commission.

3. When examining a request for inclusion in the list of recognised third countries, and also any time after its inclusion, the Commission may request any further information, including the presentation of one or more on-the-spot examination reports established by independent experts. Furthermore, the Commission may, based on risk-assessment and in case of suspected irregularities organise an on-the-spot examination by experts it designates.

4. The Commission shall assess whether the technical dossier referred to in paragraph 2 and the information referred to in paragraph 3 are satisfactory and may subsequently decide to recognise and include a third country in the list. The decision shall be taken in accordance with the procedure referred to in Article 37(2) of Regulation (EC) No 834/2007.

#### Article 9

##### **Management and review of the list of third countries**

1. The Commission shall only be required to consider a request for inclusion when the third country undertakes to accept the following conditions:
  - (a) if, after a third country has been included in the list, any changes are made to the measures in force in the third country or their implementation and in particular to its control system, that third country shall notify the Commission thereof; requests to amend the information in respect of a third country referred to in Article 7(2) shall also be notified to the Commission;
  - (b) the annual report referred to in Article 33(2) of Regulation (EC) No 834/2007 shall update the information of the technical dossier referred to in Article 8(2) of this Regulation; it shall describe in particular the monitoring and supervisory activities carried out by the competent authority of the third country, the results obtained and the corrective measures taken;
  - (c) in the light of any information received, the Commission may at any time amend the specifications relating to the

third country and may suspend the entry of that country from the list referred to in Article 7; a similar decision may also be made where a third country has not supplied information required or where it has not agreed to an on-the-spot examination.

2. If a third country does not send the annual report, referred to Article 33(2) of Regulation (EC) No 834/2007, does not keep available or does not communicate all information related to its technical dossier or control system or does not agree to an on-the-spot examination, after request by the Commission within a period which the Commission shall determine according to the severity of the problem and which generally may not be less than 30 days, that third country may be withdrawn from the list, in accordance with the procedure referred to in Article 37(2) of Regulation (EC) No 834/2007.

#### CHAPTER 2

##### **List of recognised control bodies and control authorities for the purpose of equivalence**

#### Article 10

##### **Compilation and content of the list of recognised control bodies and control authorities for the purpose of equivalence**

1. The Commission shall draw up a list of control bodies and control authorities, recognised for the purpose of equivalence in accordance with Article 33(3) of Regulation (EC) No 834/2007. The list shall be published in Annex IV to this Regulation. The procedures for drawing up and amending the list are defined in Articles 11, 16 and 17 of this Regulation. The list shall be made available to the public on the Internet in accordance with Articles 16(4) and 17 of this Regulation.
2. The list shall contain all the information necessary in respect of each control body or authority to allow verifying whether products placed on the Community market have been controlled by a control body or authority recognised in accordance with Article 33(3) of Regulation (EC) No 834/2007 and in particular:
  - (a) the name, address and code number of the control body or authority, and, when appropriate, its e-mail and Internet address;
  - (b) the third countries not listed in the list provided for in Article 7 where the products have their origin;
  - (c) the product categories concerned for each third country;
  - (d) the duration of the inclusion in the list; and

(e) the Internet website where the list of operators subject to the control system can be found, as well as a contact point where information is readily available on their certification status, the product categories concerned, as well as suspended and decertified operators and products.

3. By way of derogation from paragraph 2(b), those products originating from third countries listed in the list of recognised third countries as referred to in Article 7 which belong to a category which is not referred to in that list may be listed in the list provided for in this Article.

#### Article 11

### Procedure for requesting inclusion in the list of recognised control bodies and control authorities for the purpose of equivalence

1. The Commission shall consider whether to include a control body or control authority in the list provided for in Article 10 upon receipt of a request for inclusion from the representative of the control body or control authority concerned on the basis of the model of application made available by the Commission in accordance with Article 17(2). Only complete requests that have been received by 31 October 2009 shall be considered for the drawing up of the first list. For the following calendar years, the Commission shall undertake regular updates of the list as appropriate on the basis of complete requests that have been received before 31 October of each year.

2. The request can be introduced by control bodies and control authorities established in the Community or in a third country.

3. The request for inclusion shall consist of a technical dossier, which shall comprise all the information needed for the Commission to ensure that the conditions set out in Article 33(3) of Regulation (EC) No 834/2007 are met for products intended for export to the Community, namely:

(a) an overview of the activities of the control body or control authority in the third country or third countries, including an estimate of the number of operators involved and the expected nature and quantities of agricultural products and foodstuffs intended for export to the Community under the rules set out in Article 33(1) and (3) of Regulation (EC) No 834/2007;

(b) a description of the production standards and control measures applied in the third countries, including an assessment of the equivalence of these standards and measures with Titles III, IV and V of Regulation (EC) No 834/2007 as well as with the associated implementing rules laid down in Regulation (EC) No 889/2008;

(c) a copy of the assessment report as set out in the fourth subparagraph of Article 33(3) of Regulation (EC) No 834/2007:

(i) proving that the control body or control authority has been satisfactorily assessed on its ability to meet the conditions set out in Article 33(1) and (3) of Regulation (EC) No 834/2007;

(ii) confirming that it has effectively implemented its activities according to those conditions; and

(iii) demonstrating and confirming the equivalence of the production standards and control measures referred to in subparagraph (b) of this paragraph;

(d) proof that the control body or control authority has notified its activities to the authorities of each of the third countries concerned and its undertaking to respect the legal requirements imposed on it by the authorities of each of the third countries concerned;

(e) the Internet website where the list of operators subject to the control system can be found, as well as a contact point where information is readily available on their certification status, the product categories concerned, as well as suspended and decertified operators and products;

(f) an undertaking to comply with the provisions of Article 12;

(g) any other information deemed relevant by the control body or control authority or by the Commission.

4. When examining a request for inclusion in the list of control body or control authority, and also any time after its inclusion, the Commission may request any further information, including the presentation of one or more on-the-spot examination reports established by independent expert. Furthermore, the Commission may organise an on-the-spot examination by experts it designates on a risk-based approach and in case of suspected irregularities.

5. The Commission shall assess whether the technical dossier referred to in paragraph 2 and the information referred to in paragraph 3 are satisfactory and may subsequently decide to recognise and include a control body or control authority in the list. The decision shall be taken in accordance with the procedure referred to in Article 37(2) of Regulation (EC) No 834/2007.

## Article 12

**Management and review of the list of control bodies and control authorities for the purpose of equivalence**

1. A control body or control authority may only be included in the list referred to in Article 10 when it fulfils the following obligations:

- (a) if, after a control body or control authority has been included in the list, any changes are made to the measures applied by the control body or control authority, that control body or control authority shall notify the Commission thereof; requests to amend the information in respect of a control body or authority referred to in Article 10(2), shall also be notified to the Commission;
- (b) by 31 March every year, the control body or control authority shall send a concise annual report to the Commission. The annual report shall update the information of the technical dossier referred to in Article 11(3); it shall describe in particular the control activities carried out by the control body or control authority in the third countries in the previous year, the results obtained, the irregularities and infringements observed and the corrective measures taken; It shall furthermore contain the most recent assessment report or update of such report, which shall contain the results of the regular on-the-spot evaluation, surveillance and multiannual reassessment as referred to in Article 33(3) of Regulation (EC) No 834/2007; the Commission may request any other information deemed necessary;
- (c) in the light of any information received, the Commission may at any time amend the specifications relating to the control body or control authority and may suspend the entry of that body or authority from the list referred to in Article 10; a similar decision may also be made where a control body or control authority has not supplied information required or where it has not agreed to an on-the-spot examination;
- (d) the control body or control authority shall make available to interested parties, by electronic means, a continuously updated list of operators, and of products certified as organic.

2. If a control body or a control authority does not send the annual report, referred to in paragraph 1(b), does not keep available or does not communicate all information related to its technical dossier, control system or updated list of operators and products certified as organic, or does not agree to an on-the-spot examination, after request by the Commission within a period which the Commission shall determine according to the severity of the problem and which generally may not be less than 30 days, that control body or control authority may be withdrawn from the list of control bodies and control authorities,

in accordance with the procedure referred to in Article 37(2) of Regulation (EC) No 834/2007.

If a control body or a control authority fails to take appropriate and timely remedial action, the Commission shall withdraw it from the list without delay.

## CHAPTER 3

**Release for free circulation of products imported in accordance with Article 33 of Regulation (EC) No 834/2007**

## Article 13

**Certificate of inspection**

1. The release for free circulation in the Community of a consignment of products referred to in Article 1(2) of Regulation (EC) No 834/2007 and imported in accordance with Article 33 of that Regulation shall be conditional on:

- (a) the submission of an original certificate of inspection to the relevant Member State's authority; and
- (b) on the verification of the consignment by the relevant Member State's authority and the endorsement of the certificate of inspection in accordance with paragraph 8 of this Article.

2. The original certificate of inspection shall be established in accordance with Article 17(2) and paragraphs 3 to 7 of this Article, on the basis of the model and the notes set out in Annex V. The model notes, together with guidelines referred to in Article 17(2), shall be made available by the Commission via the computer system enabling electronic exchange of documents referred to in Article 17.

3. To be accepted, the certificate of inspection must have been issued by:

- (a) the control authority or control body which has been accepted for issuing the certificate of inspection, as referred to in Article 7(2), from a third country recognised under Article 8(4); or
- (b) the control authority or control body in the third country listed for the third country concerned recognised under Article 11(5).

4. The authority or body issuing the certificate of inspection shall only issue the certificate of inspection and endorse the declaration in box 15 of the certificate, after:

- (a) it has carried out a documentary check on the basis of all relevant inspection documents, including in particular the production plan for the products concerned, transport documents and commercial documents; and
- (b) it has either made a physical check of the consignment, or it has received an explicit declaration of the exporter declaring that the consignment concerned has been produced and/or prepared in accordance with Article 33 of Regulation (EC) No 834/2007; it shall carry out a risk-oriented verification of the credibility of this declaration.

It shall furthermore give a serial number to each issued certificate and keep a register of the delivered certificates in chronological order.

5. The certificate of inspection shall be drawn up in one of the official languages of the Community and filled in, except for the stamps and signatures, either entirely in capital letters or entirely in typescript.

The certificate of inspection shall be in one of the official languages of the Member State of destination. Where necessary, the relevant Member State's authorities may request a translation of the certificate of inspection in one of its official languages.

Uncertified alterations or erasures shall invalidate the certificate.

6. The certificate of inspection shall be made in one single original.

The first consignee or, where relevant, the importer may make a copy for the purpose of informing the control authorities and control bodies in accordance with Article 83 of Regulation (EC) No 889/2008. Any such copy shall carry the indication 'COPY' or 'DUPLICATE' printed or stamped thereon.

7. For products imported under the transitional rules stipulated in Article 19 of this Regulation, the following shall apply:

- (a) the certificate of inspection referred to in paragraph 3(b) shall, at the time it is submitted in accordance with paragraph 1, include in box 16 the declaration of the competent authority in the Member State which granted the authorisation according to the procedure provided for in Article 19;
- (b) the competent authority in the Member State which granted the authorisation may delegate the competence for the

declaration in box 16 to the control authority or control body inspecting the importer in accordance with the control measures set out in Title V of Regulation (EC) No 834/2007, or to the authorities defined as the Member State's relevant authorities;

- (c) the declaration in box 16 is not required:
- (i) when the importer presents an original document, issued by the competent authority of the Member State which granted the authorisation in accordance with Article 19 of this Regulation, demonstrating that the consignment is covered by that authorisation; or
- (ii) when the Member State's authority, which granted the authorisation referred to in Article 19, has given satisfactory evidence that the consignment is covered by that authorisation, directly to the authority in charge of the verification of the consignment; this procedure of direct information is optional for the Member State which granted the authorisation;
- (d) the document giving the evidence required in points c(i) and (ii), shall include:
- (i) the reference number of the import authorisation and the date of expiration of the authorisation;
- (ii) the name and address of the importer;
- (iii) the third country of origin;
- (iv) the details of the issuing body or authority, and, where different, the details of the inspection body or authority in the third country;
- (v) the names of the products concerned.

8. At the verification of a consignment, the original certificate of inspection shall be endorsed by the relevant Member State's authorities in box 17 and returned to the person who submitted the certificate.

9. The first consignee shall, at the reception of the consignment, complete box 18 of the original of the certificate of inspection, to certify that the reception of the consignment has been carried out in accordance with Article 34 of Regulation (EC) No 889/2008.

The first consignee shall then send the original of the certificate to the importer mentioned in box 11 of the certificate, for the purpose of the requirement laid down in the second subparagraph of Article 33(1) of Regulation (EC) No 834/2007, unless the certificate has to further accompany the consignment referred to in paragraph 1 of this Article.

10. The certificate of inspection may be established by electronic means, using the method made available to the control authorities or control bodies by the Member State concerned. The competent authorities of the Member States may require that the electronic certificate of inspection be accompanied by an advance electronic signature within the meaning of Article 2(2) of Directive 1999/93/EC of the European Parliament and of the Council<sup>(1)</sup>. In all other cases, the competent authorities shall require an electronic signature offering equivalent assurances with regard to the functionalities attributed to a signature by applying the same rules and conditions as these defined in the Commission's provisions on electronic and digitised documents, set out by Commission Decision 2004/563/EC, Euratom<sup>(2)</sup>.

#### Article 14

##### Special customs procedures

1. Where a consignment coming from a third country is assigned to customs warehousing or inward processing in the form of a system of suspension as provided for in Council Regulation (EEC) No 2913/92<sup>(3)</sup>, and subject to one or more preparations as defined in Article 2(i) of Regulation (EC) No 834/2007, the consignment shall be subject, before the first preparation is carried out, to the measures referred to in Article 13(1) of this Regulation.

The preparation may include operations such as:

- (a) packaging or repackaging; or
- (b) labelling concerning the presentation of the organic production method.

After this preparation, the endorsed original of the certificate of inspection shall accompany the consignment, and shall be presented to the relevant Member State's authority, which shall verify the consignment for the purpose of its release for free circulation.

After this procedure, the original of the certificate of inspection shall, where relevant, be returned to the importer of the consignment, referred to in box 11 of the certificate to fulfil the requirement laid down in the second subparagraph of Article 33(1) of Regulation (EC) No 834/2007.

<sup>(1)</sup> OJ L 13, 19.1.2000, p. 12.

<sup>(2)</sup> OJ L 251, 27.7.2004, p. 9.

<sup>(3)</sup> OJ L 302, 19.10.1992, p. 1.

2. Where, under a suspensive customs procedure pursuant to Regulation (EEC) No 2913/92, a consignment coming from a third country is intended to be submitted in a Member State, before its release for free circulation in the Community, to a splitting into different batches, the consignment shall be subject, before this splitting is carried out, to the measures referred to in Article 13(1) of this Regulation.

For each of the batches which results from the splitting, an extract of the certificate of inspection shall be submitted to the relevant Member State's authority, in accordance with the model and the notes set out in Annex VI. The extract from the certificate of inspection shall be endorsed by the relevant Member State's authorities in box 14.

A copy of each endorsed extract from the certificate of inspection shall be kept together with the original certificate of inspection by the person identified as the original importer of the consignment and mentioned in box 11 of the certificate of inspection. This copy shall carry the indication 'COPY' or 'DUPLICATE' printed or stamped thereon.

After the splitting, the endorsed original of each extract of the certificate of inspection shall accompany the batch concerned, and shall be presented to the relevant Member State's authority, which shall verify the batch concerned for the purpose of its release for free circulation.

The consignee of a batch shall, at the reception thereof complete the original of the extract of the certificate of inspection in box 15, in order to certify that the reception of the batch has been carried out in accordance with Article 34 of Regulation (EC) No 889/2008.

The consignee of a batch shall keep the extract of the certificate of inspection at the disposal of the control authorities and/or control bodies for not less than two years.

3. The preparation and splitting operations referred to in paragraphs 1 and 2 shall be carried out in accordance with the relevant provisions set out in Title V of Regulation (EC) No 834/2007 and in Title IV of Regulation (EC) No 889/2008.

#### Article 15

##### Non-compliant products

Without prejudice to any measures or actions taken in accordance with Article 30 of Regulation (EC) No 834/2007 and/or Article 85 of Regulation (EC) No 889/2008, the release for free circulation in the Community of products not in conformity with the requirements of that Regulation shall be conditional on the removal of references to organic production from the labelling, advertising and accompanying documents.

## TITLE IV

## COMMON RULES

## Article 16

**Assessment of the requests and publication of the lists**

1. The Commission shall examine the requests received in accordance with Articles 4, 8 and 11 with the assistance of the Committee on organic production, referred to in Article 37(1) of Regulation (EC) No 834/2007 (hereafter called 'the Committee'). For this purposes the Committee shall adopt specific internal rules of procedure.

In order to assist the Commission with the examination of the requests and with the management and review of the lists, the Commission shall set up an expert group consisting of governmental and private experts.

2. For each request received, and after appropriate consultation with Member States in accordance with the specific internal rules of procedure, the Commission shall nominate two Member States to act as co-reporters. The Commission shall divide the requests between the Member States proportionally with the number of votes of each Member State in the Committee on organic production. The co-reporting Member States shall examine the documentation and information as set out in Articles 4, 8 and 11 related to the request and shall draw up a report. For the management and review of the lists, they shall also examine the annual reports and any other information referred to in Articles 5, 9 and 12 related to the entries on the lists.

3. Taking into account the result of the examination by the co-reporting Member States, the Commission shall decide, in accordance with the procedure referred to in Article 37(2) of Regulation (EC) No 834/2007, on the recognition of third countries, control bodies or control authorities, their inclusion on the lists or any modification of the lists, including the attribution of a code number to those bodies and authorities. The decisions shall be published in the *Official Journal of the European Union*.

4. The Commission shall make the lists available to the public by any appropriate technical means, including publication on the Internet.

## Article 17

**Communication**

1. When transmitting documents or other information referred to in Articles 32 and 33 of Regulation (EC) No 834/2007 and in this Regulation to the Commission or the Member States, the competent authorities of third countries, the control authorities or the control bodies shall use electronic transmission. When specific electronic transmission systems are made available by the Commission or the Member States, they shall use these systems. The Commission and the Member States shall also use these systems to provide each other with concerned documents.

2. For the form and content of documents and information referred to in Articles 32 and 33 of Regulation (EC) No 834/2007 and in this Regulation, the Commission shall set out guidelines, models and questionnaires where appropriate and make them available in the computer system referred to in paragraph 1 of this Article. These guidelines, models and questionnaires shall be adapted and updated by the Commission, after having informed the Member States and the competent authorities of third countries, as well as the control authorities and control bodies recognised in accordance with this Regulation.

3. The computer system provided for in paragraph 1 shall be able to collect the requests, documents and information referred to in this Regulation where appropriate, including the authorisations granted pursuant to Article 19.

4. The supporting documents referred to in Articles 32 and 33 of Regulation (EC) No 834/2007 and in this Regulation, in particular in Articles 4, 8 and 11, shall be kept by the competent authorities of third countries, the control authorities or the control bodies at the disposal of the Commission and the Member States for at least three years following the year in which the controls took place or the certificates of inspection and documentary evidence were delivered.

5. Where a document or procedure provided for in Articles 32 and 33 of Regulation (EC) No 834/2007 or in the detailed rules for its application requires the signature of an authorised person or the approval of a person at one or more of the stages of that procedure, the computer systems set up for the communication of those documents must make it possible to identify each person unambiguously and provide reasonable assurance that the contents of the documents, including as regards the stages of the procedure, cannot be altered, in accordance with Community legislation, and in particular with Commission Decision 2004/563/EC, Euratom.

## TITLE V

## FINAL AND TRANSITIONAL RULES

## Article 18

**Transitional rules on the list of third countries**

Requests for inclusion from third countries submitted in accordance with Article 2 of Regulation (EC) No 345/2008 before the 1 January 2009 shall be treated as applications under Article 8 of this Regulation.

The first list of recognised countries shall include Argentina, Australia, Costa Rica, India, Israel, New Zealand and Switzerland. It shall not contain the code numbers referred to in Article 7(2)(f) of this Regulation. These code numbers shall be added before 1 July 2010 by updating the list in accordance with Article 17(2).

*Article 19***Transitional rules on equivalent import of products not originating in listed third countries**

1. In accordance with Article 40 of Regulation (EC) No 834/2007 the competent authority of a Member State may authorise importers in that Member State, where the importer has notified his activity in accordance with Article 28 of that Regulation, to place on the market products imported from third countries which are not included in the list referred to in Article 33(2) of that Regulation, provided that the importer provides sufficient evidence showing that the conditions referred to in Article 33(1)(a) and (b) of that Regulation are satisfied.

Where, having first allowed the importer or any other person concerned to comment, the Member State considers that those conditions are no longer satisfied, it shall withdraw the authorisation.

Authorisations shall expire at the latest 24 months after the publication of the first list of control bodies and control authorities recognised pursuant to Article 10 of this Regulation.

The imported product shall be covered by a certificate of inspection as set out in Article 13, issued by the control authority or the control body which has been accepted for issuing the certificate of inspection by the competent authority of the authorising Member State. The original of the certificate must accompany the goods to the premises of the first consignee. Thereafter the importer must keep the certificate at the disposal of the control body and, as appropriate the control authority, for not less than two years.

2. Each Member State shall inform the other Member States and the Commission of each authorisation granted pursuant to this Article, including information on the production standards and control arrangements concerned.

3. At the request of a Member State or at the Commission's initiative, an authorisation granted pursuant to this Article shall be examined by the Committee on organic production. If this examination discloses that the conditions referred to in

Article 33(1)(a) and (b) of Regulation (EC) No 834/2007 are not satisfied, the Commission shall require the Member State which granted the authorisation to withdraw it.

4. Member States may no longer grant the authorisations referred to in paragraph 1 of this Article from the date of 12 months after the publication of the first list of control bodies and control authorities referred to in Article 11(5) except if the imported products in question are goods whose production in the third country was controlled by a control body or control authority not on the list set up in accordance with Article 10.

5. Member States shall no longer grant any authorisation referred to in paragraph 1 from 1 January 2013.

6. Any authorisation to market products imported from a third country which had, prior to 31 December 2008 been granted to an importer by the Competent Authority of a Member State under Article 11(6) of Regulation (EEC) No 2092/91 shall expire on 31 December 2009 at the latest.

*Article 20***Repeal**

Regulations (EC) No 345/2008 and (EC) No 605/2008 are repealed.

References to the repealed Regulations shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex VII.

*Article 21***Entry into force**

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

It shall apply as from 1 January 2009.

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

Done at Brussels, 8 December 2008.

For the Commission  
Mariann FISCHER BOEL  
Member of the Commission

*ANNEX I*

**LIST OF CONTROL BODIES AND CONTROL AUTHORITIES FOR THE PURPOSE OF COMPLIANCE AND  
RELEVANT SPECIFICATIONS REFERRED TO IN ARTICLE 3**

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## ANNEX II

## MODEL OF THE DOCUMENTARY EVIDENCE

referred to in Article 6(1)

<p><b>Documentary evidence to the operator according to Articles 32(1)(c) and 29(1) of Regulation (EC) No 834/2007, required for import of compliant products in accordance with Article 6 of Regulation (EC) No 1235/2008</b></p>	
1. Document number:	
2. Name and address of operator:  main activity (producer, processor, importer, etc.):	3. Name, address and code number of control body/authority:
4. Product groups/activity:  — Plant and plant products:  — Livestock and livestock products:  — Processed products:	5. defined as:  organic production, in-conversion products, and also non-organic production, where parallel production/processing pursuant to Article 11 of Regulation (EC) No 834/2007 occurs
6. Validity period:  Plant products from ... to ...  Livestock products from ... to ...  Processed products from ... to ...	7. Date of control(s):
8. This document has been issued in accordance with Articles 32(1)(c) and 29(1) of Regulation (EC) No 834/2007 and Article 6 of Regulation (EC) No 1235/2008. The declared operator has submitted his activities under control, and meets the requirements laid down in the named Regulations.	
Date, place:	
Signature on behalf of the issuing control body/authority:	

## ANNEX III

## LIST OF THIRD COUNTRIES AND RELEVANT SPECIFICATIONS REFERRED TO IN ARTICLE 7

## ARGENTINA

1. **Product categories:**

(a) live or unprocessed agricultural products and vegetative propagating material and seeds for cultivation with the exception of:

— livestock and livestock products, bearing or intended to bear indications referring to conversion;

(b) processed agricultural products for use as food with the exception of:

— livestock products bearing or intended to bear indications referring to conversion.

2. **Origin:** products of category 1(a) and organically produced ingredients in products of category 1(b) that have been produced in Argentina.

3. **Production standards:** Ley 25 127 sobre 'Producción ecológica, biológica y orgánica'.

4. **Competent authority:** Servicio Nacional de Sanidad y Calidad Agroalimentaria SENASA, [www.senasa.gov.ar](http://www.senasa.gov.ar)

5. **Control bodies:**

— Food Safety SA, [www.foodsafety.com.ar](http://www.foodsafety.com.ar)

— Instituto Argentino para la Certificación y Promoción de Productos Agropecuarios Orgánicos SRL (Argencert), [www.argencert.com](http://www.argencert.com)

— Letis SA, [www.letis.com.ar](http://www.letis.com.ar)

— Organización Internacional Agropecuaria (OIA), [www.oia.com.ar](http://www.oia.com.ar)

6. **Certificate issuing bodies:** as at point 5.

7. **Duration of the inclusion:** 30 June 2013.

## AUSTRALIA

1. **Product categories:**

(a) unprocessed crop products and vegetative propagating material and seeds for cultivation;

(b) processed agricultural products for use as food composed essentially of one or more ingredients of plant origin.

2. **Origin:** products of category 1(a) and organically grown ingredients in products of category 1(b) that have been grown in Australia.

3. **Production standards:** National standard for organic and bio-dynamic produce.

4. **Competent authority:** Australian Quarantine and Inspection Service AQIS, [www.aqis.gov.au](http://www.aqis.gov.au)

5. **Control bodies and authorities:**

— Australian Certified Organic Pty. Ltd., [www.australianorganic.com.au](http://www.australianorganic.com.au)

— Australian Quarantine and Inspection Service (AQIS), [www.aqis.gov.au](http://www.aqis.gov.au)

— Bio-dynamic Research Institute (BDRI), [www.demeter.org.au](http://www.demeter.org.au)

— National Association of Sustainable Agriculture, Australia (NASAA), [www.nasaa.com.au](http://www.nasaa.com.au)

— Organic Food Chain Pty Ltd (OFC), [www.organicfoodchain.com.au](http://www.organicfoodchain.com.au)

6. **Certificate issuing bodies and authorities:** as at point 5.

7. **Duration of the inclusion:** 30 June 2013.

#### COSTA RICA

1. **Product categories:**

- (a) unprocessed crop products and vegetative propagating material and seeds for cultivation;
- (b) processed crop products for use as food.

2. **Origin:** products of category 1(a) and organically produced ingredients in products of category 1(b) that have been produced in Costa Rica.

3. **Production standards:** Reglamento sobre la agricultura orgánica.

4. **Competent authority:** Servicio Fitosanitario del Estado, Ministerio de Agricultura y Ganadería, [www.protecnet.go.cr/SFE/Organica.htm](http://www.protecnet.go.cr/SFE/Organica.htm)

5. **Control bodies:**

- BCS Oko-Garantie, [www.bcs-oeko.com](http://www.bcs-oeko.com)
- Eco-LOGICA, [www.eco-logica.com](http://www.eco-logica.com)

6. **Certificate issuing authority:** Ministerio de Agricultura y Ganadería.

7. **Duration of the inclusion:** 30 June 2011.

#### INDIA

1. **Product categories:**

- (a) unprocessed crop and vegetative propagating material and seeds for cultivation;
- (b) processed agricultural products for use as food composed essentially of one or more ingredients of plant origin.

2. **Origin:** products of category 1(a) and organically grown ingredients in products of category 1(b) that have been grown in India.

3. **Production standards:** National Programme for Organic Production.

4. **Competent authority:** Agricultural and Processed Food Export Development Authority APEDA, [www.apeda.com/organic](http://www.apeda.com/organic)

5. **Control bodies and authorities:**

- APOF Organic Certification Agency (AOCA), [www.aoca.in](http://www.aoca.in)
- Bureau Veritas Certification India Pvt. Ltd, [www.bureauveritas.co.in](http://www.bureauveritas.co.in)
- Control Union Certifications, [www.controlunion.com](http://www.controlunion.com)
- Ecocert SA (India Branch Office), [www.ecocert.in](http://www.ecocert.in)
- IMO Control Private Limited, [www.imo.ch](http://www.imo.ch)
- Indian Organic Certification Agency (Indocert), [www.indocert.org](http://www.indocert.org)
- Lacon Quality Certification Pvt. Ltd, [www.laconindia.com](http://www.laconindia.com)
- Natural Organic Certification Association, [www.nocaindia.com](http://www.nocaindia.com)
- OneCert Asia Agri Certification private Limited, [www.onecertasia.in](http://www.onecertasia.in)

- SGS India Pvt. Ltd, [www.in.sgs.com](http://www.in.sgs.com)
- Uttaranchal State Organic Certification Agency (USOCA), [www.organicuttarakhand.org/products\\_certification.htm](http://www.organicuttarakhand.org/products_certification.htm)
- Rajasthan Organic Certification Agency (ROCA),  
[http://www.rajasthankrishi.gov.in/Departments/SeedCert/index\\_eng.asp](http://www.rajasthankrishi.gov.in/Departments/SeedCert/index_eng.asp)

6. **Certificate issuing bodies and authorities:** as at point 5.

7. **Duration of the inclusion:** 30 June 2009.

#### ISRAEL

1. **Product categories:**

- (a) unprocessed crop products and vegetative propagating material and seeds for cultivation;
- (b) processed agricultural products for use as food composed essentially of one or more ingredients of plant origin.

2. **Origin:** products of category 1(a) and organically produced ingredients in products of category 1(b) that have been produced in Israel or that have been imported into Israel:

- either from the Community,
- or from a third country in the framework of a regime which is recognised as equivalent in accordance with the provisions of Article 33(2) of Regulation (EC) No 834/2007.

3. **Production standards:** National Standard for organically grown plants and their products.

4. **Competent authority:** Plant Protection and Inspection Services (PPIS), [www.ppis.moag.gov.il](http://www.ppis.moag.gov.il)

5. **Control bodies and authorities:**

- Agrior Ltd.-Organic Inspection & Certification, [www.agrior.co.il](http://www.agrior.co.il)
- IQC Institute of Quality & Control, [www.iqc.co.il](http://www.iqc.co.il)
- Plant Protection and Inspection Services (PPIS), [www.ppis.moag.gov.il](http://www.ppis.moag.gov.il)
- Skal Israel Inspection & Certification, [www.skal.co.il](http://www.skal.co.il)

6. **Certificate issuing bodies and authorities:** as at point 5.

7. **Duration of the inclusion:** 30 June 2013.

#### SWITZERLAND

1. **Product categories:** live or unprocessed agricultural products and vegetative propagating material, processed agricultural products for use as food, feed and seeds for cultivation with the exception of:

- products produced during the conversion period and products containing an ingredient of agricultural origin produced during the conversion period.

2. **Origin:** products and organically produced ingredients in products that have been produced in Switzerland or that have been imported into Switzerland:

- either from the Community,
- or from a third country for which Switzerland has recognised that the products have been produced and controlled in that third country to rules equivalent to those laid down in the Swiss legislation.

3. **Production standards:** Ordinance on organic farming and the labelling of organically produced plant products and foodstuffs.

4. **Competent authority:** Federal Office for Agriculture FOAG,  
<http://www.blw.admin.ch/themen/00013/00085/00092/index.html?lang=en>

**5. Control bodies:**

- Bio Test Agro (BTA), [www.bio-test-agro.ch](http://www.bio-test-agro.ch)
- bio.inspecta AG, [www.bio-inspecta.ch](http://www.bio-inspecta.ch)
- Institut für Marktökologie (IMO); [www.imo.ch](http://www.imo.ch)
- ProCert Safety AG, [www.procert.ch](http://www.procert.ch)

**6. Certificate issuing bodies:** as at point 5.**7. Duration of the inclusion:** 30 June 2013.

## NEW ZEALAND

**1. Product categories:**

- (a) live or unprocessed agricultural products and vegetative propagating material and seeds for cultivation, with the exception of:
- livestock and livestock products bearing or intended to bear indications referring to conversion,
  - products from aquaculture;
- (b) processed agricultural products for use as food with the exception of:
- livestock products bearing or intended to bear indications referring to conversion,
  - products containing products from aquaculture.

**2. Origin:** products of category 1(a) and organically produced ingredients in products of category 1(b) that have been produced in New Zealand or that have been imported into New Zealand:

- either from the Community,
- or from a third country within the framework of a regime which is recognised as equivalent in accordance with the provisions of Article 33(2) of Regulation (EC) No 834/2007,
- or from a third country whose rules of production and inspection system have been recognised as equivalent to the MAF Food Official Organic Assurance Programme on the basis of assurances and information provided by this country's competent authority in accordance with the provisions established by MAF and provided that only organically produced ingredients intended to be incorporated, up to a maximum of 5 % of products of agricultural origin, in products of category 1(b) prepared in New Zealand are imported.

**3. Production standards:** NZFSA Technical Rules for Organic Production.**4. Competent authority:** New Zealand Food Safety Authority NZFSA, <http://www.nzfsa.govt.nz/organics/>**5. Control bodies:**

- ASUREQuality, [www.organiccertification.co.nz](http://www.organiccertification.co.nz)
- BIO-GRO New Zealand, [www.bio-gro.co.nz](http://www.bio-gro.co.nz)

**6. Certificate issuing authority:** Ministry of Agriculture and Forestry (MAF) — New Zealand Food Safety Authority (NZFSA).**7. Duration of the inclusion:** 30 June 2011.

ANNEX IV

**LIST OF CONTROL BODIES AND CONTROL AUTHORITIES FOR THE PURPOSE OF EQUIVALENCE AND  
RELEVANT SPECIFICATIONS REFERRED TO IN ARTICLE 10**

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## ANNEX V

**MODEL OF THE CERTIFICATE OF INSPECTION****for import of products from organic production into the European Community referred to in Article 13**

The model of the certificate is determined with regard to:

- the text,
- the format, on one single sheet,
- the layout and the dimensions of the boxes.

**CERTIFICATE OF INSPECTION FOR IMPORT OF PRODUCTS FROM ORGANIC PRODUCTION INTO THE EUROPEAN COMMUNITY**

1. Issuing body or authority (name and address)	2. Council Regulation (EC) No 834/2007, Article 33(2) <input type="checkbox"/> or Article 33(3) <input type="checkbox"/> or Commission Regulation (EC) No 1235/2008, Article 19 <input type="checkbox"/>	
3. Serial number of the certificate of inspection	4. Reference No authorisation under Article 19	
5. Exporter (name and address)	6. Control body or control authority (name and address)	
7. Producer or preparer of the product (name and address)	8. Country of dispatch	
	9. Country of destination	
10. First consignee in the Community (name and address)	11. Name and address of the importer	
12. Marks and numbers. Container No(s). Number and kind. Trade name of the product	13. CN codes	14. Declared quantity
	<p>15. Declaration of body or authority issuing the certificate referred to in box 1.</p> <p>This is to certify that this certificate has been issued on the basis of the checks required under Article 13(4) of Regulation (EC) No 1235/2008 and that the products designated above have been obtained in accordance with rules of production and inspection of the organic production method which are considered equivalent in accordance with the provisions of Regulation (EC) No 834/2007.</p> <p>Date</p> <p>Name and signature of authorised person</p> <p align="right">Stamp of issuing authority or body</p>	

16. Declaration of the competent authority of the Member State of the European Union who granted the authorisation or its designate.

This is to certify that the products designated above have been authorised for marketing in the European Community in accordance with the procedure of Article 19 of Regulation (EC) No 1235/2008, under the authorisation number mentioned in box 4.

Date

Name and signature of the authorised person

Stamp of the competent authority or its designate in the Member State

17. Verification of the consignment by the relevant authority of the Member State.

Member State: .....

Import registration (type, number, date and office of the customs declaration): .....

Date: .....

Name and signature of authorised person

Stamp

18. Declaration of the first consignee.

This is to certify that the reception of the goods has been carried out in accordance with the provisions of Article 34 of Regulation (EC) No 889/2008.

Name of the company

Date

Name and signature of the authorised person

*Notes*

- Box 1: authority or body or other designated authority or body as referred to in Article 13(3) of Regulation (EC) No 1235/2008. This body also completes box 3 and box 15.
- Box 2: this box indicates the EC Regulations which are relevant for the issue and use of this certificate; indicate the relevant provision.
- Box 3: the serial number of the certificate given by the issuing body or authority in accordance with Article 13(4) of Regulation (EC) No 1235/2008.
- Box 4: the authorisation number in case of import under Article 19. This box is completed by the issuing body, or when the information is not yet available at the time the issuing body endorses box 15, by the importer.
- Box 5: name and address of the exporter.
- Box 6: control body or authority for monitoring compliance of the last operation (production, preparation, including packaging and labelling) with the rules of the organic production methods in the third country of dispatch.
- Box 7: operator who carried out the last operation (production, preparation, including packaging and labelling) on the consignment in the third country mentioned in box 8.
- Box 9: country of destination means the country of the first consignee in the Community.
- Box 10: name and address of the first consignee of the consignment in the Community. The first consignee shall mean the natural or legal person where the consignment is delivered and where it will be handled for further preparation and/or marketing. The first consignee shall also complete box 18.
- Box 11: name and address of the importer. The importer shall mean the natural or legal person within the European Community who presents the consignment for release for free circulation into the European Community, either on its own, or through a representative.
- Box 13: Combined Nomenclature codes for the products concerned.
- Box 14: declared quantity, expressed in appropriate units (kg of net mass, litre, etc.).
- Box 15: declaration of body or authority issuing the certificate. The signature and the stamp must be in a colour different to that of the printing.
- Box 16: only for imports under the procedure laid down in Article 19 of Regulation (EC) No 1235/2008. To be completed by the competent authority in the Member State which granted the authorisation, or by the delegated body or authority in case of delegation in accordance with Article 13(7)(b) of Regulation (EC) No 1235/2008. Not to be completed where the derogation of Article 13(7)(c) of Regulation (EC) No 1235/2008 applies.
- Box 17: shall be completed by the relevant Member State's authority either at the verification of the consignment in accordance with Article 13(1), or before the preparation or splitting operation in the circumstances referred to in Article 14 of Regulation (EC) No 1235/2008.
- Box 18: shall be filled in by the first consignee at the reception of the products, when he has carried out the checks provided for in Article 34 of Regulation (EC) No 889/2008.

## ANNEX VI

**MODEL OF THE EXTRACT OF THE CERTIFICATE OF INSPECTION****referred to in Article 14**

The model of the extract is determined with regard to:

- the text,
- the format,
- the layout and the dimensions of the boxes.

**EXTRACT No ... OF THE CERTIFICATE OF INSPECTION FOR IMPORT OF PRODUCTS FROM ORGANIC PRODUCTION INTO THE EUROPEAN COMMUNITY**

1. Body or authority having issued the underlying certificate of inspection (name and address)	2. Council Regulation (EC) No 834/2007, Article 33(2) <input type="checkbox"/> or Article 33(3) <input type="checkbox"/> or Commission Regulation (EC) No 1235/2008, Article 19 <input type="checkbox"/>	
3. Serial number of the underlying certificate of inspection	4. Reference No authorisation under Article 19	
5. Operator having split the original consignment into batches (name and address)	6. Control body or control authority (name and address)	
7. Name and address of the importer of the original consignment	8. Country of dispatch of the original consignment	9. Total declared quantity of the original consignment
10. Consignee of the batch obtained from splitting (name and address)		
11. Marks and numbers. Container No(s). Number and kind. Trade name of the batch.	12. CN code	13. Declared quantity of the batch
<p>14. Declaration of the relevant authority of the Member State endorsing the extract of the certificate.</p> <p>This extract corresponds to the batch described above and obtained by the splitting of a consignment which is covered by an original certificate of inspection with the serial number mentioned in box 3:</p> <p>Member State: .....</p> <p>Date: .....</p> <p>Name and signature of authorised person <span style="float: right;">Stamp</span></p>		
<p>15. Declaration of the consignee of the batch</p> <p>This is to certify that the reception of the batch has been carried out in accordance with Article 33 of Regulation (EC) No 889/2008.</p> <p>Name of the company</p> <p>Date:</p> <p>Name and signature of authorised person</p>		

*Notes*

Extract No ...: the extract number corresponds to the number of the batch obtained from the splitting of the original consignment.

Box 1: name of body or authority in the third country having issued the underlying certificate of inspection.

Box 2: this box indicates the EC Regulations which are relevant for the issue of this extract; indicate the relevant provision under which the underlying consignment was imported, see box 2 of the underlying certificate of inspection.

Box 3: the serial number of the underlying certificate which was given by the issuing body or authority in accordance with Article 13(4) of Regulation (EC) No 1235/2008.

Box 4: reference No of the authorisation granted under Article 19 of Regulation (EC) No 1235/2008, see box 4 of the underlying certificate of inspection.

Box 6: Control body or control authority in charge of controlling the operator having split the consignment.

Boxes 7, 8, 9: see relevant information on the underlying certificate of inspection.

Box 10: consignee of the batch (obtained from the splitting) in the European Community.

Box 12: Combined Nomenclature codes for the batch of the products concerned.

Box 13: declared quantity, expressed in appropriate units (kg of net mass, litre, etc.).

Box 14: shall be completed by the relevant Member State's authority for each of the batches resulting from the splitting operation referred to in Article 14(2) of Regulation (EC) No 1235/2008.

Box 15: shall be filled up at the reception of the batch, when the consignee has carried out the checks provided for in Article 33 of Regulation (EC) No 889/2008.

## ANNEX VII

## Correlation Table referred to in Article 20

Regulation (EC) No 345/2008	Regulation (EC) No 605/2008	This Regulation
—	Article 1(1)	Article 1
—	Article 1(2)	—
—	Article 2, introductory words and point 1	Article 2, introductory words and point 1
—	—	Article 2, point 2
—	Article 2, point 2	Article 2, point 3
—	Article 2, point 3	Article 2, point 4
—	Article 2, point 4	—
—	Article 2, point 5	Article 2, point 5
—	—	Article 3
—	—	Article 4
—	—	Article 5
—	—	Article 6
Article 1	—	Article 7
Article 2(1)	—	Article 8(1)
Article 2(2)	—	Article 8(2)
Article 2(3)	—	Article 8(3)
Article 2(4)	—	Article 8(3) and 9(2)
—	—	Article 8(4)
Article 2(5)	—	Article 9(1)
Article 2(6)	—	Article 9(3) and 9(4)
—	—	Article 10
—	—	Article 11
—	—	Article 12
—	Articles 3 and 4	Article 13
—	Article 5	Article 14
—	Article 6	Article 15
—	—	Article 16
—	—	Article 17
—	Article 7(1)	—
—	Article 7(2)	—
—	—	Article 18
—	—	Article 19
Article 3	Article 8	Article 20

Regulation (EC) No 345/2008	Regulation (EC) No 605/2008	This Regulation
Article 4	Article 9	Article 21
Annex II	—	—
—	—	Annex I
—	—	Annex II
Annex I	—	Annex III
—	—	Annex IV
—	Annex I	Annex V
—	Annex II	Annex VI
Annex III	Annex IV	Annex VII

## COMMISSION REGULATION (EC) No 1236/2008

of 11 December 2008

**amending Regulation (EC) No 1613/2000 derogating from Regulation (EEC) No 2454/93 in respect of the definition of the concept of originating products used for the purposes of the scheme of generalised preferences to take account of the special situation of Laos regarding certain exports of textiles to the Community**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code <sup>(1)</sup>, and in particular Article 247 thereof,

Having regard to Commission Regulation (EEC) No 2454/93 of 2 July 1993 laying down provisions for the implementation of Council Regulation (EEC) No 2913/92 establishing the Community Customs Code <sup>(2)</sup>, and in particular Article 76 thereof,

Whereas:

(1) By Council Regulation (EC) No 980/2005 of 27 June 2005 applying a scheme of generalised tariff preferences <sup>(3)</sup>, the Community granted generalised tariff preferences to Laos. Regulation (EC) No 980/2005 is due to lapse on 31 December 2008 but will be replaced as of 1 January 2009 by Council Regulation (EC) No 732/2008 <sup>(4)</sup>, which confirms the granting by the Community of the said tariff preferences to Laos.

(2) Regulation (EEC) No 2454/93 establishes the definition of the concept of originating products to be used for the purposes of the scheme of generalised tariff preferences. Regulation (EEC) No 2454/93 also provides for a derogation from that definition in favour of least-developed beneficiary countries benefiting from the generalised system of preferences (GSP) which submit an appropriate request to that effect to the Community.

(3) Laos has benefited from such a derogation for certain textile products under Commission Regulation (EC) No 1613/2000 <sup>(5)</sup>, which has been prolonged several times, and is due to expire on 31 December 2008.

(4) By letter dated 9 October 2008 Laos submitted a request for prolongation of the derogation in accordance with Article 76 of Regulation (EEC) No 2454/93.

(5) When the validity of Regulation (EC) No 1613/2000 was last extended, by virtue of Commission Regulation (EC) No 1806/2006 <sup>(6)</sup>, it was expected that new, simpler and more development-friendly GSP rules of origin would be applicable before expiry of the derogation. However new GSP rules of origin have not yet been adopted and it is now expected that such rules of origin will not be in place before the end of 2009.

(6) The request demonstrates that the application of the rules of origin on sufficient working or processing and regional cumulation would affect significantly the ability of the Lao garment industry to continue its exports to the Community and deter investment. This would lead to further business closures and unemployment in that country. Furthermore, it seems that application of the GSP rules of origin currently applicable for even a short period would be liable to have the effect described.

(7) The period of prolongation of the derogation should cover the time necessary to adopt and implement new GSP rules of origin. Since the conclusion of longer-term contracts benefiting from the derogation is of particular importance to the stability and growth of Lao industry, the prolongation granted should be sufficiently long to permit the economic operators to conclude such contracts.

(8) As a consequence of the application of the future new rules of origin, the Lao products which are currently eligible for preferential tariff treatment only through application of the derogation should in future be able to qualify through application of the new rules of origin. The derogation will at that moment become superfluous. In order to ensure clarity for operators, it will therefore be necessary to repeal Regulation (EC) No 1613/2000 with effect from the date on which the new rules of origin apply.

(9) The derogation should therefore be prolonged until the date of application of the new rules of origin to be laid down in Regulation (EEC) No 2454/93, but in any event it should cease to apply on 31 December 2010.

<sup>(1)</sup> OJ L 302, 19.10.1992, p. 1.

<sup>(2)</sup> OJ L 253, 11.10.1993, p. 1.

<sup>(3)</sup> OJ L 169, 30.6.2005, p. 1.

<sup>(4)</sup> OJ L 211, 6.8.2008, p. 1.

<sup>(5)</sup> OJ L 185, 25.7.2000, p. 38.

<sup>(6)</sup> OJ L 343, 8.12.2006, p. 69.

- (10) Regulation (EC) No 1613/2000 should therefore be amended accordingly.
- (11) The measures provided for in this Regulation are in accordance with the opinion of the Customs Code Committee,

the Community up to the annual quantities listed in the Annex against each product during the period from 15 July 2000 until the date of application of an amendment to Regulation (EEC) No 2454/93 in respect of the definition of the concept of originating products used for the purposes of the scheme of generalised preferences, but in any event that derogation shall cease to apply on 31 December 2010.'

HAS ADOPTED THIS REGULATION:

*Article 1*

Article 2 of Regulation (EC) No 1613/2000 is replaced by the following text:

*'Article 2*

The derogation provided for in Article 1 shall apply to products transported directly from Laos and imported into

*Article 2*

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

It shall apply from 1 January 2009.

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

Done at Brussels, 11 December 2008.

*For the Commission*  
László KOVÁCS  
*Member of the Commission*

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## COMMISSION REGULATION (EC) No 1237/2008

of 11 December 2008

**amending Regulation (EC) No 1043/2005 implementing Council Regulation (EC) No 3448/93 as regards the system of granting export refunds on certain agricultural products exported in the form of goods not covered by Annex I to the Treaty, and the criteria for fixing the amount of such refunds**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 3448/93 of 6 December 1993 laying down the trade arrangements applicable to certain goods resulting from the processing of agricultural products <sup>(1)</sup>, and in particular the first subparagraph of Article 8(3) thereof,

Whereas:

- (1) Pursuant to Article 5(3) of Commission Regulation (EC) No 1043/2005 <sup>(2)</sup> where goods are used in the manufacture of the goods exported, the refund rate to be used in calculating the amount applying to each of the basic products, to products derived from the processing thereof, or to products assimilated to one of those two categories which were used in the manufacture of the goods exported, is to be the rate applicable when the former goods are exported unprocessed.
- (2) In accordance with Article 19(1) of Regulation (EC) No 1043/2005 where the world trade situation in ovalbumin falling within CN codes 3502 11 90 and 3502 19 90 or the specific requirements of certain markets so require, the refund on those goods may be differentiated according to destination.
- (3) The combined reading of Article 5(3) and Article 19(1) of Regulation (EC) No 1043/2005 may result in the incorrect interpretation that goods, containing ovalbumin as an ingredient, which are exported to third countries, and in particular to South Korea, Japan, Malaysia, Thailand, Taiwan and the Philippines, may benefit from the higher rate of refund intended solely

for the export of ovalbumin in the unaltered state to those destinations.

- (4) For the sake of clarity and to protect the financial interests of the Community it is therefore appropriate to clarify that only exports of ovalbumin in the unaltered state can benefit from the higher rate of refund fixed for those destinations in accordance with Article 19(1) of Regulation (EC) No 1043/2005.
- (5) Regulation (EC) No 1043/2005 should therefore be amended accordingly.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee on horizontal questions concerning trade in processed agricultural products not listed in Annex I,

HAS ADOPTED THIS REGULATION:

*Article 1*

Article 19(1) of Regulation (EC) No 1043/2005 is replaced by the following:

'1. The refunds on casein falling within CN code 3501 10, on caseinates falling within CN code 3501 90 90 or, on ovalbumin falling within CN codes 3502 11 90 and 3502 19 90 exported in the unaltered state, may be differentiated according to destination if such is required by:

- (a) the world trade situation in those goods; or
- (b) specific requirements of certain markets.'

*Article 2*

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

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

Done at Brussels, 11 December 2008.

*For the Commission*

Mariann FISCHER BOEL

*Member of the Commission*

<sup>(1)</sup> OJ L 318, 20.12.1993, p. 18.

<sup>(2)</sup> OJ L 172, 5.7.2005, p. 24.

**COMMISSION REGULATION (EC) No 1238/2008****of 10 December 2008****prohibiting fishing for forkbeards in Community waters and waters not under the sovereignty or jurisdiction of third countries of V, VI and VII by vessels flying the flag of Spain**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 2371/2002 of 20 December 2002 on the conservation and sustainable exploitation of fisheries resources under the common fisheries policy <sup>(1)</sup>, and in particular Article 26(4) thereof,

Having regard to Council Regulation (EEC) No 2847/93 of 12 October 1993 establishing a control system applicable to the common fisheries policy <sup>(2)</sup>, and in particular Article 21(3) thereof,

Whereas:

- (1) Council Regulation (EC) No 2015/2006 of 19 December 2006 fixing for 2007 and 2008 the fishing opportunities for Community fishing vessels for certain deep-sea fish stocks <sup>(3)</sup> lays down quotas for 2007 and 2008.
- (2) According to the information received by the Commission, catches of the stock referred to in the Annex to this Regulation by vessels flying the flag of, or registered in, the Member State referred to therein have exhausted the quota allocated for 2008.

- (3) It is therefore necessary to prohibit fishing for that stock and its retention on board, transhipment and landing,

HAS ADOPTED THIS REGULATION:

*Article 1*

**Quota exhaustion**

The fishing quota allocated for 2008 to the Member State referred to in the Annex to this Regulation for the stock referred to therein shall be deemed to be exhausted from the date stated in that Annex.

*Article 2*

**Prohibitions**

Fishing for the stock referred to in the Annex to this Regulation by vessels flying the flag of, or registered in, the Member State referred to therein shall be prohibited from the date stated in that Annex. After that date it shall also be prohibited to retain on board, tranship or land such stock caught by those vessels.

*Article 3*

**Entry into force**

This Regulation shall enter into force on the day following that 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, 10 December 2008.

*For the Commission*

Fokion FOTIADIS

*Director-General for Maritime Affairs and Fisheries*

<sup>(1)</sup> OJ L 358, 31.12.2002, p. 59.

<sup>(2)</sup> OJ L 261, 20.10.1993, p. 1.

<sup>(3)</sup> OJ L 384, 29.12.2006, p. 28.

## ANNEX

No	10/DSS
Member State	ESP
Stock	GFB/567-
Species	Forkbeards ( <i>Phycis blennoides</i> )
Area	Community waters and waters not under the sovereignty or jurisdiction of third countries of V, VI and VII
Date	30.9.2008

**COMMISSION REGULATION (EC) No 1239/2008****of 10 December 2008****reopening the fishery for cod in Kattegat by vessels flying the flag of Sweden**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 2371/2002 of 20 December 2002 on the conservation and sustainable exploitation of fisheries resources under the Common Fisheries Policy <sup>(1)</sup>, and in particular Article 26(4) thereof,

Having regard to Council Regulation (EEC) No 2847/93 of 12 October 1993 establishing a control system applicable to common fisheries policy <sup>(2)</sup>, and in particular Article 21(3) thereof,

Whereas:

- (1) Council Regulation (EC) No 40/2008 of 16 January 2008 fixing for 2008 the fishing opportunities and associated conditions for certain fish stocks and groups of fish stocks applicable in Community waters and for Community vessels, in waters where catch limitations are required <sup>(3)</sup>, lays down quotas for 2008.
- (2) On 15 May 2008 Sweden notified the Commission, pursuant to Article 21(2) of Regulation (EEC) No 2847/93, that it would close the fishery for cod in Kattegat from 19 May 2008 onwards.
- (3) On 19 June 2008 the Commission, pursuant to Article 21(3) of Regulation (EEC) No 2847/93 and Article 26(4) of Regulation (EC) No 2371/2002,

adopted Regulation (EC) No 585/2008 establishing a prohibition of fishing for cod in Kattegat by vessels flying the flag of Sweden <sup>(4)</sup>, with effect from the same date.

- (4) According to the information received by the Commission from the Swedish authorities, a quantity of cod is still available in the Swedish quota in Kattegat. Consequently, fishing for cod in these waters by vessels flying the flag of Sweden or registered in Sweden should be authorised.
- (5) This authorisation should take effect on 13 October 2008, in order to allow the quantity of cod in question to be fished before the end of the current year.
- (6) Commission Regulation (EC) No 585/2008 should be repealed with effect from 13 October 2008,

HAS ADOPTED THIS REGULATION:

*Article 1***Repeal**

Regulation (EC) No 585/2008 is hereby repealed.

*Article 2***Entry into force**

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

It shall apply from 13 October 2008.

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

Done at Brussels, 10 December 2008.

*For the Commission*

Fokion FOTIADIS

*Director-General for Maritime Affairs and Fisheries*

<sup>(1)</sup> OJ L 358, 31.12.2002, p. 59.

<sup>(2)</sup> OJ L 261, 20.10.1993, p. 1.

<sup>(3)</sup> OJ L 19, 23.1.2008, p. 1.

<sup>(4)</sup> OJ L 162, 21.6.2008, p. 9.

## ANNEX

No	64 — Reopening
Member State	SWE
Stock	COD/03AS.
Species	Cod
Zone	Kattegat
Date	13.10.2008

**COMMISSION REGULATION (EC) No 1240/2008**  
**of 10 December 2008**  
**amending Council Regulation (EC) No 560/2005 imposing certain specific restrictive measures**  
**directed against certain persons and entities in view of the situation in Côte d'Ivoire**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 560/2005 imposing certain specific restrictive measures directed against certain persons and entities in view of the situation in Côte d'Ivoire <sup>(1)</sup>, and in particular Article 11(a) thereof,

Whereas:

- (1) Annex I to Regulation (EC) No 560/2005 lists the natural and legal persons and entities covered by the freezing of funds and economic resources under that Regulation.
- (2) On 18 December 2006 and on 21 October 2008, the Sanctions Committee of the United Nations Security

Council decided to amend the list of natural persons to whom the freezing of funds and economic resources should apply, by completing the information concerning persons already listed. Annex I should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

*Article 1*

Annex I to Regulation (EC) No 560/2005 is hereby replaced as set out by the text in the Annex to this Regulation.

*Article 2*

This Regulation shall enter into force on the day following that 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, 10 December 2008.

*For the Commission*  
Eneko LANDÁBURU  
*Director-General for External Relations*

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<sup>(1)</sup> OJ L 95, 14.4.2005, p. 1.

## ANNEX

## 'ANNEX I

**List of natural or legal persons or entities referred to in Articles 2, 4 and 7**

- (1) Charles **Blé Goudé** (*alias* Gbapé Zadi). Address: Bloc P 170, Yopougon Selmer, Côte d'Ivoire, (b) Hotel Ivoire, Abidjan, Cocody, Côte d'Ivoire. Date of birth: 1.1.1972. Place of birth: (a) Guibéroua (Gagnoa), Côte d'Ivoire, (b) Niagbrahio/Guiberoua, Côte d'Ivoire, (c) Guiberoua, Côte d'Ivoire. Nationality: Côte d'Ivoire. Passport No: (a) 04LE66241 (Côte d'Ivoire, issued on 10.11.2005, valid until 9.11.2008), (b) AE/088 DH 12 (Diplomatic passport Côte d'Ivoire, issued on 20.12.2002, valid until 11.12.2005), (c) 98LC39292 (Côte d'Ivoire, issued on 24.11.2000, valid until 23.11.2003). Travel document No: C2310421 (Switzerland, issued on 15.11.2005, valid until 31.12.2005).

Other information: (1) Address (a) in 2001, Address (b) as declared in travel document No C2310421; (2) possible *alias* or title: "Général" or "Génie de kpo"; (3) Leader of COJEP ("Young Patriots"). Repeatedly made public statements advocating violence against United Nations installations and personnel, and against foreigners; direction of and participation in acts of violence by street militias, including beatings, rapes and extrajudicial killings; intimidation of the United Nations, the International Working Group (IWG), the political opposition and independent press; sabotage of international radio stations; obstacle to the action of the IWG, the United Nations Operation in Côte d'Ivoire, (UNOCI), the French Forces and to the peace process as defined by UN Resolution 1643 (2005).

- (2) Eugène N'goran Kouadio **Djué**. Date of birth: (a) 1.1.1966, (b) 20.12.1969. Nationality: Côte d'Ivoire. Passport No: 04LE017521 (issued on 10.2.2005, valid until 10.2.2008).

Other information: Leader of the "Union des Patriotes pour la Libération Totale de la Côte d'Ivoire (UPLTICI)". Repeatedly made public statements advocating violence against United Nations installations and personnel, and against foreigners; direction of and participation in acts of violence by street militias, including beatings, rapes and extrajudicial killings; obstacle to the action of IWG, UNOCI, the French forces and to the peace process as defined by UN Resolution 1643 (2005).

- (3) Martin Kouakou **Fofié**. Date of birth: 1.1.1968. Place of birth: Bohi, Côte d'Ivoire. Nationality: Côte d'Ivoire. Identity card No: (a) 2096927 (Burkina Faso, issued on 17.3.2005), (b) 970860100249 (Côte d'Ivoire, issued on 5.8.1997, valid until 5.8.2007).

Other information: (a) Burkina Faso Nationality Certificate: CNB N.076 (17.2.2003), Father's Name: Yao Koffi **Fofié**, Mother's Name: Ama Krouama **Kossonou**; (b) Chief Corporal New Force Commandant, Korhogo Sector. Forces under his command engaged in recruitment of child soldiers, abductions, imposition of forced labour, sexual abuse of women, arbitrary arrests and extra-judicial killings, contrary to human rights conventions and to international humanitarian law; obstacle to the action of the IWG, UNOCI, French Forces and to the peace process as defined by UN Resolution 1643 (2005).'

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## II

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

## DECISIONS

## COMMISSION

## COMMISSION DECISION

of 20 May 2008

**concerning aid granted by France to the Fund for the prevention of risks to fishing and fisheries undertakings (State aid C 9/06)**

(notified under document number C(2007) 5636)

(Only the French text is authentic)

(Text with EEA relevance)

(2008/936/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

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

Having called on the parties concerned to submit their comments under that Article,

Whereas:

**1. PROCEDURE**

- (1) The Commission was aware of information relating to the existence of a fund intended to compensate for the rise in the price of fuel affecting French fisheries undertakings since 2004. According to that information, the declared objective of the fund, called the Fund for the prevention of risks to fishing (FPAP), was to even out short-term variations in the price of fuel for the fishing industry, but in practice it enabled the undertakings to benefit from a fuel price much lower than the market price.
- (2) Apparently it was planned, at the beginning, for the Fund to operate solely on the basis of contributions from the trade. The operating principle would have been simple: the Fund would have borne that part of the cost of fuel higher than a specified reference price per litre and, in return, the undertakings would have paid contributions to the FPAP when the price of fuel fell back to below the

reference price. In this way, a balance for financing the system would have been struck without there being any contribution from public funds.

- (3) However, since the market price for fuel always stayed very considerably above the reference price, the Commission took the view that operation of the FPAP was only possible as a result of the financial contribution from the State and that that financial contribution constituted State aid within the meaning of Article 87 of the EC Treaty.
- (4) On 25 August 2005 the Commission requested France to inform it, by 5 September 2005, whether specific measures had been adopted or were envisaged by the State to counter the increase in fuel costs. The Commission also pointed out that if such measures involved State aid it had to be notified of them under Article 88(3) of the Treaty.
- (5) In the absence of a reply, and in accordance with Article 10 of Council Regulation (EC) No 659/1999 of 22 March 1999 laying down detailed rules for the application of Article 93 (now Article 88) of the EC Treaty<sup>(1)</sup>, on 21 September 2005 the Commission requested France to provide it, within three weeks, with information on the Fund in order for it to be able to examine whether it actually involved State aid and, if so, whether or not that State aid was compatible with the common market.

<sup>(1)</sup> OJ L 83, 27.3.1999, p. 1.

- (6) On 7 October 2005 France replied to the Commission's request of 25 August 2005, stating that 'no measure under the State aid scheme has been implemented in France to counter the difficulties due to the recent considerable increase in the price of fuel'. However, France pointed out that it had encouraged 'an initiative taken by the trade' consisting of the creation of a fund for the prevention of risks to fishing. No mention was made in that correspondence of the advance payments granted by the State. On the contrary, it was implicit from the French authorities' reply that the financing of the Fund, managed by the trade, was based exclusively on the pooling of the members' financial capacity.
- (7) On 21 October 2005 the Commission reminded the French authorities of its formal request for information on the FPAP of 21 September 2005, granting them a new two-week deadline.
- (8) In the absence of a reply from France within the time limit set, the Commission decided, in accordance with paragraph 3 of Article 10 as referred to above, to issue France with an injunction to provide the information necessary for the examination. That injunction, dated 5 December 2005, was sent on 6 December 2005 with a three-week deadline for reply.
- (9) France replied by letter dated 21 December 2005 and received by the Commission on 27 December 2005. That letter referred back to a previous reply, dated 6 December and received on 8 December, sent in reply to the Commission's letter of 21 September 2005 (see recital 5 of this Decision). In those two letters France forwarded the Commission the FPAP's articles of association and the three agreements on the introduction of a repayable State advance to the FPAP.
- (10) After examining these replies and the documents enclosed, on 8 March 2006 the Commission informed France of its decision to initiate the formal investigation procedure provided for in Article 88(2) of the EC Treaty and Article 6 of Regulation (EC) No 659/1999.
- (11) The Commission decision to initiate the formal investigation procedure was published in the *Official Journal of the European Union* of 19 April 2006 <sup>(2)</sup>. The Commission called on interested parties to submit their comments on the measures in question within one month.
- (12) France submitted its comments on 21 April 2006 in the form of a note from its authorities. That note is accompanied by a list of defensive points which seems to have been originally intended for internal use; the list explains the position to be taken vis-à-vis the Commission's arguments.
- (13) On 17 May 2006 Ménard, Quimbert et associés, a law firm in Nantes ('MQA' in the following) sent a fax indicating their intention to make comments on behalf of the FPAP at a later date, and accordingly requested that they be granted time to do so. The Commission accepted an extension of two weeks. MQA then forwarded, by ordinary post dated 17 May received by the Commission on 23 May, a statement under the letterhead of Coopération Maritime signed by Mr de Feuardent, the Secretary-General of the FPAP, dated 18 May. A third letter from MQA, also dated 17 May and received by the Commission on 14 June, was 'a new version of [its] comments following correction of a number of clerical errors'. In reality these were documents not previously forwarded to the Commission comprising additional comments to the statement by Mr de Feuardent referred to above, accompanied by a number of documents relating to the operation of the FPAP (articles of association, rules of procedure, information notes, tax treatment of contributions, and a letter relating to a joint audit by the Inspectorate-General for Finance and the Inspectorate-General for Agriculture and Fisheries). Finally, the last letter from MQA, dated 12 June 2006 and sent to the Commission the same day by fax, following on from its letter of 19 May 'dated 17 May by mistake, sending [you] the comments made by Mr de Feuardent, Secretary-General of the Confédération de la Coopération, de la Mutualité et du Crédit Maritime, dated 18 May 2006' contained the same additional comments as those sent by the third letter of 17 May, but without the accompanying documents.

<sup>(2)</sup> OJ C 91, 19.4.2006, p. 30.

- (14) On 14 June 2006 the Commission sent France the third letter from MQA of 17 May 2006 (the version announced as correcting the clerical errors) and MQA's last letter of 12 June 2006, requesting France to send its comments to reach it within one month. On 12 July 2006 France requested an extension of the deadline to 1 September. On 18 July 2006 the Commission accepted an additional period of one month. On 26 September 2006 France replied that it had no particular comments to make, but pointed out that the MQA letter of 17/19 May 2006 did not tally with Mr de Feuardent's comments. On 9 October 2006 the Commission gave France details of the correspondence received from MQA and requested it to confirm within ten days that the French authorities had indeed been aware of Mr de Feuardent's statement. France replied on 23 October 2006 that it did not have the statement, which it had in fact only mentioned previously because the letter (from MQA) dated 12 June mentioned it. Since France stated that it had not received that letter, the Commission officially sent it a copy on 27 October 2006, requesting any comments that France had to be sent to it by 15 November.
- (15) On 27 November 2006 France informed the Commission that it did not have any particular comments to make on the document.
- 2. DESCRIPTION**
- 2.1. Presentation of the FPAP and its activities**
- (16) In accordance with the French act of 21 March 1884, as amended by the act of 12 March 1920, the FPAP is constituted in the form of a trade association. The draft articles of association were approved by the constituent assembly held on 10 February 2004 and the articles of association themselves are dated 9 April 2004.
- (17) According to the articles of association (Article 4), the association has been set up for a period of 99 years. Its seat is in Paris at: 24, rue du Rocher, i.e. the same address as the Confédération de la Coopération, de la Mutualité et du Crédit Maritime ('Coopération Maritime' in the following).
- (18) Under Article 7, the founding members are the Coopération Maritime, the central contracting and development agency Cecomer, the retail traders' cooperative society, which is in fact the central contracting agency of the maritime cooperatives whose function is, in particular, to supply equipment and operating material for fisheries undertakings, the Small-Scale Fishery Management Centre, and two persons active in the fishing industry. At the constituent assembly on 10 February 2004 these five founding members were appointed administrators of the FPAP until the ordinary general meeting to be held in 2007. Thus the FPAP appears to have been set up by the fisheries sector and organisations commercially involved in it (maritime cooperatives, central contracting agency and fisheries undertaking management centres).
- (19) Applicants for membership must provide proof that they are active in the fishing industry. However, the association may take in 'any other person willing to give their moral support to the association', provided that the number of employees of this category of member does not exceed 5 % of the number of the association's members. In its letter of 6 December 2005 France points out that the FPAP has 2 013 members and 2 385 vessels, accounting for 30 % of the French fleet.
- (20) Article 2 of the articles of association states that: 'The purpose of the association is to develop products so as to enable fisheries undertakings to cover the following risks: fluctuations in the price of diesel, maritime pollution or health risks linked to pollution, the closure of quotas or a significant reduction in fishing opportunities, and market risks. Its title shall be the Fund for the prevention of risks to fishing'. The FPAP is thus designed to be a mutual insurance company providing a number of benefits for its members in exchange for their contributions.
- (21) France forwarded copies of three agreements concluded between the State and the FPAP relating to the introduction of repayable advances to the Fund by the State. The advances are paid via the Office national inter-professionnel des produits de la mer et de l'aquaculture (Ofimer). The first agreement, dated 12 November 2004, covers an amount of EUR 15 million; the second, dated 27 May 2005, an amount of EUR 10 million; and the third, dated 11 October 2005, an amount of EUR 40 million. According to these three agreements, an amount of EUR 65 million was therefore advanced to the FPAP.
- (22) According to the list of defensive points enclosed with the note from France of 21 April 2006 (see recital 12 of this Decision), it is also possible that another advance of EUR 12 million was paid to the FPAP (see recital 40 of this Decision).

- (23) According to Article 1 of these agreements, 'the FPAP shall operate on the basis of contributions paid by its members in order to cover the setting up of financial cover against the risks resulting from fluctuations in the price of oil and the associated administrative costs'. The agreements show that, although under its articles of association it is formally conceived as having quite a wide range of objectives as regards the benefits that it may provide (see recital 20 of this Decision), in reality the FPAP restricted its activity to providing financial cover for fisheries undertakings against the rise in the price of fuel.
- (24) Under Article 2 of the agreement of 12 November 2004, 'the purpose of the advance shall be the setting up of a cover mechanism against fluctuations in international oil prices from 1 November 2004; the advance will enable financial options to be acquired on futures markets. The compensation paid to members of the Fund shall correspond to the difference in price between the maximum price covered and the average monthly price in the reference index for the month under consideration'. Article 2 of the agreement of 27 May 2005 is drafted almost identically: instead of the 'setting up' of a cover mechanism, it provides for the 'continuation' of this mechanism and it gives 1 March 2005 as the date from which cover will be provided for advances paid under this agreement. The same applies to the agreement of 11 October 2005; Article 2 provides that, for the advance paid, the Fund is to continue providing cover '... from 1 July 2005 and until 31 December 2005 at least, by buying financial options on the futures markets, up to 17 euro cent/l'. It states that 'the compensation paid to members of the Fund shall be equivalent, at most, to the difference in price between a price of 30 euro cent/l and the average monthly reference price for the month under consideration, where the latter is higher than 30 euro cent/l'.
- (25) The detailed rules of procedure of the FPAP show that this cover mechanism operates by means of guarantee agreements between the FPAP and its member undertakings. Members pay a registration fee of EUR 150 plus a guarantee contribution based on an estimated quantity of fuel expressed in litres at a rate of 0,035 cent per litre of fuel. In return, the fisheries undertakings receive an allowance determined on the basis of the volume consumed, up to a maximum of the volume insured. The method of calculating the allowance is detailed in the rules of procedure.
- (26) Article 3 of the agreements referred to in recital 21 states that advances may be paid by Ofimer only after certain supporting documents have been provided. These must include the minutes of the FPAP's governing body authorising management of the State advance and, in the case of the first two agreements, detailing the use to which the advance is to be put, and a forecast budget. In its note dated 6 December 2005 France confirmed that the amounts indicated, covering a total of EUR 65 million, were actually granted to the FPAP. That note specifies that these advances are granted 'to ensure the operation of the FPAP, as soon as possible, for the period November 2004 to the end of December 2005'.
- (27) In addition, the FPAP undertakes to keep accounts so that, on request, information on how the advances have been used and resources and expenditure have been allocated can be obtained. The accounting documents must be kept for ten years and must be made available to the various State bodies on request.
- (28) Article 4 sets the interest rate at which the FPAP is to repay the advances to Ofimer at 4,45 %. The amount of EUR 15 million covered by the agreement of 12 November 2004 has to be repaid by 1 November 2006, the EUR 10 million covered by the agreement of 27 May 2005 by 1 May 2007, and the EUR 40 million covered by the agreement of 11 October 2005 by 1 July 2007.
- (29) In view of the three (possibly four) agreements signed between the French State and the Fund, FPAP's activity within the framework of the first of the objectives set out in Article 2 of the articles of association (to enable fisheries undertakings to cover the risks relating to the fluctuation in the price of diesel) is therefore two-fold:
- (a) to counter fluctuations in the price of oil by acquiring options on the futures markets in the petroleum products sector; and

(b) to partially compensate for the additional cost induced by high oil prices for the vessels of Fund members where the fuel price exceeds a certain threshold.

- (30) As regards State aid, the Fund must be considered under these two aspects, on the one hand where it acts as an economic operator on futures markets, and on the other where it compensates fisheries undertakings for part of the costs incurred in fuel purchases with the aim of reducing their running costs.

## 2.2. Reasons for initiating the formal investigation procedure

- (31) The reasons for initiating the formal investigation were as follows.

### 2.2.1. Regarding the acquisition of options on futures markets

- (32) The advance paid to the FPAP can be regarded as a short-term loan at a rate of 4,45 %. However, the Commission notes that the Fund has no real estate and that its current assets are extremely small because they only come from its members' contributions. This is why a bank would never have granted such a loan.
- (33) As a result, the Fund is at a financial advantage compared to other undertakings active on the same futures markets. That advantage constitutes State aid for the Fund. None of the provisions of Article 87 of the EC Treaty or the guidelines which the Commission has adopted for assessing State aid schemes allows it to be regarded as compatible with the common market.

- (34) In addition, as a result of this activity, the FPAP's member fisheries undertakings can buy fuel at reduced prices. This constitutes aid which results in a reduction of running costs for the undertakings covered by the Fund. However, in accordance with paragraph 3.7 of the Guidelines for the examination of State aid to fisheries and aquaculture<sup>(3)</sup>, this type of operating aid, which is not accompanied by any obligation, must normally be regarded as being incompatible with the common market.

### 2.2.2. Regarding compensation for fisheries undertakings of part of the costs incurred in the purchase of fuel

- (35) Here also, the aid results in a reduction of running costs for the FPAP's member undertakings. In the same way, none of the provisions of Article 87 of the EC Treaty or

the guidelines which the Commission has adopted for assessing State aid schemes allows it to be regarded as compatible with the common market. Likewise, in accordance with paragraph 3.7 of the guidelines for the fisheries sector, this type of operating aid, which is not accompanied by any obligation, must be regarded as being incompatible with the common market.

### 2.2.3. Conclusion

- (36) In view of all the information in its possession, the Commission took the view that there were serious doubts about the compatibility with the common market of this aid scheme, which benefits both the FPAP itself and its member fisheries undertakings.

## 3. COMMENTS MADE BY FRANCE AND THE PARTIES CONCERNED

### 3.1. Comments made by France

- (37) The comments made by France are set out in the reply of 21 April 2006. After that date no additional remark was made on the arguments developed by the FPAP and MQA.
- (38) France points out that the Commission's analysis should concentrate on the nature of and the conditions for granting the advance authorised by the State and not on FPAP's activities.
- (39) In this respect it observes that:
- the applicable rates are higher than the reference rates laid down by the Commission to establish the existence of State aid in soft loans,
  - the scheme cannot be regarded as State aid as long as the repayment deadlines have not passed. In this respect France points out that these deadlines were set at 1 November 2006, 1 May 2007 and 1 July 2007 respectively,
  - the Commission's argument, according to which no bank would have granted such an advance to the FPAP, has no foundation, because guarantee mechanisms could have been introduced. France also points out that the FPAP is the only French trade organisation made up of fisheries undertakings with the objective of acting on the oil futures market and that membership of the Fund is free.

<sup>(3)</sup> OJ C 229, 14.9.2004, p. 5.

- (40) The Commission also notes that, in the list of defensive points enclosed with its reply (see recital 12 of this Decision), France indicates that 'it does not appear necessary to point out that it was decided to pay an advance of EUR 12 million, since to date the agreement has not been signed. Nevertheless, we should not box ourselves into a corner. It is proposed that it should be pointed out that this is being considered'.

### 3.2. Comments made by the FPAP

- (41) The Commission received several letters from MQA with various contents and sent in a disordered fashion (see details at recital 13 of this Decision), which may be summarised as follows: a statement under the Coopération Maritime letterhead dated 18 May 2006 signed by the Secretary-General of the FPAP, and additional comments by MQA on behalf of the FPAP, accompanied by a number of documents relating to the operation of the FPAP (articles of association, rules of procedure, information notes, tax treatment of contributions, and a letter relating to a joint audit by the Inspectorate-General for Finance and the Inspectorate-General for Agriculture and Fisheries).

- (42) An analysis of the documents received from MQA shows that the FPAP endorses the arguments made by France, pointing out that one cannot prejudge 'the pure and simple cancellation of the debt on its expiry date' as long as no repayment default has been established. On the other issues, unlike France, the FPAP concentrates its arguments not on the nature of and the conditions for granting the aid, but on the Fund's articles of association and its activities.

- (43) The main arguments put forward by the FPAP to dispute the claim that the advances granted by France constitute State aid and are incompatible with the common market may be summarised as follows:

— the FPAP is not an ordinary economic operator, because it is a trade association acting exclusively in the interest of its members with no profit motive and set up as a 'prevention group'. Thus, when it organises the pooling of risks with a compensation system based on a reference price, it is not acting as an ordinary commercial operator, 'but as a union of consumers of petroleum products seeking more to protect themselves against the market that to operate on it'. Initially it was designed to be self-sufficient in theory since it was envisaged that contributions paid in but not used could be reimbursed.

The FPAP also points to the total transparency of its management: in this respect, since it does not carry out any economic activity for its own account, it cannot have any impact on the relevant futures market. The FPAP also points out that a joint audit is carried out by the Inspectorate-General for Finance and the Inspectorate-General for Agriculture and Fisheries,

— the FPAP does not act on a relevant market, because the market in fishery products is exposed to numerous other distortions of competition resulting from the various national policies for implementing the common fisheries policy. The market must therefore be seen as a 'mosaic of regional micro-markets'. This intervention therefore does not affect trade conditions. The FPAP also points out that the assessment of competition must be seen in context because a major part of the increase in and distortion of the costs affecting the fishing industry is due to 'tolls' or 'penalties' resulting in particular from Community measures, which is far from the image of a large, open market.

- (44) In fact, the FPAP's intervention is aimed at facilitating the maintenance of fishing within a regional framework and preventing deep-sea vessels from falling back on closer grounds or trawlers from targeting more specific and less energy-consuming fisheries. Its aim is to protect resources, maintain balance and safeguard the diversity of the system by means of a phase of adaptation. In this way, the FPAP anticipated the recovery and restructuring plans and the planned raising of the ceiling for *de minimis* aid. For these reasons, the FPAP puts forward the following arguments:

— it is not accurate to say that the advances granted by the State were without any conditions attaching. On the contrary, they 'were subject to the condition that there was immediate transparent management [and] above all that a sustainable policy was laid down which was subject to general inspection',

— just above one third of its intervention (EUR 25 million out of EUR 65 million) related directly to advances to employees and can be regarded as direct social assistance,

— the aid is the result of an extraordinary situation since the Commission itself acknowledges the sector's exceptional economic and social difficulties,

— the FPAP points out that it bears civil liability under French law and that its liability is unlimited. For this reason, given the lack of default on repayment, the criterion applied by the Commission to regard this assistance as State aid is insufficient.

- (45) Lastly, together with its comments MQA forwarded copies of two letters from the minister responsible for the budget to the FPAP showing that the FPAP and all its members benefit from tax schemes. In the case of the FPAP these consist of exemption from corporation tax and, probably, business tax and, in the case of fishermen-owners, the possibility of deducting the contributions paid to the trade association from their taxable income.

#### 4. ASSESSMENT

- (46) This Decision does not relate to the tax advantages referred to in recital 45, since the Commission was not aware of them at the time it decided to initiate the formal investigation procedure. Those tax advantages are the subject of a special assessment, under case number NN 38/07, to determine whether they constitute State aid and, if so, whether that aid is compatible with the common market.

- (47) In relation to State aid, the objective of the FPAP has to be considered in two ways:

— firstly, it is aimed at acquiring financial options on the futures markets. Although this is not explicitly stated, those futures markets are obviously the markets for oil or oil by-products. Thus the FPAP, while being constituted as a trade association, operates on these futures markets by acquiring options, as any ordinary private company active on this kind of market and operating according to the rules of the market economy would do. The aid for the acquisition of options on the futures markets is assessed later on in Section 4.1 of this Decision;

— secondly, the FPAP is aimed at paying to its member fisheries undertakings the difference between the average monthly reference price and, according to the agreements of 12 November 2004 and 27 May 2005, the ‘maximum price covered’ or, according to the agreement of 11 October 2005, a price of 30 euro cent per litre if the average monthly price in the reference index is higher than that price. The average

monthly reference price is laid down by the FPAP. The compensation paid by the FPAP to the fisheries undertakings for the purchase of fuel is analysed later on in Section 4.2 of this Decision.

#### 4.1. Aid for the FPAP: aid for the acquisition of options on the futures markets

##### 4.1.1. Existence of State aid

##### 4.1.1.1. The FPAP is an undertaking within the meaning of Article 87 of the EC Treaty

- (48) It is essential in the first place to establish whether the FPAP can be regarded as an undertaking. If that is not the case, Article 87(1) does not apply to the FPAP. On this question, the Commission points out that, as has been consistently held in case law, in the context of competition law the concept of an ‘undertaking’ covers any entity engaged in an economic activity, regardless of the legal status of the entity or the way in which it is financed<sup>(4)</sup>. Any activity consisting in offering goods and services on a given market is an economic activity<sup>(5)</sup>.

- (49) Companies active on the futures markets for raw material products are usually private companies functioning according to the rules of the market economy. The aim of operations carried out on these futures markets is, for the operator, to bet on the expectation that the purchase price of the product, if it is acquired in the future at the normal market price, will be different from the price at which the option is subscribed. Thus, an operator active on such a market takes a risk because of the uncertainty of price changes. In the case in point, the FPAP actually acted as an operator on the futures markets for petroleum products. By doing this, it is also an economic operator in the fisheries sector, since it provides the Cecomer company, a founding member and administrator of the FPAP and the central contracting agency for maritime cooperatives, with fuel at a price different from that which that company would buy at the normal market price. If the operation to acquire options, which is an operation of a speculative nature, is successful, the price of the fuel resold to the cooperatives is lower than the market rate. The FPAP thus takes a risk, hoping that it will be able to draw financial advantage from it. The maritime cooperatives, for their part, then sell on their fuel to the fisheries undertakings at a price depending on the price at which they were able to acquire it from Cecomer. The

<sup>(4)</sup> Judgment of the Court of Justice in Joined Cases C-159/91 and C-160/91 *AGF-Cancava* [1993] ECR I-637.

<sup>(5)</sup> Judgment of the Court of Justice in Case C-222/04 *Cassa di Risparmio* [2006] ECR I-289.

characteristics of the operations for transferring ownership of the fuel acquired by the FPAP to Cecomer, the retail traders' cooperative society, are not known. However, and although Cecomer is a founding member of the FPAP, this involves operations carried out between two independent entities. These fuel ownership transfer operations are of a contractual nature. This is because, although they probably display specific characteristics, the agreements under which these operations are carried out are nonetheless private-law agreements and consequently private-law contracts. The FPAP's activity, thus consisting of intervention on the futures markets for petroleum products in order to buy those products with a view to selling them on to Cecomer, a commercial company, is evidently an activity of an economic nature. Also, in its Decision to initiate the procedure, the Commission observed that: 'The purpose of the FPAP is to enable the acquisition of financial options on the futures markets. Although this is not explicitly stated, those futures markets are obviously the markets for oil or oil by-products. Thus the FPAP, while being constituted as a trade association, operates on these futures markets by buying and selling options, as any ordinary private company active on this kind of market and operating according to the rules of the market economy would do'. In their replies, France and the FPAP did not dispute the fact that the FPAP undertook such operations of buying and selling options. France does not make any comments on this. As regards the FPAP, it merely points out that 'the FPAP operated on the world commodities market with specialised brokers or financial institutions. It is difficult to imagine a more competitive, more extensive or more volatile market. Consequently, the Fund did not enjoy any tariff advantage, nor any special conditions vis-à-vis all the other operators on the market.... The question therefore comes down to the source of the funds advanced...'. It therefore does not question the Commission's claim that it acts as an ordinary operator on these futures markets. It should also be noted that the function of the FPAP is by no means that of a public fund administrator acting in the public interest. Neither can it be regarded as an instance of the exercise of public power prerogatives by the State or by a body under its responsibility.

- (50) Therefore the FPAP must clearly be regarded as an undertaking within the meaning of Community competition law. There is no need to study its characteristics or articles of association. In particular, the fact that it may be non-profit-making is of no relevance. Also, even if were regarded, to use the FPAP's own terms, as a 'union of consumers of petroleum products seeking more to protect themselves against the market that to operate on it', these 'consumers' are in fact economic operators (maritime cooperatives and fisheries undertakings) seeking to reduce their running costs. However, this reaction, which is perfectly logical on the part of economic operators, means that the operators cannot be regarded as individual consumers within the meaning of Article 87(2)(a) of the Treaty, which authorises aid of a social character granted to them.

Therefore, the arguments put forward by France or the FPAP itself relating to its articles of association, its rules of procedure, its objectives or its specific situation on the petroleum products market cannot be accepted.

#### 4.1.1.2. The private creditor principle <sup>(6)</sup>

- (51) The Commission takes the view that, in this case, it is justified to assess the existence of State aid by applying the private creditor principle.
- (52) The funds coming from the three advances, for which the grant conditions are known, had to be repaid at an interest rate of 4,45 %. As regards the possible fourth advance, of an amount of EUR 12 million, it may be assumed that it was granted under identical or very similar conditions. This State contribution therefore corresponds in practice to a loan granted at that rate. Admittedly, that rate is higher than the reference rate used by the Commission to determine the element of aid existing in a soft loan, which was 4,43 % in 2004 <sup>(7)</sup> and has been 4,08 % since 1 January 2005 <sup>(8)</sup>. Consequently, in theory, it is possible that there was no State aid in the advances granted if it was granted on normal market-economy terms.
- (53) However, the Commission takes the view that the advances were not granted on normal market-economy terms insofar as no private creditor would have agreed to grant the amounts in question in the absence of a guarantee of the viability of the FPAP's activity and the probability of recovery by the expiry date.
- (54) The FPAP's start-up capital is made up of its members' contributions (see recitals 23 and 25). Neither France nor the FPAP have provided figures of the resources obtained from these contributions. Also, according to the list of defensive points enclosed with the reply of 21 April 2006, after stating that 'when the reply of 6 December 2005 was being drafted, this information was proposed in the draft but was deleted during the interministerial check', the French authorities take the view that 'it is not necessary to give a reply now'.

<sup>(6)</sup> Judgment of the Court of Justice in Case C-342/96 *Spain v Commission* [1999] ECR I-2459; judgment of the Court of Justice in Case C-256/97 *DMTransports* [1999] ECR I-3913; judgment of the Court of First Instance in Case T-152/99 *Andrés Molina* [2002] ECR II-3049.

<sup>(7)</sup> OJ C 307, 17.12.2003, p. 11.

<sup>(8)</sup> OJ C 220, 8.9.2005, p. 2.

- (55) Nevertheless the Commission supposes that these are relatively modest amounts compared to the probable extent of the expenditure, since, on the basis of the information given in the statement signed by the Secretary-General of the FPAP, the 'Detailed Rules of Procedure of the FPAP' of November 2004 and the 'information note from the FPAP' of January 2006, a rough estimate can be made: approximately 2 500 members (the number of members of the FPAP according to the French authorities) pay a membership fee of EUR 150 each, i.e. EUR 375 000, to which the contributions covering the guarantee risk proper (see recital 25) must be added. Assuming that the entire volume of diesel consumed is covered, and based on the indicative consumption of a 24-metre trawler as reported by the FPAP (approximately 10 tonnes of fuel per week), and assuming activity for a maximum of 48 weeks a year, i.e. a consumption of 480 tonnes (although the number of weeks of activity is probably closer to 38 to 40 than 48), and the unit value of the contribution to the FPAP, i.e. EUR 0,0035 per litre, the figure arrived at for 2 500 vessels is a total of EUR 4 200 000 per year. The third source of contributions comes from the possibility, as provided for in the articles of association, for the association to take in 'any person willing to provide moral support for the trade association', up to a maximum of 5 % of the number of members. This is probably a marginal amount. In the absence of any indication of the number of such members willing to provide moral support and the amount that they contribute, we will assume, as a very generous estimate, additional revenue of about EUR 125 000 (125 members whose activities do not relate to fishing, i.e. the maximum permitted by the FPAP's articles of association (5 % of 2 500 members) × EUR 1 000).
- (56) Thus the total revenue from the various contributions would amount to EUR 4 200 000 + EUR 375 000 + EUR 125 000, i.e. EUR 4 700 000 per year. This is an extremely optimistic assumption, calculated on the basis of an indicative consumption of a 24-metre trawler operating for 48 weeks a year, and on the assumption that all the fuel consumed is covered. The Commission is only taking it to find out what the theoretical maximum amount of revenue for the FPAP could be. However, if we consider that France indicates that the number of member vessels is 2 385, including a considerable proportion of coastal vessels of less than 12 metres, whose annual fuel consumption is closer to 200 tonnes than the 480 tonnes used in the above calculation, it is probable that the actual amount is significantly less. This is because, since the French fleet comprises approximately 1 500 vessels of more than 12 metres and 95,3 % of the vessels of that size are covered by the FPAP<sup>(9)</sup>, i.e. approximately 1 400 vessels, it can be deduced that
- approximately 1 000 vessels of less than 12 metres are also covered by the FPAP. It is therefore highly certain that the total annual revenue is below this amount of EUR 4,7 million.
- (57) Following calculation of this hypothetical revenue, the Commission observes that the FPAP, on the one hand, apparently has no real estate and that, in addition, its current assets, made up only of its members' contributions, are very small. For this reason, the Commission takes the view that, under normal market-economy conditions, a bank, such as *Crédit Maritime*, for example, which describes itself in its own terms as 'the natural partner of the fishing industry', would never have lent (or 'advanced' to use the terms of the agreements concluded between the State and the FPAP) the amounts in question (or even only part of the amounts) to the FPAP to operate on a futures market, without having obtained reasonable assurance beforehand of its probable solvency on expiry of the loan.
- (58) France objects, claiming that this conclusion is 'an allegation not based on any precise survey of banking organisations, and that a system of securities could have been set up'. However, a survey carried out by the *Chambre nationale des conseils et experts financiers* (National chamber of financial advisers and experts)<sup>(10)</sup> at thirty-five banks provides a fairly accurate picture of the standards applied in French financial institutions when granting loans to their customers. To limit their credit risk vis-à-vis their customers, the management of financial institutions requires compliance with standard ceilings based on a number of ratios allowing the financial health of the undertaking and its ability to serve its debt to be assessed, according to various criteria such as its own funds, balance sheet, the level of long-term indebtedness, turnover and financial costs. It follows from this analysis in particular that a ratio of 'total banking debt to own funds' higher than 2,50 triggers a risk indicator which, although it does not totally compromise the granting of a loan

<sup>(9)</sup> Contrary to what appeared in the Decision initiating the formal investigation procedure, vessels in this category (more than 12 metres) do not account for 95,3 % of FPAP member vessels. In fact they account for 95,3 % of the vessels in this category which are covered by the FPAP.

<sup>(10)</sup> N. Coulon: The new business bank debt ratios, *BANQUE* No 511, December 1990, quoted by Alain Galesnes in '*Le diagnostic bancaire de l'entreprise* (Business banking diagnostics)' in *Editions du Centre d'Etudes et de Recherches Financières appliquées (CEREFIA)*, Rennes, 1994/2004.

leads the establishment to take increased securities. In the case of the FPAP, if the EUR 65 million in advances are set against the optimistic estimate of its own funds set out above (EUR 4,7 million, see recital 56), the ratio is 13,82, i.e. almost six times the maximum risk. Of course, if the actual amount of the advances were higher (EUR 77 million, taking into account the possible additional advance of EUR 12 million referred to in recital 22), or if the actual amount of own funds were appreciably smaller, this hypothetical ratio would increase further. With such a risk level, a bank would never have considered granting a loan, even though the use of real securities (such as pledging the purchase options or the fuel stocks acquired by the FPAP as collateral) or personal securities (taking out a mortgage on the members' personal assets and pledging their vessels as collateral) is in fact one of the methods used by banks to minimise the risk of insolvency. However, it will be observed that, if the personal securities of the members were liable to be claimed, the fisheries undertakings would probably have been more reluctant to become members of the FPAP. There are also other client risk transfer or sharing methods, such as part-financing the loan by several banks, the use of guarantee companies or subscribing to regional or departmental guarantee funds (as a rule themselves counter-guaranteed by guarantee companies) but, in all cases, a guarantee is generally extended only to basically healthy and potentially profitable undertakings, and only ever up to an amount not exceeding 50 % of the debt (i.e. in the case of the FPAP, an amount of slightly more than EUR 30 million, leaving a residual risk of almost three times the maximum risk).

(59) When France comments on these methods, saying that security systems 'could have been' set up, it implicitly admits that they were not set up in this case and that the State advance was granted without securities comparable to those in use by banks being sought. Under these circumstances, the Commission concludes that France did not behave like a private creditor and that it did not have any security that the FPAP was in a position to repay the funds placed at its disposal.

(60) In addition, the FPAP, through its Board, points out that it bears civil liability under French law and that this liability is unlimited, noting that trade association action may entail responsibility for large amounts. The Commission admits that very large amounts may be at stake, with an organisation like the FPAP where the operations undertaken on the futures markets present

undeniable risks and may involve significant losses. That being so, there is nothing to say that the FPAP's liability in the event of significant losses will be covered by its members. None of the documents provided (articles of association, rules of procedure or information note) refers to such a mechanism. The only financial consideration appearing in these documents relates to the contribution, for which it is indicated that it is forfeited to the trade association when a member steps down (Article 10). The Commission also observes that the act of 21 March 1884, under which the FPAP was set up, is the act which has allowed the creation of trade associations in France. It is certainly not in the spirit of such an act to entail the commercial, and therefore financial, liability of the members of the trade association concerned. As a result, in the event of major financial losses, the Commission does not see how the losses can be compensated by its members.

(61) Taking all of the above factors into account, the Commission takes the view that the private creditor principle has not been complied with.

#### 4.1.1.3. Existence of a financial advantage granted by means of State resources

(62) The Commission takes the view that, even in the case of the higher assumption, the estimated amount of revenue from the various member contributions would never have enabled the FPAP to operate on a futures market without the assistance of external funding. This external funding was provided by the State, via Ofimer, in the form of at least three advances spread out between November 2004 and October 2005, covering a total amount, according to the information forwarded by France, of EUR 65 million. A fourth advance of EUR 12 million was probably also paid, since the list of defensive points quoted in recital 22 implies that the agreement was in the course of being signed at that date.

(63) France has not submitted any evidence contradicting this assessment. The list of defensive points also states: 'As regards its funding, the FPAP is considered [by the Commission] not to be able to operate without the repayable State advance. No argument can be put forward against this'. In addition, for the Commission, the advances were granted under conditions which are not normal market conditions (see recitals 51 to 61 of this Decision).

- (64) Also, the Commission observes that neither France nor the FPAP have given it any indication of the amount of funds invested by the FPAP on the futures markets, or of the result of the transactions carried out on them. Again, according to the list of defensive points, the French authorities deliberately chose not to submit this information, since it states that '... this information could be provided to the Commission. However, the advisability of providing such information now must be gauged'. The Commission notes that it did not receive such information, neither in that letter nor at a later date.
- (65) Lastly, France and the FPAP and its Board take the view that the Commission cannot prejudge the existence of State aid as long as no repayment default has been established (France: 'the repayable advance cannot be regarded as State aid as long as the repayment deadline has not fallen'; FPAP: 'Can this amount be repaid or not? That is the main question being asked by the Commission'; MQA: 'None of the loans to the FPAP granted by France has expired. At this stage there is no repayment default nor any indication by the French government suggesting that the debt will be purely and simply cancelled on expiry'). The Commission would point out in this respect that regarding the aid to the FPAP as State aid is first and foremost the result of the French Decision to grant a loan to the FPAP that it would not otherwise have obtained, even if the repayment deadlines had been met. The Commission questions the solvency of the FPAP on expiry of the loan because this question is at the core of the assessment of its situation in relation to the normal conditions for granting a loan by a private bank and not because it suspects that a loan has been transferred into straightforward financial assistance.
- (66) From this point of view, if it turned out that advances were not repaid within the time limits, or not repaid at all, this would confirm both that the FPAP was not in a position to perform the tasks provided for in its articles of association without external loans, and that it would never have been granted such assistance by a bank under normal market conditions. However, in this connection the Commission observes that France has not informed it of any repayment of advances granted to the FPAP. They had to be repaid on 1 November 2006 in the case of the advance of EUR 15 million covered by the agreement of 12 November 2004, 1 May 2007 in the case of the advance of EUR 10 million covered by the agreement of 27 May 2005 and on 1 July 2007 in the case of the advance of EUR 40 million covered by the agreement of 11 October 2005 (see recital 21). Regarding the fourth advance which the FPAP may have received (see recital 22), neither the date of the agreement nor the final repayment date are known.
- (67) The three known expiry dates have now passed. The first had even already passed when France sent its last letter to the Commission on 27 November 2006, after the Decision to initiate the formal investigation procedure. The Commission takes the view that, if this advance had actually been repaid, France or the FPAP itself would have informed the Commission without delay since one of the arguments put forward to counter the Commission's assessment was that these advances could not be regarded as State aid as long as the repayment deadline had not fallen. There is no doubt that, if the first advance had been repaid, France would have informed the Commission of this in its letter of 27 November 2006 and would then have done the same for the second and third advances, which had to be repaid by 1 May and 1 July 2007, and for the possible fourth advance. What is more, the reports published in the trade press suggest that there has been no repayment up to now. Thus, the Commission takes the view that the aid initially granted in the form of an advance was transformed into aid in the form of a direct subsidy.
- (68) Consequently, for all the reasons set out above, the Commission considers that the State advances represent a financial advantage granted by means of State financial resources.
- 4.1.1.4. Existence of a financial advantage imputable to the State
- (69) The Commission observes that the three agreements concluded between the State and the FPAP expressly stipulate that the purpose of the public funds paid is the creation of a cover mechanism against fluctuations in international oil prices and that the mechanism will enable financial options to be acquired on the futures markets. However, it is obvious that the FPAP's initial liquid assets, which were supplied only by its members' contributions, could not have enabled it to undertake such operations, at least not on the scale to which they were. This is because the first agreement, dated 12 November 2004, indicates that the purpose of the advance of EUR 15 million was to 'enable the

mechanism to be started'. Therefore it was indeed thanks to these advances that the FPAP was in a position to undertake significant acquisition operations on the futures markets.

(70) In other words, it appears that the State actively supported the creation of the FPAP, constituted as a trade association, and its involvement on the futures markets for petroleum products, although such an activity does not reflect the normal activity of a trade association, and that that activity was conducted in competition with private operators under competition conditions which are not normal. Also, France recognised, as early as 7 October 2005, that 'the government has encouraged an initiative by the trade, i.e. the creation of a fund for the prevention of risks to fishing. This fund, managed by the trade, enables fishermen (...) to pool their financial capacity to buy financial options on the futures market to cover themselves against the risk of fluctuations in the price of fuel', while omitting to state that the fishermen's 'financial capacity' referred to was based on State resources, since two advances had already been paid by that date. However, there is no doubt that the FPAP had to take account of the requirements of the public authorities in deciding how to use the funds placed at its disposal. From this point of view, the introduction of an interministerial inspection with the remit of 'auditing the FPAP mechanism in its current operation and checking that the conditions for expenditure are satisfactory as regards public-expenditure law and rules, while complying with the commitments entered into by the managers of the funding' demonstrates the State's concern to ensure that the FPAP's funds were in fact used for the purpose laid down in the agreements.

(71) Consequently, taking all of the above factors into account, the Commission takes the view that the financial advantage represented by the advances granted to the FPAP for the acquisition of financial options on the oil futures markets is imputable to the State<sup>(1)</sup>.

#### 4.1.1.5. Existence of a financial advantage which distorts or threatens to distort competition

(72) The FPAP enjoys a financial advantage compared to the other companies operating on the futures markets, whether they are companies customarily active on these markets or companies which are or may be set up in the same way as the FPAP, in the form of a trade association in the other Member States or even in France itself.

(73) France argues that 'the FPAP cannot be regarded as receiving preferential treatment over other private organisations which could have played the same role because it is the only French professional organisation aimed at bringing together fisheries undertakings to buy options on the futures market'. In reply, the Commission observes that the FPAP's position as regards competition rules should not be assessed solely vis-à-vis other French organisations made up of fisheries undertakings and playing the same role as it, but vis-à-vis all French and European operators that may be active on the futures market for petroleum products.

(74) In addition, the FPAP disputes the claim that it enjoyed preferential conditions for carrying out its activity as investor on the futures market — in its own words: 'the FPAP operated on the world commodities market with specialised brokers or financial institutions (...) [It] did not enjoy any tariff advantage, nor any special conditions vis-à-vis all the other operators on the market'. The Commission does not claim that the FPAP's financial advantage arose from preferential treatment of the FPAP by the other actors of the market, but that the Fund could only operate on this market because it had a financial intervention margin granted by the State going beyond the FPAP's own financial capacity, while the State did not grant it under conditions similar to other companies which may have had the same interest as the FPAP in operating on this market (undertakings in other sectors affected by the rise in the cost of oil, for example) or which operate on this market for reasons linked to their economic or commercial strategies (oil companies, for example).

<sup>(1)</sup> Judgment of the Court of Justice in Case C-482/99 *France v Commission* [2002] ECR I-4397, in particular paragraphs 53 to 56.

(75) Also, the FPAP recognises the existence of this advantage. In a document from the Confédération de la Coopération Maritime, not forwarded to the Commission but published on the website of the 'Assises de la pêche et de l'aquaculture de la Région Bretagne' <sup>(12)</sup>, Mr de Feuarent, summarising the main points discussed at a meeting with the Region of Brittany on 24 May 2006, writes: 'The State has granted assistance of EUR 65 million to date. Also, the FPAP has made a profit of several million euro on options on the commodities market, which is an undeniable value added'. The Commission concludes from this that the FPAP was only able to acquire financial options on the petroleum products market thanks to the public funds at its disposal but not at the disposal of other organisations or undertakings, and that it drew direct benefit from that. Consequently, the advantage which it enjoyed distorts or threatens to distort competition.

#### 4.1.1.6. Existence of a financial advantage affecting trade between Member States

(76) In having operated on the commodities market, as Mr de Feuarent indicates, the FPAP operated on the world oil market.

(77) Its activity therefore went beyond a strictly French framework, so that the advances granted must indeed be considered as affecting trade between Member States.

#### 4.1.1.7. Conclusion

(78) Thus, the four requirements for establishing the existence of State aid are met: the advances paid to the FPAP come from State resources, they are imputable to the State, they distort or threaten to distort competition, and they affect trade between Member States. The aid enjoyed by the FPAP therefore does constitute State aid within the meaning of Article 87 of the EC Treaty as regards the part of its funding coming from State resources used for the acquisition of options on the petroleum product futures market.

#### 4.1.2. Compatibility with the common market

(79) As the agreements concluded between the State and the FPAP indicate, this State aid in the form of advances was aimed at enabling the FPAP to begin operating on the futures markets for oil and oil by-products and continue doing so. It is therefore operating aid for the FPAP. In its letter of 6 December 2005, France also recognises that the amounts indicated were advanced 'in order to ensure the operation of the FPAP'.

(80) Under Article 87(2) and (3) of the Treaty, certain categories of aid are or may be considered compatible with the common market. It should be examined whether the operating aid for the FPAP falls under one of these categories.

(81) The Commission observes that this aid does not match any of the cases provided for in Article 87(2).

(82) This is because it is not intended to make good damage caused by natural disasters or other exceptional occurrences. The Commission would point out in this connection that fluctuations in oil prices are inherent in economic activity. Fluctuations also affect other sectors of activity which consume petroleum products in all the Member States of the European Union and cannot be regarded as a natural disaster or an exceptional occurrence within the meaning of Article 87 of the Treaty. The aid is therefore not compatible with the common market under Article 87(2)(b) of the Treaty.

(83) Nor can the aid be considered compatible with the common market on the basis of direct application of Article 87(3) of the Treaty, with the various cases provided for.

(a) It is obviously not aid to promote the economic development of areas where the standard of living is abnormally low or where there is serious under-employment (the case provided for in Article 87(3)(a)). The aid is in fact intended to enable the FPAP to operate on the relevant futures markets. It is therefore not related to the aid referred to in Article 87(3)(a).

<sup>(12)</sup> <http://pecheaquaculture.region-bretagne.fr>

- (b) The FPAP cannot be regarded as an important project of European interest or aid to remedy a serious disturbance in the economy of a Member State (the cases provided for in Article 87(3)(b)). This is because the FPAP is specifically French and the other Member States did not express their intention to set up funds of the same kind. Therefore there is no European dimension to the Fund. As regards the consideration as to whether the aid is intended to remedy a serious disturbance in the economy of a Member State, the Commission observes that there is no evidence making it possible to say that providing money for a fund of this kind could bring about such a remedy. As regards the aid for the FPAP itself, the aid benefits only one economic entity and, even if it is linked to aid granted to fisheries undertakings, does not benefit the economy of a Member State as a whole. In addition, the Commission would point out that it has always taken the view that the public authorities should not intervene financially against the rise in the price of oil. On the contrary their role should be, in particular, pursuing incentive policies for undertakings so that they adapt to the new economic conditions created by the price increase. That is why aid aimed at making it possible for an economic entity to operate on the relevant futures markets does not match the desired objective.
- (c) The existence of the FPAP cannot, in itself, meet the requirements of Article 87(3)(c), which stipulates that aid intended to facilitate the development of certain economic activities or of certain economic regions may be compatible with the common market where it does not adversely affect trading conditions to an extent that is contrary to the common interest. There is no evidence that the development of or increase in operating on the oil futures markets is desirable. Moreover, that activity is not linked to an economic region. That is why the aid cannot be considered compatible with the common market under Article 87(3)(c).
- (d) Lastly, this kind of aid does not fall under the categories of aid which may be considered compatible with the common market by a Decision of the Council adopted in accordance with Article 87(3)(e).
- (84) The Commission also notes that none of the guidelines that it has adopted for assessing State aid applies to this operating aid for the FPAP.
- (85) In conclusion, therefore, the result is that the aid for the FPAP for the acquisition of options on the futures markets cannot be considered compatible with the common market under any of the exemptions permitted by the Treaty.
- #### 4.2. Aid for fisheries undertakings: reduction of expenditure on fuel
- (86) Before analysing the aid which led to the formal initiation of the investigation procedure, the Commission must give an opinion on the FPAP's argument that the aid granted to itself and fisheries undertakings should be considered in the light of a raising of the *de minimis* threshold in the fisheries sector. According to the FPAP, the amounts in question (approximately EUR 16 000 per undertaking on average, excluding the aid which it regards as being direct social assistance for fishermen) is considerably lower than those which were in the process of being adopted at the time of payment of the compensation by the FPAP (EUR 30 000 per undertaking)<sup>(13)</sup>. In their reply the French authorities also refer to the raising of the *de minimis* threshold but do not seek to apply it to this aid scheme.
- (87) First of all, the Commission points out that, under Article 3 of Commission Regulation (EC) No 1860/2004 of 6 October 2004 on the application of Articles 87 and 88 of the EC Treaty to *de minimis* aid in the agriculture and fisheries sectors<sup>(14)</sup>, i.e. the provision in force at the time the aid was granted to fisheries undertakings, the maximum amount of *de minimis* aid was EUR 3 000 per undertaking over three years. The aid under consideration in this Decision considerably exceeds that amount and in its comments France did not mention any application of this ceiling to the undertakings which could have benefited from it. Moreover, even if the amount of EUR 30 000, which appears in Regulation (EC) No 875/2007 recently adopted by the Commission<sup>(15)</sup>, is higher than the EUR 16 000 referred to above by the FPAP, that amount is only an average. In addition, France is wrong to arrive at this amount of EUR 16 000, since it excludes the part of the aid which it regards as social assistance and which has to be taken into account in the assessment (see recitals 122 and 123). Thus, given the differences in size of the FPAP's member fisheries undertakings, it is certain that the amount of the aid granted to some undertakings is greater than EUR 30 000. For
- <sup>(13)</sup> This is the threshold ultimately laid down in Commission Regulation (EC) No 875/2007 (see footnote 14).
- <sup>(14)</sup> OJ L 325, 28.10.2004, p. 4.
- <sup>(15)</sup> See footnote 14.

example, for trawlers from 20 to 25 metres, the annual amount of the allowance is around EUR 35 000, i.e. EUR 70 000 for the two years 2005 and 2006<sup>(16)</sup>. In any event, as indicated above, France did not seek application of the new *de minimis* ceiling and did not provide any evidence that it did so. Consequently, taking all of the above factors into account, in the context of the constant review of State aid schemes the Commission is obliged to verify compliance of this aid with the provisions of Article 87 of the Treaty.

#### 4.2.1. Existence of State aid

- (88) France takes the view that the Commission has no valid reason to extend its assessment of the existence of State aid to this aspect of the Fund's activities. According to France, 'recognition of aid as State aid must be based solely on an *ad hoc* assessment of the repayable State advance and not on an assessment of the FPAP's activities. Thus the French authorities request that only the first part (Part 3.1) of the assessment be developed. Part 3.2 amounts to a condemnation of the activities of the FPAP, which is a trade association purchasing options to cover its members against fluctuations in the price of diesel'<sup>(17)</sup>.
- (89) In reply, the Commission points out that, as has been consistently held in case law, aid is not characterised by its causes or objectives, but is defined according to its effects<sup>(18)</sup>. In addition to acquiring financial options on the futures markets, the aim of the FPAP, according to the agreements concluded with the State, is to pay compensation to fisheries undertakings corresponding to the difference in price between the maximum price covered and the average monthly price in the reference index for the month under consideration. Consequently, the Commission takes the view that the fisheries undertakings enjoyed specific advantages as a result of the system set up by the FPAP and that it is necessary to analyse the effects of the advances granted by the State not only from the point of view of the advantage granted to the FPAP, but also from the point of view of the advantages granted to the fisheries undertakings.

<sup>(16)</sup> Source: *Observatoire économique régional des pêches de Bretagne. 'Résultats des flottilles artisanales 2005/2006'* (Regional economic observatory of fisheries in Brittany, 'Results for craft fleets 2005/2006'), Summary.

<sup>(17)</sup> The references to Parts 3.1 and 3.2 refer to the Decision initiating the formal investigation procedure mentioned in recital 11. Part 3.1 dealt with the aid for the acquisition of options on the futures markets and the resultant financial advantages for the FPAP and the fisheries undertakings; Part 3.2 dealt with the compensation for the purchase of fuel for those undertakings.

<sup>(18)</sup> In particular: judgments of the Court of Justice in Case 173/73 *Italy v Commission* [1974] ECR 709; in Case C-241/94 *France v Commission* (known as 'Kimberly Clark') [1996] ECR I-4551; in Case C-480/98 *Spain v Commission* [2000] ECR I-8717; and in Case C-5/01 *Belgium v Commission* [2002] ECR I-11991.

#### 4.2.1.1. Existence of a financial advantage granted through State resources

- (90) The advantage drawn by fisheries undertakings from the FPAP's activities is two-fold: on the one hand it consists of the possibility of obtaining fuel at an advantageous price, and on the other of receipt of an allowance partially compensating for their expenditure on fuel.
- (91) As regards the first aspect, the acquisition of options on the futures markets by the FPAP, which then passed on the forward-bought fuel to the Cecomer company, the maritime cooperatives' central contracting agency, enabled the FPAP's member undertakings to buy fuel acquired by those cooperatives at a price lower than that on the ordinary market. But, as indicated above (see recital 75 of this Decision), this was possible only because 'The State has granted assistance of EUR 65 million to date. Also, the FPAP has made a profit of several million euro on options on the commodities market, which is an undeniable value added'. The Commission therefore notes that the supply of fuel to fisheries undertakings at a price lower than that on the ordinary market was possible due to the advances granted by the State and the FPAP's own resources, i.e. the product of its members' contributions and the profits from speculative operations on the futures market for petroleum products.
- (92) The funds used to finance the compensation paid to fisheries undertakings also came from two sources (State resources and resources from the FPAP's private activity).
- (93) As described in recital 24 of this Decision, the FPAP bears the difference in price that exists, under the agreements of 12 November 2004 and 27 May 2005, between the 'maximum price covered' and the average monthly price in the reference index and, under the agreement of 11 October 2005, between 30 euro cent per litre and the average monthly reference price if the latter is higher than 30 euro cent.

- (94) The 'evening-out' mechanism provided for was originally based on the assumption that the additional costs exceeding a reference price in times of high prices could be compensated by means of the contributions paid by the members in times of lower prices. Thus the system would be self-financing. Referring to Mr de Feuardent's document already mentioned in recital 75 of this Decision, 'technically the FPAP was able to take the first options from April 2004 onwards; at that time, Cecomer's requirements (approximately 200 million litres) for 2005 could be met at 0,28 cent/litre, i.e. approximately EUR 4 million'. Thus, at the beginning of 2004 the FPAP could perhaps have covered the relatively modest needs of the 'diesel insurance' out of its own resources. It therefore appears that, as it was originally designed, the Fund could have been self-sufficient.
- (95) However, since oil prices stayed at a very high level and the FPAP's membership expanded, it rapidly acquired a large number of members. The result was that the cost of this 'diesel insurance' exploded and could only be supported by using the advances granted to the FPAP by the State.
- (96) If we attempt to estimate the appropriations necessary for the FPAP to cover the expenditure on 'diesel insurance' for 2005, we can start from the assumption that the level of fuel consumption for which compensation was claimed by the fisheries undertakings probably increased from 200 million litres (see recital 94) to a volume that can be estimated at almost 900 million litres. This is because, if we take the averages for annual consumption which served as the basis for the calculations in recitals 55 and 56, the consumption of 1 000 vessels of less than 12 metres would be 1 000 vessels × 200 tonnes/vessel, i.e. 200 000 tonnes, and the consumption of vessels of more than 12 metres would be 1 400 vessels × 480 tonnes/vessel, i.e. 672 000 tonnes, which is in total 872 000 tonnes (or 872 million litres). In reality, as indicated in recital 55, if we consider that vessels fish for 38 weeks a year rather than 48, consumption is probably closer to 700 000 tonnes (1 000 vessels of less than 12 m × 158 tonnes, i.e. 158 000 tonnes and 1 400 vessels of more than 12 m × 380 tonnes, i.e. 532 000 tonnes). Assuming a
- ceiling on compensation of 12 cent per litre, which was applied to the third advance<sup>(19)</sup>, the annual financial requirements of the FPAP were thus about EUR 85 million. Considering the fact that the fisheries undertakings perhaps only insured part of their fuel consumption, the appropriations required were probably less, but the order of magnitude remains at several tens of millions of euro a year, as compared to the initial estimate of EUR 4 million for 2005. It is therefore obvious that the FPAP could not have coped with the cover guaranteed to its members, in exchange for their contributions, without receiving external funding, in this case the advances granted by the State.
- (97) In this context, the FPAP received public funding to meet the needs of this 'diesel insurance', with the proviso that it managed the funds as efficiently as possible. The FPAP's liquid assets are thus composed of funds coming from the members' contributions, the State advances, and the potential profits of its activities on the oil futures markets. The part of the funding coming from the State advances is undeniably State resources. As regards the profits made on the futures markets which enabled the fisheries undertakings to be supplied with less expensive fuel, it was only possible for them to be made thanks to the existence of the State resources, which gave the FPAP the means to undertake financial transactions on the futures markets. In addition, although the exact characteristics of the agreements concluded between the FPAP and Cecomer are not known and cannot be deduced from any of the documents forwarded by France, the Commission supposes that the compensation paid to the member undertakings, consisting of the difference in price, was lower than if Cecomer and the maritime cooperatives had supplied fuel to the fishermen which had been bought on the ordinary market, i.e. without the FPAP's operations on the futures markets. Thus, the profit from the FPAP's operations on the futures markets was transferred to Cecomer, the supply cooperative of the maritime cooperatives, and ultimately to the fisheries undertakings which obtain their fuel from them. The practical effect was certainly that the FPAP could continue paying compensation for a longer period than if the FPAP had only been an intermediate body solely responsible for distributing the EUR 65 (or 77) million provided by the State under cover of the 'diesel insurance' mechanism.

<sup>(19)</sup> See paragraph II of the speech by Mr D. Bussereau, the Minister for Agriculture and Fisheries, delivered on 30 June 2005 at the general meeting of the *Comité national des pêches maritimes et des élevages marins*, which can be found at the following Internet address: [http://agriculture.gouv.fr/IMG/pdf/discours\\_300605\\_ag-cnpm.pdf](http://agriculture.gouv.fr/IMG/pdf/discours_300605_ag-cnpm.pdf).

- (98) The Commission therefore takes the view that it was indeed by means of State resources, irrespective of whether they were fed directly into the FPAP's liquid assets or they were used to make profits further increasing those assets, that the fisheries undertakings were able to enjoy a financial advantage, on the one hand by having the possibility of obtaining supplies of fuel at an advantageous price, and on the other by receiving a compensatory allowance calculated on the basis of a reference price.

#### 4.2.1.2. Existence of a financial advantage imputable to the State

- (99) The three, or possibly four, agreements concluded between the State and the FPAP provide that the ultimate purpose of the public funds paid in the form of advances is to partially compensate fisheries undertakings for the cost of fuel. The compensation paid to the fishermen in the form of an allowance equivalent to the difference between a reference price and a price at the pump comes in addition to a reduction in the price of diesel at the pump of the supplier, who is, as a rule, the maritime cooperative.

- (100) The FPAP's liquid assets, originally made up of its members' contributions then supplemented by an initial advance by the State, enabled it to operate on the futures markets and make profits, although those profits were not sufficient to enable it to simultaneously pay the compensatory allowance guaranteed to the fisheries undertakings in return for their contributions. However, two, or possibly three, additional advances enabled it to continue its activities before it gradually had to reduce its holdings in order to have the liquidity required to pay the allowances. The Commission observes that the Decisions on the operations on the futures markets were taken by the President of the FPAP. They were actually implemented by commissioning brokers and specialised financial institutions (see recital 74), and the amount of remuneration paid to them by the FPAP is not known to the Commission. However, although the FPAP's articles of association provide that the President must consult the Board of Directors 'to decide on proposed cover plans', the State is not represented on that Board. Thus, although the FPAP was generally required 'to keep accounts so that, on request, information on how the advances have been used and the

Fund's resources and expenditure have been allocated can be obtained', the State did not have any part in the Decision on the strategy to be followed by the FPAP for acquiring these financial options or on the level of the financial compensation to be paid to the undertakings. Consequently, although, as was demonstrated in paragraph 4.1.1.4, there is no doubt that the aid consisting of the granting of the three, or possibly four, advances is imputable to the State, that is not the case for the additional advantages enjoyed by the fisheries undertakings resulting, on the one hand, from their contributions and, on the other, from the prudent management of the FPAP's liquid assets as a whole. This is because, although the aid ultimately paid to the fishermen was higher than the public funds originally received by the FPAP thanks to the operations undertaken on the futures markets, the part of the aid exceeding the amount of the public funding advanced did not result from a State Decision. Thus, even if it is not possible, from an accounting point of view, to identify precisely what came from State resources and what came from the Fund's own resources, since it was the liquid assets as a whole which were used to operate on the oil futures markets and pay the compensatory allowance, in the Commission's view the advantage resulting from the difference between the total amount of aid paid to the fisheries undertakings and the total amount of the State advances transferred to the fisheries undertakings is not imputable to the State.

#### 4.2.1.3. Existence of a financial advantage which distorts or threatens to distort competition

- (101) The Commission considers that the reduction in fuel expenditure enjoyed by the FPAP's member fisheries undertakings favours those undertakings because they are the only ones able to benefit from the reduction. Their position is strengthened in relation to other undertakings competing with them on the Community market, irrespective of whether they are other fisheries undertakings or undertakings in other sectors of economic activity with an interest in reducing their running costs as regards fuel expenditure. Moreover, since the cover mechanism is targeted only at fisheries undertakings, the advantage thus granted to those undertakings must be regarded as a sectoral advantage not accessible to other sectors. But, by favouring a particular sector, any form of aid distorts or threatens to distort competition (see Commission Decision 2006/269/EC of 8 February 2006 on tax deductions for professional fishermen (Sweden) <sup>(20)</sup>, recitals 31 and 35).

<sup>(20)</sup> OJ L 99, 7.4.2006, p. 21.

- (102) France objects that this aid did not favour the FPAP's member undertakings insofar as 'membership of the FPAP is free and open to all fisheries undertakings provided that they pay their contribution'. MQA adds that membership is open 'without consideration of the structure or nationality of the recipient'. Lastly, the FPAP points out that 'the FPAP's member undertakings are held by French capital, but also by Spanish and Dutch capital'.
- (103) In reply, the Commission observes that the only fisheries undertakings which may join the FPAP are those which have vessels registered in metropolitan France or the overseas departments. Therefore undertakings with Dutch or Spanish capital holding French vessels may indeed become members of the FPAP. It is certainly those vessels to which France and the FPAP allude in their replies. But other Community vessels may not become members.
- (104) All the undertakings enjoying the compensation paid by the FPAP compete on the Community market with undertakings whose vessels fly the flag of the other Member States and which also have an interest in reducing their running costs as regards fuel expenditure, but which do not have at their disposal any compensation system of the kind set up by the FPAP. For that reason, the advantage enjoyed by the member fisheries undertakings or fisheries undertakings which have not yet become members but which are able to do so, i.e. all the undertakings having fishing vessels flying the French flag, is clearly a distortion of competition.
- (105) The FPAP also takes the view that the factors distorting competition must be sought elsewhere. Referring to the existence of major additional costs which, according to it, are not economically justified, such as costs resulting from the management of the multiannual guidance plans for the fishing fleet, i.e. management of the fleet's overall capacity, or costs relating to management of 'production rights', the FPAP points out in particular that "The "rights" attaching to national "policies" represent (...) the real factor distorting European competition [and] they result mainly from the economic field'.
- (106) In this connection the Commission observes that these costs, whether or not they are higher or lower in France than in the other Member States, are the result of the constraints of the regulatory framework in which fishing is carried out today. In its communication of 26 February 2007 on rights-based management tools in fisheries <sup>(21)</sup>, the Commission points out that the Community fisheries sector is characterised by a multiplicity of management instruments and mechanisms and that comparable situations are treated in sometimes very different ways, depending on the Member State. The result is, in particular, that selling and buying are current practice in some Member States, either within established markets or indirectly. The costs mentioned by the FPAP are the costs with which the fleets of the various Member States are confronted and correspond to the level of economic development of the fisheries sector. They result from the implementation at national level of the management measures which the common fisheries policy lays down or makes necessary. This implementation does not justify the introduction of specific aid in an individual Member State. For that reason, contrary to what the FPAP argues, the distortion of competition must not be assessed within the confines of a 'relevant market', for example a 'regional micro-market', a concept to which it refers, but, as is provided for under the Treaty, within the common market as a whole. Thus, if the effect of the FPAP's aid is to facilitate the maintenance of fishing within a regional framework and protect resources by preventing deep-sea vessels from falling back on closer grounds or trawlers from targeting more specific fisheries, as is argued by the FPAP, it perfectly matches aid which distorts or threatens to distort competition and therefore, in this respect, State aid.
- (107) Also, for all the reasons set out above, the Commission considers that the funds advanced by the State and enjoyed by the fisheries undertakings, via the FPAP, distort or threaten to distort competition.
- 4.2.1.4. Existence of a financial advantage which affects trade between Member States
- (108) The FPAP disputes the fact that the aid granted to the association's member fisheries undertakings affects trade between the Member States. Thus, according to the FPAP, these undertakings carry out their activities in 'a market which is by no means unique, but which is based more on a "mosaic" of regional micro-markets'.

<sup>(21)</sup> COM(2007) 73 final.

- (109) In reply, the Commission notes that the total value of French exports of fishery and aquaculture products to the rest of the world was EUR 1 290 million in 2005, 80 % of which went to the Member States of the European Union. Similarly, the total value of imports of this category of products to France in 2005 was EUR 3 693 million, 40 to 60 % of which, according to sources, came from the Member States of the European Union<sup>(22)</sup>. By comparison, the total value of French production was EUR 1 868 million. Consequently, without going into a detailed quantified economic analysis<sup>(23)</sup>, it is clear that, regardless of the price variations for each species recorded each day in French or European ports, the volume of trade in the supply balance of fishery and aquaculture products between France and the rest of Europe is considerable. Measures aimed at favouring a significant number of French fisheries undertakings (more than 30 % of the fleet) by reducing their running costs necessarily have an impact on trade between Member States in the fisheries sector.
- (110) It is therefore clear that the advantage enjoyed by fisheries undertakings by bearing part of their running costs affects trade between Member States.

#### 4.2.1.5. Conclusion

- (111) The four requirements for establishing the existence of State aid are only partially met. The advantage enjoyed by fisheries undertakings does result from the use of State resources, it distorts or threatens to distort competition and it affects trade between Member States. On the other hand, it is imputable to the State only up to the amount of the advances, since those advances constitute only a part of the FPAP's liquid assets and the State did not intervene in the choices made by the FPAP to make profitable use of the funds placed at its disposal. Thus, the Commission concludes that State aid within the meaning of Article 87 of the EC Treaty exists only to the extent of the public funding provided, i.e. EUR 65 or 77 million.
- (112) Finally, the Commission observes that the French authorities, notwithstanding their replies of 7 October 2005 and 21 April 2006, do not actually dispute the Commission's conclusions on the existence of State aid. This is because, during the examination of the draft finance act for 2007 by the national parliament, the Minister for Agriculture and Fisheries, questioned on the future of the FPAP, replied: 'the FPAP has been operational since 1 November 2004, but the European Commission is monitoring it closely, because it involves State aid'<sup>(24)</sup>.

<sup>(22)</sup> Source: Ofimer, *Les chiffres-clés de la filière pêche et aquaculture en France* (Key figures for fishing and aquaculture in France), 2006 edition. Also, Eurostat and Global Trade Information Service.

<sup>(23)</sup> Judgment of the Court of First Instance in Case T-241/95 *Het Vlaamse Gewest v Commission* [1998] ECR II-717, paragraph 67.

<sup>(24)</sup> National parliament — Minutes of the session of 25 October 2006, hearing of Mr Dominique Bussereau, Minister for Agriculture and Fisheries.

#### 4.2.2. Compatibility with the common market

- (113) Under Article 87(2)(3) of the Treaty, certain categories of aid are or may be considered compatible with the common market.
- (114) The Commission observes that this aid does not match any of the cases provided for in Article 87(2) of the Treaty.
- (a) In arguing that the FPAP acted as 'a consumer defence organisation' or as a 'union of consumers of petroleum products', MQA seems to suggest that aid for fisheries undertakings could be treated as 'aid having a social character, granted to individual consumers' as provided for in Article 87(2). In this respect, the Commission would only observe that that paragraph refers specifically to 'individual consumers' and not undertakings, and that, consequently, it cannot apply to the present case (see also recital 50 of this Decision). This aid is therefore not compatible with the common market under Article 87(2)(a) of the Treaty.
- (b) The aid is not aid intended to make good damage caused by natural disasters or other exceptional occurrences, since fluctuations in oil prices are inherent in economic activity. They also affect other sectors of activity which consume petroleum products in all Member States of the European Union and cannot be regarded as a natural disaster or an exceptional occurrence within the meaning of Article 87(2)(b). However, MQA objects to this analysis, arguing that the aid does result from an exceptional situation 'since the Commission itself admits the sector's exceptional economic and social difficulties'. It is certainly true that the fisheries sector has to cope with particular difficulties which the Commission analysed in detail in its communication of 9 March 2006 entitled 'improving the economic situation in the fishing industry'<sup>(25)</sup>. In this communication, the Commission showed that the sources of the sector's economic and social difficulties lie in its inadequate structural adjustment to the constraints to which its activity is subject. It also set out various proposals for overcoming the fisheries sector's economic difficulties. Examining the compatibility of certain operating aid, it points out very clearly:

<sup>(25)</sup> COM(2006) 103 final.

'The current difficulties in the fishing industry have been aggravated by the recent increase in fuel prices. This has led to calls from the fishing industry for public intervention to compensate for this sudden increase in costs. Such aid would constitute operating aid which is incompatible with the Treaty. The Commission would not approve any aid notified for this purpose'. Referring to a guarantee scheme comparable to that initially thought of when the FPAP was set up, it adds 'The Commission could approve such a scheme only if it were to provide guarantees of reimbursement of all public aid under commercial conditions, which, in the current economic circumstances, seems very unlikely'. Fluctuations in the cost of inputs, including fuel, are inherent in economic activity and cannot in themselves constitute an exceptional occurrence.

In view of the foregoing, the Commission considers that the State aid in question enjoyed by the fisheries undertakings is not compatible with the common market under Article 87(2)(b) of the Treaty.

(115) Nor can the aid be considered compatible with the common market on the basis of Article 87(3) of the Treaty and the various cases which it provides for.

(a) It is not aid to promote the economic development of areas where the standard of living is abnormally low or where there is serious underemployment (the case provided for in Article 87(3)(a) of the Treaty). This aid is intended to reduce the running costs of fisheries undertakings. Admittedly, the FPAP points out that the aid is intended to facilitate the maintenance of fishing within a regional framework. However, the Commission notes that the aid is granted to fisheries undertakings regardless of their registered place of business or the home port of the vessels that they operate. It therefore bears no relation to the aid referred to in Article 87(3)(a).

(b) Nor can the aid be regarded as aid intended to promote the implementation of an important project of common European interest or as aid to remedy a serious disturbance in the economy of a Member State. It bears no relation to an important project of common European interest. Nor can it be described as aid intended to remedy a serious disturbance in the economy of a Member State. This is because the aid granted to fisheries undertakings is aimed at remedying the difficulties of undertakings in an individual economic sector and

not undertakings in the French economy as a whole. The sectoral nature of this aid is undeniable since the rise in the cost of oil not only affected undertakings in the fisheries sector but all undertakings across all sectors of activity. And, in this respect, the Commission has always taken the view that the public authorities should not intervene financially to compensate for the rise, but on the contrary provide incentives for undertakings to adapt to the resultant new economic conditions. Thus, in view of all these factors, the Commission considers that the FPAP for fisheries undertakings cannot be considered compatible under Article 87(3)(b).

(c) As regards Article 87(3)(c), the reduction of fuel expenditure cannot, in itself, meet the requirements it lays down, according to which aid intended to facilitate the development of certain economic activities or of certain economic regions may be compatible with the common market where it does not adversely affect trading conditions to an extent that is contrary to the common interest. This is because the aid in question is not aimed at encouraging the development of fishing activities towards sustainable fishing, in accordance with the objectives of the common fisheries policy. On the contrary it maintains the level of fishing effort without providing fisheries undertakings with any incentive to reduce their fuel expenditure. Consequently, their effect is to slow down the necessary adaptation of fisheries undertakings to the constraints resulting from the rise in the price of oil. Moreover, this activity is not linked to a particular economic area. That is why the aid cannot be considered compatible with the common market under Article 87(3)(c).

(d) Lastly, this type of aid obviously does not fall under aid to promote culture and heritage conservation or aid considered compatible with the common market by Decision of the Council adopted in accordance with Article 87(3)(e).

(116) The result of all these factors is that the State aid granted to fisheries undertakings to reduce their fuel expenditure is not covered by any of the derogations provided for in Article 87 of the Treaty.

(117) Since this is aid for fisheries undertakings, it must also be assessed in the light of the Guidelines for the examination of State aid to fisheries and aquaculture ('Guidelines' in the following).

- (118) The effect of the aid is to reduce the running costs of fisheries undertakings. It displays the characteristics of operating aid.
- (119) First of all the Commission would point out that, under point 3.5 of the Guidelines, 'State aid may not be protective in its effect: it must serve to promote the rationalisation and efficiency of the production and marketing of fishery products. Any such aid must yield lasting improvements so that the industry can develop solely on the basis of market earnings'.
- (120) However, as set out in recital 115(c) of this Decision, the reduction in fuel expenditure is not aimed at developing fisheries activities towards sustainable fishing, in accordance with the objectives of the common fisheries policy, but the continuation of the fisheries undertakings' activity unchanged. This is why the Commission takes the view that this aid is indeed protective in its effect, as referred to in point 3.5 of the Guidelines, and therefore cannot be considered compatible with the principle laid down by the Guidelines.
- (121) It is true that, in its replies to the initiation of the formal investigation procedure, France indicated that 'the actions of the FPAP anticipated useful measures which the recovery and restructuring plans, once ratified, will only illustrate and confirm'. However, it was only much later, in January 2008, that France informed the Commission of the implementation of measures presented as being aid schemes for the rescue and restructuring of fisheries undertakings, registered by the Commission under number NN 09/08 and currently in the process of being assessed. Nevertheless, even if France's argument, i.e. that the action taken by the FPAP anticipates to a certain degree the aid schemes for rescue and restructuring, is accepted, that does not affect their compatibility with the common market as a result of the fundamental differences between the measures implemented by the FPAP and the requirements which the aid schemes for the rescue and restructuring of undertakings must meet, which are described in the Community guidelines on State aid for rescuing and restructuring firms in difficulty<sup>(26)</sup>. This is because, contrary to what is required in those guidelines, the aid resulting from the action taken by the FPAP was granted indiscriminately to all fisheries undertakings and not only to undertakings in difficulty. Moreover, rescue aid may not exceed a period of six months and must take the form of a repayable loan or a guarantee. As regards restructuring aid, it must be granted under specific conditions and for a limited duration. However, the aid granted by France via the FPAP does not meet any of the conditions laid down: fisheries undertakings have been receiving this aid since 2004, it is not granted in the form of a loan or guarantee, and no provision has been made for its repayment under a restructuring plan.
- (122) The FPAP also considers that the aid granted is justified by the fact that in reality it is aid for employees' income. In this connection the FPAP writes: 'The FPAP is set up as a "prevention group" constituting a legal safety perimeter for its 2 500 member undertakings within the meaning of the French Act.... In this connection, the aid for employees' income within the restructuring perimeter is authorised. It does not affect the competition rules in any way. On the contrary, it is in line with the Community principles guaranteeing employees a fair minimum income'. The FPAP goes on to state that the system of payment for fishermen in France by giving them a share of the crew's profit has had the effect of depriving the employees of fisheries undertakings of their wages or even putting them in debt to the shipowners. Lastly, it points out that 25 million of the 65 million advance granted by the State 'directly relate to advances to employees and must be regarded as direct social assistance'. MQA adds: 'If the loans are regarded as aid, not for the FPAP, which is transparent, but for its member fisheries undertakings, it really would be social assistance, since the financial assistance thus granted would be directly linked to the sailors' pay'.
- (123) These statements prompt the Commission to make a few comments:
1. First of all, it is surprised to read that almost 40 % (25 million out of 65 million) of the cash advances granted by the State in order, according to the three agreements described above (see recital 21 of this Decision), to enable the acquisition of financial options on the petroleum product futures markets, 'directly relate to advances to the employees and must be regarded as direct social assistance'.

<sup>(26)</sup> OJ C 244, 1.10.2004, p. 2.

2. The Commission supposes that this is a rhetorical shortcut on the part of the FPAP, designed to show that the action taken by the FPAP reducing the running costs of fisheries undertakings, given the system of payment by giving employees a share of the profit, ultimately benefits the employees of these undertakings. In that sense the action could be regarded as 'direct social assistance'. In fact nothing in the file indicates that there has been any direct social assistance, i.e. aid paid by the FPAP directly to the employees of these undertakings. What is more, the FPAP's articles of association make no provision for this at all (see recital 20 of this Decision).

3. However, that may be, i.e. whether the aid may have been paid directly to the employees or the effect of the action taken by the FPAP was to provide a benefit for those employees, enabling them to supplement their income based on the system of a share of profits, the Commission points out that, according to settled case-law<sup>(27)</sup>, the concept of aid encompasses advantages granted by public authorities which, in various forms, mitigate the charges which are normally included in the budget of an undertaking. In this sense, wages are indisputably a part of such charges and an undertaking cannot count on public funding to bear them. Consequently, the fact that the advantages enjoyed by fisheries undertakings in the form of the possibility of buying fuel at preferential prices and partial compensation for their fuel expenditure did in reality, according to the FPAP and MQA, benefit the employees of those undertakings is of no relevance for assessing the compatibility of this aid with the common market. It is sufficient to establish that the effect of the advantages granted to fisheries undertakings out of public funds was a reduction of the charges which normally have to be paid out of those undertakings' budgets.

4. Similarly, the Commission cannot accept the claim that the aid for employees' income is authorised, on

the one hand because it is in line with the Community principles guaranteeing employees a fair minimum income and on the other because the system of payment by means of a share of profits is particularly unfavourable to French sailors. This is because, under the principle of subsidiarity, the rules on minimum wages fall entirely within the jurisdiction of the Member States. In France, as regards sailors' wages, this obligation is laid down in Articles L.742-2, D.742-1 and D.742-2 of the Labour Code. As recalled by a judgment of the Rennes Court of Appeal of 16 June 1998<sup>(28)</sup>, those provisions, which apply generally, apply to employees covered by the Maritime Labour Code, whatever the method of remuneration adopted. The fact that the shipowner and his or her employees agreed at the start that sailors would be paid a share of the (potential) profits does not exempt the shipowner from guaranteeing the sailors' remuneration at least equal to the minimum wage for the period in which they are on board. In other words, the share of profits in the fishing industry must be at least equivalent to the remuneration calculated in accordance with the growth-indexed minimum wage. In this respect Article 34 of the Maritime Labour Code<sup>(29)</sup> refers to 'a national trades agreement or extended branch agreements [for laying down], independently of the actual time worked, the period(s) for calculating the growth-indexed minimum wage for share-fishermen'. The branch agreement, Article 9(1) of which guarantees a minimum gross annual remuneration for share-fishermen, was signed on 28 March 2001<sup>(30)</sup>. This provision was made compulsory, for all employers and employees covered by this agreement, by an interministerial decree of 3 July 2003<sup>(31)</sup>. The wage cost produced by this legal obligation is thus part of the running costs of fisheries undertakings, the same as expenditure on fuel. Under these circumstances, the Commission therefore cannot accept the argument that the French State is justified in intervening financially because shipowners are failing to meet their legal obligation to ensure a minimum wage for their employees, even where they are share-fishermen.

<sup>(27)</sup> Judgment of the Court of Justice in Case C-251/97 *French Republic v Commission* [1999] ECR I-6639, paragraph 35.

<sup>(28)</sup> Judgment of the Rennes Court of Appeal of 16 June 1998 *Marziou v Louzaouen*, in *Le Droit Maritime Français*, No 588, December 1998, p. 1201 et seq. (*Editions Lamy*).

<sup>(29)</sup> Available at [www.legifrance.gouv.fr/](http://www.legifrance.gouv.fr/)

<sup>(30)</sup> Official bulletin of the Ministry of Infrastructure No 13 of 25 July 2003, available at [www2.equipement.gouv.fr/bulletinofficiel/fiches/BO200313/Une.htm](http://www2.equipement.gouv.fr/bulletinofficiel/fiches/BO200313/Une.htm)

<sup>(31)</sup> Published in the *Journal officiel de la République française* 203 of 3 September 2003, p. 15051.

(124) According to MQA, the measures in question may also be socioeconomic measures: 'the guidelines (...) state that socioeconomic measures may be declared compatible. In this particular case, the FPAP is completely transparent and the schemes classified as aid by the Commission have an obvious socioeconomic character'.

(125) The Commission notes that MQA has not provided any evidence enabling the aid in question to be examined under point 4.5 of the Guidelines, which provide that, on a case-by-case basis, direct aid for workers equivalent to socioeconomic measures may be considered compatible with the common market. This is because that point specifies that they may only be considered compatible 'provided that it forms part of socioeconomic back-up measures compensating income losses linked to measures designed to achieve an adjustment of capacity adopted pursuant to Article 11(1) of Regulation (EC) No 2371/2002' (Council Regulation (EC) No 2371/2002 of 20 December 2002 on the conservation and sustainable exploitation of fisheries resources under the common fisheries policy<sup>(32)</sup>). However, the creation of the FPAP is not part of an overall plan for the adjustment of fishing capacity adopted under Regulation (EC) No 2371/2002. Therefore in no way does the argument put forward by MQA justify the grant of such operating aid.

(126) MQA also points out that it is not correct to state that the aid was granted unconditionally. According to MQA, 'as a condition for granting these loans the State required the FPAP to produce various supporting documents so as to be able to ensure proper management of funds and establish that the Fund and its members were determined to implement sustainable solutions for the new production conditions in the fisheries sector'. MQA points to this transparent accounting requirement and the State Decision to request that an interministerial audit be carried out.

(127) The Commission notes the transparency and monitoring requirement, but observes that this would appear to be an elementary requirement, since this is assistance financed out of public funds. However, it regrets that, in such a context of transparency, the French authorities did not send it all the detailed figures and information on

the Fund's activities, despite the requests made during the procedure. Lastly, it notes that it was never informed of the audit mentioned by MQA, nor *a fortiori* of its conclusions, which the French authorities were requested to provide by mid-November 2005.

(128) Consequently, the Commission considers that the advances granted by the State do in fact fall under the category of operating aid referred to in point 3.7 of the Guidelines, according to which: 'State aid which is granted without imposing any obligation serving the objectives of the Common Fisheries Policy on the part of recipients and which is intended to improve the situation of undertakings and increase their business liquidity (...) is, as operating aid, incompatible with the common market'. These advances are therefore incompatible with the common market.

## 5. CONCLUSION

(129) The Commission holds that France, in breach of Article 88(3) of the Treaty, has unlawfully implemented the various aid schemes which are the subject of this Decision.

(130) On the basis of the analysis developed in part 4.1 of this Decision, the Commission considers that the FPAP's additional business liquidity resulting from the granting of three, or possibly four, advances totalling EUR 65 million, or possibly EUR 77 million, constitutes State aid incompatible with the common market under Article 87(2) and (3) of the Treaty. This is because, since no bank would have granted advances such as those granted to the FPAP and, according to the information available, the advances have not been repaid, the advances have become a direct subsidy (see recital 67) and therefore State aid covering the amount in question.

(131) On the basis of the analysis developed in part 4.2 of this Decision, the Commission considers that the aid granted in the form of advances to the FPAP and which enabled fisheries undertakings to buy fuel at an advantageous price and to benefit from a compensatory allowance under the diesel insurance, constitutes State aid incompatible with the common market under Article 87(2) and (3) of the Treaty.

<sup>(32)</sup> OJ L 358, 31.12.2002, p. 59.

## 6. RECOVERY

(132) The amount of State aid paid by France is EUR 65 million, or EUR 77 million if a fourth agreement existed. In accordance with Article 14(1) of Regulation (EC) No 659/1999, where negative Decisions are taken in cases of unlawful aid, the Commission must decide that the Member State concerned must take all necessary measures to recover the aid from the beneficiary. The purpose is achieved once the aid in question, together where appropriate with default interest, has been repaid by the recipient or, in other words, by the undertakings which actually benefited from it<sup>(33)</sup>. The purpose of the recovery will therefore be achieved when this amount of EUR 65 or EUR 77 million has been repaid.

(133) In order to determine what has to be recovered from the FPAP on the one hand and the fisheries undertakings on the other, account should be taken of the fact that the objective of the FPAP, although it acts as an economic operator on the futures markets, is to grant allowances to fisheries undertakings under the diesel insurance system which it set up, and to provide them with fuel at an advantageous price. The analysis made in this Decision of the general operation of this particular system shows that the FPAP fulfilled its mission by gradually transferring the aid granted by the State. For that reason, the aid to be recovered from the FPAP is the part of the EUR 65 or EUR 77 million which was not transferred to the fisheries undertakings, and the aid to be recovered from the fisheries undertakings is therefore the part which was transferred to them.

(134) The Commission is not aware of the amount which was actually transferred by the FPAP to the fisheries undertakings. In this connection the Commission observes that, despite an injunction addressed to France to provide all the necessary information on the FPAP's operation, it has not forwarded any details of how the Fund's financial resources were used or of its accounts. In the absence of this information and in order to take account of the Court's Decisions<sup>(34)</sup>, the Commission thinks it useful to provide guidelines on the methodology to be used for determining the amount of aid to be recovered.

(135) In laying down these guidelines, the Commission took into account the fact that, under the agreements, the FPAP is required to keep accounts so that information on how the advances have been used and resources and expenditure have been allocated can be obtained, and undertook to keep the accounting documents for a minimum period of ten years, and make them available

to the various State bodies on request (see recital 27). On the basis of this information, the authorities or bodies instructed to apply the recovery Decision will be able to obtain information on the FPAP's liquid assets and the cash situation at the time the Decision has to be implemented. Also, since the fisheries undertakings' accounts are normally kept by management groups belonging to the Centre de gestion de la pêche artisanale (Small-Scale Fishery Management Centre), which is represented on the FPAP's Board of Directors, it is also possible to identify the allowances paid by the FPAP in the undertakings' accounts.

### 6.1. Recovery from the FPAP

(136) The amount of incompatible aid to be recovered from the FPAP is equivalent to that part of the State aid which was not ultimately transferred to the fisheries undertakings, i.e. the amount of the advances which funded the operating costs of the FPAP and the amount of the advances that it kept as liquid assets. It will be possible for the authority instructed to implement recovery to find out the total amount of the operating costs from the FPAP's accounts. Given the fungible nature of money and the impossibility of knowing what money is used where, the Commission takes the view that the proportion of State advances which financed these operating costs is the total amount of those expenses multiplied by the ratio of the advances to the sum of the advances and the FPAP's own funds (its members' contributions). In the same way, the amount of the advances kept as liquid assets can be determined by multiplying the remaining liquid assets by the same ratio.

### 6.2. Recovery from the fisheries undertakings

(137) As indicated above, the aid to be recovered from the fisheries undertakings as a whole is equivalent to the EUR 65 or 77 million of advances, less the amount to be recovered from the FPAP in accordance with the details given in recital 136. As regards the State aid to be recovered from each one of those undertakings, account must be taken of the fact that it is not possible, from an accounting point of view, to make a distinction between aid which is classified as State aid and aid which is not imputable to the State (see paragraph 4.2.1.2 of this Decision).

(138) The Commission takes the view that the State aid to be recovered from each undertaking can be calculated on the basis of the allowance received by each undertaking under the diesel insurance.

<sup>(33)</sup> Judgment of the Court of Justice in Case C-277/00 *Germany v Commission* [2004] ECR I-3925, paragraph 75.

<sup>(34)</sup> Judgment of the Court of Justice in Case C-480/98 *Spain v Commission* [2000] ECR I-8715, paragraph 25.

(139) By taking this allowance as the basis for calculation, the Commission leaves aside the subsidy-equivalent of the saving made by each fisheries undertaking as a result of the purchase of fuel at a price lower than the market price. The Commission considers that it is justified to do so because the undertakings which benefited from preferential prices for their fuel are the same as those which benefited from the allowances under the diesel insurance. They did this in completely comparable respective proportions since the more one undertaking bought fuel at a preferential price the more allowances it obtained, and vice versa. By choosing this basis, no element of distortion is thus introduced between the undertakings concerned in relation to the repayment obligations which they will have to meet. Also, the Commission notes that, if these subsidy-equivalents were to be taken into account in the basis for calculation, it would be necessary for this purpose to calculate, for each purchase of fuel carried out in the FPAP's period of activity on the oil futures markets, the difference between the expenditure which would have resulted from purchase during the day in question and the cost actually invoiced by the cooperative after having determined what the price on the day applicable would have been for the type of fuel bought at the particular place of supply. This method would have been more difficult to implement. That is why the Commission thinks it preferable to recommend a basis for calculation which will facilitate the task of the authorities and bodies instructed to implement the recovery Decision.

(140) Consequently, the Commission considers that the State aid to be recovered from each undertaking can be calculated on the basis of the allowance received by each undertaking under the diesel insurance. The State aid to be recovered must be calculated by multiplying that allowance by a percentage corresponding to the ratio of the overall amount of the State aid to be recovered from the fisheries undertakings to the overall amount of the allowances paid to the fisheries undertakings by the FPAP under the diesel insurance.

(141) The amount to be recovered from each fisheries undertaking must thus be calculated according to the following formulas:

$$R * Und = I \times \frac{(Advances - R * FPAP)}{Total I}$$

Where:

$R * Und$  = amount to be recovered from the fisheries undertaking

$I$  = amount of the allowance received by the fisheries undertaking under the diesel insurance

$Advances$  = EUR 65 or 77 million

$R * FPAP$  = amount to be recovered from the FPAP in accordance with the details given in recital 136

$Total I$  = total amount of the allowances paid by the FPAP to the fisheries undertakings under the diesel insurance

(142) This formula takes account of the supposition that the FPAP made profits on the futures markets which were then passed on completely to the fisheries undertakings. As described in this Decision, that is the most plausible case. However, consideration should also be given to the theoretical case in which the FPAP made losses on the futures markets, with the result that the fisheries undertakings would have received an overall amount of allowances lower than the amount of the advances less the amount to be recovered from the FPAP. In such a case, the quotient  $(Advances - R * FPAP) / Total I$  would generally be greater than 1, in particular if the amount 'R\*FPAP' is small. Application of the above formula would therefore mean that the overall amount to be recovered from the fisheries undertakings would be higher than that which they received. For that reason, in this particular case, the amount to be recovered from each undertaking should be the amount of the allowance received by the undertaking under the 'diesel insurance'. In this particular case, the balance of the State advances and the allowances paid to the fisheries undertakings would have to be recovered from the FPAP, which would actually have retained that difference.

(143) State aid for the fisheries undertakings cannot be made subject to recovery if, on the date on which it was granted, it meets the conditions of Regulation (EC) No 1860/2004 or Regulation (EC) No 875/2007 on *de minimis* aid,

HAS ADOPTED THIS DECISION:

#### Article 1

The aid granted to the Fund for the prevention of risks to fishing (FPAP) for the acquisition of financial options on the oil futures market and implemented unlawfully by France in breach of Article 88(3) of the Treaty is incompatible with the common market.

#### Article 2

The aid granted to fisheries undertakings in the form of a reduction of their fuel expenditure and unlawfully granted by France in breach of Article 88(3) of the Treaty is incompatible with the common market.

*Article 3*

Individual aid granted to a fisheries undertaking under Article 2(1) of Council Regulation (EC) No 994/98<sup>(35)</sup> shall not be subject to recovery if, at the time it is granted, it meets the conditions laid down by the regulation adopted under Article 2 of Regulation (EC) No 994/98 applicable at the time the aid was granted.

*Article 4*

1. France shall recover the incompatible aid referred to in Articles 1 and 2 from the beneficiaries.

2. The sums to be recovered shall bear interest from the date on which they were placed at the disposal of the beneficiaries until their actual recovery.

3. The interest shall be calculated on a compound basis in accordance with Chapter V of Commission Regulation (EC) No 794/2004<sup>(36)</sup>.

4. France shall cancel all outstanding payments of the aid referred to in Articles 1 and 2 with effect from the date of adoption of this Decision.

*Article 5*

1. Recovery of the aid referred to in Articles 1 and 2 shall be immediate and effective.

2. France shall ensure that this Decision is implemented within four months of the date of its notification.

*Article 6*

1. Within two months of notification of this Decision, France shall submit the following information to the Commission:

- (a) the total amount (principal and recovery interests) to be recovered from the FPAP;
- (b) a detailed description of the measures already taken and planned to comply with this Decision;
- (c) documents demonstrating that the FPAP has been ordered to repay the aid.

2. France shall keep the Commission informed of the progress of the national measures taken to implement this Decision until recovery of the aid referred to in Article 1 has been completed. It shall immediately submit, on simple request by the Commission, information on the measures already taken and planned to comply with this Decision. It shall also provide detailed information concerning the amounts of aid and recovery interest already recovered from the FPAP.

*Article 7*

1. Within two months of notification of this Decision, France shall submit the following information to the Commission:

- (a) a list of fisheries undertakings that have received aid as referred to in Article 2 and the total amount of aid received by each of them;
- (b) the total amount (principal and recovery interests) to be recovered from each beneficiary;
- (c) a detailed description of the measures already taken and planned to comply with this Decision;
- (d) documents demonstrating that the beneficiaries have been ordered to repay the aid.

2. France shall keep the Commission informed of the progress of the national measures taken to implement this Decision until recovery of the aid referred to in Article 2 has been completed. It shall immediately submit, on simple request by the Commission, information on the measures already taken and planned to comply with this Decision. It shall also provide detailed information concerning the amounts of aid and recovery interest already recovered from the beneficiaries.

*Article 8*

This Decision is addressed to the French Republic.

Done at Brussels, 20 May 2008.

*For the Commission*  
Joe BORG  
*Member of the Commission*

<sup>(35)</sup> OJ L 142, 14.5.1998, p. 1.

<sup>(36)</sup> OJ L 140, 30.4.2004, p. 1.

## COMMISSION DECISION

of 5 December 2008

**concerning the non-inclusion of sulphuric acid in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance***(notified under document number C(2008) 7612)***(Text with EEA relevance)**

(2008/937/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

sulphuric acid the rapporteur Member State was France and all relevant information was submitted in October 2007.

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 <sup>(1)</sup>, and in particular the fourth subparagraph of Article 8(2) thereof,

(4) The Commission examined sulphuric acid in accordance with Article 24a of Regulation (EC) No 2229/2004. A draft review report for that substance was reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and finalised on 26 September 2008 in the format of the Commission review report.

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 1112/2002 <sup>(2)</sup> and (EC) No 2229/2004 <sup>(3)</sup> lay down the detailed rules for the implementation of the fourth 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 sulphuric acid.

(3) For sulphuric acid the effects on human health and the environment have been assessed in accordance with the provisions laid down in Regulations (EC) No 1112/2002 and (EC) No 2229/2004 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 20 of Regulation (EC) No 2229/2004. For

(5) During the examination of this active substance by the Committee, it was concluded, taking into account comments received from Member States, that the existing evidence is not sufficient to finalise the consumer risk assessment and to set a reliable Acceptable Operator Exposure Level (AOEL) and such value is necessary to conduct the operator risk assessment. Moreover, other concerns which were identified by the rapporteur Member State in its assessment report are included in the review report for the substance.

(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 have not demonstrated that it may be expected that, under the proposed conditions of use, plant protection products containing sulphuric acid satisfy in general the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC.

(7) Sulphuric acid 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 sulphuric acid are withdrawn within a fixed period of time and are not renewed and that no new authorisations for such products are granted.

<sup>(1)</sup> OJ L 230, 19.8.1991, p. 1.

<sup>(2)</sup> OJ L 168, 27.6.2002, p. 14.

<sup>(3)</sup> OJ L 379, 24.12.2004, p. 13.

- (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 sulphuric acid 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 sulphuric acid 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 sulphuric acid in accordance with Article 6(2) of Directive 91/414/EEC and 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<sup>(1)</sup>, in view of a possible inclusion in its Annex I.
- (11) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

*Article 1*

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

*Article 2*

Member States shall ensure that:

- (a) authorisations for plant protection products containing sulphuric acid are withdrawn by 5 June 2009;
- (b) no authorisations for plant protection products containing sulphuric acid 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 5 June 2010 at the latest.

*Article 4*

This Decision is addressed to the Member States.

Done at Brussels, 5 December 2008.

*For the Commission*

Androulla VASSILIOU

*Member of the Commission*

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<sup>(1)</sup> OJ L 15, 18.1.2008, p. 5.

## COMMISSION DECISION

of 9 December 2008

**on the list of the beneficiary countries which qualify for the special incentive arrangement for sustainable development and good governance, provided for in Council Regulation (EC) No 732/2008 applying a scheme of generalised tariff preferences for the period from 1 January 2009 to 31 December 2011**

(notified under document number C(2008) 8028)

(2008/938/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 732/2008 of 22 July 2008 applying a scheme of generalised tariff preferences for the period from 1 January 2009 to 31 December 2011 and amending Regulations (EC) No 552/97, (EC) No 1933/2006 and Commission Regulations (EC) No 1100/2006 and (EC) No 964/2007<sup>(1)</sup>, and in particular Article 10(2) thereof,

Whereas:

(1) Regulation (EC) No 732/2008 provides for the granting of a special incentive arrangement for sustainable development and good governance to developing countries which satisfy certain requirements established under its Articles 8 and 9.

(2) Each developing country wishing to avail itself of the special incentive arrangement had to submit a request to that effect by 31 October 2008, accompanied by comprehensive information concerning ratification of the relevant conventions, the legislation and measures to implement effectively the provisions of the conventions and its commitment to accept and comply fully with the monitoring and review mechanism envisaged in the relevant conventions and related instruments. To be granted the request, the requesting country also has to be considered to be a vulnerable country as defined in Article 8(2) of Regulation (EC) No 732/2008.

(3) The Commission has examined the requests made, in accordance with the provisions of Article 10(1) of Regulation (EC) No 732/2008, and has established the list of beneficiary countries which fulfil the criteria. Accordingly, the special incentive arrangement should be granted to those countries from 1 January 2009 to 31 December 2011.

(4) In accordance with Article 10(6) of Regulation (EC) No 732/2008, the fulfilment of criteria which are also subject of the pending investigations with regard to Sri Lanka<sup>(2)</sup> and El Salvador<sup>(3)</sup> initiated by the Commission pursuant to Article 18(2) of Council Regulation (EC) 980/2005<sup>(4)</sup>, is being examined in the course of these investigations.

(5) Timely publication of this Decision in the *Official Journal of the European Union* should ensure that the obligation pursuant to Article 10(3) of Regulation (EC) No 732/2008, to publish a notice in the *Official Journal of the European Union* listing the countries benefiting from the special incentive arrangement for sustainable development and good governance as from 1 January 2009, is met.

(6) The measures provided for in this Decision are in accordance with the opinion of the Generalised Preferences Committee,

HAS ADOPTED THIS DECISION:

*Article 1*

The following developing countries shall benefit from the special incentive arrangement for sustainable development and good governance provided for in Regulation (EC) No 732/2008 from 1 January 2009 to 31 December 2011:

(AM) Armenia  
 (AZ) Azerbaijan  
 (BO) Bolivia  
 (CO) Colombia  
 (CR) Costa Rica  
 (EC) Ecuador  
 (GE) Georgia  
 (GT) Guatemala  
 (HN) Honduras  
 (LK) Sri Lanka

<sup>(1)</sup> OJ L 211, 6.8.2008, p. 1.

<sup>(2)</sup> OJ L 277, 18.10.2008, p. 34.

<sup>(3)</sup> OJ L 108, 18.4.2008, p. 29.

<sup>(4)</sup> OJ L 169, 30.6.2005, p. 1.

(MN) Mongolia  
(NI) Nicaragua  
(PE) Peru  
(PY) Paraguay  
(SV) El Salvador  
(VE) Venezuela

Ecuador, the Republic of El Salvador, Georgia, the Republic of Guatemala, the Republic of Honduras, Mongolia, the Republic of Nicaragua, the Republic of Paraguay, the Republic of Peru, the Democratic Socialist Republic of Sri Lanka and the Bolivarian Republic of Venezuela.

Done at Brussels, 9 December 2008.

*Article 2*

This Decision is addressed to: the Republic of Armenia, the Republic of Azerbaijan, the Republic of Bolivia, the Republic of Colombia, the Republic of Costa Rica, the Republic of

*For the Commission*  
Catherine ASHTON  
*Member of the Commission*

**NOTE TO THE READER**

The institutions have decided no longer to quote in their texts the last amendment to cited acts.

Unless otherwise indicated, references to acts in the texts published here are to the version of those acts currently in force.