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### Legislation

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

## I

(Acts whose publication is obligatory)

**COUNCIL REGULATION (EC) No 1582/2006****of 24 October 2006****amending Regulation (EEC) No 1907/90, as regards the derogation on egg washing**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2771/75 of 29 October 1975 on the common organisation of the market in eggs <sup>(1)</sup>, and in particular Article 2(2) thereof,

Having regard to the proposal from the Commission,

Whereas:

- (1) Article 6(4) of Council Regulation (EEC) No 1907/90 of 26 June 1990 on certain marketing standards for eggs <sup>(2)</sup> lays down the criteria for the derogation enabling packing centres to continue to wash eggs until 31 December 2006. A derogation has been granted to nine packing centres in Sweden and one in the Netherlands.

- (2) Regulation (EEC) No 1907/90 has been repealed by Council Regulation (EC) No 1028/2006 of 19 June 2006 on marketing standards for eggs <sup>(3)</sup> with effect from 1 July 2007. Accordingly, the transitional period for egg washing should be extended until that date.

- (3) Regulation (EEC) No 1907/90 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

*Article 1*

In the first subparagraph of Article 6(4) of Regulation (EEC) No 1907/90, the date '31 December 2006' shall be replaced by the date '30 June 2007'.

*Article 2*

This Regulation shall enter into force on the seventh 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 Luxembourg, 24 October 2006.

*For the Council*

*The President*

J. KORKEAOJA

<sup>(1)</sup> OJ L 282, 1.11.1975, p. 49. Regulation as last amended by Regulation (EC) No 679/2006 (OJ L 119, 4.5.2006, p. 1).

<sup>(2)</sup> OJ L 173, 6.7.1990, p. 5. Regulation as last amended by Regulation (EC) No 1039/2005 (OJ L 172, 5.7.2005, p. 1).

<sup>(3)</sup> OJ L 186, 7.7.2006, p. 1.

**COUNCIL REGULATION (EC) No 1583/2006**

**of 23 October 2006**

**imposing a definitive anti-dumping duty on imports of ethanolamines originating in the United States of America**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 384/96 of 22 December 1995 on protection against dumped imports from countries not members of the European Community<sup>(1)</sup> (hereinafter referred to as the basic Regulation), and in particular Articles 9 and 11(2) thereof,

Having regard to the proposal submitted by the Commission, after consulting the Advisory Committee,

Whereas:

**A. PROCEDURE**

**1. Measures in force**

- (1) In February 1994, the Council imposed, by Regulation (EC) No 229/94<sup>(2)</sup> definitive anti-dumping duties on imports of ethanolamines (product concerned) originating in the United States of America (USA). The duties took the form of minimum-price-based variable duties for the three types of ethanolamines, i.e. monoethanolamine (MEA), diethanolamine (DEA) and triethanolamine (TEA).
- (2) Following a request of the Conseil européen des fédérations de l'industrie chimique (CEFIC) an expiry and interim review pursuant to Articles 11(2) and 11(3) of the basic Regulation was initiated in February 1999. By Regulation (EC) No 1603/2000<sup>(3)</sup> the Council concluded these reviews and imposed definitive anti-dumping measures on imports of ethanolamines originating in the USA. The form of the measures was changed as they took the form of a specific fixed duty

per tonnes of all types of ethanolamine. Two of the three companies benefiting from an individual anti-dumping duty were Dow Chemical Company and Union Carbide Corporation.

- (3) After disinvestment of Dow Chemical Company's ethanolamine business into the company INEOS LLC, the individual anti-dumping duty of EUR 69,40 per tonne applicable to Dow Chemical Company was attributed to INEOS LLC<sup>(4)</sup>. However, since the Dow Chemical Company acquired on 6 February 2001 all shares of Union Carbide Corporation, a company benefiting from an individual anti-dumping duty of EUR 59,25 per tonne, the Dow Chemical Company is still active in the ethanolamine business. The Union Carbide Corporation still exists but has become part of the Dow Chemical Company group and does no longer have any independent production activities.

**2. Request for an expiry review**

- (4) Following the publication in November 2004 of a notice of impending expiry of the anti-dumping measures applicable to imports of ethanolamines originating in the USA<sup>(5)</sup>, the Commission received on 25 April 2005 a request for a review pursuant to Article 11(2) of the basic Regulation.
- (5) The request was lodged by CEFIC on behalf of producers representing a major proportion, in this case more than 75 %, of the total Community production of ethanolamine.
- (6) The request was based on the grounds that expiry of the measures would be likely to result in a continuation or recurrence of dumping and injury to the Community industry. Having determined, after consultation of the Advisory Committee, that sufficient evidence existed for the initiation of an expiry review, the Commission initiated by notice of initiation an investigation<sup>(6)</sup> pursuant to Article 11(2) of the basic Regulation.

<sup>(1)</sup> OJ L 56, 6.3.1996, p. 1. Regulation as last amended by Regulation (EC) No 2117/2005 (OJ L 340, 23.12.2005, p. 17).

<sup>(2)</sup> OJ L 28, 2.2.1994, p. 40.

<sup>(3)</sup> OJ L 185, 25.7.2000, p. 1.

<sup>(4)</sup> OJ C 306, 10.12.2002, p. 2.

<sup>(5)</sup> OJ C 276, 11.11.2004, p. 2.

<sup>(6)</sup> OJ C 183, 26.7.2005, p. 13.

### 3. Investigation

(7) The Commission's services officially advised the Community producers, the exporting producers in the USA, importers/traders, user industries known to be concerned, as well as the authorities of the USA of the initiation of the review. Interested parties were given the opportunity to make their views known in writing and to request a hearing within the time limit set out in the notice of initiation.

(8) The Commission's services sent questionnaires to all parties known to be concerned and to those who requested a questionnaire within the time limit set out in the notice of initiation.

(9) The Commission also gave the parties directly concerned the opportunity to make their views known in writing and to request a hearing within the time limit set out in the notice of initiation.

(10) Replies to the questionnaire were received from two exporting producers in the USA and their nine related importers in the Community, one related importer in Switzerland, three Community producers (the applicant Community producers), and one industrial user in the Community. One Community producer did not fully reply to the questionnaire and only submitted succinct information and two industrial users in the Community made their views known.

(11) The Commission's services sought and verified all the information deemed necessary for the purpose of the determination of the likelihood of continuation or recurrence of dumping and injury and for the determination of the Community interest. Verification visits were carried out at the premises of the following companies:

(a) Applicant Community producers

BASF AG, Ludwigshafen, Germany  
 Innovene Europe Ltd, Staines, United Kingdom  
 SASOL GmbH, Marl, Germany

(b) Exporting producers in the USA

The Dow Chemical Company, Midland, Michigan and Houston, Texas, USA

(c) Related importers in the Community

Dow Chemical Iberica SL, Tarragona, Spain  
 INEOS Oxide Ltd, Antwerp, Belgium

(d) Related importer in Switzerland

Dow Europe GmbH, Horgen, Switzerland

(e) Industrial users in the Community

Degussa Goldschmidt Espana SA, Granollers, Spain

### 4. Investigation period

(12) The investigation regarding the continuation or recurrence of dumping and injury covered the period from 1 July 2004 to 30 June 2005 (the RIP). The examination of the trends relevant for the assessment of a likelihood of a continuation or recurrence of injury covered the period from 1 January 2002 up to the end of the RIP (period considered).

## B. PRODUCT CONCERNED AND LIKE PRODUCT

### 1. Product concerned

(13) The product concerned is the same as that covered by the previous investigations. Ethanolamines are obtained by making ethylene oxide (EO), itself a result of a reaction of ethylene and oxygen, react with ammonia. This synthesis leads to three competing reactions and to three different types of ethanolamines: monoethanolamine (MEA), diethanolamine (DEA) and triethanolamine (TEA), depending on how many times EO is bound. The maximum number of combinations is limited by the number of hydrogen elements in ammonia, namely three. The proportions of the three types in the total output are determined by the production installation design, but can, to a certain extent, be controlled by the ammonia/EO (the molar ratio). Community installations are typically based on naphtha as energy carrier, whereas US installations are natural gas based.

(14) The product concerned is used as an intermediate and/or additive for surfactants used in detergents and personal care products, cosmetics, fertilisers and crop protection agents (glyphosate), corrosion inhibitors, lubrication oils, textile auxiliaries and fabric softeners (esterquats), photographic chemicals, paper and metalworks, as a grinding and binding aid for cement production and as a gas scrubber absorption aid (sweetening the gas by removing acids). Since late 2004, beginning 2005, the product is also increasingly used for wood treatment. Finally, the product can also be used by the manufacturers themselves or by their related manufacturers in the production of ethylene amines.

## 2. Like product

- (15) As in the previous investigations, it was shown that the product concerned produced in the USA and sold to the Community is identical in terms of physical and technical characteristics to the product produced and sold in the Community by the Community producers and that there is no difference in use between those products. It has further been found that the product concerned produced in the USA and sold to the Community is identical to that sold on the US domestic market. Therefore, all these products must be considered to be like products within the meaning of Article 1(4) of the basic Regulation.

### C. LIKELIHOOD OF A CONTINUATION OR RECURRENCE OF DUMPING

- (16) In accordance with Article 11(2) of the basic Regulation, it was examined whether dumping was currently taking place and, if so, whether or not the expiry of the measures would be likely to lead to a continuation or recurrence of dumping.

#### 1. Preliminary remarks

- (17) Of the four US exporting producers named in the complaint, two did cooperate in the investigation.
- (18) The two cooperating exporting producers represented 100 % of imports to the Community during the RIP, which amounted to 41 000 tonnes. Imports into the Community of the product concerned originating in the USA represented 16,7 % of Community consumption during the RIP down from 29 % during the previous investigation period (1998).

#### 2. Dumping of imports during the RIP

##### *Normal value*

- (19) With regard to the two cooperating US exporting producers, normal value was established for each type of the product concerned, based on the price paid or payable on the domestic market in the USA by unrelated customers pursuant to Article 2(1) of the basic Regulation, since these sales were found to have been made in sufficient quantities and in the ordinary course of trade.

##### *Export price*

- (20) As in the original and in the previous review investigation, this investigation showed again that the two cooperating US exporting producers exported the product concerned to the Community via companies

which are related. As a consequence, and in accordance with Article 2(9) of the basic Regulation, export prices were constructed on the basis of the prices at which the imported product was first resold to independent customers in the Community. Allowance was made for all costs incurred between importation and resale, including selling, general and administrative costs and the profit realised in the Community by the importing companies during the RIP.

##### *Comparison*

- (21) The normal value was compared with the average export price for each type of the product concerned, on an ex-works basis and at the same level of trade. In accordance with Article 2(10) of the basic Regulation, and for the purpose of ensuring a fair comparison, differences in factors which were claimed and demonstrated to affect price and price comparability were taken into account. Adjustments were made for inland and ocean freight, deferred rebates, handling and packaging costs, credit costs and import duties, which were all deducted from the resale prices in order to arrive at an ex-works basis.

##### *Dumping margin*

- (22) In accordance with Article 2(11) of the basic Regulation, the dumping margin was established per product type on the basis of a comparison of the weighted average normal value with the weighted average export prices at the same level of trade. This comparison showed the existence of dumping during the RIP, even if at a lower level than established in the previous review. The weighted average dumping margin expressed as a percentage of the cif value at the Community frontier was 4,8 % for INEOS and 20,3 % for Dow Chemical.

#### 3. Development of imports should measures be repealed

##### *Preliminary remarks*

- (23) Further to the analysis of the existence of dumping during the RIP, the likelihood of the continuation of dumping was examined.

##### *Level of dumping in case the measures are repealed*

- (24) The removal of the measures would allow exporters to reduce their export prices. A reduction of export prices would make the US product more attractive on the Community market. If the export prices were reduced commensurate to the level of the duties, the dumping margins observed during the RIP would be 13,4 % for INEOS and 28,3 % for Dow Chemical.

*Further room for exports to the Community market because of unused US production capacity*

- (25) It is estimated that the unused production capacity in the US during the RIP is about 90 000 tonnes. This was calculated on the basis of information from the two cooperating exporting producers as well as information from leading market journals. Compared to an estimated installed total capacity in the USA of 650 000 tonnes, total estimated fulfilled demand and captive use of 560 000 tonnes implies a capacity utilisation rate of 86 %, which is rather low given the favourable market conditions during the RIP. The relatively low capacity utilisation rate was a consequence of operational problems in certain production facilities. The spare capacity of 90 000 tonnes should be compared to the volume of exports from the US to the Community during the RIP (41 088 tonnes) and total Community consumption (246 670 tonnes). In other words, there is considerable potential to increase exports from the US and take over a large part of the Community market. The propensity of increased exports to the Community is further supported by the 45 000 tonnes capacity expansion ongoing in 2006 in Mexico and Brazil, both important export markets for the US producers.

- (26) To conclude, there is some spare capacity available which could be used to produce more ethanolamine and to sell it on the Community market should measures be lifted.

*Evolution of the prices in the Community market and in the exporting country market*

- (27) The ethanolamine market has been characterised by strong growth in the demand for DEA in the years 2000-2001, triggered by the use of DEA in the production of glyphosate herbicides, which are used in a process to allow genetically modified crops to resist such herbicides. The demand for TEA is specifically driven by the use in the cement sector and by the producers of fabric softeners. Since 2004, the market for MEA has increased considerably following a US Regulation, effective 1 January 2005, prohibiting the use of alternative metal based products for wood treatment, causing an additional estimated demand of MEA of 80 000 tonnes. As a consequence, the worldwide price level of ethanolamines is high because of high demand.

- (28) The investigation showed that US domestic prices are on average higher than average sales prices on the Community market. Industrial users seem to obtain similar conditions on both markets as they are often multinational companies that negotiate their sourcing on a worldwide basis and select suppliers that are capable of delivering on a similar scale. However, US

domestic price for all types of ethanolamines were found to be higher when charged to traders and distributors. This type of sales on the US domestic market is typically conducted on a spot basis, whereas sales on the Community market are rather established on a fixed term contract basis. This implies that sales prices on the Community are set for a longer period and are more stable.

- (29) Sales to traders and distributors by the two cooperating exporting producers represent only 13 % of the volumes sold on the US domestic market and 32 % of sales on the Community market, but the US domestic prices were on average 35 % higher than the Community prices for this level of trade. This supported the finding that, given the spot nature of sales to traders and distributors, US domestic prices are adapting more rapidly to price fluctuations. Therefore, in a context of increasing prices, US domestic prices will have a tendency to be relatively higher than Community prices. On the other hand, this level of trade represents the smaller part of sales on both the US domestic and Community markets.

- (30) For industrial users, which constitute the majority of customers, the termination of the measures would probably not influence the price level at which ethanolamine is sold in the Community market, since it was observed that the burden of the measures was carried by the US exporting producers. In that scenario, the latter may achieve more profitable sales and would have an incentive to increase exports to the Community market. However, these industrial users might use the disappearance of the measures as a bargaining tool to obtain lower prices from both US exporting producers and the Community industry.

*Relationship between the US export prices to third countries and to the Community*

- (31) Export prices of the product concerned to the other main export markets, namely to Canada and South America, show no regular pattern. Sales prices are sometimes lower and sometimes higher than in the USA and to the Community market depending on the sales conditions. Lower volumes shipped typically entail higher sales prices.

- (32) In summary, for both cooperating exporting producers, the US market in principle remains the most important sales market. However, given that 17 % of production was exported during the RIP, sales to the Community and to the rest of the world continue to play an important role in the overall use and profitability of production capacities installed.

*Possible short-term development of imports*

- (33) In the short term, as regards the two cooperating US producers, it can be expected that their import volumes will remain at least stable. Indeed, even with the measures in force and notwithstanding the attractiveness of the US market, they have continued to serve their Community-based clients. A reduction of export volumes may possibly be expected from the US producer INEOS after the takeover of Innovene, with its production facilities in the Community, once the company would have de-bottlenecked the acquired production facilities and have expanded by installing new capacity in the Community, which is not expected to become operational before 2008. At the same time it is expected that the US exporting producers will have repaired the hurricane damage faced in the second half of 2005 and become fully operational again in the second half of 2006/beginning 2007, thereby producing additional quantities which may be sold to the Community market.

- (34) As to the non-cooperating US producers, which accounted for 27 % of US production capacity during the RIP, it cannot be excluded that they take up exports to the Community again, should measures be allowed to lapse.

*Possible development of worldwide capacity and demand*

- (35) An analysis was also carried out of possible medium term (up to 5 years) developments of demand and production capacity in the Community, the USA and the rest of the world. It was also analysed how the expected situation on demand and supply would affect the price levels in the Community. All figures in the following recitals are based on information sourced from the companies BASF, Dow and INEOS and the chemical industry's leading reference publications by PCI and Tecnon.
- (36) Taking into account the projections of both US and Community producers on future demand and production capacity, growth on the Community market is foreseen to be lower than in the rest of the world. The projected Community average growth rate on an annual basis stands at around 3 % in the medium term, compared to 7 % in Asia and 4,2 % projected worldwide.
- (37) In 2004, demand on the European market exceeded Community installed production capacity by approxi-

mately 40 000 tonnes. The inverse situation existed in the USA, where the existing capacity was some 90 000 tonnes higher than the effective use and sale of the product, which nevertheless did not negatively affect the high price levels, because of operational production problems limiting supply to the customers. Confronting the projected growth rates with the announced capacity expansions, some excess capacity over demand on the Community market can be expected as from 2008, in particular because of the likely implementation of INEOS' investment plans in the Community, which would increase the installed capacity in the Community by one quarter to a third. Such capacity expansion is expected not to become operational before early 2008. Although such increase in capacity might at the same time be partially compensated by a reduction of imports into the Community and increased export sales by Community producers, it is expected that total installed capacity in the Community by all producers would surpass demand on the Community market during 2008.

- (38) On the basis of evidence at the disposal of the Commission, the current excess capacity in the USA is expected to continue at least in the short term because domestic demand, although growing, will not absorb the spare capacity that will become operational again. Over a longer time frame up to 2010, excess capacity is expected to disappear, reducing the incentive for US producers to export. At the same time there are predictions of substantial shortages in Asia. This is illustrated by the fact that Dow Chemical has formed a joint venture with Petronas, called Optimal, and has installed 75 000 tonnes capacity in Malaysia, dedicated to serve the Asian ethanalamine market.

- (39) More in general, by 2010, worldwide production capacity is likely to have increased from around 1 300 000 tonnes to 1 785 000 tonnes. This includes new capacity installed in the Community (+ 205 000), in the USA (+ 80 000), Saudi Arabia (+100 000) and Asia (+ 100 000). World demand at a projected growth rate of 4,2 % would by 2010 have increased to between 1 550 000 tonnes and 1 700 000 tonnes. Taking into account that some capacity surplus is always absorbed by stoppages for maintenance and that therefore a certain buffer is needed, the projection for 2010 shows excess capacity in the Community, equilibrium in the USA and shortage in Asia and the rest of the world. In sum, the various capacity expansions do not point to a propensity for US exporting producers to dump on the Community market because of the likely match of supply and demand on a worldwide level. It should however be noted that this is an assessment referring to developments in the medium term, i.e. 2008 to 2010.



*Conclusion on the likelihood of a continuation or recurrence of dumping*

- (40) It is recalled that dumping during the RIP was found to exist for both cooperating exporting producers, however at a lower level than in the previous review investigation.
- (41) Compared to the previous review investigation, market share of US imports decreased from 29 % to 16,7 %. There appears to be 90 000 tonnes spare capacity in the USA, the low utilisation rate during the IP being a consequence of temporary events, and the use of an estimated 27 % of US installed capacity could not be investigated due to a lack of cooperation. It cannot be entirely ruled out that these non-cooperating producers would return to the Community market at dumped prices if the measures were allowed to lapse. Although demand on the US market is expected to be stronger than in the Community, the excess capacity in the USA is expected only to be absorbed in the medium term. Moreover, in order to maintain the profitability of production capacities installed, there currently exists an incentive for all producers to increase their sales to the Community market, should measures be repealed.
- (42) To conclude, there is a likelihood of continuation of dumping and a risk of an increase of the volume of imports possibly exerting a downward pressure on prices in the Community, at least in the short term, if measures were repealed.

**D. DEFINITION OF THE COMMUNITY INDUSTRY**

- (43) The three applicant Community producers fully cooperated in the investigation. During the RIP, they represented 80 % of the Community production. There is one additional supporting Community producer which supplied information in particular concerning its production but which did not reply to the full questionnaire. Hence, he had to be considered as non-cooperating.
- (44) It should be noted that since Regulation (EC) No 1603/2000 publishing the measures that are currently in force, Union Carbide Ltd (UK), which was taken over by the Dow Chemical Company, no longer produces ethanolamine in the Community. Furthermore, BP Chemicals changed its name to Innovene and Condea changed its name to Sasol. Finally, INEOS Oxide Ltd, the UK-based parent company of INEOS Americas LLC, acquired Innovene on 16 December 2005. Both companies, INEOS Americas LLC and Innovene, continued to fully cooperate in the proceeding.
- (45) On this basis the three Community producers are BASF AG, Innovene and Sasol and they constitute the

Community industry within the meaning of Article 4(1) and Article 5(4) of the basic Regulation.

- (46) The investigation showed that, as in the previous review investigation, part of the production of ethanolamine in the Community is intended for internal, or captive, use. The share is estimated at around one third of total Community production, as it was during the previous review investigation. Captive production was found at the premises of one of the producers included in the Community industry. This producer runs a plant which is earmarked and used for the sole purpose of captive use. The investigation confirmed that the applicant Community producers do not purchase the product concerned for trading purposes or for their captive use from independent parties, either inside or outside the Community. Ethanolamine for captive use is therefore not considered to be in competition with ethanolamine available on the Community market (hereafter the free market).

**E. SITUATION ON THE COMMUNITY MARKET**

**1. Consumption on the Community market**

Community consumption	2002	2003	2004	RIP
Total tonnes	283 992	331 194	358 830	366 645
Index	100	117	126	129
Captive tonnes	97 768	107 539	118 584	119 975
Index	100	110	121	123
Free market tonnes	186 224	223 655	240 246	246 670
Index	100	120	129	132

Source: Eurostat statistics and questionnaire replies.

- (47) The determination of total Community consumption was based on the combination of production minus the exports of all producers in the Community and the imports from third countries into the Community market. Compared to the year 2002, consumption during the RIP has increased by 29 % or by 83 000 tonnes. The growth was especially pronounced between 2002 and 2003 (+ 17 % or + 48 000 tonnes) but it continued during 2004 and the RIP, although at a lower pace. Consumption has been increasing as a consequence of increased demand for ethanolamines, based on a wide and expanding field of applications. The most important demand drivers since 2002 have been DEA for glyphosate production, TEA for esterquats and MEA for wood treatment.

- (48) Free market consumption increased by 32 % (or by 60 000 tonnes) over the period considered with an increase of 20 % (or 37 000 tonnes) between 2002 and 2003.
- (49) Concerning the captive market, consumption increased by 23 % or by 22 000 tonnes due to increased use of ethanolamines in production processes of other chemicals.

## 2. Imports from the USA, volume, market share and import prices

US Imports	2002	2003	2004	RIP
Tonnes	46 075	40 576	40 512	41 088
Index	100	88	88	89
Market share	24,7 %	18,1 %	16,9 %	16,7 %
Import price EUR/tonne	979,63	915,15	975,09	995,55
Index	100	93	100	102

Source: Eurostat statistics and questionnaire replies.

- (50) The volume of imports into the Community from the USA decreased by 12 % between 2002 and 2003 and has remained at that level since. The market share was determined on the basis of free market consumption in the Community and has declined from 24,7 % to 16,7 % over the period considered, which constitutes a loss of 8 percentage points. The drop of imports and market share between 2002 and 2003 coincided with a 7 % overall decline of the average import price. Between 2002 and 2003, the US exporting producers did not participate in the expansion of the free market consumption in the Community. Also after 2003, the US exporting producers did not increase their market share, although import prices increased again. In a sellers' market, such increased attractiveness would normally have caused additional sales, but US exporting producers did not come back to the Community market as expected, because of operational problems and even more attractive conditions on the US domestic market.
- (51) It should be noted that the above prices were collected from the Eurostat import statistics. They do not distinguish the product mix and contain various sales conditions which cannot be compared to those applied by other operators on the Community market. A precise price comparison between dumped imports and Community producers' prices at the same level of trade

was carried out and explained in recital (53) below. Over the period considered, the average import price increased modestly by 2 %. All imports into the Community originating in the USA were made via related importers and the import prices therefore are transfer prices within the company's group. In the previous review investigation, such import prices were found to have been artificially set in order to at least partially absorb the anti-dumping measures then in force. The related importers in the Community incurred significant losses during the former RIP and the margins they realised between purchase price (actual import price) and resale price on the Community market were not sufficient to cover the costs incurred between importation and resale. This was the reason that the previous review investigation led to the revision of the form of the anti-dumping measures and that specific fixed duty rates per tonne were imposed.

- (52) In the current review investigation, both the US exporting producers and their related importers in the Community were found to have realised profits during the RIP and the related importers' margins were found to have conformed to market conditions. The sales price levels compared to normal value and/or cost of production allowed for adequate profits for all companies involved in markets characterised by high sales prices.
- (53) The comparison of cif import prices at Community frontier charged to independent customers including anti-dumping duties with the Community industry's ex-work prices, for the same product types and on the same level of trade, led to the establishment of undercutting of the Community industry's sales prices by between 7,3 % and 17,5 %.

## 3. Imports from other third countries, volume, market share and import prices

Imports from other third countries	2002	2003	2004	RIP
Tonnes	17 596	18 688	12 276	8 773
Index	100	106	70	50
Market share	9,4 %	8,4 %	3,4 %	2,4 %
Import price EUR/tonne	1 034,23	970,75	982,67	955,24
Index	100	94	95	92

Source: Eurostat statistics.

- (54) Imports from other third countries halved over the period considered. The market share of the main exporting other countries, mainly Russia and Iran, has indeed become marginal. According to the user industry, this decreasing trend is due to the fact that it was difficult to obtain exactly the requested quantities at a precise delivery date in the two aforementioned countries.

#### 4. Economic situation of the Community industry

##### Output, production capacity and capacity utilisation

	2002	2003	2004	RIP
Production in tonnes	206 481	242 350	279 307	290 625
Index	100	117	135	141
Capacity in tonnes	263 320	273 820	302 070	311 820
Index	100	104	115	118
Capacity utilisation	78,4 %	88,5 %	92,5 %	93,2 %

- (55) Over the period considered, production has increased by 41 %. At the same time capacity was extended by 18 %, leading to an improvement of capacity utilisation from 78,4 % to 93,2 %.
- (56) The production capacity increase between 2002 and 2003 is marginal and reflects some efficiency improvements. From 2004 on, more intensive de-bottlenecking and new capacity expansions can be observed.

##### Inventories

Inventories	2002	2003	2004	RIP
Tonnes	9 543	10 883	10 228	7 596
Index	100	114	107	80

- (57) The level of inventories is compared at the end of each year 2002 to 2004 and varies to a certain degree depending upon orders. The level at the end of the RIP is lower, but shows the situation at 30 June 2005 and is therefore not properly comparable with year end inventories. This is because of the fact that, in view of somewhat lower demand from industrial users during the summer months, companies schedule lower production and maintenance of the production facilities.

##### Sales volume, market share and sales price

	2002	2003	2004	RIP
Sales volume	130 214	144 103	167 054	175 953
Index	100	111	128	135
Market share in total consumption (including captive use)	45,9 %	43,5 %	46,6 %	48,0 %
Market share in free market consumption	69,9 %	64,4 %	69,5 %	71,3 %
Sales price EUR/tonne (free market sales)	801,77	758,49	835,68	936,08
Index	100	95	104	117

- (58) The Community industry's sales volume to unrelated customers increased by 35 % over the period considered. Both the market share of total Community consumption and of free market consumption indicate that after a loss of market share between 2002 and 2003, market share has stabilised and stood at 48 % in relation to total consumption respectively 71,3 % in the free market during the RIP. The average price level of sales to unrelated customers followed a similar pattern and after a decrease of 5 % between 2002 and 2003, the price level in the free market during the RIP was 17 % higher than in 2002.
- (59) Compared to the price level during the RIP of the previous review investigation, which coincided with the calendar year 1998, sales prices in 2004 and during the current RIP were on average respectively 22,7 % and 37,5 % higher than in 1998. No invoices are issued with regard to the production destined for captive consumption which is used in integrated production facilities.

##### Factors affecting Community prices

- (60) Consumption has been continually increasing over the last decade, from 152 000 tonnes in 1995 to 367 000 tonnes during the RIP, which represents an annual increase of 9,7 %. The more recent increase of consumption over the period considered, from 2002 to the RIP, was 10,7 % on an annual basis, compared to a 7 % annual increase of capacity. This evolution has supported high price levels in the Community, at the same time pushing the Community industry towards an important improvement of capacity utilisation rates from 78,4 % to 93,2 %, leading to a 14,5 % annual increase of production. In absolute terms production increased by 84 000 tonnes compared to an increase of consumption of 83 000 tonnes, and capacity expanded by only 48 500 tonnes.

	2002	2003	2004	RIP
Average cost of production EUR/tonne	779,53	749,85	746,84	790,60
Index	100	96	96	101

- (61) High and increasing demand compared to a lower pace of capacity expansion and overall reduction of imports have sustained the price level of ethanolamine in the Community. Moreover, the sales margins have hardly been influenced by the full cost of production per tonne over the period considered, as the price increase was mainly due to market developments. The increase of cost of production by 5,9 % between 2004 and the RIP was the consequence of an increasing naphtha price, which is an oil based energy driver used in the production of ethylene oxide, the main raw material in the production of ethanolamine in the Community.

#### Employment, productivity and wages

	2002	2003	2004	RIP
Employment	102	103	101	102
Index	100	101	99	99
Productivity tonnes per employee	2 016	2 354	2 755	2 861
Index	100	117	137	142
Wages in EUR 1 000	6 860	7 526	8 018	7 598
Index	100	110	117	111
Average wage per employee (EUR)	66 976	73 105	79 097	74 797
Index	100	109	118	112

- (62) Employment at the level of the Community industry for the like product remained stable during the period considered. The production process is largely automated and therefore not labour-intensive. At the same time, due to constant improvements and de-bottlenecking of the production installations, productivity increased by 42 % over the period considered.
- (63) Over the period considered, wages increased by 11 % with a peak in 2004 which can be attributed to restructuring efforts and redundancies by one of the complaining Community producers. The average wage per employee followed a similar pattern.

#### Profitability

Sales to unrelated parties in the Community	2002	2003	2004	RIP
Sales value in EUR 1 000	104 402	109 301	139 603	164 705
Index	100	105	134	158
Cost of production in EUR 1 000	101 506	108 056	124 763	139 100
Index	100	106	123	137
Profitability	2,8 %	1,1 %	10,6 %	15,5 %

- (64) The profitability over the period considered on free market sales of the product concerned to unrelated parties in the Community increased from 2,8 % in 2002 to 15,5 % during the RIP, after a decline to 1,1 % in 2003. This improvement of profitability since 2003 is to be seen in the context of stable imports from the USA, and an increasing demand, with a consequence of both increased sales volumes and an increased sales price level, which during 2004 and the RIP were more pronounced than the increase of the cost of production.

#### Investments, return on investment and ability to raise capital

	2002	2003	2004	RIP
Investments in EUR 1 000	1 170	9 975	687 478	388 476
Index	100	852	58 750	33 198
Return on investment	2,2 %	0,9 %	10,2 %	17,6 %

- (65) The price levels obtained in the Community determine whether companies are inclined to build additional capacity. Over the period 2002 to 2003, return on investment was not considered sufficiently high in order to warrant the installation of additional production installations. As a consequence, companies limited themselves to some de-bottlenecking and efficiency improvements. The continuously increasing demand combined with only limited capacity increase has supported higher price levels, to such an extent that since 2004 it became again realistic to implement previously shelved investment projects.

(66) Concerning the ability to raise capital, it should be noted that the ethanalamine production is only a small part of the overall production of chemical products by the Community industry, which mostly represent major international chemical companies, which enjoy high overall levels of cash flow and auto-financing and credit-worthiness. Thus, the Community industry in general did not have major problems in raising capital.

#### Cash flow

	2002	2003	2004	RIP
Cash flow in EUR 1 000	4 842	3 301	16 863	27 596
Index	100	68	348	570
Cash flow on turnover	4,6 %	3,0 %	12,1 %	16,6 %

(67) The evolution of the cash flow is a further illustration of the link between price levels, profitability and the return on investment. After low cash flow levels in 2002 and 2003, the Community industry returned to double-digit figures for the cash flow in relation to turnover since 2004 and its level for most companies is sufficiently high in order to direct funding towards new investments in the ethanalamines business.

#### Growth

(68) The Community industry benefited from the growth of the market over the period considered, which is illustrated by the increase of its market share of total consumption from 45,9 % to 48 % and of its market share of free consumption from 69,9 % to 71,3 %.

#### Magnitude of the dumping margin

(69) Dumping continued during the RIP, even if at levels lower than established in the previous review investigation.

#### Recovery from the effects of past dumping

(70) As demonstrated above, the Community industry indeed has had the chance to recover from past dumping, in particular in terms of sales prices and profitability.

#### Export activity of the Community industry

	2002	2003	2004	RIP
Export volume tonnes	15 631	15 278	16 709	17 428
Index	100	98	107	111

(71) The Community industry's export volumes to third countries increased by 11 % over the period considered which corresponds to 4 % on average on an annual basis, which is largely in line with the expansion of world consumption. It illustrates that the Community industry is competitive on world markets.

#### 5. Conclusion on the situation on the Community market

(72) The volume of ethanalamine consumed on the Community market expanded by 29 % while imports from the USA declined by 11 % over the period considered. At the same time, the Community industry could increase its sales volume and thereby stabilise and even slightly increase its market share.

(73) The economic situation of the Community industry improved with respect to most of the economic indicators: production (+ 41 %), production capacity (+ 18 %) and capacity utilisation, sales volume (+ 35 % or + 45 000 tonnes) and value (+ 58 %), productivity, market share (+ 2 percentage points), cash flow and profitability, investments and return on investment. The development of the costs of production per tonne remained below the development of sales prices. The Community industry moreover benefited from the growth of the Community market and kept pace with world demand evolution as its export activity increased by 11 % in volume.

(74) To conclude, in view of the positive development of the indicators pertaining to the Community industry, it is considered to be in a good situation. It could not be established that material injury has continued. Therefore, it was examined whether there is a likelihood of recurrence of injury should measures be allowed to lapse.

#### F. LIKELIHOOD OF A RECURRENCE OF INJURY

##### Summary of the analysis of the likelihood of the continuation of dumping and of the recurrence of injurious dumping

(75) It is recalled that exporting producers in the USA were still practicing dumping during the RIP, even if at a reduced level compared to the previous investigation. Removal of the measures could, if the export prices were reduced commensurately, lead to dumping margins between 13,4 % and 28,3 % for the cooperating exporting producers, whereas the behaviour of the non-cooperating producers, that represented 42 % of the imports in the original investigation, remains unknown. The latter, however, being subject to the highest anti-dumping measures, would have the highest incentive to return to the Community market, if measures were terminated.

- (76) At the same time it is estimated that a spare capacity of 90 000 tonnes exists currently in the US market, once the operational problems and the effect of the hurricane will have been remedied.
- (77) It was therefore concluded that there is a likelihood of continuation of dumping and a risk of an increase of the volume of imports exerting a downward pressure on prices in the Community, at least in the short term, if measures were repealed.
- (78) It is normally the case that an increase of dumped imports would exercise a downward pressure on the sales price level and would negatively affect the Community industry's profitability as well as its financial recovery that was observed during the period considered. In this context, it should be noted that the level of undercutting would substantially increase should measures be repealed.

*Expected shift of US production from MEG to ethanolamine*

- (79) It is expected that US producers will to a certain extent redirect the use of the main raw material ethylene oxide (EO) from the production of monoethyleneglycol (MEG) to the production of ethanolamine.
- (80) The raw material EO is used in the production of other chemical products or derivatives, mostly ethylene glycols and in particular monoethyleneglycol (MEG). EO-capacity is limited to only a few locations in the world given its highly explosive and toxic nature, subject to special environmental, health, security and defence regulations. As a consequence, the allocation of EO depends upon the market prices of its derivatives.
- (81) Historically, a certain hierarchy existed in price levels: the ethylene price was higher than MEG and the price for ethanolamine was higher than both ethylene and MEG prices. However, since the end of 2003, MEG prices in the Community significantly increased and they became higher than ethylene prices and at certain periods of time even higher than ethanolamine prices. As a consequence, EO has been increasingly redirected towards MEG production, thereby creating a relative scarcity for EO in the market, at the same time contributing to keep ethanolamine prices at a relatively high level.
- (82) However, Middle East countries are currently investing in naphtha-based ethylene glycol capacity. New production capacity of MEG is expected to become operational in the short term in Kuwait (with participation of Dow Chemical), Saudi Arabia and Iran. Given the fact that naphtha is an oil-based material, these countries will have a clear comparative advantage in terms of cost. It is therefore reasonable to expect that the MEG price will go down in the short term and, that US producers will have reduced possibilities to sell MEG in particular in

Asia, where the Chinese textile and polyester activities already take more than 30 % of worldwide MEG consumption. This would be the case in particular for one of the non-cooperating exporting producers which is currently an important exporter of MEG to Asia. As a consequence, it can be expected that the US producers would turn towards the production of more ethanolamine, thereby exerting a downward pressure on prices and creating a need to find additional clients outside of the US domestic market and thus resorting to the Community market.

*Evolution of prices and possibility to adapt prices to cost of production after the RIP*

- (83) Bearing in mind the current stable situation of the Community industry, the likelihood of a recurrence of injury caused by a downward pressure on prices also depends upon the magnitude of such price decrease and the evolution of other factors, such as the cost of production and the possibility to pass cost increases on to clients. In this respect, it was investigated what was the situation after the RIP.
- (84) Additional data was collected in order to verify whether the conclusions drawn on the basis of the analysis of the period considered and more in particular the RIP remained valid during the second half of 2005 and the first five months of 2006.
- (85) During the second semester of 2005, prices on the Community market for all types of ethanolamines continued to rise by between 11,4 % and 14,7 %. The average price increase on the US market was even more pronounced with 22 %. Hurricane damage in Louisiana was primarily responsible for occasional US domestic market shortages.
- (86) This evolution continued into the first five months of 2006 but at a remarkably lower pace: prices on the Community market rose between 2,8 % and 4 % and on the US domestic market by 9,9 %, illustrating a gradual curing of the local operational and damage problems.
- (87) Compared to the RIP, oil prices increased considerably during the second half of 2005 and were on average some 30 % higher, affecting further the cost of naphtha, the increase of which began in the second half of the RIP (first semester of 2005). US import prices into the Community seem to adjust less rapidly to the increase of raw material prices, partly because of the slower adjustment of contract prices and in an effort to protect market share and partly because the US producers' production installations are gas based instead of naphtha based, with gas price increases lagging on oil price increases.

- (88) The oil prices continued on average to increase by 10 % into the first five months 2006, negatively affecting the profitability of the Community industry because of the observed bending of the upward sales price evolution.
- (89) The investigation of the events after the IP seems to point to a turning point in the evolution of the ethanolamine Community market. Sales prices seem to have reached a ceiling and for certain ethanolamine types even showed a minor decrease. There are indications that an increase of the cost of production will not easily be translated into higher sales prices to clients. However, it is unclear at this moment to what extent the increasing cost of production and the downward pressure on profitability will entail an injurious situation for the Community industry in the medium term.

*Conclusion on the likelihood of recurrence of injury*

- (90) In case measures were repealed, there is a short term likelihood of a significant increase of dumped US imports to the Community with downward pressure on prices as a consequence.
- (91) In the medium term, this could be aggravated by the increase of ethanolamine production in the US in reaction to reduced MEG sales opportunities, necessitating the US producers to find additional sales markets and thereby redirecting larger volumes to the Community market.
- (92) The apparent end of the increase of sales prices in the beginning of 2006 and the adverse evolution of the cost of production due to the oil price evolution also seem to negatively affect the Community industry's profitability.
- (93) All these factors point to a likelihood of recurrence of injury. However, some of the above conclusions are based on events likely to happen in the medium term.

**G. COMMUNITY INTEREST**

**1. Preliminary remark**

- (94) In accordance with Article 21 of the basic Regulation, it was examined whether maintaining the anti-dumping measures currently in force would be against the interest of the Community as a whole. The determination of Community interest was based on an appreciation of all the various interests involved, i.e. those of the Community industry, importers, traders, wholesalers and industrial users of the product concerned.
- (95) It should be recalled that in the previous investigations, the imposition of measures was not considered to be against the Community interest. Furthermore, the

present investigation is an expiry review, thus analysing a situation in which anti-dumping measures are in place.

- (96) On this basis it was examined whether, despite the conclusion on the likelihood of a continuation of dumping and likelihood of recurrence of injury, compelling reasons exist which would lead to the conclusion, in this particular case, that it is not in the Community interest to maintain measures.

**2. Interest of the Community industry**

- (97) It is recalled that dumping during the RIP was still present and that there exists a likelihood of continuation of dumping of the product concerned originating in the USA and of recurrence of injury to the Community industry.
- (98) The Community industry has proven to be a viable and competitive industry, confirmed by the positive development of most economic indicators, in particular profitability, cash flow and return on investment. The previously imposed anti-dumping measures have contributed to the current price level on the Community market, allowing the Community industry to restore a profitability that allows for a sufficient return on investment, to a degree where new capacity investments become economically feasible. In particular the US exporting producer INEOS, which after the takeover of Innovene became de facto a Community producer, announced important investments in the Community. The continuation of the measures would also contribute to uphold the profitability of this investment project. Therefore, it is in the interest of the Community industry to maintain measures against dumped imports from the USA.

**3. Interest of importers and traders/wholesalers**

- (99) Given the lack of cooperation of any trader and wholesaler, it was concluded that the absence or continuation of measures does not affect these parties to a great extent. Moreover, the investigation did not show the existence of any unrelated importers; all imports into the Community of the product concerned originating in the USA appear to transfer over importers related to the US exporting producers.
- (100) Continuation of the measures will not change the current situation of the related importers, who were found to have realised profits during the RIP at margins conform to market conditions. Of course, discontinuation of the measures could be in the interest of the related importers in case the sales price level to clients would not be affected and in case the US exporting producers would not claim part or all of the resulting extra profit margin while setting the prices at which related importers can purchase ethanolamine.

#### 4. Interest of industrial users

- (101) Based on the fact that the continuation of the measures would represent a second renewal of anti-dumping measures, particular attention was paid to the interest of the industrial users.
- (102) Only users from the esterquat business for fabric softeners came forward in this investigation. One industrial user, representing around 14 % of total US imports during the RIP, replied to the questionnaire, two others made their views known and forwarded information on the cost structure of production of the finished goods. Esterquats are produced on the basis of TEA and are used as fabric softeners, commercialised by the so-called 'soapers' such as Procter & Gamble, Unilever, Henkel, Benckiser and Colgate. These industrial users argue that the increase of the TEA price is putting their businesses in danger and that there exists a shortage of supply on the Community market. Both factors would be alleviated if the anti-dumping measures were allowed to lapse. Moreover, the continuation of production in the Community is allegedly in jeopardy if profitability of the esterquat business is not improved.
- (103) It was found that during the RIP TEA represented around 23 % of the total cost of production of esterquats, up from 22 % in 2003 but overall comparable to the situation that existed in 2002, the first year of the period considered. After the RIP, given the price evolution of TEA observed, the incidence of TEA in the full cost of the finished product is expected to be even more important. It is clear that an elimination of the anti-dumping measures would at least in the short term alleviate the burden of the cost of TEA as raw material. This cost reduction, under the hypothesis that the abolition of measures would be fully translated into a lower purchase price, would reduce the cost of TEA by approximately 7 %. The effect in the full cost of production of the finished goods would be a reduction of around 1 %, improving the profitability by the same margin.
- (104) It was found that profitability in the esterquat business has indeed deteriorated over the period considered from around 18 % to 8 %. However, the decline of the sales price of esterquats by 6 % over the period considered seems to have been the major contributing factor, causing the relative importance of production costs in the sales price to rise by almost 10 %. The sector seems to undergo the effect of a move east, in particular to Russia, where lower cost solutions can be found in general, but more specifically for the purchase of the other main raw material 'thalo fatty acid'. This product

of bovine origin can be replaced by the vegetal 'palm-styrene' for which supply in the east is more abundant. Moreover, the soapers, for reasons of efficiency, demand a local presence of their suppliers, which may be the main reason for a possible delocalisation out of the Community.

- (105) Finally, the claim of a shortage of supply of TEA in the Community market was examined but found not to be substantiated, based on offers put forward by certain producers, which were not accepted by the users concerned.
- (106) In summary, although it is recognised that the increasing price of TEA has exercised a negative pressure on the cost of production of the finished products of the industrial users that came forward, this pressure is rather limited and the abolition of the anti-dumping measures would only provide a marginal alleviation. Other factors, such as the cost of other raw materials and the requirements made by the customers of the products, were found to have a much more significant influence. Therefore, it was decided that a continuation of the measures would not significantly affect the industrial users.

#### 5. Conclusion on Community interest

- (107) The investigation has shown that the existing anti-dumping measures have contributed to the recovery of the Community industry. The Community industry would benefit from a continuation of the measures by upholding current profitable price levels, allowing for additional investment. If measures were allowed to lapse, this would endanger this recovery process. Therefore, the continuation of measures is in the interest of the Community industry.
- (108) Unrelated importers do not seem to exist and unrelated traders/wholesalers did not come forward. All imports originating in the USA are made via related traders, who, while measures were in place, were found to have obtained market conform profit margins during the RIP.
- (109) Furthermore, in the past, the existing measures appear not to have had any significant negative effect on the economic situation of the users. On the basis of the information collected during the current investigation, any price increase, if at all, resulting from the imposition of anti-dumping measures, does not appear to be disproportionate when compared to the benefit of the Community industry achieved by the removal of the trade distortion caused by the dumped imports.



(110) Regarding the Community interest, it is therefore concluded that there are no compelling reasons not to continue imposing the anti-dumping measures currently in force against imports of ethanolamines originating in the USA.

(111) It is therefore considered appropriate to maintain the current anti-dumping measures against imports of ethanolamines originating in the USA.

#### H. ANTI-DUMPING MEASURES

(112) All parties were informed of the essential facts and considerations on the basis of which it was intended to recommend that the existing measures be maintained. They were also granted a period to submit comments and claims subsequent to disclosure.

(113) The investigation showed that spare capacities exist in the country concerned and that dumping continued during the RIP. The situation of the Community industry improved over the period considered with respect of most of the injury factors mainly due to favourable market conditions worldwide. On the basis of the positive development of the economic situation of the Community industry, it could not be established that material injury has continued. The investigation on the likelihood of recurrence of injury however showed that a number of factors such as the spare capacity existing in the USA, the reduced sales opportunities for MEG, the situation of the ethanolamine both worldwide and at Community level, point to a likelihood of recurrence of injury in the medium term.

(114) It follows from the above that, as provided for by Article 11(2) of the basic Regulation, the anti-dumping measures applicable to imports of ethanolamines originating in the United States of America, imposed by Regulation (EC) No 1603/2000, as last amended by a notice regarding the anti-dumping fixed duty rate applicable to INEOS<sup>(1)</sup>, should be maintained. It is further considered that measures should be maintained for an additional period of two years only.

(115) On the one hand, a likelihood of recurrence of injurious dumping has been established based on the facts that (i) dumping by US exporting producers has continued notwithstanding the measures in force, and (ii) there is an expectation of increased imports into the Community because of existing excess production capacity of 90 000 tonnes in the USA that will become operational again by the end of 2006 and considering that there is no corresponding domestic demand to absorb this capacity in the USA. Additionally, the main non-cooperating US producer currently subject to the highest anti-dumping duty and therefore also having the highest incentive to return to the Community market in case the measures lapse, has the necessary distribution network at its

disposal because it sells other chemical products in the Community market.

(116) On the other hand, US excess capacity is expected to disappear gradually towards 2010 at the latest and the planned capacity expansions by one of the cooperating US exporting producers in the Community are scheduled to come online by the end of 2008, thus in two years time. The latter considerations, combined with continuing uncertainty about the influence of the evolution of the oil prices on the profitability of the Community industry, justify the limitation of the maintenance of the measures to two years.

(117) After this period of two years, the Commission will, if appropriate, initiate a new review investigation in accordance with Article 11 of the basic Regulation ex officio. will apply,

HAS ADOPTED THIS REGULATION:

#### Article 1

1. A definitive anti-dumping duty is hereby imposed on imports of ethanolamines falling within CN codes ex 2922 11 00 (monoethanolamine) (TARIC code 2922 11 00 10), ex 2922 12 00 (diethanolamine) (TARIC code 2922 12 00 10) and 2922 13 10 (triethanolamine), originating in the United States of America.

2. The rate of the definitive anti-dumping duty applicable to the net, free at Community frontier price, before duty, of the products described above and manufactured by the companies below shall be as follows:

Country	Company	Specific fixed duty
United States of America	The Dow Chemical Corporation 2030 Dow Center Midland, Michigan 48674 USA (TARIC additional code A115)	EUR 59,25 per tonne
	INEOS Americas LLC 7770 Rangeline Road Theodore, Alabama 36582 USA (TARIC additional code A145)	EUR 69,40 per tonne
	Huntsman Chemical Corporation 3040 Post Oak Boulevard PO Box 27707 Houston, Texas 77056 (TARIC additional code A116)	EUR 111,25 per tonne
	All other companies (TARIC additional code A999)	EUR 111,25 per tonne

<sup>(1)</sup> OJ C 306, 10.12.2002, p. 2.

3. Unless otherwise specified, the provisions in force concerning customs duties shall apply.

reduced by a percentage which corresponds to the apportioning of the price actually paid or payable.

4. In cases where goods have been damaged before entry into free circulation and, therefore, the price actually paid or payable is apportioned for the determination of the customs value pursuant to Article 145 of Commission Regulation (EEC) No 2454/93 <sup>(1)</sup>, the amount of the anti-dumping duty, calculated on the basis of the amounts set above, shall be

*Article 2*

This Regulation shall enter into force on the day following that of its publication in the *Official Journal of the European Union* and shall be in force for a period of two years.

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

Done at Luxembourg, 23 October 2006.

*For the Council*  
*The President*  
J.-E. ENESTAM

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

**COMMISSION REGULATION (EC) No 1584/2006**  
**of 24 October 2006**  
**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 Commission Regulation (EC) No 3223/94 of 21 December 1994 on detailed rules for the application of the import arrangements for fruit and vegetables <sup>(1)</sup>, and in particular Article 4(1) thereof,

Whereas:

- (1) Regulation (EC) No 3223/94 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 the Annex thereto.

- (2) In compliance with the above criteria, the standard import values must be fixed at the levels set out in the Annex to this Regulation,

HAS ADOPTED THIS REGULATION:

*Article 1*

The standard import values referred to in Article 4 of Regulation (EC) No 3223/94 shall be fixed as indicated in the Annex hereto.

*Article 2*

This Regulation shall enter into force on 25 October 2006.

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

Done at Brussels, 24 October 2006.

*For the Commission*

Jean-Luc DEMARTY

*Director-General for Agriculture and  
Rural Development*

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<sup>(1)</sup> OJ L 337, 24.12.1994, p. 66. Regulation as last amended by Regulation (EC) No 386/2005 (OJ L 62, 9.3.2005, p. 3).

## ANNEX

**to Commission Regulation of 24 October 2006 establishing the 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	052	63,3
	096	23,2
	204	40,7
	999	42,4
0707 00 05	052	142,9
	096	30,8
	204	42,1
	999	71,9
0709 90 70	052	98,7
	204	43,6
	999	71,2
0805 50 10	052	57,7
	388	70,8
	524	57,8
	528	55,3
	999	60,4
0806 10 10	052	90,2
	400	192,3
	508	289,2
	999	190,6
0808 10 80	388	80,2
	400	129,9
	404	100,0
	800	140,0
	804	140,2
	999	118,1
0808 20 50	052	107,3
	400	199,1
	720	51,9
	999	119,4

<sup>(1)</sup> Country nomenclature as fixed by Commission Regulation (EC) No 750/2005 (OJ L 126, 19.5.2005, p. 12). Code '999' stands for 'of other origin'.

**COMMISSION REGULATION (EC) No 1585/2006**  
**of 24 October 2006**  
**amending Annex III to Council Regulation (EC) No 318/2006**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 318/2006 of 20 February 2006 on the common organisation of the markets in the sugar sector <sup>(1)</sup>, and in particular Article 10(1) thereof,

Whereas:

- (1) Annex III to Regulation (EC) No 318/2006 lays down the national and regional quotas for the production of sugar, isoglucose and inulin syrup. For the 2006/2007 marketing year those quotas must be adjusted by 30 September 2006.
- (2) The adjustments result in particular from the application of Articles 8 and 9 of Regulation (EC) No 318/2006, which provide for the allocation of additional sugar quotas and additional and supplementary isoglucose quotas. The adjustments must take account of the communications from the Member States provided for in Article 12 of Regulation (EC) No 952/2006 of 29 June 2006 laying down detailed rules for the application of Council Regulation (EC) No 318/2006 as regards the management of the Community market in sugar and the quota system <sup>(2)</sup> relating in particular to the additional and supplementary quotas already allocated on the date on which the communication is drawn up.
- (3) The adjustments to the quotas in Annex III to Regulation (EC) No 318/2006 also result from the application of Article 3 of Council Regulation (EC) No 320/2006 of 20 February 2006 establishing a temporary scheme for the restructuring of the sugar industry in the Community and amending Regulation (EC) No 1290/2005 on the financing of the common agricultural policy <sup>(3)</sup>, which

provides for restructuring aid for undertakings which renounce their quotas. It is therefore necessary to take account of the renounced quotas in accordance with the Communication from the Commission (2006/C 234/04) of 29 September 2006 on the estimated availability of financial resources for granting of restructuring aid for the 2006/2007 marketing year <sup>(4)</sup>.

- (4) The adjustment of the quotas laid down in Annex III to Regulation (EC) No 318/2006 is without prejudice to the conditions governing the grant of the aid provided for in Chapter 10f of Council Regulation (EC) No 1782/2003 of 29 September 2003 establishing common rules for direct support schemes under the common agricultural policy and establishing certain support schemes for farmers and modifying Regulations (EEC) No 2019/93, (EC) 1452/2001, (EC) 1454/2001, (EC) 1868/94, (EC) No 1251/1999, (EC) 1673/2000, (EEC) No 2358/71 and (EC) No 2529/2001 <sup>(5)</sup> and in Article 7 of Regulation (EC) No 320/2006.
- (5) Annex III to Regulation (EC) No 318/2006 should therefore be amended accordingly.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for Sugar,

HAS ADOPTED THIS REGULATION:

*Article 1*

Annex III to Regulation (EC) No 318/2006 is hereby replaced by the Annex to this Regulation.

*Article 2*

This Regulation shall enter into force on the third 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, 24 October 2006.

*For the Commission*

Mariann FISCHER BOEL

*Member of the Commission*

<sup>(1)</sup> OJ L 58, 28.2.2006, p. 1.

<sup>(2)</sup> OJ L 178, 1.7.2006, p. 39.

<sup>(3)</sup> OJ L 58, 28.2.2006, p. 42.

<sup>(4)</sup> OJ C 234, 29.9.2006, p. 9.

<sup>(5)</sup> OJ L 270, 21.10.2003, p. 1. Regulation as last amended by Regulation (EC) No 1406/2006 (OJ L 265, 26.9.2006, p. 1).

## ANNEX

## 'ANNEX III

## NATIONAL AND REGIONAL QUOTAS

Member States or regions (1)	Sugar (2)	Isoglucose (3)	Inulin syrup (4)
Belgium	819 812	85 694	0
Czech Republic	454 862	—	—
Denmark	420 746	—	—
Germany	3 655 456	42 360	—
Greece	317 502	15 433	—
Spain	903 843	98 845	—
France (metropolitan)	3 552 221	23 755	0
French overseas departments	480 245	—	—
Ireland	0	—	—
Italy	778 706	24 301	—
Latvia	66 505	—	—
Lithuania	103 010	—	—
Hungary	401 684	164 736	—
Netherlands	864 560	10 891	0
Austria	387 326	—	—
Poland	1 671 926	32 056	—
Portugal (mainland)	34 500	11 870	—
The autonomous region of the Azores	9 953	—	—
Slovakia	207 432	50 928	—
Slovenia	52 973	—	—
Finland	146 087	14 210	—
Sweden	325 700	—	—
United Kingdom	1 138 627	32 602	—
Total	16 793 675	607 681	0

**COMMISSION REGULATION (EC) No 1586/2006****of 24 October 2006****amending Regulation (EC) No 1483/2006 as regards the quantities covered by the standing invitation to tender for the resale on the Community market of cereals held by the intervention agencies of the Member States**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1784/2003 of 29 September 2003 on the common organisation of the market in cereals <sup>(1)</sup>, and in particular Article 6 thereof,

Whereas:

- (1) Commission Regulation (EC) No 1483/2006 <sup>(2)</sup> opened standing invitations to tender for the resale on the Community market of cereals held by the intervention agencies of the Member States.
- (2) In view of the situation on the Community markets for common wheat, maize and rye and of the changes in demand for cereals in various regions in recent weeks, new quantities of cereals held in intervention should be made available in some Member States. The intervention agencies in the Member States concerned should therefore be authorised to increase the quantities put out to tender by 350 000 tonnes of common wheat in

Germany, 350 000 tonnes in Hungary, 172 272 tonnes in Sweden, 174 021 tonnes in Denmark and 30 000 tonnes in Finland, 100 000 tonnes of maize in Hungary and 100 000 tonnes in Slovakia, and 236 565 tonnes of rye in Germany.

- (3) Regulation (EC) No 1483/2006 should be amended accordingly.
- (4) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for Cereals,

HAS ADOPTED THIS REGULATION:

*Article 1*

Annex I to Regulation (EC) No 1483/2006 is hereby replaced by the Annex hereto.

*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, 24 October 2006.

*For the Commission*  
Mariann FISCHER BOEL  
*Member of the Commission*

<sup>(1)</sup> OJ L 270, 21.10.2003, p. 78. Regulation as amended by Commission Regulation (EC) No 1154/2005 (OJ L 187, 19.7.2005, p. 11).

<sup>(2)</sup> OJ L 276, 7.10.2006, p. 58.

## ANNEX

## ANNEX I

## LIST OF INVITATIONS TO TENDER

Member State	Quantities of cereals made available for sale on the Community market (tonnes)				Intervention agency Name, address and contact details
	Common wheat	Barley	Maize	Rye	
Belgique/België	0	0	—	—	Bureau d'intervention et de restitution belge/Belgisch Interventie- en Restitutiebureau Rue de Trèves/Trierstraat 82 B-1040 Bruxelles/Brussel Tél. (32-2) 287 24 78 Fax (32-2) 287 25 24 E-mail: webmaster@birb.be
Česká republika	0	0	0	—	Státní zemědělský intervenční fond Odbor rostlinných komodit Ve Smečkách 33 CZ-110 00, Praha 1 Téléphone: (420) 222 87 16 67, 222 87 14 03 Télécopieur: (420) 296 80 64 04 e-mail: dagmar.hejrovska@szif.cz
Danmark	174 021	0	—	—	Direktoratet for FødevareErhverv Nyropsgade 30 DK-1780 København Téléphone: (45) 33 95 88 07 Télécopieur: (45) 33 95 80 34 e-mail:mij@dfef.dk and pah@dfef.dk
Deutschland	350 000	0	—	336 565	Bundesanstalt für Landwirtschaft und Ernährung Deichmanns Aue 29 D-53179 Bonn Téléphone: (49-228) 68 45-37 04 télécopieur 1: (49-228) 68 45-39 85 télécopieur 2: (49-228) 68 45-32 76 e-mail: pflanzlErzeugnisse@ble.de
Eesti	0	0	—	—	Põllumajanduse Registrite ja Informatsiooni Amet Narva mnt 3, 51009 Tartu Téléphone: (372) 7371 200 Télécopieur: (372) 7371 201 e-mail: pria@pria.ee
Ελλάδα	—	—	—	—	Οργανισμός Πληρωμών και Ελέγχου Κοινοτικών Ενισχύσεων Προσανατολισμού και Εγγυήσεων (ΟΠΕΚΕΠΕ) Αχαρνών 241 GR-104 46 Αθήνα Τηλ. (30-210) 21 24 787 (30-210) 21 24 754 Φαξ (30-210) 21 24 791 e-mail: ax17u073@minagric.gr
España	—	—	—	—	Secretaría General de Intervención de Mercados (FEGA) Almagro, 33 E-28010 Madrid Téléphone: (34) 913 47 47 65 Télécopieur: (34) 913 47 48 38 e-mail: sgintervencion@fega.mapa.es
France	0	0	—	—	Office national interprofessionnel des grandes cultures (ONIGC) 21, avenue Bosquet F-75326 Paris Cedex 07 Tél. (33-1) 44 18 22 29 et 23 37 Fax (33-1) 44 18 20 08 et 20 80 e-mail: m.meizels@onigc.fr et f.abeasis@onigc.fr



Member State	Quantities of cereals made available for sale on the Community market (tonnes)				Intervention agency Name, address and contact details
	Common wheat	Barley	Maize	Rye	
Ireland	—	0	—	—	Intervention Operations, OFI, Subsidies & Storage Division, Department of Agriculture & Food Johnstown Castle Estate, County Wexford Téléphone: (353-53) 916 34 00 Télécopieur: (353-53) 914 28 43
Italia	—	—	—	—	Agenzia per le Erogazioni in Agricoltura — AGEA Via Torino, 45 I-00184 Roma Téléphone: (39) 06 49 49 97 55 Télécopieur: (39) 06 49 49 97 61 E-mail: d.spampinato@agea.gov.it
Kypros/Kibris	—	—	—	—	
Latvija	0	0	—	—	Lauku atbalsta dienests Republikas laukums 2, Rīga, LV – 1981 Téléphone: (371) 702 7893 Télécopieur: (371) 702 7892 e-mail: lad@lad.gov.lv
Lietuva	0	0	—	—	The Lithuanian Agricultural and Food Products Market regulation Agency L. Stuokos-Guceviciaus Str. 9-12, Vilnius, Lithuania Téléphone: (370-5) 268 5049 Télécopieur: (370-5) 268 5061 e-mail: info@litfood.lt
Luxembourg	—	—	—	—	Office des licences 21, rue Philippe II, Boîte postale 113 L-2011 Luxembourg Tél. (352) 478 23 70 Fax (352) 46 61 38 Télex: 2 537 AGRIM LU
Magyarország	350 000	0	100 000	—	Mezőgazdasági és Vidékfejlesztési Hivatal Soroksári út 22–24. H-1095 Budapest Téléphone (36-1) 219 45 76 Télécopieur: (36-1) 219 89 05 E-mail: erteresites@mvh.gov.hu
Malta	—	—	—	—	
Nederland	—	—	—	—	Dienst Regelingen Roermond Postbus 965 6040 AZ Roermond Nederland Tel. (31) 475 35 54 86 Fax (31) 475 31 89 39 E-mail: p.a.c.m.van.de.lindelooft@minlnv.nl
Österreich	0	0	0	—	AMA (Agrarmarkt Austria) Dresdnerstraße 70 A-1200 Wien Téléphone: (43-1) 331 51-258 (43-1) 331 51-328 Télécopieur: (43-1) 331 51-46 24 (43-1) 331 51-44 69 e-mail: referat10@ama.gv.at

Member State	Quantities of cereals made available for sale on the Community market (tonnes)				Intervention agency Name, address and contact details
	Common wheat	Barley	Maize	Rye	
Polska	0	0	0	—	Agencja Rynku Rolnego Biuro Produktów Roślinnych Nowy Świat 6/12 PL-00-400 Warszawa Tel.: (48-22) 661 78 10 Faks: (48-22) 661 78 26 E-mail: cereals-intervention@arr.gov.pl
Portugal	—	—	—	—	Instituto Nacional de Intervenção e Garantia Agrícola (INGA) Rua Castilho, n.º 45-51 1269-163 Lisboa Téléphone: (351) 21 751 85 00 (351) 21 384 60 00 Télécopieur: (351) 21 384 61 70 e-mail: inga@inga.min-agricultura.pt edalberto.santana@inga.min-agricultura.pt
Slovenija	—	—	—	—	Agencija Republike Slovenije za kmetijske trge in razvoj podeželja Dunajska 160, 1000 Ljubjana Téléphone: (386) 1 580 76 52 Télécopieur: (386) 1 478 92 00 e-mail: aktrp@gov.si
Slovensko	0	0	100 000	—	Pôdohospodárska platobná agentúra Oddelenie obilnín a škrobu Dobrovičova 12 815 26 Bratislava Slovenská republika Tel.: (421-2) 58 24 32 71 Fax: (421-2) 53 41 26 65 e-mail: jvargova@apa.sk
Suomi/Finland	30 000	0	—	—	Maa- ja metsätalousministeriö (MMM)/Jord- och skogsbruksministeriet Interventioyksikkö – Intervention Unit Malminkatu 16, Helsinki/Malmgatan 16, Helsingfors PL/PB 30 FI-00023 Valtioneuvosto/Statsrådet Puhelin/Telefon (358-9) 160 01 Faksi/Fax (358-9) 16 05 27 72 (358-9) 16 05 27 78 Sähköposti/E-post: intervention.unit@mmm.fi
Sverige	172 272	0	—	—	Jordbruksverket S-55182 Jönköping Tfn: (46-36) 15 50 00 Fax: (46-36) 19 05 46 e-mail: jordbruksverket@sjv.se
United Kingdom	—	0	—	—	Rural Payments Agency Lancaster House Hampshire Court Newcastle upon Tyne NE4 7YH Téléphone: (44-191) 226 58 82 Télécopieur: (44-191) 226 58 24 e-mail: cerealsintervention@rpa.gov.uk

The symbol “—” means no intervention stock of this cereal in this Member State.’

**COMMISSION REGULATION (EC) No 1587/2006****of 23 October 2006****amending Council Regulation (EC) No 765/2006 concerning restrictive measures against President Lukashenko and certain officials of Belarus**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 765/2006 of 18 May 2006 concerning restrictive measures against President Lukashenko and certain officials of Belarus <sup>(1)</sup>, and in particular Article 8(a) thereof,

Whereas:

- (1) In accordance with Regulation (EC) No 765/2006, all funds and economic resources belonging to, owned, held or controlled by President Lukashenko as well as those belonging to, owned, held or controlled by certain other officials of Belarus who are responsible for the violations of international electoral standards in the presidential elections in Belarus on 19 March 2006 and the crackdown on civil society and democratic opposition, and those natural or legal persons, entities and bodies associated with them, as listed in Annex I to that Regulation, are frozen.

- (2) Council Decision 2006/718/CFSP <sup>(2)</sup> amended Annex IV to Common Position 2006/276/CFSP <sup>(3)</sup> which sets out the list of natural and legal persons, entities and bodies to whom the freezing of funds and economic resources provided for in the Common Position, should apply. Annex I should therefore be amended accordingly.

- (3) In order to ensure that the measures provided for in this Regulation are effective, this Regulation must enter into force immediately,

HAS ADOPTED THIS REGULATION:

*Article 1*

Annex I to Regulation (EC) No 765/2006 is hereby amended as set out in the Annex to this Regulation.

*Article 2*

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

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

Done at Brussels, 23 October 2006.

*For the Commission*

Eneko LANDÁBURU

*Director-General for External Relations*

<sup>(1)</sup> OJ L 134, 20.5.2006, p. 1.

<sup>(2)</sup> See page 72 of this Official Journal.

<sup>(3)</sup> OJ L 101, 11.4.2006, p. 5. Common Position as amended by Common Position 2006/362/CFSP (OJ L 134, 20.5.2006, p. 45).

## ANNEX

Annex I to Regulation (EC) No 765/2006 is amended as follows:

- (1) Three columns, entitled 'Address', 'Passport number' and 'Nationality', respectively, shall be inserted in Annex I.
- (2) The following natural persons shall be added:
  - (a) 'Name: Bortnik, Sergei. Name in Belarusian spelling: БОРТНИК Сяргей. Name in Russian spelling: БОРТНИК Сергей. Position: Public prosecutor. Address: Ul. Sarganovo 80-263, Minsk, Belarus. Date of Birth: 28.5.1953. Place of Birth: Minsk. Passport No: MP 0469554.'
  - (b) 'Name: Migun, Andrei. Name in Belarusian spelling: МИГУН Андрэй. Name in Russian spelling: МИГУН Андрэй. Position: Public prosecutor. Address: Ul. Goretskovo 53-16, Minsk, Belarus. Date of Birth: 5.2.1978. Place of Birth: Minsk. Passport No: MP 1313262.'
  - (c) 'Name: Rybakov, Alexei. Name in Belarusian spelling: РЫБАКОЎ Аляксей. Name in Russian spelling: РЫБАКОВ Алексей. Position: Judge of the Minsk Moskovsky District Court. Address: Ul. Jesenina 31-1-104, Minsk, Belarus.'
  - (d) 'Name: Yasinovich, Leonid Stanislavovich. Name in Belarusian spelling: ЯСІНОВІЧ Леанід Станіслававіч. Name in Russian spelling: ЯСИНОВИЧ Леонид Станиславович. Position: Judge of the Minsk Tsentralny District Court. Address: Ul. Gorovtsa 4-104, Minsk, Belarus. Date of birth: 26.11.1961. Place of birth: Buchany, Vitebsk district, Belarus. Passport No: MP 0515811.'
- (3) The entry 'Name: Naumov, Vladimir Vladimirovich. Date of birth: 1956. Position: Minister of the Interior' shall be replaced by:

'Name: Naumov, Vladimir Vladimirovich. Date of birth: 7.2.1956. Position: Minister of the Interior.'

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**COMMISSION REGULATION (EC) No 1588/2006****of 23 October 2006****establishing a prohibition of fishing for Northern prawn in Norwegian waters, south of 62° N 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 51/2006 of 22 December 2005 fixing for 2006 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 2006.
- (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 2006.

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

HAS ADOPTED THIS REGULATION:

*Article 1***Quota exhaustion**

The fishing quota allocated to the Member State referred to in the Annex to this Regulation for the stock referred to therein for 2006 shall be deemed to be exhausted from the date set out 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 set out in that Annex. It shall be prohibited to retain on board, tranship or land such stock caught by those vessels after that date.

*Article 3***Entry into force**

This Regulation shall enter into force on the 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, 23 October 2006.

For the Commission

Jörgen HOLMQUIST

Director-General for Fisheries and Maritime Affairs

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

<sup>(2)</sup> OJ L 261, 20.10.1993, p. 1. Regulation as last amended by Regulation (EC) No 768/2005 (OJ L 128, 21.5.2005, p. 1).

<sup>(3)</sup> OJ L 16, 20.1.2006, p. 1. Regulation as last amended by Commission Regulation (EC) No 1262/2006 (OJ L 230, 24.8.2006 p. 4).

## ANNEX

No	42
Member State	Sweden
Stock	PRA/04-N.
Species	Northern prawn ( <i>Pandalus borealis</i> )
Zone	Norwegian waters, south of 62° N (EC waters)
Date	6 October 2006

**COMMISSION REGULATION (EC) No 1589/2006****of 24 October 2006****establishing a prohibition of fishing for redfish in NAFO zone 3M by vessels flying the flag of Estonia, Germany, Latvia, Lithuania and Portugal**

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 51/2006 of 22 December 2005 fixing for 2006 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 2006.
- (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 States referred to therein have exhausted the quota allocated for 2006.

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

HAS ADOPTED THIS REGULATION:

*Article 1***Quota exhaustion**

The fishing quota allocated to the Member States referred to in the Annex to this Regulation for the stock referred to therein for 2006 shall be deemed to be exhausted from the date set out 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 States referred to therein shall be prohibited from the date set out in that Annex. It shall be prohibited to retain on board, tranship or land such stock caught by those vessels after that date.

*Article 3***Entry into force**

This Regulation shall enter into force on the 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, 24 October 2006.

*For the Commission*

Jörgen HOLMQUIST

*Director-General for Fisheries and Maritime Affairs*

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

<sup>(2)</sup> OJ L 261, 20.10.1993, p. 1. Regulation as last amended by Regulation (EC) No 768/2005 (OJ L 128, 21.5.2005, p. 1).

<sup>(3)</sup> OJ L 16, 20.1.2006, p. 1. Regulation as last amended by Commission Regulation (EC) No 1262/2006 (OJ L 230, 24.8.2006, p. 4).

## ANNEX

No	39
Member States	Estonia, Germany, Latvia, Lithuania and Portugal
Stock	RED/N3M.
Species	Redfish ( <i>Sebastes</i> spp.)
Zone	NAFO 3M
Date	4 October 2006



## COMMISSION REGULATION (EC) No 1590/2006

of 24 October 2006

**determining the extent to which the applications for import licences lodged from 16 to 18 October 2006 for butter originating in New Zealand under the import tariff quota managed according to Regulation (EC) No 1452/2006 can be accepted**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1255/1999 of 17 May 1999 on the common organisation of the market in milk and milk products <sup>(1)</sup>, and in particular Article 29 thereof,

Having regard to Commission Regulation (EC) No 1452/2006 of 29 September 2006 providing for interim measures for the management of a tariff quota for New Zealand butter for October to December 2006 and derogating from (EC) Regulation (EC) No 2535/2001 <sup>(2)</sup> and in particular Article 3(2) thereof,

Whereas:

(1) 7 applications for import licences for butter originating in New Zealand (under quota No 09.4589) were lodged

in the competent authorities from 16 to 18 October 2006 according to Regulation (EC) No 1452/2006. These applications concerned a total of 14 294,6 tonnes.

(2) As this quantity is equal to the available quantity of 14 294,6 tonnes, all applications can be accepted,

HAS ADOPTED THIS REGULATION:

*Article 1*

Applications for import licences for butter originating in New Zealand lodged pursuant to Regulation (EC) No 1452/2006 from 16 to 18 October 2006 and notified to the Commission by 20 October 2006 shall be accepted.

*Article 2*

This Regulation shall enter into force on 25 October 2006.

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

Done at Brussels, 24 October 2006.

*For the Commission*

Jean-Luc DEMARTY

*Director-General for Agriculture and  
Rural Development*

<sup>(1)</sup> OJ L 160, 26.6.1999, p. 48. Regulation as last amended by Regulation (EC) No 1913/2005 (OJ L 307, 25.11.2005, p. 2).

<sup>(2)</sup> OJ L 271, 30.9.2006, p. 40.

**COMMISSION DIRECTIVE 2006/86/EC****of 24 October 2006****implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells****(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells<sup>(1)</sup>, and in particular Article 8, Articles 11(4) and 28(a), (c), (g) and (h) thereof,

Whereas:

- (1) Directive 2004/23/EC lays down standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells intended for human applications, and of manufactured products derived from human tissues and cells intended for human applications, so as to ensure a high level of human health protection.
- (2) In order to prevent the transmission of diseases by human tissues and cells for human applications and to ensure an equivalent level of quality and safety, Directive 2004/23/EC calls for the establishment of specific technical requirements for each one of the steps in the human tissues and cells application process, including standards and specifications with regard to a quality system for tissue establishments.
- (3) An accreditation, designation, authorisation or licensing system for tissue establishments and for the preparation processes at the tissue establishments should be established in Member States in accordance with Directive 2004/23/EC, in order to ensure a high level of protection of human health. It is necessary to lay down the technical requirements for this system.
- (4) The requirements for accreditation, designation, authorisation or licensing of tissue establishments should cover the organisation and management, personnel, equipment

and materials, facilities/premises, documentation and records and quality review. Accredited, designated, authorised or licensed tissue establishments should comply with additional requirements for the specific activities they carry out.

- (5) The air quality standard during the processing of tissues and cells is a key factor that may influence the risk of tissue or cell contamination. An air quality with particle counts and microbial colony counts equivalent to those of Grade A, as defined in the European Guide to Good Manufacturing Practice, Annex 1 and Commission Directive 2003/94/EC<sup>(2)</sup>, is generally required. However, in certain situations, an air quality with particle counts and microbial colony counts equivalent to those of Grade A standard is not indicated. In these circumstances it should be demonstrated and documented that the chosen environment achieves the quality and safety required for the type of tissue and cells, process and human application concerned.
- (6) The scope of this Directive should embrace the quality and safety of human tissues and cells during coding, processing, preservation, storage and distribution to the healthcare establishment where they will be applied to the human body. However, it should not extend to the human application of these tissues and cells (such as implantation surgery, perfusion, insemination or transfer of embryos). The provisions of this Directive concerning traceability and the reporting of serious adverse reactions and events apply also to the donation, procurement and testing of human tissues and cells regulated by Commission Directive 2006/17/EC<sup>(3)</sup>.
- (7) The use of tissues and cells for human application carries a risk of disease transmission and other potential adverse effects in recipients. In order to monitor and reduce these effects, specific requirements for traceability and a Community procedure for notifying serious adverse reactions and events should be set out.

<sup>(1)</sup> OJ L 102, 7.4.2004, p. 48.<sup>(2)</sup> <http://pharmacos.eudra.org/F2/eudraxlex/vol-4/home.htm> and OJ L 262, 14.10.2003, p. 22.<sup>(3)</sup> OJ L 38, 9.2.2006, p. 40.

- (8) Suspected serious adverse reactions, in the donor or in the recipient, and serious adverse events from donation to distribution of tissues and cells, which may influence the quality and safety of tissues and cells and which may be attributed to procurement (including donor evaluation and selection), testing, processing, preservation, storage and distribution of human tissues and cells should be notified without delay to the competent authority.
- (9) Serious adverse reactions may be detected during or following procurement in living donors or during or following human application. They should be reported to the associated tissue establishment for subsequent investigation and notification to the competent authority. This should not preclude a procurement organisation or an organisation responsible for human application from also directly notifying the competent authority if it so wishes. This Directive should define the minimum data needed for notification to the competent authority, without prejudice to the ability of Member States to maintain or introduce in their territory more stringent and protective measures which comply with the requirements of the Treaty.
- (10) In order to minimise transmission costs, avoid overlaps and increase administrative efficiency, modern technologies and e-government solutions should be used to perform the tasks related to the transmission and treatment of information. These technologies should be based on a standard exchange format using a system suitable for the management of reference data.
- (11) To facilitate traceability and information on the main characteristics and properties of tissues and cells, it is necessary to lay down the basic data to be included in a single European code.
- (12) This Directive respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union.
- (13) The measures provided for in this Directive are in accordance with the opinion of the Committee set up by Article 29 of Directive 2004/23/EC,
- (a) human tissues and cells intended for human applications; and
- (b) manufactured products derived from human tissues and cells intended for human applications, where those products are not covered by other directives.
2. The provisions of Articles 5 to 9 of this Directive, concerning traceability and the reporting of serious adverse reactions and events shall also apply to the donation, procurement and testing of human tissues and cells.

## Article 2

### Definitions

For the purposes of this Directive, the following definitions apply:

- (a) 'reproductive cells' means all tissues and cells intended to be used for the purpose of assisted reproduction;
- (b) 'partner donation' means the donation of reproductive cells between a man and a woman who declare that they have an intimate physical relationship;
- (c) 'quality system' means the organisational structure, defined responsibilities, procedures, processes, and resources for implementing quality management and includes all activities which contribute to quality, directly or indirectly;
- (d) 'quality management' means the coordinated activities to direct and control an organisation with regard to quality;
- (e) 'Standard Operating Procedures' (SOPs) means written instructions describing the steps in a specific process, including the materials and methods to be used and the expected end product;
- (f) 'validation' (or 'qualification' in the case of equipment or environments) means establishing documented evidence that provides a high degree of assurance that a specific process, piece of equipment or environment will consistently produce a product meeting its predetermined specifications and quality attributes; a process is validated to evaluate the performance of a system with regard to its effectiveness based on intended use;

HAS ADOPTED THIS DIRECTIVE:

## Article 1

### Scope

1. This Directive shall apply to the coding, processing, preservation, storage and distribution of:

- (g) 'traceability' means the ability to locate and identify the tissue/cell during any step from procurement, through processing, testing and storage, to distribution to the recipient or disposal, which also implies the ability to identify the donor and the tissue establishment or the manufacturing facility receiving, processing or storing the tissue/cells, and the ability to identify the recipient(s) at the medical facility/facilities applying the tissue/cells to the recipient(s); traceability also covers the ability to locate and identify all relevant data relating to products and materials coming into contact with those tissues/cells;
- (h) 'critical' means potentially having an effect on the quality and/or safety of or having contact with the cells and tissues;
- (i) 'procurement organisation' means a health care establishment or a unit of a hospital or another body that undertakes the procurement of human tissues and cells and that may not be accredited, designated, authorised or licensed as a tissue establishment;
- (j) 'organisations responsible for human application' means a health care establishment or a unit of a hospital or another body which carries out human application of human tissues and cells.
- (b) organisations responsible for human application of tissues and cells have procedures in place to retain the records of tissues and cells applied and to notify tissue establishments without delay of any serious adverse reactions observed during and after clinical application which may be linked to the quality and safety of tissues and cells;
- (c) tissue establishments that distribute tissue and cells for human application provide information to the organisation responsible for human application of tissues and cells about how that organisation should report serious adverse reactions as referred to in (b).

2. Member States shall ensure that tissue establishments:

- (a) have procedures in place to communicate to the competent authority without delay all relevant available information about suspected serious adverse reactions as referred to in paragraph 1(a) and (b);
- (b) have procedures in place to communicate to the competent authority without delay the conclusion of the investigation to analyse the cause and the ensuing outcome.

3. Member States shall ensure that:

- (a) the responsible person referred to in Article 17 of Directive 2004/23/EC notifies the competent authority of the information included in the notification set out in Part A of Annex III;

- (b) tissue establishments notify the competent authority of the actions taken with respect to other implicated tissues and cells that have been distributed for human applications;

- (c) tissue establishments notify the competent authority of the conclusion of the investigation, supplying at least the information set out in Part B of Annex III.

#### Article 3

##### **Requirements for the accreditation, designation, authorisation or licensing of tissue establishments**

A tissue establishment must comply with the requirements set out in Annex I.

#### Article 4

##### **Requirements for the accreditation, designation, authorisation, licensing of tissue and cell preparation processes**

Preparation processes at the tissue establishments must comply with the requirements set out in Annex II.

#### Article 5

##### **Notification of serious adverse reactions**

1. Member States shall ensure that:

- (a) procurement organisations have procedures in place to retain the records of tissues and cells procured and to notify tissue establishments without delay of any serious adverse reactions in the living donor which may influence the quality and safety of tissues and cells;

*Article 6***Notification of serious adverse events**

1. Member States shall ensure that:
  - (a) procurement organisations and tissue establishments have procedures in place to retain the records and to notify tissue establishments without delay of any serious adverse events that occur during procurement which may influence the quality and/or safety of human tissues and cells;
  - (b) organisations responsible for human application of tissues and cells have procedures in place to notify tissue establishments without delay of any serious adverse events that may influence the quality and safety of the tissues and cells;
  - (c) tissue establishments provide to the organisation responsible for human application information about how that organisation should report serious adverse events to them that may influence the quality and safety of the tissues and cells.

2. In the case of assisted reproduction, any type of gamete or embryo misidentification or mix-up shall be considered to be a serious adverse event. All persons or procurement organisations or organisations responsible for human application performing assisted reproduction shall report such events to the supplying tissue establishments for investigation and notification to the competent authority.

3. Member States shall ensure that tissue establishments:
  - (a) have procedures in place to communicate to the competent authority without delay all relevant available information about suspected serious adverse events as referred to in paragraph 1(a) and (b);
  - (b) have procedures in place to communicate to the competent authority without delay the conclusion of the investigation to analyse the cause and the ensuing outcome.

4. Member States shall ensure that:
  - (a) the responsible person referred to in Article 17 of Directive 2004/23/EC notifies the competent authority of the information included in the notification set out in Part A of Annex IV;
  - (b) tissue establishments evaluate serious adverse events to identify preventable causes within the process;
  - (c) tissue establishments notify the competent authority of the conclusion of the investigation, supplying at least the information set out in Part B of Annex IV.

*Article 7***Annual reports**

1. Member States shall submit to the Commission an annual report, by 30 June of the following year, on the notification of serious adverse reactions and events received by the competent authority. The Commission shall submit to the competent authorities of Member States a summary of the reports received. The competent authority shall make this report available to tissue establishments.
2. Data transmission shall comply with the data exchange format specifications as set out in Annex V, part A and B, and shall provide all the information necessary to identify the sender and maintain its reference data.

*Article 8***Communication of information between competent authorities and to the Commission**

Member States shall ensure that their competent authorities communicate to each other and to the Commission such information as is appropriate with regard to serious adverse reactions and events, in order to guarantee that adequate actions are taken.

*Article 9***Traceability**

1. Tissue establishments shall have effective and accurate systems to uniquely identify and label cells/tissues received and distributed.
2. Tissue establishments and organisations responsible for human application shall retain the data set out in Annex VI for at least 30 years, in an appropriate and readable storage medium.

*Article 10***European coding system**

1. A single European identifying code shall be allocated to all donated material at the tissue establishment, to ensure proper identification of the donor and the traceability of all donated material and to provide information on the main characteristics and properties of tissues and cells. The code shall incorporate at least the information set out in Annex VII.
2. Paragraph 1 shall not apply to partner donation of reproductive cells.

*Article 11***Transposition**

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 1 September 2007, at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with Article 10 of this Directive, by 1 September 2008.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

*Article 12***Entry into force**

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

*Article 13***Addressees**

This Directive is addressed to the Member States.

Done at Brussels, 24 October 2006.

*For the Commission*  
Markos KYPRIANOU  
*Member of the Commission*

## ANNEX I

**Requirements for accreditation, designation, authorisation or licensing of tissue establishments as referred to in Article 3****A. ORGANISATION AND MANAGEMENT**

1. A responsible person must be appointed having qualifications and responsibilities as provided in Article 17 of Directive 2004/23/EC.
2. A tissue establishment must have an organisational structure and operational procedures appropriate to the activities for which accreditation/designation/authorisation/licensing is sought; there must be an organisational chart which clearly defines accountability and reporting relationships.
3. Every tissue establishment must have access to a nominated medical registered practitioner to advise on and oversee the establishment's medical activities such as donor selection, review of clinical outcomes of applied tissues and cells or interaction as appropriate with clinical users.
4. There must be a documented quality management system applied to the activities for which accreditation/designation/authorisation or licensing is sought, in accordance with the standards laid down in this Directive.
5. It must be ensured that the risks inherent in the use and handling of biological material are identified and minimised, consistent with maintaining adequate quality and safety for the intended purpose of the tissues and cells. The risks include those relating in particular to the procedures, environment, staff health status specific to the tissue establishment.
6. Agreements between tissue establishments and third parties must comply with Article 24 of Directive 2004/23/EC. Third party agreements must specify the terms of the relationship and responsibilities as well as the protocols to be followed to meet the required performance specification.
7. There must be a documented system in place, supervised by the responsible person, for ratifying that tissues and/or cells meet appropriate specifications for safety and quality for release and for their distribution.
8. In the event of termination of activities the agreements concluded and the procedures adopted in accordance with Article 21(5) of Directive 2004/23/EC shall include traceability data and material concerning the quality and safety of cells and tissues.
9. There must be a documented system in place that ensures the identification of every unit of tissue or cells at all stages of the activities for which accreditation/designation/authorisation/licensing is sought.

**B. PERSONNEL**

1. The personnel in tissue establishments must be available in sufficient number and be qualified for the tasks they perform. The competency of the personnel must be evaluated at appropriate intervals specified in the quality system.
2. All personnel should have clear, documented and up-to-date job descriptions. Their tasks, responsibilities and accountability must be clearly documented and understood.
3. Personnel must be provided with initial/basic training, updated training as required when procedures change or scientific knowledge develops and adequate opportunities for relevant professional development. The training programme must ensure and document that each individual:
  - (a) has demonstrated competence in the performance of their designated tasks;
  - (b) has an adequate knowledge and understanding of the scientific/technical processes and principles relevant to their designated tasks;

- (c) understands the organisational framework, quality system and health and safety rules of the establishment in which they work, and
- (d) is adequately informed of the broader ethical, legal and regulatory context of their work.

### C. EQUIPMENT AND MATERIALS

1. All equipment and material must be designed and maintained to suit its intended purpose and must minimise any hazard to recipients and/or staff.
2. All critical equipment and technical devices must be identified and validated, regularly inspected and preventively maintained in accordance with the manufacturers' instructions. Where equipment or materials affect critical processing or storage parameters (e.g. temperature, pressure, particle counts, microbial contamination levels), they must be identified and must be the subject of appropriate monitoring, alerts, alarms and corrective action, as required, to detect malfunctions and defects and to ensure that the critical parameters are maintained within acceptable limits at all times. All equipment with a critical measuring function must be calibrated against a traceable standard if available.
3. New and repaired equipment must be tested when installed and must be validated before use. Test results must be documented.
4. Maintenance, servicing, cleaning, disinfection and sanitation of all critical equipment must be performed regularly and recorded accordingly.
5. Procedures for the operation of each piece of critical equipment, detailing the action to be taken in the event of malfunctions or failure, must be available.
6. The procedures for the activities for which accreditation/designation/authorisation/licensing is sought, must detail the specifications for all critical materials and reagents. In particular, specifications for additives (e.g. solutions) and packaging materials must be defined. Critical reagents and materials must meet documented requirements and specifications and when applicable the requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices <sup>(1)</sup> and Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices <sup>(2)</sup>.

### D. FACILITIES/PREMISES

1. A tissue establishment must have suitable facilities to carry out the activities for which accreditation/designation/authorisation or licensing is sought, in accordance with the standards laid down in this Directive.
2. When these activities include processing of tissues and cells while exposed to the environment, this must take place in an environment with specified air quality and cleanliness in order to minimise the risk of contamination, including cross-contamination between donations. The effectiveness of these measures must be validated and monitored.
3. Unless otherwise specified in point 4, where tissues or cells are exposed to the environment during processing, without a subsequent microbial inactivation process, an air quality with particle counts and microbial colony counts equivalent to those of Grade A as defined in the current European Guide to Good Manufacturing Practice (GMP), Annex 1 and Directive 2003/94/EC is required with a background environment appropriate for the processing of the tissue/cell concerned but at least equivalent to GMP Grade D in terms of particles and microbial counts.
4. A less stringent environment than specified in point 3 may be acceptable where:
  - (a) a validated microbial inactivation or validated terminal sterilisation process is applied;
  - (b) or, where it is demonstrated that exposure in a Grade A environment has a detrimental effect on the required properties of the tissue or cell concerned;

<sup>(1)</sup> OJ L 169, 12.7.1993, p. 1. Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

<sup>(2)</sup> OJ L 331, 7.12.1998, p. 1. Directive as amended by Regulation (EC) No 1882/2003.



- (c) or, where it is demonstrated that the mode and route of application of the tissue or cell to the recipient implies a significantly lower risk of transmitting bacterial or fungal infection to the recipient than with cell and tissue transplantation;
  - (d) or, where it is not technically possible to carry out the required process in a Grade A environment (for example, due to requirements for specific equipment in the processing area that is not fully compatible with Grade A).
5. In point 4(a), (b), (c) and (d), an environment must be specified. It must be demonstrated and documented that the chosen environment achieves the quality and safety required, at least taking into account the intended purpose, mode of application and immune status of the recipient. Appropriate garments and equipment for personal protection and hygiene must be provided in each relevant department of the tissue establishment along with written hygiene and gowning instructions.
  6. When the activities for which accreditation/designation/authorisation or licensing is sought involve storage of tissues and cells, the storage conditions necessary to maintain the required tissue and cell properties, including relevant parameters such as temperature, humidity or air quality must be defined.
  7. Critical parameters (e.g. temperature, humidity, air quality) must be controlled, monitored, and recorded to demonstrate compliance with the specified storage conditions.
  8. Storage facilities must be provided that clearly separate and distinguish tissues and cells prior to release/in quarantine from those that are released and from those that are rejected, in order to prevent mix-up and cross-contamination between them. Physically separate areas or storage devices or secured segregation within the device must be allocated in both quarantine and released storage locations for holding certain tissue and cells collected in compliance with special criteria.
  9. The tissue establishment must have written policies and procedures for controlled access, cleaning and maintenance, waste disposal and for the re-provision of services in an emergency situation.

#### E. DOCUMENTATION AND RECORDS

1. There must be a system in place that results in clearly defined and effective documentation, correct records and registers and authorised Standard Operating Procedures (SOPs), for the activities for which accreditation/designation/authorisation/licensing is sought. Documents must be regularly reviewed and must conform to the standards laid down in this Directive. The system must ensure that work performed is standardised, and that all steps are traceable; i.e. coding, donor eligibility, procurement, processing, preservation, storage, transport, distribution or disposal, including aspects relating to quality control and quality assurance.
2. For every critical activity, the materials, equipment and personnel involved must be identified and documented.
3. In the tissue establishments all changes to documents must be reviewed, dated, approved, documented and implemented promptly by authorised personnel.
4. A document control procedure must be established to provide for the history of document reviews and changes and to ensure that only current versions of documents are in use.
5. Records must be shown to be reliable and a true representation of the results.
6. Records must be legible and indelible and may be handwritten or transferred to another validated system, such as a computer or microfilm.
7. Without prejudice to Article 9(2), all records, including raw data, which are critical to the safety and quality of the tissues and cells shall be kept so as to ensure access to these data for at least 10 years after expiry date, clinical use or disposal.
8. Records must meet the confidentiality requirements laid down in Article 14 of Directive 2004/23/EC. Access to registers and data must be restricted to persons authorised by the responsible person, and to the competent authority for the purpose of inspection and control measures.

**F. QUALITY REVIEW**

1. An audit system must be in place for the activities for which accreditation/designation/authorisation/licensing is sought. Trained and competent persons must conduct the audit in an independent way, at least every two years, in order to verify compliance with the approved protocols and the regulatory requirements. Findings and corrective actions must be documented.
  2. Deviations from the required standards of quality and safety must lead to documented investigations, which include a decision on possible corrective and preventive actions. The fate of non-conforming tissues and cells must be decided in accordance with written procedures supervised by the responsible person and recorded. All affected tissues and cells must be identified and accounted for.
  3. Corrective actions must be documented, initiated and completed in a timely and effective manner. Preventive and corrective actions should be assessed for effectiveness after implementation.
  4. The tissue establishment should have processes in place for review of the performance of the quality management system to ensure continuous and systematic improvement.
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## ANNEX II

**Requirements for the authorisation of tissue and cell preparation processes at the tissue establishments as referred to in Article 4**

The competent authority shall authorise each tissue and cell preparation process after evaluation of the donor selection criteria and procurement procedures, the protocols for each step of the process, the quality management criteria, and the final quantitative and qualitative criteria for cells and tissues. This evaluation must comply at least with the requirements set out in this Annex.

**A. RECEPTION AT THE TISSUE ESTABLISHMENT**

Upon reception of procured tissues and cells at the tissue establishment, the tissues and cells must comply with the requirements defined in Directive 2006/17/EC.

**B. PROCESSING**

When the activities for which the accreditation/designation/authorisation/licensing is sought include processing of tissues and cells, the tissue establishment procedures must comply with the following criteria:

1. The critical processing procedures must be validated and must not render the tissues or cells clinically ineffective or harmful to the recipient. This validation may be based on studies performed by the establishment itself, or on data from published studies or, for well established processing procedures, by retrospective evaluation of the clinical results for tissues supplied by the establishment.
2. It has to be demonstrated that the validated process can be carried out consistently and effectively in the tissue establishment environment by the staff.
3. The procedures must be documented in SOPs which must conform to the validated method and to the standards laid down in this Directive, accordingly with Annex I(E), points 1 to 4.
4. It must be ensured that all processes are conducted in accordance with the approved SOPs.
5. Where a microbial inactivation procedure is applied to the tissue or cells, it must be specified, documented, and validated.
6. Before implementing any significant change in processing, the modified process must be validated and documented.
7. The processing procedures must undergo regular critical evaluation to ensure that they continue to achieve the intended results.
8. Procedures for discarding tissue and cells must prevent the contamination of other donations and products, the processing environment or personnel. These procedures must comply with national regulations.

**C. STORAGE AND RELEASE OF PRODUCTS**

When the activities for which the accreditation/designation/authorisation/licensing is sought include storage and release of tissues and cells, the authorised tissue establishment procedures must comply with the following criteria:

1. Maximum storage time must be specified for each type of storage condition. The selected period must reflect among others possible deterioration of the required tissue and cell properties.
2. There must be a system of inventory hold for tissues and/or cells to ensure that they cannot be released until all requirements laid down in this Directive have been satisfied. There must be a standard operating procedure that details the circumstances, responsibilities and procedures for the release of tissues and cells for distribution.

3. A system for identification of tissues and cells throughout any phase of processing in the tissue establishment must clearly distinguish released from non-released (quarantined) and discarded products.
4. Records must demonstrate that before tissues and cells are released all appropriate specifications are met, in particular all current declaration forms, relevant medical records, processing records and test results have been verified according to a written procedure by a person authorised for this task by the responsible person as specified in Article 17 of Directive 2004/23/EC. If a computer is used to release results from the laboratory, an audit trail should indicate who was responsible for their release.
5. A documented risk assessment approved by the responsible person as defined in Article 17 of Directive 2004/23/EC must be undertaken to determine the fate of all stored tissues and cells following the introduction of any new donor selection or testing criterion or any significantly modified processing step that enhances safety or quality.

#### D. DISTRIBUTION AND RECALL

When the activities for which the accreditation/designation/authorisation/licensing is sought include distribution of tissues and cells, the authorised tissue establishment procedures must comply with the following criteria:

1. Critical transport conditions, such as temperature and time limit must be defined to maintain the required tissue and cell properties.
2. The container/package must be secure and ensure that the tissue and cells are maintained in the specified conditions. All containers and packages need to be validated as fit for purpose.
3. Where distribution is carried out by a contracted third party, a documented agreement must be in place to ensure that the required conditions are maintained.
4. There must be personnel authorised within the tissue establishment to assess the need for recall and to initiate and coordinate the necessary actions.
5. An effective recall procedure must be in place, including a description of the responsibilities and actions to be taken. This must include notification to the competent authority.
6. Actions must be taken within pre-defined periods of time and must include tracing all relevant tissues and cells and, where applicable, must include trace-back. The purpose of the investigation is to identify any donor who might have contributed to causing the reaction in the recipient and to retrieve available tissues and cells from that donor, as well as to notify consignees and recipients of tissues and cells procured from the same donor in the event that they might have been put at risk.
7. Procedures must be in place for the handling of requests for tissues and cells. The rules for allocation of tissues and cells to certain patients or health care institutions must be documented and made available to these parties upon request.
8. A documented system must be in place for the handling of returned products including criteria for their acceptance into the inventory, if applicable.

#### E. FINAL LABELLING FOR DISTRIBUTION

1. The primary tissue/cell container must provide:
  - (a) type of tissues and cells, identification number or code of the tissue/cells, and lot or batch number where applicable;
  - (b) identification of the tissue establishment;
  - (c) expiry date;

- (d) in the case of autologous donation, this has to be specified (for autologous use only) and the donor/recipient has to be identified;
- (e) in the case of directed donations - the label must identify the intended recipient;
- (f) when tissues and cells are known to be positive for a relevant infectious disease marker, it must be marked as: BIOLOGICAL HAZARD.

If any of the information under points (d) and (e) above cannot be included on the primary container label, it must be provided on a separate sheet accompanying the primary container. This sheet must be packaged with the primary container in a manner that ensures that they remain together.

2. The following information must be provided either on the label or in accompanying documentation:

- (a) description (definition) and, if relevant, dimensions of the tissue or cell product;
- (b) morphology and functional data where relevant;
- (c) date of distribution of the tissue/cells;
- (d) biological determinations carried out on the donor and results;
- (e) storage recommendations;
- (f) instructions for opening the container, package, and any required manipulation/reconstitution;
- (g) expiry dates after opening/manipulation;
- (h) instructions for reporting serious adverse reactions and/or events as set out in Articles 5 to 6;
- (i) presence of potential harmful residues (e.g. antibiotics, ethylene oxide etc).

#### F. EXTERNAL LABELLING OF THE SHIPPING CONTAINER

For transport, the primary container must be placed in a shipping container that must be labelled with at least the following information:

- (a) identification of the originating tissue establishment, including an address and phone number;
  - (b) identification of the organisation responsible for human application of destination, including address and phone number;
  - (c) a statement that the package contains human tissue/cells and HANDLE WITH CARE;
  - (d) where living cells are required for the function of the graft, such as stem cells gametes and embryos, the following must be added: 'DO NOT IRRADIATE';
  - (e) recommended transport conditions (e.g. keep cool, in upright position, etc.);
  - (f) safety instructions/method of cooling (when applicable).
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## ANNEX III

## NOTIFICATION OF SERIOUS ADVERSE REACTIONS

## PART A

**Rapid notification for suspected serious adverse reactions**

Tissue establishment
Report identification
Reporting date (year/month/day)
Individual affected (recipient or donor)
Date and place of procurement or human application (year/month/day)
Unique Donation identification number
Date of suspected serious adverse reaction (year/month/day)
Type of tissues and cells involved in the suspected serious adverse reaction
Type of suspected serious adverse reaction(s)

## PART B

**Conclusions of serious adverse reactions investigation**

Tissue establishment
Report identification
Confirmation date (year/month/day)
Date of serious adverse reaction (year/month/day)
Unique donation identification number
Confirmation of serious adverse reaction (Yes/No)
Change of type of serious adverse reaction (Yes/No) If Yes, <i>Specify</i>
Clinical outcome (if known) — Complete recovery — Minor sequelae — Serious sequelae — Death
Outcome of the investigation and final conclusions
Recommendations for preventive and corrective actions

## ANNEX IV

## NOTIFICATION OF SERIOUS ADVERSE EVENTS

## PART A

## Rapid notification for suspected serious adverse events

Tissue establishment				
Report identification				
Reporting date (year/month/day)				
Date of serious adverse event (year/month/day)				
Serious adverse event, which may affect quality and safety of tissues and cells due to a deviation in:	Specification			
	Tissues and cells defect	Equipment failure	Human error	Other (specify)
Procurement				
Testing				
Transport				
Processing				
Storage				
Distribution				
Materials				
Others (specify)				

## PART B

## Conclusions of Serious Adverse Events investigation

Tissue establishment
Report identification
Confirmation date (year/month/day)
Date of serious adverse event (year/month/day)
Root cause analysis (details)
Corrective measures taken (details)



## ANNEX V

## ANNUAL NOTIFICATION FORMAT

## PART A

## Annual notification format for serious adverse reactions

Reporting country			
Reporting date 1 January-31 December (year)			
Number of serious adverse reaction(s) per type of tissue and cell (or product in contact with the tissues and cells)			
	Type of tissue/cell (or product in contact with the tissues and cells)	Number of serious adverse reaction(s)	Total number of tissues/cells of this type distributed (if available)
1			
2			
3			
4			
...			
Total			
Total number of tissues and cells distributed (including type of tissue and cell for which no serious adverse reactions were reported):			
Number of recipients affected (total number of recipients):			
Nature of the serious adverse reactions reported		Total number of serious adverse reaction(s)	
Transmitted bacterial infection			
Transmitted viral infection	HBV		
	HCV		
	HIV-1/2		
	Other (Specify)		
Transmitted parasitical infection	Malaria		
	Other (Specify)		
Transmitted malignant diseases			
Other disease transmissions			
Other serious reactions (Specify)			

## PART B

**Annual notification format for serious adverse events**

Reporting country				
Reporting date 1 January-31 December (year)				
Total number of tissues and cells processed				
Total number of serious adverse events, which may have affected quality and safety of tissues and cells due to a deviation in:	Specification			
	Tissues and cells defect (specify)	Equipment failure (specify)	Human error (specify)	Other (specify)
Procurement				
Testing				
Transport				
Processing				
Storage				
Distribution				
Materials				
Others (specify)				

## ANNEX VI

**Information on the minimum donor/recipient data set to be kept as required in Article 9****A. BY TISSUE ESTABLISHMENTS**

Donor identification

Donation identification that will include at least:

- Identification of the procurement organisation or Tissue establishment
- Unique Donation ID number
- Date of procurement
- Place of procurement
- Type of donation (e.g. single v multi-tissue; autologous v allogenic; living v deceased)

Product identification that will include at least:

- Identification of the tissue establishment
- Type of tissue and cell/product (basic nomenclature)
- Pool number (if applicable)
- Split number (if applicable)
- Expiry date
- Tissue/cell status (i.e. quarantined, suitable for use etc.)
- Description and origin of the products, processing steps applied, materials and additives coming into contact with tissues and cells and having an effect on their quality and/or safety.
- Identification of the facility issuing the final label

Human application identification that will include at least:

- Date of distribution/disposal
- Identification of the clinician or end user/facility

**B. BY ORGANISATIONS RESPONSIBLE FOR HUMAN APPLICATION**

- (a) Identification of the supplier tissue establishment
  - (b) Identification of the clinician or end user/facility
  - (c) Type of tissues and cells
  - (d) Product identification
  - (e) Identification of the recipient
  - (f) Date of application
-

## ANNEX VII

**Information contained in the European Coding System**

- (a) Donation identification:
    - Unique ID number
    - Identification of the tissue establishment
  - (b) Product identification:
    - Product code (basic nomenclature)
    - Split number (if applicable)
    - Expiry date
-

## II

(Acts whose publication is not obligatory)

## COUNCIL

## COUNCIL DECISION

of 27 March 2006

**on the signing and provisional application of the Agreement between the European Community and the Council of Ministers of the Republic of Albania on certain aspects of air services**

(2006/716/EC)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 80(2), in conjunction with Article 300(2), first sentence of the first subparagraph thereof,

Having regard to the proposal from the Commission,

Whereas:

- (1) The Council has authorised the Commission on 5 June 2003 to open negotiations with third countries on the replacement of certain provisions in existing bilateral agreements with a Community agreement.
- (2) The Commission has negotiated on behalf of the Community an agreement with the Republic of Albania on certain aspects of air services, hereinafter referred to as 'the Agreement', in accordance with the mechanisms and directives in the Annex to the Council's decision authorising the Commission to open negotiations with third countries on the replacement of certain provisions in existing bilateral agreements with a Community agreement.
- (3) The Agreement should be signed and provisionally applied, subject to its conclusion at a later date,

HAS DECIDED AS FOLLOWS:

*Article 1*

The signing of the Agreement between the European Community and the Council of Ministers of the Republic of

Albania on certain aspects of air services is hereby approved on behalf of the Community, subject to the Council Decision concerning the conclusion of the said Agreement.

The text of the Agreement is attached to this Decision.

*Article 2*

The President of the Council is hereby authorised to designate the person(s) empowered to sign the Agreement on behalf of the Community subject to its conclusion.

*Article 3*

Pending its entry into force, the Agreement shall be applied provisionally from the first day of the first month following the date on which the Parties have notified each other of the completion of the necessary procedures for this purpose.

*Article 4*

The President of the Council is hereby authorised to make the notification provided in Article 8(2) of the Agreement.

Done at Brussels, 27 March 2006.

*For the Council*

*The President*

H. GORBACH

**AGREEMENT****between the Council of Ministers of the Republic of Albania and the European Community on certain aspects of air services**

THE COUNCIL OF MINISTERS OF THE REPUBLIC OF ALBANIA

of the one part, and

THE EUROPEAN COMMUNITY

of the other part

(hereinafter referred to as the Parties),

NOTING that bilateral air service agreements have been concluded between several Member States of the European Community and the Republic of Albania containing provisions contrary to European Community law,

NOTING that the European Community has exclusive competence with respect to several aspects that may be included in bilateral air service agreements between Member States of the European Community and third countries,

NOTING that under European Community law Community air carriers established in a Member State have the right to non-discriminatory access to air routes between the Member States of the European Community and third countries,

HAVING REGARD to the agreements between the European Community and certain third countries providing for the possibility for the nationals of such third countries to acquire ownership in air carriers licensed in accordance with European Community law,

RECOGNISING that provisions of the bilateral air service agreements between Member States of the European Community and the Republic of Albania, which are contrary to European Community law, must be brought into conformity with it in order to establish a sound legal basis for air services between the European Community and the Republic of Albania and to preserve the continuity of such air services,

NOTING that it is not a purpose of the European Community, as part of these negotiations, to increase the total volume of air traffic between the European Community and the Republic of Albania, to affect the balance between Community air carriers and air carriers of the Republic of Albania, or to negotiate amendments to the provisions of existing bilateral air service agreements concerning traffic rights,

HAVE AGREED AS FOLLOWS:

*Article 1***General provisions**

1. For the purposes of this Agreement, 'Member States' shall mean Member States of the European Community.
2. References in each of the Agreements listed in Annex I to nationals of the Member State that is a party to that Agreement shall be understood as referring to nationals of the Member States of the European Community.
3. References in each of the Agreements listed in Annex I to air carriers or airlines of the Member State that is a party to that

Agreement shall be understood as referring to air carriers or airlines designated by that Member State.

*Article 2***Designation by a Member State**

1. The provisions in paragraphs 2 and 3 of this Article shall supersede the corresponding provisions in the Articles listed in Annex II(a) and (b) respectively, in relation to the designation of an air carrier by the Member State concerned, its authorisations and permissions granted by the Republic of Albania, and the refusal, revocation, suspension or limitation of the authorisations or permissions of the air carrier, respectively.

2. On receipt of a designation by a Member State, the Republic of Albania shall grant the appropriate authorisations and permissions with minimum procedural delay, provided that:

- (i) the air carrier is established, under the Treaty establishing the European Community, in the territory of the designating Member State and has a valid Operating Licence in accordance with European Community law;
- (ii) effective regulatory control of the air carrier is exercised and maintained by the Member State responsible for issuing its Air Operator's Certificate and the relevant aeronautical authority is clearly identified in the designation; and
- (iii) the air carrier is owned and shall continue to be owned directly or through majority ownership by Member States and/or nationals of Member States, and/or by other States listed in Annex III and/or nationals of such other States, and shall at all times be effectively controlled by such States and/or such nationals.

3. The Republic of Albania may refuse, revoke, suspend or limit the authorisations or permissions of an air carrier designated by a Member State where:

- (i) the air carrier is not established, under the Treaty establishing the European Community, in the territory of the designating Member State or does not have a valid Operating Licence in accordance with European Community law;
- (ii) effective regulatory control of the air carrier is not exercised or not maintained by the Member State responsible for issuing its Air Operator's Certificate, or the relevant aeronautical authority is not clearly identified in the designation; or
- (iii) the air carrier is not owned, directly or through majority ownership, or it is not effectively controlled by Member States and/or nationals of Member States, and/or by other States listed in Annex III and/or nationals of such other States.

In exercising its right under this paragraph, the Republic of Albania shall not discriminate between Community air carriers on the grounds of nationality.

#### Article 3

##### **Rights with regard to regulatory control**

1. The provisions in paragraph 2 of this Article shall complement the Articles listed in Annex II(c).

2. Where a Member State has designated an air carrier whose regulatory control is exercised and maintained by another Member State, the rights of the Republic of Albania under the safety provisions of the Agreement between the Member State that has designated the air carrier and the Republic of Albania shall apply equally in respect of the adoption, exercise or maintenance of safety standards by that other Member State and in respect of the operating authorisation of that air carrier.

#### Article 4

##### **Taxation of aviation fuel**

1. The provisions in paragraph 2 of this Article shall complement the corresponding provisions in the Articles listed in Annex II(d).

2. Notwithstanding any other provision to the contrary, nothing in each of the Agreements listed in Annex II(d) shall prevent a Member State from imposing taxes, levies, duties, fees or charges on fuel supplied in its territory for use in an aircraft of a designated air carrier of the Republic of Albania that operates between a point in the territory of that Member State and another point in the territory of that Member State or in the territory of another Member State.

#### Article 5

##### **Tariffs for carriage within the European Community**

1. The provisions in paragraph 2 of this Article shall complement the articles listed in Annex II(e).

2. The tariffs to be charged by the air carrier(s) designated by the Republic of Albania under an agreement listed in Annex I containing a provision listed in Annex II(e) for carriage wholly within the European Community shall be subject to European Community law.

#### Article 6

##### **Annexes to the Agreement**

The Annexes to this Agreement shall form an integral part thereof.

#### Article 7

##### **Revision or amendment**

The Parties may, at any time, revise or amend this Agreement by mutual consent.

*Article 8***Entry into force and provisional application**

1. This Agreement shall enter in force when the Parties have notified each other in writing that their respective internal procedures necessary for its entry into force have been completed.
2. Notwithstanding paragraph 1, the Parties agree to provisionally apply this Agreement from the first day of the month following the date on which the Parties have notified each other of the completion of the procedures necessary for this purpose.
3. Agreements and other arrangements between Member States and the Republic of Albania which, at the date of signature of this Agreement, have not yet entered into force and are not being applied provisionally are listed in Annex I(b). This Agreement shall apply to all such Agreements and arrangements upon their entry into force or provisional application.

*Article 9***Termination**

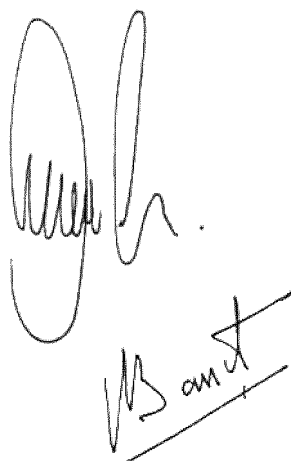
1. In the event that an Agreement listed in Annex I is terminated, all provisions of this Agreement that relate to the Agreement listed in Annex I concerned shall terminate at the same time.
2. In the event that all Agreements listed in Annex I are terminated, this Agreement shall terminate at the same time.

IN WITNESS WHEREOF, the undersigned, being duly authorised, have signed this Agreement.

Done at Salzburg in duplicate, on this fifth day of May in the year two thousand and six, in the Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Slovak, Slovenian, Spanish, Swedish and Albanian languages.



Por la Comunidad Europea  
 Za Evropské společenství  
 For Det Europæiske Fællesskab  
 Für die Europäische Gemeinschaft  
 Euroopa Ühenduse nimel  
 Για την Ευρωπαϊκή Κοινότητα  
 For the European Community  
 Pour la Communauté européenne  
 Per la Comunità europea  
 Eiropas Kopienas vārdā  
 Europos bendrijos vardu  
 Az Európai Közösség részéről  
 Ghall-Komunità Ewropea  
 Voor de Europese Gemeenschap  
 W imieniu Wspólnoty Europejskiej  
 Pela Comunidade Europeia  
 Za Európske spoločenstvo  
 Za Evropsko skupnost  
 Euroopan yhteisön puolesta  
 För Europeiska gemenskapen  
 Per Komunitetin European



Por el Consejo de Ministros de la República de Albania  
 Za Radu ministrû Albánské republiky  
 For Republikken Albaniens ministerråd  
 Für den Ministerrat der Republik Albanien  
 Albaania Vabariigi ministrite nõukogu nimel  
 Για το Υπουργικό Συμβούλιο της Δημοκρατίας της Αλβανίας  
 For the Council of Ministers of the Republic of Albania  
 Pour le Conseil des ministres de la République d'Albanie  
 Per il Consiglio dei Ministri della Repubblica d'Albania  
 Albānijas Republikas Ministru padomes vārdā  
 Albanijos Republikos Ministrų Tarybos vardu  
 Az Albán Köztársaság Minisztertanácsa részéről  
 Ghall-Kunsill tal-Ministri għar-Repubblika ta' l-Albanija  
 Voor de Ministerraad van de Republiek Albanië  
 W imieniu Rady Ministrów Republiki Albanii  
 Pelo Conselho de Ministros da República da Albânia  
 Za Radu ministrov Albánskej republiky  
 Za Ministrski Svet Republike Albanije  
 Albanian tasavallan ministerineuvoston puolesta  
 För Republiken Albaniens ministerråd  
 Per Keshillin e Ministrave te Republikes se Shqiperise



## ANNEX I

**List of agreements referred to in Article 1 of this Agreement**

(a) Air service agreements between the Republic of Albania and Member States of the European Community which, at the date of signature of this Agreement, have been concluded, signed and/or are being applied provisionally

— Air Transport Agreement between the Austrian Federal Government and the Government of the Republic of Albania, signed at Vienna on 18 March 1993 (hereinafter referred to as Albania-Austria Agreement);

— Agreement between the Government of the Kingdom of Belgium and the Government of the Republic of Albania on Air Transport, signed at Brussels on 14 November 2002 (hereinafter referred to as Albania-Belgium Agreement);

To be read together with the Memorandum of Understanding done at Brussels on 18 June 2002.

— Air Transport Agreement between the Government of Czechoslovak Republic and the Government of the People's Republic of Albania, signed at Tirana on 20 May 1958 (hereinafter referred to as Albania-Czech Republic Agreement);

— Agreement between the Government of the French Republic and the Government of the People's Socialist Republic of Albania relating to Civil Air Transport, initialled at Tirana on 12 January 1989 (hereinafter referred to as Albania-France Agreement);

— Agreement between the Government of the Federal Republic of Germany and the Government of the Republic of Albania concerning Civil Air Transport, signed at Tirana on 22 April 1992 (hereinafter referred to as Albania-Germany Agreement);

— Agreement between the Government of the Hellenic Republic and the Government of the People's Socialist Republic of Albania on Civil Air Transport, signed at Tirana on 16 July 1977 (hereinafter referred to as Albania-Greece Agreement);

As well as the Memorandum of Understanding done at Athens on 25 June 1998.

— Agreement between the Government of Hungarian's People's Republic and the Government of the People's Republic of Albania concerning the regulation of Civil Air Transport between Hungary and Albania, signed at Budapest on 16 January 1958 (hereinafter referred to as Albania-Hungary Agreement);

— Agreement between the Government of the Italian Republic and the Government of Albania concerning Air Services, signed at Tirana on 18 December 1992 (hereinafter referred to as Albania-Italy Agreement);

— Agreement between the Kingdom of the Netherlands and the Republic of Albania for Air Services between and beyond their respective territories, signed at The Hague on 25 September 1996 (hereinafter referred to as Albania-Netherlands Agreement);

— Agreement between the Government of the Polish People's Republic and the Government of the People's Republic of Albania concerning Air Services, signed at Tirana on 8 July 1957 (hereinafter referred to as Albania-Poland Agreement);

— Agreement between the Government of the Republic of Slovenia and the Government of the Republic of Albania relating to Scheduled Air Services, signed at Ljubljana on 10 November 1992 (hereinafter referred to as Albania-Slovenia Agreement);

— Agreement between the Government of United Kingdom of Great Britain and Northern Ireland and the Government of the Republic of Albania concerning Air Services, signed at London on 30 March 1994 (hereinafter referred to as Albania-UK Agreement);

To be read together with the Memorandum of Understanding done at London on 14 November 2002.

(b) Air service agreements and other arrangements initialled or signed between the Republic of Albania and Member States of the European Community which, at the date of signature of this Agreement, have not yet entered into force and are not being applied provisionally.

## ANNEX II

**List of Articles in the Agreements listed in Annex I and referred to in Articles 2 to 5 of this Agreement**

## (a) Designation by a Member State:

- Article 3(5) of the Albania-Austria Agreement;
- Article 3 of the Albania-Germany Agreement;
- Article 3(1) and (2) of the Albania-Greece Agreement;
- Article 6 of the Albania-France Agreement;
- Article 2 of the Albania-Hungary Agreement;
- Article 4 of the Albania-Italy Agreement;
- Article 4 of the Albania-Netherlands Agreement;
- Articles 2 and 3 and Annex II point 1, of the Albania-Poland Agreement;
- Article 7 of the Albania-Slovenia Agreement;
- Article 4 of the Albania-UK Agreement.

## (b) Refusal, revocation, suspension or limitation of authorisations or permissions:

- Article 4(1a) of the Albania-Austria Agreement;
- Article 5 of the Albania-Belgium Agreement;
- Article 4 of the Albania-Germany Agreement;
- Article 3(3) of the Albania-Greece Agreement;
- Article 7 of the Albania-France Agreement;
- Article 5 of the Albania-Italy Agreement;
- Article 5 of the Albania-Netherlands Agreement;
- Article 8 of the Albania-Slovenia Agreement;
- Article 5 of the Albania-UK Agreement.

## (c) Regulatory control

## (d) Taxation of aviation fuel:

- Article 7 of the Albania-Austria Agreement;
- Article 10 of the Albania-Belgium Agreement;
- Article 4 of the Albania-Czech Republic Agreement;
- Article 10 of the Albania-Germany Agreement;
- Article 7 of the Albania-Greece Agreement;
- Article 13 of the Albania-France Agreement;
- Article 6 of the Albania-Italy Agreement;
- Article 10 of the Albania-Netherlands Agreement;
- Article 6 of the Albania-Poland Agreement;
- Article 10 of the Albania-Slovenia Agreement;
- Article 8 of the Albania-UK Agreement.

- (e) Tariffs for Carriage within the European Community:
- Article 11 of the Albania-Austria Agreement;
  - Article 13 of the Albania-Belgium Agreement;
  - Article 2 of the Albania-Czech Republic Agreement;
  - Article 14 of the Albania-Germany Agreement;
  - Article 6 of the Albania-Greece Agreement;
  - Article 17 of the Albania-France Agreement;
  - Article 8 of the Albania-Italy Agreement;
  - Article 6 of the Albania-Netherlands Agreement;
  - Article 7 of the Albania-Poland Agreement;
  - Article 14 of the Albania-Slovenia Agreement;
  - Article 7 of the Albania-UK Agreement.
- 

ANNEX III

**List of other States referred to in Article 2 of this Agreement**

- (a) The Republic of Iceland (under the Agreement on the European Economic Area);
  - (b) The Principality of Liechtenstein (under the Agreement on the European Economic Area);
  - (c) The Kingdom of Norway (under the Agreement on the European Economic Area);
  - (d) The Swiss Confederation (under the Agreement between the European Community and the Swiss Confederation on Air Transport).
-

# COMMISSION

## COMMISSION DECISION

of 4 September 2006

### laying down a code and standard rules for the transcription into a machine-readable form of the data of the basic surveys of areas under vines

(notified under document number C(2006) 3881)

(Codified version)

(2006/717/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 357/79 of 5 February 1979 on statistical surveys of areas under vines<sup>(1)</sup>, and in particular Article 4(2) and (4) and Article 6(7) thereof,

Whereas:

(1) Commission Decision 79/491/EEC of 17 May 1979 laying down a code and standard rules for the transcription into a machine-readable form of the data of the basic surveys of areas under vines<sup>(2)</sup> has been substantially amended several times<sup>(3)</sup>. In the interests of clarity and rationality, the said Decision should be codified.

(2) Regulation (EEC) No 357/79 requires the Member States to submit to the Commission the information collected in the framework of the basic surveys of areas under vines in the form of a schedule of tables broken down by geographical units which are to be fixed in accordance with the procedure laid down in Article 8 of the said Regulation, i.e. by a Commission Decision following an opinion from the Standing Committee on Agricultural Statistics.

<sup>(1)</sup> OJ L 54, 5.3.1979, p. 124. Regulation as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

<sup>(2)</sup> OJ L 129, 28.5.1979, p. 9. Decision as last amended by Decision 1999/661/EC (OJ L 261, 7.10.1999, p. 42).

<sup>(3)</sup> See Annex IV.

(3) Those Member States which process their survey results electronically of areas under vines should submit these results to the Commission in a machine-readable form. These codes for transmitting survey results are also determined in accordance with the procedure laid down in Article 8 of Regulation (EEC) No 357/79.

(4) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Agricultural Statistics,

HAS ADOPTED THIS DECISION:

#### Article 1

The machine-readable form for submission of the data provided for in Article 2 of Regulation (EEC) No 357/79 by those Member States which process their survey results electronically shall be magnetic tape.

#### Article 2

The codes and rules governing the transcription on to magnetic tape of the data provided for in Article 2 of Regulation (EEC) No 357/79 shall be as set out in Annexes I, II and III to this Decision.

#### Article 3

Decision 79/491/EEC is repealed.

References to the repealed Decision shall be construed as references to this Decision and shall be read in accordance with the correlation table set out in Annex V.

*Article 4*

This Decision is addressed to the Member States.

Done at Brussels, 4 September 2006.

*For the Commission*

*The President*

José Manuel BARROSO

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## ANNEX I

**MAGNETIC TAPE SPECIFICATION FOR THE DELIVERY TO EUROSTAT OF THE DATA OF THE BASIC SURVEYS OF THE AREAS UNDER VINES****(Regulation (EEC) No 357/79)**

## GENERAL PROVISIONS

- I. The information recorded in accordance with the characteristics referred to in Article 2 of Regulation (EEC) No 357/79 is to be delivered to Eurostat in the following form by those Member States which process their survey information electronically:
  1. The information shall refer to summaries of holdings if the survey is exhaustive (or to raised summaries of holdings if the survey is based on random sampling) and not to individual holdings.
  2. The information shall be delivered on nine-track magnetic tape/1 600 BPI (630 bytes/cm) standard label.
  3. The information shall be of fixed record length consisting of 308 positions, and shall be recorded in EBCDIC.
  4. The first two fields of each record shall contain information to permit identification. The first field (three positions) identifies the geographical unit, the codification of which is given in the detailed provisions and in Annex II.
  5. The second field (two positions) identifies the table in the schedule of tables provided for in Regulation (EEC) No 357/79. The codification of these tables is given in the detailed provisions.
  6. The number and size of the fields in each record vary according to the table. If all the 308 positions are not filled in the case of certain tables, the record shall be completed by blanks.
  7. The information shall be entered right justified in each field.
  8. Surface area data shall be given in hectares to two decimal places with a virtual point.
  9. Member States shall have a choice as to blocking factor and Eurostat must be informed as to what blocking factor has been used.
  10. The records shall be sorted according to geographical unit, table, and size classes or variety, in that order.
  11. Standard administrative procedures governing the transmission of the magnetic tape files to Eurostat shall be established jointly by Eurostat and the Member States.
- II. The following pages give for each table and for the various items of a record:
  - (a) the codes which are to be used;
  - (b) the maximum number of digits required for the item in question;
  - (c) the consecutive numbering of the positions for the various items.

## DETAILED PROVISIONS

The first two fields of each record contain the following information:

	Code	Number of digits	Byte number on tape
1. Geographical unit	See Annex II	3	1-3
2. Tables		2	4-5
1	10		
2.1	21		
2.2	22		
2.3	23		
2.4	24		
2.5	25		
2.6	26		
3	30		
4	40		
5 <sup>(1)</sup>	50		

<sup>(1)</sup> For these tables, it would be desirable for Member States which process their basic survey information electronically to send the information provided for in Article 6(2) of Regulation (EEC) No 357/79 to Eurostat on magnetic tape.

The following list gives the record specifications by tables:

	Code	Number of digits	Byte number on tape
<b>Table 1</b>			
1.1. <i>Size classes of area under vines (ha)</i>		2	6-7
≤ 0·10	01		
0·10 ≤ 0·20	02		
0·20 ≤ 0·30	03		
0·30 ≤ 0·50	04		
0·50 ≤ 1	05		
1 ≤ 2	06		
2 ≤ 3	07		
3 ≤ 5	08		
5 ≤ 10 (b)	11		
10 ≤ 20 (a)(b)	12		
20 ≤ 30 (a)(b)	13		
≥ 30 (a)(b)	14		
≥ 10	21		
≥ 5	31		
All classes	41		

(a) For the geographical units, the use of a single size class '≥ 10 ha' is optional for France and Italy.

(b) For the geographical units, the use of a single size class '≥ 5 ha' is optional for Germany, Greece and Luxembourg.



	Code	Number of digits	Byte number on tape
1.2. <i>Total</i>			
Holdings		7	8-14
UAA (ha)		10	15-24
Area (ha)		9	25-33
1.3. <i>Wine-grape varieties</i>			
<i>Total</i>			
Holdings		7	34-40
UAA (ha)		10	41-50
Area (ha)		9	51-59
<i>Quality wines psr</i>			
Holdings		7	60-66
UAA (ha)		10	67-76
Area		9	77-85
<i>Other wines</i>			
<i>Total</i>			
Holdings		7	86-92
UAA (ha)		10	93-102
Area (ha)		9	103-111
<i>Of which for spirits</i>			
Holdings		7	112-118
UAA (ha)		10	119-128
Area (ha)		9	129-137
1.4. <i>Table grapes</i>			
Holdings		7	138-144
UAA (ha)		10	145-154
Area (ha)		9	155-163
1.5. <i>Planted rootstock for grafting</i>			
Holdings		7	164-170
UAA (ha)		10	171-180
Area (ha)		9	181-189
1.6. <i>Area for propagation</i>			
<i>Nurseries</i>			
Holdings		7	190-196
UAA (ha)		10	197-206
Area (ha)		9	207-215
<i>Parent vines</i>			
Holdings		7	216-222
UAA (ha)		10	223-232
Area (ha)		9	233-241
1.7. <i>Grapes for drying</i>			
Holdings		7	242-248
UAA (ha)		10	249-258
Area (ha)		9	259-267

	Code	Number of digits	Byte number on tape
<b>Table 2</b> (Tables 2.1 to 2.6)			
2.1. <i>Size classes of area under vines (ha) (See Table 1)</i>	See Table 1	2	6-7
2.2. <i>Total</i>			
Holdings		7	8-14
UAA (ha)		10	15-24
Area (ha)		9	25-33
> 0 ≤ 10			
Holdings		7	34-40
UAA (ha)		10	41-50
Area (ha)		9	51-59
10 ≤ 25			
Holdings		7	60-66
UAA (ha)		10	67-76
Area (ha)		9	77-85
25 ≤ 50			
Holdings		7	86-92
UAA (ha)		10	93-102
Area (ha)		9	103-111
50 ≤ 75			
Holdings		7	112-118
UAA (ha)		10	119-128
Area (ha)		9	129-137
75 ≤ 90			
Holdings		7	138-144
UAA (ha)		10	145-154
Area (ha)		9	155-163
≥ 90			
Holdings		7	164-170
UAA (ha)		10	171-180
Area (ha)		9	181-189
<b>Table 3</b>			
3.1. <i>Size classes of area under vines (see Table 1)</i>	See Table 1	2	6-7
3.2. <i>Total</i>			
Holdings		7	8-14
Total (ha)		9	15-23
Quality wines psr (ha)		9	24-32
0			
Holdings		7	33-39
Total (ha)		9	40-48
Quality wines psr (ha) (the value must be 0)		9	49-57
> 0 ≤ 10			
Holdings		7	58-64
Total (ha)		9	65-73
Quality wines psr (ha)		9	74-82

	Code	Number of digits	Byte number on tape
10 ≤ 25			
Holdings		7	83-89
Total (ha)		9	90-98
Quality wines psr (ha)		9	99-107
25 ≤ 50			
Holdings		7	108-114
Total (ha)		9	115-123
Quality wines psr (ha)		9	124-132
50 ≤ 75			
Holdings		7	133-139
Total (ha)		9	140-148
Quality wines psr (ha)		9	149-157
75 ≤ 90			
Holdings		7	158-164
Total (ha)		9	165-173
Quality wines psr (ha)		9	174-182
90 ≤ 100			
Holdings		7	183-189
Total (ha)		9	190-198
Quality wines psr (ha)		9	199-207
100			
Holdings		7	208-214
Total (ha)		9	215-223
Quality wines psr (ha) (equals preceding field)		9	224-232
<b>Table 4</b>			
There are three varieties per record; the three varieties have the same structure			
4.1. First variety			
4.1.1. Variety			
The variety codes are given in Annex III	See Annex III	4	6-9
4.1.2. Age classes			
All			
Area (ha)		9	10-18
Age class 1			
Classification	10	2	19-20
Area (ha)		9	21-29
Age class 2			
Classification	20	2	30-31
Area (ha)		9	32-40
Age class 3			
Classification	30	2	41-42
Area (ha)		9	43-51

	Code	Number of digits	Byte number on tape
Age class 4			
Classification	40	2	52-53
Area (ha)		9	54-62
Age class 5			
Classification	41	2	63-64
Area (ha)		9	65-73
Age class 6			
Classification	45	2	74-75
Area (ha)		9	76-84
Age class 7			
Classification	21	2	85-86
Area (ha)		9	87-95
Age class 8			
Classification	22	2	96-97
Area (ha)		9	98-106
4.2. <i>Second variety</i>			
4.2.1. Variety	See Annex III	4	107-110
4.2.2. Age classes			
All (ha)		9	111-119
Age classes 1 to 8			
Classification		8 fields of 2	} 120-207
Area (ha)		8 fields of 9	
4.3. <i>Third variety</i>			
4.3.1. Variety	See Annex III	4	208-211
4.3.2. Age classes			
All (ha)		9	212-220
Age classes 1 to 8			
Classification		8 fields of 2	} 221-308
Area (ha)		8 fields of 9	

The zones for each variety in the record must always be completed by zeros when all the classes are not used.

If there is only one variety (or two varieties) in the last record, the information relating to the missing variety (varieties) is to be indicated by zeros (bytes 107-308, or 208-308).

	Code	Number of digits	Byte number on tape
<b>Table 5</b>			
5.1. <i>All</i>			
Area (ha)		9	6-14
5.2. <i>Quality wines psr</i>			
Total (ha)		9	15-23
Yield class I			
Classification (!)		2	24-25
Area (ha)		9	26-34

	Code	Number of digits	Byte number on tape
Yield class II			
Classification <sup>(1)</sup>		2	35-36
Area (ha)		9	37-45
Yield class III			
Classification <sup>(1)</sup>		2	46-47
Area (ha)		9	48-56
Yield class IV			
Classification <sup>(1)</sup>		2	57-58
Area (ha)		9	59-67
Yield class V			
Classification <sup>(1)</sup>		2	68-69
Area (ha)		9	70-78
5.3. <i>Other wines</i>			
Total (ha)		9	79-87
Yield classes I to V			
Classification <sup>(1)</sup>		5 fields of 2	} 88-142
Area (ha)		5 fields of 9	

<sup>(1)</sup> The codes for this yield classification (number and limits) will be established subsequently.

## ANNEX II

## GEOGRAPHICAL UNITS LAID DOWN BY ARTICLE 4(3) OF REGULATION (EEC) No 357/79

	Code		Code
GERMANY	100	Extremadura B (provincia de Cáceres)	730
(wine-growing regions)		Andalucía A (provincia de Cádiz)	731
Ahr	101	Andalucía B (provincia de Córdoba)	732
Mittelrhein	102	Andalucía C (provincia de Huelva)	733
Mosel-Saar-Ruwer	103	Andalucía D (provincia de Málaga)	734
Nahe	104	Andalucía E (provincias de Almería, Granada, Jaén y Sevilla)	735
Rheinhessen	105	Canarias	736
Pfalz	106		
Hessische Bergstraße	107	FRANCE	200
Rheingau	108	(departments or groups of departments)	
Württemberg	109	Aude	201
Baden	110	Gard	202
Franken	111	Hérault	203
Saale-Unstrut	112	Lozère	204
Sachsen	113	Pyrénées-Orientales	205
		Var	206
GREECE	600	Vaucluse	207
Ανατολική Μακεδονία, Θράκη	601	Bouches-du-Rhône	208
Κεντρική Μακεδονία	602	Gironde	209
Δυτική Μακεδονία	603	Gers	210
Ήπειρος	604	Charente	211
Θεσσαλία	605	Charente-Maritime	212
Ιόνια Νησιά	606	Ardèche	213
Δυτική Ελλάδα	607	Aisne	214
Στερεά Ελλάδα	608	Seine-et-Marne	215
Αττική	609	Ardenne, Aube, Marne, Haute-Marne	250
Πελοπόννησος	610	Cher, Eure-et-Loir, Indre, Indre-et-Loire, Loir-et-Cher, Loiret	251
Βόρειο Αιγαίο	611	Côte-d'Or, Nièvre, Saône-et-Loire, Yonne	252
Νότιο Αιγαίο	612	Meurthe-et-Moselle, Meuse, Moselle, Vosges	253
Κρήτη	613	Bas-Rhin, Haut-Rhin	254
		Doubs, Jura, Haute-Saône, Territoire-de-Belfort	255
SPAIN	700	Loire-Atlantique, Maine-et-Loire, Sarthe, Vendée	256
(provinces or autonomous regions)		Deux-Sèvres, Vienne	220
Galicia	701	Dordogne, Landes, Lot-et-Garonne, Pyrénées-Atlantiques	221
Principado de Asturias	702	Ariège, Aveyron, Haute-Garonne, Lot, Hautes-Pyrénées, Tarn,	222
Cantabria	703	Tarn-et-Garonne	
País Vasco A (Territorio Histórico de Álava)	704	Corrèze, Haute-Vienne	223
País Vasco B (Territorios Históricos de Guipúzcoa y Vizcaya)	705	Ain, Drôme, Isère, Loire, Rhône, Savoie, Haute-Savoie	224
Navarra	706	Cantal, Allier, Haute-Loire, Puy-de-Dôme	257
La Rioja	707	Alpes-de-Haute-Provence, Hautes-Alpes, Alpes-Maritimes	225
Aragón A (provincia de Zaragoza)	708	Corse-du-Sud, Haute-Corse	258
Aragón B (provincias de Huesca y Teruel)	709		
Catalunya A (provincia de Barcelona)	710	ITALY	300
Catalunya B (provincia de Tarragona)	711	(provinces)	
Catalunya C (provincias de Girona y Lleida)	712	Torino	301
Illes Balears	713	Vercelli	302
Castilla y León A (provincia de Burgos)	714	Novara	303
Castilla y León B (provincia de León)	715	Cuneo	304
Castilla y León C (provincia de Valladolid)	716	Asti	305
Castilla y León D (provincia de Zamora)	717	Alessandria	306
Castilla y León E (provincias de Ávila, Palencia, Salamanca, Segovia y Soria)	718	Biella	307
Comunidad de Madrid	719	Verbano-Cusio-Ossola	308
Castilla-La Mancha A (provincia de Albacete)	720	Aosta	309
Castilla-La Mancha B (provincia de Ciudad Real)	721	Imperia	310
Castilla-La Mancha C (provincia de Cuenca)	722	Savona	311
Castilla-La Mancha D (provincia de Guadalajara)	723	Genova	312
Castilla-La Mancha E (provincia de Toledo)	724	La Spezia	313
Comunidad Valenciana A (provincia de Alicante)	725	Varese	314
Comunidad Valenciana B (provincia de Castellón)	726	Como	315
Comunidad Valenciana C (provincia de Valencia)	727	Sondrio	316
Región de Murcia	728	Milano	317
Extremadura A (provincia de Badajoz)	729	Bergamo	318
		Brescia	319
		Pavia	320

	Code		Code
Cremona	321	Chieti	376
Mantova	322	Campobasso	377
Lecco	323	Isernia	378
Lodi	324	Foggia	379
Bolzano-Bozen	325	Bari	380
Trento	326	Taranto	381
Verona	327	Brindisi	382
Vicenza	328	Lecce	383
Belluno	329	Potenza	384
Treviso	330	Matera	385
Venezia	331	Cosenza	386
Padova	332	Catanzaro	387
Rovigo	333	Reggio di Calabria	388
Pordenone	334	Crotone	389
Udine	335	Vibo Valentia	390
Gorizia	336	Trapani	391
Trieste	337	Palermo	392
Piacenza	338	Messina	393
Parma	339	Agrigento	394
Reggio nell'Emilia	340	Caltanissetta	395
Modena	341	Enna	396
Bologna	342	Catania	397
Ferrara	343	Ragusa	398
Ravenna	344	Siracusa	399
Forlì	345	Sassari	400
Rimini	346	Nuoro	401
Massa Carrara	347	Cagliari	402
Lucca	348	Oristano	403
Pistoia	349		
Firenze	350		
Livorno	351	LUXEMBOURG	500
Pisa	352	(constitutes a single geographical unit)	
Arezzo	353		
Siena	354		
Grosseto	355	AUSTRIA	900
Prato	356	Burgenland	901
Perugia	357	Niederösterreich	902
Terni	358	Steiermark	903
Pesaro e Urbino	359	Wien und die anderen Bundesländer	904
Ancona	360		
Macerata	361		
Ascoli Piceno	362	PORTUGAL	800
Viterbo	363	Entre Douro e Minho	801
Rieti	364	Trás-os-Montes	802
Roma	365	Beira Litoral	803
Latina	366	Beira Interior	804
Frosinone	367	Ribatejo e Oeste	805
Caserta	368	Alentejo	806
Benevento	369	Algarve	807
Napoli	370	Região Autónoma dos Açores	808
Avellino	371	Região Autónoma da Madeira	809
Salerno	372		
L'Aquila	373		
Teramo	374	UNITED KINGDOM	550
Pescara	375	(constitutes a single geographical unit)	

## ANNEX III

**CODES FOR SPECIFIED VARIETIES OF WINE GRAPES FOR THE TRANSMISSION TO EUROSTAT OF THE RESULTS OF THE STATISTICAL SURVEYS OF AREAS UNDER VINES****(Regulation (EEC) No 357/79)**

Varieties	Code
Individual varieties (to be specified)	
Black	1000-1799
Total	1800
White and other colours	2000-2799
Total	2800
Total individual varieties	3800
Other varieties	
Black	1900
White and other colours	2900
Total	3900
All varieties	
Black	1999
White and other colours	2999
Total	3999



## ANNEX IV

**Repealed Decision with its successive amendments**

Commission Decision 79/491/EEC	(OJ L 129, 28.5.1979, p. 9)
Commission Decision 85/620/EEC	(OJ L 379, 31.12.1985, p. 1)
Commission Decision 96/20/EC	(OJ L 7, 10.1.1996, p. 6)
Commission Decision 1999/661/EC	(OJ L 261, 7.10.1999, p. 42)

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## ANNEX V

**CORRELATION TABLE**

Decision 79/491/EEC	This Decision
Article 1	Article 1
Article 2	Article 2
—	Article 3
Article 3	Article 4
Annex I	Annex I
Annex II	Annex II
Annex III	Annex III
—	Annex IV
—	Annex V

(Acts adopted under Title V of the Treaty on European Union)

**COUNCIL DECISION 2006/718/CFSP**  
**of 23 October 2006**  
**implementing Common Position 2006/276/CFSP concerning restrictive measures against certain officials of Belarus**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to Common Position 2006/276/CFSP of 10 April 2006 concerning restrictive measures against certain officials of Belarus <sup>(1)</sup>, and in particular Article 2 thereof, in conjunction with the second indent of Article 23(2) of the Treaty on European Union,

Whereas:

- (1) On 10 April 2006, the Council adopted Common Position 2006/276/CFSP, which confirmed the existing restrictive measures against the persons responsible for the violations of international electoral standards in the Presidential elections in Belarus on 19 March 2006 and the crackdown on civil society and democratic opposition and those natural or legal persons, entities or bodies associated with them.
- (2) On 18 May 2006, the Council adopted Common Position 2006/362/CFSP amending Common Position 2006/276/CFSP, in order to impose a freezing of funds and economic resources on the persons, as well as the natural or legal persons, entities or bodies associated with them, referred to above.
- (3) In accordance with Common Position 2006/276/CFSP, the Council has reviewed the restrictive measures and decided, in the light of recent developments, that

further individuals responsible for the crackdown on civil society and democratic opposition should be targeted. The lists contained in Annexes III and IV to Common Position 2006/276/CFSP should therefore be amended accordingly,

HAS DECIDED AS FOLLOWS:

*Article 1*

Annexes III and IV to Common Position 2006/276/CFSP shall be replaced by the text appearing in the Annex to this Decision.

*Article 2*

This Decision shall take effect on the date of its adoption.

*Article 3*

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

Done at Luxembourg, 23 October 2006.

*For the Council*  
*The President*  
J.-E. ENESTAM

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<sup>(1)</sup> OJ L 101, 11.4.2006, p. 5. Common Position as amended by Common Position 2006/362/CFSP (OJ L 134, 20.5.2006, p. 45).

## ANNEX

## ANNEX III

## List of persons referred to in Article 1(1)(c)

Names (English transcription)	Names (Belarusian spelling)	Names (Russian spelling)	Date of birth	Place of birth	Address	Passport number	Position
Lukashenko Aleksandr Grigorievich (Lukashenka Alaksandr Ryhoravich)	Лукашэнка Аляксандр Рыгоравіч	ЛУКАШЕНКО Александр Григорьевич	30.8.1954	Kopyys, Vitebsk district			President
Nevyglas Gennady Nikolaeovich (Nievuyhlas Hienadz Mikalaevich)	Невуглас Геннадзь Мікалаевіч	НЕВЬГУПАС Геннадий Николаевич	11.2.1954	Parahonsk, Pinsk district			Head of President's Administration
Perkevich Natalya Vladimirovna (Piatkevich Natallia Uladzimirauna)	Пяткевіч Наталля Уладзіміраўна	ПЕТКЕВИЧ Наталья Владимировна	24.10.1972	Minsk			Deputy Head of President's Administration
Rubinov Anatoly Nikolaeovich (Rubinau Anatol Mikalaevich)	Рубінаў Анатоль Мікалаевіч	РУБИНОВ Анатолий Николаевич	15.4.1939	Mogilev			Deputy Head in charge of Media and Ideology, PA
Proleskovsky Oleg Vitoldovich Pralaskouski Aleh Vitoldavich,	Праляскоўскі Олег Вітольдавіч	ПРОЛЕСКОВСКИЙ Олег Витольдович	1.10.1963	Zagorsk (Russia, now Sergijev Posad)			Aide and Head of the Main Ideological Department, PA
Radkov Aleksandr Mikhailovich (Radzkou Alaksandr Mikhailavich)	Радзькоў Аляксандр Міхайлавіч	РАДЬКОВ Александр Михайлович	1.7.1951	Volpa, Volnia Byahovskogo rayona Motalievskoy oblasti			Minister of Education
Rusakevich Vladimir Vasilevich (Rusakevich Uladzimir Vasilevich)	Русакевіч Уладзімір Васільевіч	РУСАКЕВИЧ Владимир Васильевич	13.9.1947	Vugonoshchi, Byegonoshi, Brestskaya oblast			Minister of Information
Golovanov Viktor Grigorievich Halavanau Viktor Ryhoravich,	Галаванав Віктар Рыгоравіч	ГОЛОВАНОВ Виктор Григорьевич	1952	Borisov			Minister of Justice

Names (English transcription)	Names (Belarusian spelling)	Names (Russian spelling)	Date of birth	Place of birth	Address	Passport number	Position
Zimovsky Alexander Leonidovich (Zimouski Alaksandr Leonidavich)	Зімоўскі Аляксандр Леанідавіч	ЗИМОВСКИЙ Александр Леонидович	10.1.1961	Germany			Member of the Upper House of the Parliament; Head of the national state tele-radio company
Konoplyev Vladimir Nikolaevich (Knaprljou Uładzimir Mikalaevich)	Канопл’еў Уладзімір Мікалаевіч	КОНОШПЕВ Владимир Николаевич	3.1.1954	Akulitsy, d. Akulinitsy Mогилевского района			Chairman of the Lower House of the Parliament
Cherginets Nikolai Ivanovich (Charhiniets Mikalai Ivanavich)	Чэргінец Мікалай Іванавіч	ЧЕРГИНЕЦ Николай Иванович	17.10.1937	Minsk			Chairman of the Foreign Affairs Committee of the Upper House
Kostyan Sergei Ivanovich (Kastian Siarhiei Ivanavich)	Касцяня Сяргей Іванавіч	КОСТЯН Сергей Иванович	15.1.1941	Usokhi, Mogilev-district, Усохи Кличевского района Могилевской области			Chairman of the Foreign Affairs Committee of the Lower House
Orda Mikhail Sergeevich (Orda Mikhail Siarhieevich)	Орда Міхаіл Сяргеєвіч	ОРДА Михаил Сергеевич	28.9.1966	Dyatlovo, Grodno-district, Дятлово Гродненской области			Member of the Upper House, leader of BRSM
Lozovik Nikolai Ivanovich (Lazavik Mikalai Ivanavich)	Лазавік Мікалай Іванавіч	ЛОЗОВИК Николай Иванович	18.1.1951	Nevinyanu, Minsk-district, Невиняны Вилейского р-на Минской обл			Deputy of the CEC
Miklashevich Petr Petrovich (Miklashevich Piotr Piatrovich)	Міклашэвіч Пётр Пятровіч	МИКЛАШЕВИЧ Петр Петрович	1954	Kosuta, Minsk-district, Косуца Минской области			Prosecutor General
Slizhevsky Oleg Leonidovich (Slizheuski Aleh Leonidavich)	Слізжэўскі Алег Леанідавіч	СЛИЖЕВСКИЙ Олег Леонидович					Head of the Division of Social Organisations, Parties and NGOs, Ministry of Justice

Names (English transcription)	Names (Belarusian spelling)	Names (Russian spelling)	Date of birth	Place of birth	Address	Passport number	Position
Khariton Aleksandr (Khariton Alaksandr)	Харытон Аляксандр	ХАРИТОН Александр					Consultant of the Division of Social Organisations, Parties and NGOs of the Ministry of Justice
Smirnov Evgeny Aleksandrovich (Smirnov Yauhien Alaksandravich)	Смірноў Яўген Аляксандравіч	СМИРНОВ Евгений Александрович	15.3.1949	Ryuzandistrict, Russia			First Deputy of the Chairman of the Economic Court
Reutskaya Nadezhda Zalovna (Ravutskaya Nadzjeja Zalatana)	Равуцкая Надзея Залаўна	РЕУТСКАЯ Надежда Заловна					Judge of the Moscow district of Minsk
Trubnikov Nikolai Alekseevich (Trubnikau Mikalai Alakseevich)	Трубнікаў Мікалай Аляксеевіч	ТРУБНИКОВ Николай Алексеевич					Judge of the Partizanskiy district of Minsk
Kurpryanov Nikolai Mikhailovich (Kurpryanau Mikalai Mikhailavich)	Курп'янаў Мікалай Міхайлавіч	КУПРЯНОВ Николай Михайлович					Deputy Prosecutor General
Sukhorenko Stepan Nikolaevich (Sukharenka Stsiapan Mikalaevich)	Сухарэнка Сцяпан Мікалаевіч	СУХОРЕНКО Степан Николаевич	27.1.1957	Zhdidichi, Mogilev-district, Здудичи Светлогорского района Гомельской области			Chairman of KGB
Dementei Vasily Ivanovich (Dzemiantisiei Vasil Ivanavich)	Дземянцэй Васіль Іванавіч	ДЕМЕНТЕЙ Василий Иванович					First deputy, KGB
Kozik Leonid Petrovich (Kozik Leamid Pietrovich)	Козік Леанід Пятровіч	КОЗИК Леонид Петрович	13.7.1948	Borisov			Head of the Federation of Trade Unions
Koleda Alexandr Mikhailovich (Kalada Alaksandr Mikhailavich)	Калёда Аляксандр Міхайлавіч	КОЛЕДА Александр Михайлович					Chairman of the Elections Commission of the Brest district
Mikhasiev Vladimir Ilyich (Mikhasiou Uladzimir Ilich)	Міхасеў Уладзімір Ільіч	МИХАСЕВ Владимир Ильич					Chairman of the CEC of the Gomel district

Names (English transcription)	Names (Belarusian spelling)	Names (Russian spelling)	Date of birth	Place of birth	Address	Passport number	Position
Luchina Leonid Aleksandrovich	Лучына Леанід Аляксандравіч	ЛУЧИНА Леонид Александрович	18.11.1947	Minsk district			Chairman of the CEC of the Grodno district
Karpenko Igor Vasilievich (Karpenka Ihar Vasilievich)	Карпенка Ігар Васільевіч	КАРПЕНКО Игорь Васильевич	28.4.1964	Novokuznetsk, Russia Новокузнецк Кемеровской области, Россия			Chairman of the CEC of the Minsk City
Kurlovich Vladimir Anatolievich (Kurlovich Uladzimir Anatolievich)	Курловіч Уладзімір Анатольевіч	КУРЛОВИЧ Владимир Анатольевич					Chairman of the CEC of the Minsk district
Metelitsa Nikolai Timofeevich (Miatsehlitsa Mikalai Tsima-feevich)	Мяцеліца Мікалай Цімафеевіч	МЕТЕЛИЦА Николай Тимофеевич					Chairman of the CEC of the Mogilev district
Pishchulenok Mikhail Vasilievich (Pishchulenak Mikhail Vasilievich)	Пішчулёнак Міхаіл Васільевіч	ПИЩУЛЕНОК Михаил Васильевич					Chairman of the CEC of the Vitebsk district
Rybakov Alexei	Рыбакоў Аляксей	РЫБАКОВ Алексей			Ul. Jesenina 31-1-104, Minsk		Judge of the Minsk Moskovsky District Court
Bortnik Sergei Aleksandrovich	Бортнік Сяргей Аляксандравіч	БОРТНИК Сергей Александрович	28.5.1953	Minsk	Ul. Sarganovo 80-263, Minsk	MP0469554	Public Prosecutor
Yasinovich Leonid Stanislavovich	Ясіновіч Леанід Станіслававіч	ЯСИНОВИЧ Леонид Станиславович	26.11.1961	Buchany, Vitebsk district	Ul. Gorovtva 4-104, Minsk	MP0515811	Judge of the Minsk Tsentralny District Court
Migun Andrei Arkadevich	Мігун Андрэй Аркадзевіч	МИГУН Андрей Аркаевич	5.2.1978	Minsk	Ul. Goretzkovo Maksima 53-16, Minsk	MP1313262	Public Prosecutor

## ANNEX IV

## List of persons referred to in Article 1a

Names (English transcription)	Names (Belarusian spelling)	Names (Russian spelling)	Date of birth	Place of birth	Address	Passport number	Position
Lukashenko Aleksandr Grigorievich (Lukashenka Alaksandr Ryhoravich)	Лукашенка Аляксандр Рыгоравіч	ЛУКАШЕНКО Александр Григорьевич	30.8.1954	Kopyus, Vitebsk district			President
Neuvyglas Gennady Nikolaevich (Nievuyhlas Hienadz Mikalaevich)	Невыглас Геннадзь Мікалаевіч	НЕВЫГЛАС Геннадий Николаевич	11.2.1954	Parahonsk, Pinsk district			Head of President's Administration
Petkevich Natalya Vladimirovna (Piatkevich Natallia Uladzimirava)	Пяткевіч Наталля Уладзіміраўна	ПЕТКЕВИЧ Наталья Владимировна	24.10.1972	Minsk			Deputy Head of President's Administration
Rubinov Anatoly Nikolaevich (Rubinau Anatol Mikalaevich)	Рубінаў Анатоль Мікалаевіч	РУБИНОВ Анатолий Николаевич	15.4.1939	Mogilev			Deputy Head in charge of Media and Ideology, PA
Proleskovsky Oleg Vitoldovich Pralaskouski Aleh Vitoldavich,	Праляскоўскі Олег Вітольдавіч	ПРОЛЕСКОВСКИЙ Олег Витольдович	1.10.1963	Zagorsk (Russia, now Sergijev Posad)			Aide and Head of the Main Ideological department, PA
Radkov Aleksandr Mikhailovich (Radzkou Alaksandr Mikhailavich)	Радзькоў Аляксандр Міхайлавіч	РАДЬКОВ Александр Михайлович	1.7.1951	Уотпуа, Вогня Быховскага раёна Могілеўскай абласці			Minister of Education
Rusakevich Vladimir Vasiyevich (Rusakevich Uladzimir Vasiievich)	Русакевіч Уладзімір Васільевіч	РУСАКЕВИЧ Владимир Васильевич	13.9.1947	Уугоношчы, Брэстская абласць			Minister of Information
Golovanov Viktor Grigorievich Halavanau Viktor Ryhoravich,	Галаванаў Віктар Рыгоравіч	ГОЛОВАНОВ Виктор Григорьевич	1952	Borisov			Minister of Justice
Zimovsky Alexander Leonidovich (Zimouski Alaksandr Lieanidavich)	Зімоўскі Аляксандр Леанідавіч	ЗИМОВСКИЙ Александр Леонидович	10.1.1961	Germany			Member of the Upper House of the Parliament; Head of the national state tele-radio company

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Koporyuev Vladimir Nikolaevich (Копор'юв Уладзімір Мікалаевіч)	Каналіў Уладзімір Мікалаевіч	КОНОПЛЕВ Владимир Николаевич	3.1.1954	Akulimtsy, d. Mopilevskogo rayona			Chairman of the Lower House of the Parliament
Cherginets Nikolai Ivanovich (Чагінцэц Мікалай Іванавіч)	Чагінцэц Мікалай Іванавіч	ЧЕРГИНЕЦ Николай Иванович	17.10.1937	Minsk			Chairman of the Foreign Affairs Committee of the Upper House
Kostyan Sergei Ivanovich (Кастыян Сяргей Іванавіч)	Кастыян Сяргей Іванавіч	КОСТЯН Сергей Иванович	15.1.1941	Usokhi, Mogilev-district, Усохи Кличевского района Могилевской области			Chairman of the Foreign Affairs Committee of the Lower House
Orda Mikhail Sergeevich (Орда Міхаіл Сяргеевіч)	Орда Міхаіл Сяргеевіч	ОРДА Михаил Сергеевич	28.9.1966	Dyatlovo, Grodno-district, Дятлаво Гродненской области			Member of the Upper House, leader of BRSM
Lozovik Nikolai Ivanovich (Лазавік Мікалай Іванавіч)	Лазавік Мікалай Іванавіч	ЛОЗОВИК Николай Иванович	18.1.1951	Neviniany, Minsk-district, Невиняны Вилейского р-на Минской обл			Deputy of the CEC
Miklashevich Petr Petrovich (Мікласевіч Пётр Пятровіч)	Мікласевіч Пётр Пятровіч	МИКЛАШЕВИЧ Петр Петрович	1954	Kosuta, Minsk-district, Косу́та Минской области			Prosecutor General
Slizhevsky Oleg Leonidovich (Слізжэўскі Алег Леанідавіч)	Слізжэўскі Алег Леанідавіч	СЛИЗЖЕВСКИЙ Олег Леонидович					Head of the Division of Social Organisations, Parties and NGOs, Ministry of Justice
Kharyton Aleksandr (Харытон Аляксандр)	Харытон Аляксандр	ХАРИТОН Александр					Consultant of the Division of Social Organisations, Parties and NGOs of the Ministry of Justice
Smirnov Evgeny Aleksandrovich (Смірноў Яўген Аляксандравіч)	Смірноў Яўген Аляксандравіч	СМИРНОВ Евгений Александрович	15.3.1949	Ryuzandistrict, Russia			First Deputy of the Chairman of the Economic Court



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Reutskaya Nadezhda Zalovna (Ravutskaya Nadzieja Zalauna)	Равудкая Надзея Залаўна	РЕУТСКАЯ Надежда Заловна					Judge of the Moscow district of Minsk
Trubnikov Nikolai Alekseevich (Trubnikau Mikalai Alakseevich)	Трубнікау Мікалай Аляксеевіч	ТРУБНИКОВ Николай Алексеевич					Judge of the Partizanskiy district of Minsk
Kurpyanov Nikolai Mikhailovich (Kurpyanau Mikalai Mikhailavich)	Курпянаў Мікалай Міхайлавіч	КУРПЯНОВ Николай Михайлович					Deputy Prosecutor General
Sukhorenko Stepan Nikolaevich (Sukharanka Stsiapan Mikalaevich)	Сухарэнка Сцяпан Мікалаевіч	СУХОРЕНКО Степан Николаевич	27.1.1957	Zhdudichi, Mogilev-district, Здудичи Светлогорского района Гомельской области			Chairman of KGB
Dementei Vasily Ivanovich (Dzemiantsei Vasil Ivanavich)	Дземянцэй Васіль Іванавіч	ДЕМЕНТЕЙ Василий Иванович					First deputy, KGB
Kozik Leonid Petrovich (Kozik Leamid Pietrovich)	Козік Леанід Пятровіч	КОЗИК Леонид Петрович	13.7.1948	Bortsov			Head of the Federation of Trade Unions
Koleda Alexandr Mikhailovich (Kalada Alaksandr Mikhailavich)	Калёда Аляксандр Міхайлавіч	КОЛЕДА Александр Михайлович					Chairman of the Elections Commission of the Brest district
Mikhashev Vladimir Ilyich (Mikhasiou Uladzimir Ilich)	Міхасеў Уладзімір Ільіч	МИХАСЕВ Владимир Ильич					Chairman of the CEC of the Gomel district
Luchina Leonid Aleksandrovich	Лучына Леанід Аляксандравіч	ЛУЧИНА Леонид Александрович	18.11.1947	Minsk district			Chairman of the CEC of the Grodno district
Karpenko Igor Vasilevich (Karpenka Ihar Vasilievich)	Карпенка Ігар Васільевіч	КАРПЕНКО Игорь Васильевич	28.4.1964	Novokuznetsk, Russia Новокузнецк Кемеровской области, Россия			Chairman of the CEC of the Minsk City
Kurtovich Vladimir Anatolevich (Kurlovich Uladzimir Anatolevich)	Курловіч Уладзімір Анатольевіч	КУРЛОВИЧ Владимир Анатольевич					Chairman of the CEC of the Minsk district

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Metelitsa Nikolai Timofeevich (Miatseilitsa Mikalai Tsima- feevich)	Мяцеліца Мікалай Цімафеевіч	МЕТЕЛИЦА Николай Тимофеевич					Chairman of the CEC of the Mogilev district
Pishchulenok Mikhail Vasi- lievich (Pishchulenak Mikhail Vasi- lievich)	Пішчулёнак Міхаіл Васільевіч	ПИЩУЛЕНОК Михаил Васильевич					Chairman of the CEC of the Vitebsk district
Sheyman (Sheiman), Victor Vladimirovich			26.5.1958	Grodno region			State Secretary of the Security Council
Pavlichenko (Pavliuchenko), Dmitri (Dmitry) Valeniyevich			1966	Vitebsk			Head of the Special Response Group at the Ministry of the Interior (SOBR)
Naumov, Vladimir Vladi- mirovich			7.2.1956				Minister of the Interior
Yermoshina Lydia Mihajlovna			29.1.1953	Slutsk (Minsk Region)			Chairwoman of the Central Election Commission
Podobed Yuri Nikolaevich			5.3.1962	Slutsk (Minsk Region)			Lieutenant Colonel of Militia, Unit for Special Purposes (OMON), Ministry of Internal Affairs
Rybakov Alexei	Рыбакоў Аляксей	РЫБАКОВ Алексей			Ul. Jesenina 31-1-104, Minsk		Judge of the Minsk Moskovsky District Court
Bortnik Sergei Aleksandrovich	Бортнік Сяргей Аляксандравіч	БОРТНИК Сергей Александрович	28.5.1953	Minsk	Ul. Surganovo 80-263, Minsk	MP0469554	Public Prosecutor
Yasinovich Leonid Stanisla- vovich	Ясіновіч Леанід Станіслававіч	ЯСИНОВИЧ Леонид Станиславович	26.11.1961	Buchany, Vitebsk district	Ul. Gorovtva 4-104, Minsk	MP0515811	Judge of the Minsk Tsen- tralny District Court
Migun Andrei Arkadevich	Мігун Андрэй Аркадзевіч	МИГУН Андрей Аркадеевич	5.2.1978	Minsk	Ul. Goretskovo Maksima 53-16, Minsk	MP1313262	Public Prosecutor*