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I

(Acts whose publication is obligatory)

COMMISSION REGULATION (EC) No 794/2006
of 29 May 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 ⁽¹⁾, 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 30 May 2006.

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

Done at Brussels, 29 May 2006.

For the Commission

J. L. DEMARTY

*Director-General for Agriculture and
Rural Development*

⁽¹⁾ 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 29 May 2006 establishing the standard import values for determining the entry price of certain fruit and vegetables

(EUR/100 kg)		
CN code	Third country code ⁽¹⁾	Standard import value
0702 00 00	052	86,5
	204	37,0
	999	61,8
0707 00 05	052	114,7
	999	114,7
0709 90 70	052	98,4
	999	98,4
0805 10 20	204	34,0
	220	39,7
	388	80,8
	624	52,0
	999	51,6
0805 50 10	388	83,1
	528	54,5
	999	68,8
0808 10 80	388	88,1
	400	126,4
	404	100,2
	508	83,9
	512	85,2
	524	88,5
	528	89,8
	720	111,6
	804	109,0
	999	98,1
0809 20 95	052	227,5
	999	227,5

⁽¹⁾ 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 795/2006**of 29 May 2006****amending Regulation (EC) No 27/2006 as regards the quantity covered by the standing invitation to tender for the export of common wheat held by the German intervention agency**

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 ⁽¹⁾, and in particular Article 6 thereof,

Whereas:

- (1) Commission Regulation (EC) No 27/2006 ⁽²⁾ has opened a standing invitation to tender for the export of 1 500 000 tonnes of common wheat held by the German intervention agency.
- (2) The invitations to tender made since this invitation to tender was opened have almost completely exhausted the quantities made available to the economic operators. In view of the strong demand recorded in recent weeks and the market situation, new quantities should be made available and the German intervention agency should be authorised to increase by 500 000 tonnes the quantity put out to tender for export.
- (3) Regulation (EC) No 27/2006 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

Article 2 of Regulation (EC) No 27/2006 is hereby replaced by the following:

'Article 2

The invitation to tender shall cover a maximum of 2 000 000 tonnes of common wheat for export to third countries with the exception of Albania, Bosnia and Herzegovina, Bulgaria, Croatia, the former Yugoslav Republic of Macedonia, Liechtenstein, Romania, Serbia and Montenegro (*) and Switzerland.

(*) Including Kosovo as defined in UN Security Council Resolution 1244 of 10 June 1999.'

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, 29 May 2006.

For the Commission

Mariann FISCHER BOEL

Member of the Commission

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

⁽²⁾ OJ L 6, 11.1.2006, p. 15. Regulation as amended by Commission Regulation (EC) No 505/2006 (OJ L 92, 30.3.2006, p. 4).

COMMISSION REGULATION (EC) No 796/2006**of 29 May 2006****suspending the buying-in of butter at 90 % of the intervention price and opening the buying-in by tendering for the period expiring on 31 August 2006**

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 ⁽¹⁾, and in particular Article 10 thereof,

Whereas:

(1) Commission Regulation (EC) No 343/2006 ⁽²⁾ has opened the buying-in of butter at 90 % of the intervention price in certain Member States for the period 1 March to 31 August 2006.

(2) The second subparagraph of Article 6(1) of Regulation (EC) No 1255/1999 provides that the Commission may suspend the buying-in of butter at 90 % of the intervention price where the quantities offered for intervention in the period from 1 March to 31 August 2006 exceed 50 000 tonnes.

(3) Since the threshold of 50 000 tonnes is met, the buying-in of butter at fixed price should be suspended. Regulation (EC) No 343/2006 should therefore be repealed.

(4) In order to continue to support the butter market, the buying-in of butter should be authorised under a standing invitation to tender in accordance with the third subparagraph of Article 6(1) of Regulation (EC) No 1255/1999 in those Member States where the market price of butter is less than 92 % of the intervention price.

(5) Commission Regulation (EC) No 2771/1999 of 16 December 1999 laying down detailed rules for the application of Council Regulation (EC) No 1255/1999 as regards intervention of the market in butter and cream ⁽³⁾ lays down rules to be followed when the Commission decides that the buying-in is to take place under a standing invitation to tender.

(6) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for Milk and Milk Products,

HAS ADOPTED THIS REGULATION:

Article 1

The buying-in of butter at 90 % of the intervention price, opened by Regulation (EC) No 343/2006, is suspended in the Community in accordance with the second subparagraph of Article 6(1) of Regulation (EC) No 1255/1999.

Regulation (EC) No 343/2006 is repealed.

Article 2

1. Buying-in of butter by tendering, as provided for in the third subparagraph of Article 6(1) of Regulation (EC) No 1255/1999, is hereby open from 30 May to 31 August 2006 in the following Member States, under the conditions provided for in Section 3a of Regulation (EC) No 2771/1999:

- Belgium
- Czech Republic
- Germany
- Estonia
- Spain
- France
- Ireland
- Italy
- Latvia
- Luxembourg
- Netherlands
- Poland
- Portugal
- Finland
- Sweden
- United Kingdom.

⁽¹⁾ 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).

⁽²⁾ OJ L 55, 25.2.2006, p. 17. Regulation as last amended by Regulation (EC) No 697/2006 (OJ L 121, 6.5.2006, p. 29).

⁽³⁾ OJ L 333, 24.12.1999, p. 11. Regulation as last amended by Regulation (EC) No 2107/2005 (OJ L 337, 22.12.2005, p. 20).

2. The list set out in paragraph 1 may be amended by the Commission on the basis of the market prices over two consecutive weeks for the purposes of application of the third and fourth subparagraphs of Article 6(1) of Regulation (EC) No 1255/1999.

Article 3

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, 29 May 2006.

For the Commission
Mariann FISCHER BOEL
Member of the Commission

COMMISSION DIRECTIVE 2006/50/EC**of 29 May 2006****amending Annexes IVA and IVB to Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market****(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market ⁽¹⁾, and in particular Article 29 thereof,

Whereas:

- (1) Annexes IVA and IVB to Directive 98/8/EC set out the requirements for the dossiers to be submitted by applicants for, respectively, inclusion of an active substance consisting of micro-organisms including viruses and fungi in Annex I or IA to that Directive, and authorisation of a biocidal product based on preparations of such micro-organisms including viruses and fungi.
- (2) It is necessary to adapt Annexes IVA and IVB to Directive 98/8/EC to technical progress and to developments in related legislation, in particular Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market ⁽²⁾ and Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms ⁽³⁾, in order to provide a better basis for carrying out the risk assessments for micro-organisms and the biocidal products containing them. In addition, there have been scientific and technical developments within the field of microbiology and biotechnology. Providing for a similar structure of the data requirements in the framework of Directive 98/8/EC with those of Directive 91/414/EEC will facilitate the work of applicants submitting dossiers within both legal frameworks and the work of the Member States authorities evaluating such dossiers. It is therefore appropriate to update the data requirements for micro-organisms including viruses and fungi currently contained in Directive 98/8/EC and to align them as far as possible with those established in the framework of Directive 91/414/EEC.

- (3) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Biocidal Products.

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annexes IVA and IVB to Directive 98/8/EC are replaced by the text set out in the Annex to this Directive.

Article 2

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

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 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 29 May 2006.

For the Commission

Stavros DIMAS

Member of the Commission

⁽¹⁾ OJ L 123, 24.4.1998, p. 1. Directive as amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).

⁽²⁾ OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2006/39/EC (OJ L 104, 13.4.2006, p. 30).

⁽³⁾ OJ L 106, 17.4.2001, p. 1. Directive as last amended by Regulation (EC) No 1830/2003 (OJ L 268, 18.10.2003, p. 24).

ANNEX

ANNEX IV A

DATA SET FOR ACTIVE SUBSTANCES

MICRO-ORGANISMS INCLUDING VIRUSES AND FUNGI

1. For the purposes of this Annex, the term micro-organisms shall be understood as including also viruses and fungi. Dossiers on active micro-organisms shall address at least all the points listed under "Dossier requirements" below. For all micro-organisms subject to an application for inclusion into Annex I or IA, all available relevant knowledge and information in literature must be provided. The information related to the identification and characterisation of a micro-organism including mode of action is particularly important and must be entered in sections I to IV and provides the basis for an assessment of potential impacts on human health and of environmental effects.
2. Where information is not necessary owing to the nature of the micro-organism Article 8(5) shall apply.
3. A dossier within the meaning of Article 11(1) shall be prepared on strain level of the micro-organism unless information is submitted that shows that the species is known to be sufficiently homogeneous regarding all characteristics, or the applicant provides other arguments in accordance with Article 8(5).
4. Where the micro-organism has been genetically modified within the meaning of Article 2(2) of Directive 2001/18/EC, a copy of the evaluation of the data concerning the assessment of the risks to the environment as established in Article 4(2) of that Directive, shall also be submitted.
5. If the biocidal product action is known to be partly or entirely due to the effect of a toxin/metabolite, or if significant residues of toxins/metabolites are to be expected not related to the effect of the active micro-organism, a dossier for the toxin/metabolite shall be submitted in accordance with the requirements of Annexes IIA and, where specified, the relevant parts of Annex IIIA.

Dossier requirements

SECTIONS:

- I. Identity of the micro-organism
- II. Biological properties of the micro-organism
- III. Further information on the micro-organism
- IV. Analytical methods
- V. Effects on human health
- VI. Residues in or on treated materials, food and feed
- VII. Fate and behaviour in the environment
- VIII. Effects on non-target organisms
- IX. Classification and labelling
- X. Summary and evaluation of sections I to IX including conclusions of the risk assessment and recommendations

The following data will be required to support submissions on the above points.

I. IDENTITY OF THE MICRO-ORGANISM

- 1.1. Applicant
- 1.2. Manufacturer
- 1.3. Name and species description, strain characterisation
 - 1.3.1. Common name of the micro-organism (including alternative and superseded names)
 - 1.3.2. Taxonomic name and strain indicating whether it is a stock variant, a mutant strain or a genetically modified organism (GMO); for viruses, taxonomic designation of the agent, serotype, strain or mutant
 - 1.3.3. Collection and culture reference number where the culture is deposited
 - 1.3.4. Methods, procedures and criteria used to establish the presence and identity of the micro-organism (e.g. morphology, biochemistry, serology, etc.)
- 1.4. Specification of the material used for manufacturing of formulated products
 - 1.4.1. Content of the micro-organism
 - 1.4.2. Identity and content of impurities, additives, contaminating micro-organisms
 - 1.4.3. Analytical profile of batches

II. BIOLOGICAL PROPERTIES OF THE MICRO-ORGANISM

- 2.1. History of the micro-organism and its uses. Natural occurrence and geographical distribution
 - 2.1.1. Historical background
 - 2.1.2. Origin and natural occurrence
- 2.2. Information on target organism(s)
 - 2.2.1. Description of the target organism(s)
 - 2.2.2. Mode of action
- 2.3. Host specificity range and effects on species other than the target organism
- 2.4. Development stages/life cycle of the micro-organism
- 2.5. Infectiveness, dispersal and colonisation ability
- 2.6. Relationships to known plant or animal or human pathogens
- 2.7. Genetic stability and factors affecting it
- 2.8. Information on the production of metabolites (especially toxins)
- 2.9. Antibiotics and other anti-microbial agents
- 2.10. Robustness to environmental factors
- 2.11. Effects on materials, substances and products

III. FURTHER INFORMATION ON THE MICRO-ORGANISM

- 3.1. Function
- 3.2. Field of use envisaged
- 3.3. Product type(s) and category of users for which the micro-organism should be listed in Annex I, IA or IB

- 3.4. Method of production and quality control
- 3.5. Information on the occurrence or possible occurrence of the development of resistance of the target organism(s)
- 3.6. Methods to prevent loss of virulence of seed stock of the micro-organism
- 3.7. Recommended methods and precautions concerning handling, storage, transport or fire
- 3.8. Procedures for destruction or decontamination
- 3.9. Measures in case of an accident
- 3.10. Procedures for waste management
- 3.11. Monitoring plan to be used for the active micro-organism including handling, storage, transport and use

IV. ANALYTICAL METHODS

- 4.1. Methods for the analysis of the micro-organism as manufactured
- 4.2. Methods to determine and quantify residues (viable or non-viable)

V. EFFECTS ON HUMAN HEALTH

TIER I

- 5.1. Basic information
 - 5.1.1. Medical data
 - 5.1.2. Medical surveillance on manufacturing plant personnel
 - 5.1.3. Sensitisation/allergenicity observations
 - 5.1.4. Direct observation, e.g. clinical cases
- 5.2. Basic studies
 - 5.2.1. Sensitisation
 - 5.2.2. Acute toxicity, pathogenicity, and infectiveness
 - 5.2.2.1. Acute oral toxicity, pathogenicity and infectiveness
 - 5.2.2.2. Acute inhalation toxicity, pathogenicity and infectiveness
 - 5.2.2.3. Intraperitoneal/subcutaneous single dose
 - 5.2.3. *In vitro* genotoxicity testing
 - 5.2.4. Cell culture study
 - 5.2.5. Information on short-term toxicity and pathogenicity
 - 5.2.5.1. Health effects after repeated inhalatory exposure
 - 5.2.6. Proposed treatment: first aid measures, medical treatment
 - 5.2.7. Any pathogenicity and infectiveness to humans and other mammals under conditions of immunosuppression

END OF TIER I

TIER II

- 5.3. Specific toxicity, pathogenicity and infectiveness studies
- 5.4. Genotoxicity — *In vivo* studies in somatic cells
- 5.5. Genotoxicity — *In vivo* studies in germ cells

END OF TIER II

- 5.6. Summary of mammalian toxicity, pathogenicity and infectiveness and overall evaluation

VI. RESIDUES IN OR ON TREATED MATERIALS, FOOD AND FEED

- 6.1. Persistence and likelihood of multiplication in or on treated materials, feedingstuffs or foodstuffs
- 6.2. Further information required
 - 6.2.1. Non-viable residues
 - 6.2.2. Viable residues
- 6.3. Summary and evaluation of residues in or on treated materials, food and feed

VII. FATE AND BEHAVIOUR IN THE ENVIRONMENT

- 7.1. Persistence and multiplication
 - 7.1.1. Soil
 - 7.1.2. Water
 - 7.1.3. Air
- 7.2. Mobility
- 7.3. Summary and evaluation of fate and behaviour in the environment

VIII. EFFECTS ON NON-TARGET ORGANISMS

- 8.1. Effects on birds
- 8.2. Effects on aquatic organisms
 - 8.2.1. Effects on fish
 - 8.2.2. Effects on freshwater invertebrates
 - 8.2.3. Effects on algae growth
 - 8.2.4. Effects on plants other than algae
- 8.3. Effects on bees
- 8.4. Effects on arthropods other than bees
- 8.5. Effects on earthworms
- 8.6. Effects on soil micro-organisms

- 8.7. Further studies
 - 8.7.1. Terrestrial plants
 - 8.7.2. Mammals
 - 8.7.3. Other relevant species and processes
- 8.8. Summary and evaluation of effects on non-target organisms

IX. CLASSIFICATION AND LABELLING

The dossier shall be accompanied by a reasoned proposals for allocating an active substance which is a micro-organism to one of the risk groups specified in Article 2 of Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work ⁽¹⁾ together with indications on the need for products to carry the biohazard sign specified in Annex II to that Directive.

X. SUMMARY AND EVALUATION OF SECTIONS I TO IX INCLUDING CONCLUSIONS OF THE RISK ASSESSMENT AND RECOMMENDATIONS

⁽¹⁾ OJ L 262, 17.10.2000, p. 21.

ANNEX IVB

DATA SET FOR BIOCIDAL PRODUCTS

MICRO-ORGANISMS INCLUDING VIRUSES AND FUNGI

1. For the purposes of this Annex, the term micro-organisms shall be understood as including also viruses and fungi. This Annex provides data requirements for the authorisation of a biocidal product based on preparations of micro-organisms. For all biocidal products based on preparations containing micro-organisms that are subject to application, all available relevant knowledge and information in literature should be provided. The information related to the identification and characterisation of all components in a biocidal product is particularly important and must be entered in sections I to IV and provides the basis for an assessment of possible impacts on human health and the environment.
2. Where, information is not necessary owing to the nature of the biocidal product Article 8(5) shall apply.
3. Information may be derived from existing data where a justification acceptable to the competent authority is provided. In particular, the provisions of Directive 67/548/EEC and Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations ⁽¹⁾ shall be used wherever possible to minimise animal testing.
4. Where testing is done, a detailed description (specification) of the material used and its impurities, according to the provisions of Section II, must be provided. Where necessary, data as established in Annexes IIB, IIIB shall be required for all the toxicologically/eco-toxicologically relevant chemical components of the biocidal product, in particular if the components are substances of concern as defined in Article 2(1)(e).
5. In cases where a new preparation is to be dealt with, extrapolation from Annex IVA, could be acceptable, provided that all the possible effects of the components, especially on pathogenicity and infectiveness, are evaluated.

Dossier requirements

SECTIONS:

- I. Identity of the biocidal product
- II. Physical, chemical and technical properties of the biocidal product
- III. Data on application
- IV. Further information on the biocidal product
- V. Analytical methods
- VI. Efficacy data
- VII. Effects on human health
- VIII. Residues in or on treated materials, food and feed
- IX. Fate and behaviour in the environment
- X. Effects on non-target organisms
- XI. Classification, packaging and labelling of the biocidal product
- XII. Summary and evaluation of sections I to XI including conclusions of the risk assessment and recommendations

The following data will be required to support submissions on the above points.

⁽¹⁾ OJ L 200, 30.7.1999, p. 1. Directive as last amended by Commission Directive 2006/8/EC (OJ L 19, 24.1.2006, p. 12).

I. IDENTITY OF THE BIOCIDAL PRODUCTS

- 1.1. Applicant
- 1.2. Manufacturer of the biocidal product and the micro-organism(s)
- 1.3. Trade name or proposed trade name, and manufacturer's development code number of the biocidal product
- 1.4. Detailed quantitative and qualitative information on the composition of the biocidal product
- 1.5. Physical state and nature of the biocidal product
- 1.6. Function

II. PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES OF THE BIOCIDAL PRODUCT

- 2.1. Appearance (colour and odour)
- 2.2. Storage stability and shelf-life
 - 2.2.1. Effects of light, temperature and humidity on technical characteristics of the biocidal product
 - 2.2.2. Other factors affecting stability
- 2.3. Explosivity and oxidising properties
- 2.4. Flash point and other indications of flammability or spontaneous ignition
- 2.5. Acidity, alkalinity and pH value
- 2.6. Viscosity and surface tension
- 2.7. Technical characteristics of the biocidal product
 - 2.7.1. Wettability
 - 2.7.2. Persistent foaming
 - 2.7.3. Suspensibility and suspension stability
 - 2.7.4. Dry sieve test and wet sieve test
 - 2.7.5. Particle size distribution (dustable and wettable powders, granules), content of dust/fines (granules), attrition and friability (granules)
 - 2.7.6. Emulsifiability, re-emulsifiability, emulsion stability
 - 2.7.7. Flowability, pourability (rinsability) and dustability
- 2.8. Physical, chemical and biological compatibility with other products including biocidal products with which its use is to be authorised or registered
 - 2.8.1. Physical compatibility
 - 2.8.2. Chemical compatibility
 - 2.8.3. Biological compatibility
- 2.9. Summary and evaluation of physical, chemical and technical properties of the biocidal product

III. DATA ON APPLICATION

- 3.1. Field of use envisaged
- 3.2. Mode of action
- 3.3. Details of intended use

- 3.4. Application rate
- 3.5. Content of micro-organism in material used (e.g. in the application device or bait)
- 3.6. Method of application
- 3.7. Number and timing of applications and duration of protection
- 3.8. Necessary waiting periods or other precautions to avoid adverse effects to human and animal health and the environment
- 3.9. Proposed instructions for use
- 3.10. Category of users
- 3.11. Information on the possible occurrence of the development of resistance
- 3.12. Effects on the materials or products treated with the biocidal product
-
- IV. FURTHER INFORMATION ON THE BIOCIDAL PRODUCT
- 4.1. Packaging and compatibility of the biocidal product with proposed packaging materials
- 4.2. Procedures for cleaning application equipment
- 4.3. Re-entry periods, necessary waiting periods or other precautions to protect man, livestock and the environment
- 4.4. Recommended methods and precautions concerning: handling, storage, transport or fire
- 4.5. Measures in the case of an accident
- 4.6. Procedures for destruction or decontamination of the biocidal product and its packaging
- 4.6.1. Controlled incineration
- 4.6.2. Others
- 4.7. Monitoring plan to be used for the active micro-organism and other micro-organism(s) contained in the biocidal product including handling, storage, transport and use
-
- V. ANALYTICAL METHODS
- 5.1. Methods for the analysis of the biocidal product
- 5.2. Methods to determine and quantify residues
-
- VI. EFFICACY DATA
-
- VII. EFFECTS ON HUMAN HEALTH
- 7.1. Basic acute toxicity studies
- 7.1.1. Acute oral toxicity
- 7.1.2. Acute inhalation toxicity
- 7.1.3. Acute percutaneous toxicity
- 7.2. Additional acute toxicity studies
- 7.2.1. Skin irritation
- 7.2.2. Eye irritation
- 7.2.3. Skin sensitisation

- 7.3. Data on exposure
 - 7.4. Available toxicological data relating to non-active substances
 - 7.5. Supplementary studies for combinations of biocidal products
 - 7.6. Summary and evaluation of effects on human health
 - VIII. RESIDUES IN OR ON TREATED MATERIALS, FOOD AND FEED
 - IX. FATE AND BEHAVIOUR IN THE ENVIRONMENT
 - X. EFFECTS ON NON-TARGET ORGANISMS
 - 10.1. Effects on birds
 - 10.2. Effects on aquatic organisms
 - 10.3. Effects on bees
 - 10.4. Effects on arthropods other than bees
 - 10.5. Effects on earthworms
 - 10.6. Effects on soil micro-organisms
 - 10.7. Additional studies on additional species or higher tier studies such as studies on selected non-target organisms
 - 10.7.1. Terrestrial plants
 - 10.7.2. Mammals
 - 10.7.3. Other relevant species and processes
 - 10.8. Summary and evaluation of effects on non-target organisms
 - XI. CLASSIFICATION, PACKAGING AND LABELLING OF THE BIOCIDAL PRODUCT

As established in Article 20, proposals including justification for the classification and labelling of the biocidal product in accordance with the provisions set in Directive 67/548/EEC and Directive 1999/45/EC must be submitted. The classification comprises of the description of the category/categories of danger and qualifying risk phrases for all dangerous properties. On the basis of the classification, a proposal for labelling including the hazard symbol(s) and indications of danger, risk phrases and safety phrases should be given. The classification and labelling shall be in regard to the chemical substances contained in the biocidal product. If necessary, specimens of proposed packaging shall be submitted to the competent authority of a Member State.

The dossier shall be accompanied by a reasoned proposal for allocation to one of the risk groups specified in Article 2 of Directive 2000/54/EC together with indications on the need for products to carry the biohazard sign specified in Annex II to that Directive.
 - XII. SUMMARY AND EVALUATION OF SECTIONS I TO XI INCLUDING CONCLUSIONS OF THE RISK ASSESSMENT AND RECOMMENDATIONS'
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II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 3 May 2006

concerning draft national provisions notified by the Kingdom of the Netherlands under Article 95(5) of the EC Treaty laying down limits on the emissions of particulate matter by diesel powered vehicles

(notified under document number C(2006) 1791)

(Only the Dutch text is authentic)

(2006/372/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community, and in particular Article 95(5) and (6) thereof,

Whereas:

I. FACTS

1. Relevant Community legislation

- (1) Directive 98/69/EC of the European Parliament and of the Council of 13 October 1998 relating to measures to be taken against air pollution by emissions from motor vehicles and amending Council Directive 70/220/EEC of 20 March 1970 on the approximation of the laws of the Member States relating to measures to be taken against air pollution by gases from positive-ignition engines of motor vehicles ⁽¹⁾ sets a limit value for particulate emissions at 25 milligrams per kilometre (see Section 5.3.1.4 of Annex I to the Directive) for diesel vehicles in category M as defined in Annex II, Section A, to Council Directive 70/156/EEC of 6 February 1970 on the approximation of the laws of the Member States relating to the type-approval of motor vehicles and their trailers ⁽²⁾ — except vehicles the maximum mass of which exceeds 2 500 kg — and N₁, class I. This limit value applies from 1 January 2005 to new types of vehicles and from 1 January 2006 to new vehicles. The Directive also sets a limit value for particulate emissions of 40 milligrams per kilometre for diesel vehicles in category N₁, Class II and a limit value for particulate emissions of 60 milligrams per kilometre for diesel vehicles in category N₁, Class III and M whose

maximum mass exceeds 2 500 kg. These two latter limit values apply from 1 January 2006 to new types of vehicles and from 1 January 2007, to new vehicles.

- (2) According to Article 2(1) of Directive 98/69/EC ‘... no Member State may, on grounds relating to air pollution by emissions from motor vehicles:

— refuse to grant EC type-approval pursuant to Article 4(1) of Directive 70/156/EEC, or

— refuse to grant national type-approval, or

— prohibit the registration, sale or entry into service of vehicles, pursuant to Article 7 of Directive 70/156/EEC,

if the vehicles comply with the requirements of Directive 70/220/EEC, as amended by this Directive’.

- (3) On 21.12.2005, the Commission adopted a proposal for a Regulation of the European Parliament and of the Council on type-approval of motor vehicles with respect to emissions and on access to vehicle repair information, amending Directive 72/306/EEC and Directive .../.../EC (Euro 5 proposal) ⁽³⁾. The proposal reduces the particulate matter emission limit for diesel vehicles to 5 milligrams per kilometre. This new limit value will apply to new types of vehicles of category M and N₁, class I, from 18 months + 1 day after entry into force of the Regulation and to new vehicles of category M and N₁, class I, from 36 months from the date of entry into force of the Regulation.

⁽¹⁾ OJ L 350, 28.12.1998, p. 1.

⁽²⁾ OJ L 42, 23.2.1970, p. 1.

⁽³⁾ COM(2005) 683 final.

(4) Directive 99/30/EC of the Council of 22 April 1999 relating to limit values for sulphur dioxide, nitrogen dioxide and oxides of nitrogen, particulate matter and lead in ambient air⁽⁴⁾, which should be read in conjunction with Council Directive 96/62/EC of 27 September 1996 on ambient air quality assessment and management⁽⁵⁾, lays down limit values for concentrations in ambient air of PM₁₀, defined as 'particulate matter which passes through a size-selective inlet with a 50 % efficiency cut-off at 10 µm aerodynamic diameter'. In accordance with Article 5 of Directive 99/30/EC, such limit values have been legally binding since 1 January 2005. In accordance with Annex III of the same Directive, the annual limit value for the protection of human health is 40 µg/m³, while the 24 hour limit value for the protection of human health is 50 µg/m³, not to be exceeded more than 35 times in a calendar year.

(5) Article 7(3) of Directive 96/62/EC stipulates that 'Member States shall draw up action plans indicating the measures to be taken in the short term where there is a risk of the limit values and/or alert thresholds being exceeded, in order to reduce that risk and to limit the duration of such an occurrence. Such plans may, depending on the individual case, provide for measures to control and, where necessary, suspend activities, including motor-vehicle traffic, which contribute to the limit values being exceeded'.

2. National provision notified

(6) The Kingdom of the Netherlands has notified the Commission of a draft decree intended to impose a mandatory limit value for the emissions of particulate matter of 5 mg per kilometre on commercial vehicles with a maximum permissible weight of 1 305 kg (N₁ vehicles, class I) and passenger cars (M₁ vehicles) as defined in Article 1.1(h) and 1.1(at) of the Voertuigreglement. The decree would apply to all such vehicles first used after 31 December 2006, which have a diesel engine. This would imply that these vehicles are fitted with particulate filters.

(7) The measure notified by the Dutch authorities constitutes an amendment to the legislation concerning the permanent requirements that must be complied with by vehicles and their component parts throughout their useful life (Voertuigreglement). Checks on compliance with these permanent requirements are performed under the procedure for the regular inspection of vehicles and may be conducted by the police.

(8) According to its explanatory memorandum, the notified measure does not concern the type-approval procedure. It would seem that vehicles EC type-approved in another Member State will not be refused registration by the Dutch authorities and vehicles complying with the requirements of Directive 70/220/EEC, as amended by Directive 98/69/EC, should continue to be granted type-approval by the Dutch authorities. However, the first time these vehicles go through technical inspection or whenever they are checked by the police, they will be found not to be compliant with the notified measure.

(9) In conclusion, the notified measure imposes a ban on the use of new vehicles of category N₁, class I and M₁ emitting more than 5 mg/km of particulate matter, as from 1 January 2007.

II. PROCEDURE

(10) By letter of 2 November 2005, the Kingdom of the Netherlands notified the Commission, in accordance with Article 95(5) of the EC Treaty of its intention to adopt a draft decree laying down regulations to limit the emissions of particulate matter by diesel powered vehicles in derogation of the provisions of Directive 98/69/EC.

(11) By letter of 23 November 2005, the Commission informed the Dutch government that it had received the notification under Article 95(5) of the EC Treaty and that the six-month period for its examination under Article 95(6) started on 5 November 2005, the day following the day on which the notification was received.

(12) By letter of 17 January 2006, the Commission informed the other Member States of the notification received from the Kingdom of the Netherlands. The Commission also published a notice regarding the notification in the *Official Journal of the European Union*⁽⁶⁾ in order to inform other interested parties of the national provisions that the Kingdom of the Netherlands intended to introduce as well as the grounds invoked to that effect.

(13) By letter of 10 March 2006, the Netherlands authorities informed the Commission of a recent report by the Netherlands Environmental Assessment Agency entitled 'New understanding of the scale of the particulate matter problem' which shows that levels of PM₁₀ are 10-15 % lower than previously assumed.

⁽⁴⁾ OJ L 163, 29.6.1999, p. 41.

⁽⁵⁾ OJ L 296, 21.11.1996, p. 55.

⁽⁶⁾ OJ C 12, 18.1.2006, p. 5.

- (14) In order to assess the arguments put forward by the Dutch authorities, the Commission asked for the scientific and technical advice of a consortium of consultants coordinated by TNO (Nederlandse Organisatie voor ~~toegepast-natuurwetenschappelijk~~ onderzoek). The consortium submitted its report to the Commission on 27 March 2006 ⁽⁷⁾.

III. LEGAL ASSESSMENT

1. Consideration of admissibility

- (15) Article 95(5) of the EC Treaty reads as follows: 'If, after the adoption by the Council or by the Commission of a harmonisation measure, a Member State deems it necessary to introduce national provisions based on new scientific evidence relating to the protection of the environment or the working environment on grounds of a problem specific to that Member State arising after the adoption of the harmonisation measure, it shall notify the Commission of the envisaged provisions as well as the grounds for introducing them.'
- (16) The notification submitted by the Dutch authorities is intended to obtain approval for the introduction of new national provisions which are deemed to be incompatible with Directive 70/220/EEC, as amended by Directive 98/69/EC. This Directive constitutes a measure of total harmonisation of the technical requirements for the type approval of motor vehicles with regard to their emissions. It lays down a limit value for particulate emissions from diesel cars and light vans at 25 mg/km.
- (17) When comparing the provisions of Directive 70/220/EEC, as amended by Directive 98/69/EC, with the national measures notified by the Dutch authorities it emerges that the Dutch proposal sets more stringent requirements for the technical control of motor vehicles on grounds relating to air pollution by their emissions than those laid down in the Directive. In particular the notified measure imposes a mandatory limit value for the emissions of particulate matter of 5 mg/km on commercial vehicles with a maximum permissible weight of 1 305 kg (N₁ vehicles, class I) and passenger cars (M₁ vehicles), thus preventing the use of vehicles in these categories complying with the requirements of Directive 70/220/EEC, as amended by Directive 98/69/EC. It should be noted that the Directive will be deprived of its effect if Member States could impose different requirements on vehicles on grounds relating to air pollution by their emissions for the purposes of technical controls. Indeed, an EC type-approval should remain valid for a number of years and certainly well beyond the first vehicle inspection. Any other interpretation would enable the Member States to bypass the EC type-approval system.

- (18) As required by Article 95(5) of the EC Treaty, the Netherlands notified the Commission of the actual wording of the provisions that they intend to introduce going beyond those set out in Directive 70/220/EEC, as amended by Directive 98/69/EC. The request was accompanied by an explanation of the reasons which, in their opinion, justify the introduction of the provisions.

- (19) The notification submitted by the Netherlands in order to obtain approval for the introduction of national provisions derogating from the provisions of Directive 70/220/EEC, as amended by Directive 98/69/EC, is therefore to be considered admissible under Article 95(5) of the EC Treaty.

2. Assessment of merits

- (20) In accordance with Article 95 of the EC Treaty, the Commission has to ensure that all the conditions are fulfilled enabling a Member State to make use of the possibilities of derogation provided for in this Article.
- (21) The Commission must therefore assess whether the conditions provided for by Article 95(5) of the EC Treaty are met. This Article requires that when a Member State deems it necessary to introduce national provisions derogating from a harmonisation measure, the Member State should base it on:
- (a) new scientific evidence relating to the protection of the environment or the working environment;
 - (b) grounds of a problem specific to that Member State arising after the adoption of the harmonisation measure.
- (22) In addition, pursuant to Article 95(6) of the EC Treaty, where it considers that the introduction of such national provisions is justified, the Commission must check whether or not those national provisions are a means of arbitrary discrimination or a disguised restriction on trade between Member States and whether or not they constitute an obstacle to the functioning of the internal market.
- (23) In accordance with the Court's case law, any exception to the principle of the uniform application of Community law and of the unity of the internal market must be strictly interpreted. Article 95(5) of the EC Treaty provides an exception to the principles of uniform application of Community law and the unity of the market. Therefore, it must be interpreted in such a way that its scope is not extended beyond the cases for which it formally provides.

⁽⁷⁾ TNO report, 06.OR.VM.013.1/IJR 'Evaluation of the Dutch request for derogation to Directive 98/69/EC', March 27, 2006 (hereinafter referred to as the TNO report).

- (24) In the light of the timeframe established by Article 95(6) of the EC Treaty, the Commission, when examining whether the national measures notified under Article 95(5) are justified, has to take as a basis 'the grounds' put forward by the notifying Member State. This means that, according to the provisions of the EC Treaty, the responsibility of proving that the national measures are justified lies with the Member State making the request. Given the procedural framework established by Article 95 of the EC Treaty, including in particular a strict deadline for a decision to be adopted, the Commission normally has to limit itself to examining the relevance of the elements which are submitted by the requesting Member State, without having itself to seek possible reasons or justifications.

1. Existence of new scientific evidence

- (25) According to the Dutch authorities, their request is justified because new scientific evidence on the environmental and health effects of particulate matter has become available since the adoption of Directive 98/69/EC. This new information shows that excessive particulate matter emissions have harmful effects on human health, such as premature deaths and impaired lung functions.

- (26) The documents submitted by the Netherlands in relation to the new scientific evidence on the environmental and health effects of particulate matter include national and international studies, publications and reviews on the subject. The documents provide a comprehensive overview of the existing scientific knowledge concerning the range of health effects linked to exposure to particulate matter that has emerged since the adoption of Directive 98/69/EC.

- (27) The Dutch authorities point out that the link between exposure to airborne particles and a range of health effects has been proven and emphasised in many recent scientific publications. The health effects of particulate matter can be divided into those arising from relatively short periods of exposure ('acute') and those from long-term exposure ('chronic'). The studies submitted by the Netherlands show that although the health effects of short-term exposure are not negligible, long-term exposure to airborne particulate matter has more significant impacts. Effects related to short-term exposure include: inflammatory reactions in the lung, respiratory symptoms, adverse effects on the cardiovascular system and increases in medication use, hospital admissions and mortality. The effects related to long-term exposure include: increases in lower

respiratory symptoms and chronic obstructive pulmonary disease, reductions in lung function in children and adults, and reduction in life expectancy, due mainly to cardiopulmonary mortality and probably to lung cancer.

- (28) The Dutch authorities submitted documents showing that although the health effects of the various sub-fractions and various sources of particulate matter is not entirely clear, recent epidemiological and toxicological studies showed that particles generated by combustion processes, such as soot from diesel engines, are particularly important in terms of health effects. Primary combustion derived particles have especially harmful effects on health because of their composition (presence of transitional metals and reactive organic compounds) and because of their very small size. Due to their small size, combustion derived particles have the potential to sidestep the human body's protective mechanisms and penetrate into the blood stream and various tissues. The Dutch authorities point to the fact that epidemiological studies on large scale populations have been unable to identify a threshold concentration below which ambient particulate matter has no effect on mortality and morbidity.

- (29) The Dutch authorities consider that although it is currently not possible to sufficiently quantify the health impacts of particulate matter, on grounds of protection of the health of the Dutch population and on the basis of the precautionary principle, it is essential to act as swiftly as possible to reduce by the greatest possible extent exposure to traffic-generated soot particles.

- (30) In the Dutch authorities' view, recent scientific studies show that susceptible population groups are subject to higher health risks associated with particulate matter. These groups comprise those who are innately more susceptible to the effects of exposure to particulate matter (e.g. those with genetic predisposition, very young children, aged people, people with respiratory disorders and lung diseases), those who become more susceptible as a result of environmental or social factors or personal behaviour and those who are exposed to unusually large amounts of air pollutants as a result of living near a main road or spending long hours outdoors. Due to the fact that in the Netherlands a large proportion of the population is living in an urban environment and near busy roads, the Dutch authorities claim that the health risk related to particle matter for the population is considerable.

- (31) The Commission notes that the environmental and health effects related to particulate matter concentrations were already known to a certain extent before the adoption of Directive 98/69/EC. There was already an impression that smaller particles had more significant impacts on health than coarse particles. However, few studies on this issue were available. Since then, a large number of new epidemiological studies on many aspects of exposure and health effects of particulate matter have been completed showing in particular evidence to conclude that fine particles are more hazardous than larger ones⁽⁸⁾. The availability of such new studies led the World Health Organisation to produce updates of its 'Air Quality Guidelines for Europe' for particulate matter in 2000, 2003 and 2004⁽⁹⁾.
- (32) In the light of the foregoing, it would appear that the Netherlands has provided new scientific evidence relating to the protection of the environment as required by Article 95(5) of the EC Treaty. This scientific evidence was not available at the time of adoption of Directive 98/69/EC.
2. *Problem specific to the Netherlands arising after the adoption of Directive 98/68/EC*
- (33) The Dutch authorities take the view that the Netherlands is facing a specific problem that has arisen after the adoption of Directive 98/69/EC. First, they argue that the Netherlands has been experiencing difficulties for around one and a half years in complying with Directive 99/30/EC. Secondly, they note that the number of diesel cars has risen in the Netherlands due to higher petrol prices, the wider availability of diesel car models, and the greatly improved performance and fuel efficiency of diesel engines. Such an increase in the share of diesel cars was not expected when Directive 98/69/EC was adopted. The share of diesel cars has risen from up from below 15 % in 1995 to around 25 % now. All of these factors have meant that the full extent of the air quality problem was not realised until after 1998.
- (34) According to the Dutch authorities, particulate matter is a cause of major concern in the Netherlands because of the high population density and a more highly concentrated infrastructure than in other European countries. They take the view that the Netherlands occupies a special position in Europe by virtue of its intensive use of space, with high density of people, cattle, traffic and industry. In their view, this situation leads to high emissions per square kilometre. Furthermore, the Dutch authorities claim that the Netherlands has to cope with a major amount of pollution from abroad. In particular, 45 % of the particulate matter concentration in the Netherlands is caused by human activity, of which two thirds is generated abroad. However, in urban areas, the anthropogenic contribution from sources in the Netherlands is 30-45 %, with traffic being a significant source.
- (35) The Dutch authorities claim that air quality in many areas of the Netherlands does not comply with the European limit values for particulate matter as set out in Directive 99/30/EC. Though particulate matter emissions in the Netherlands have declined sharply between 1990 and 2003, according to the Dutch authorities, due to the high volume of traffic and the high concentration of people and buildings in the Netherlands, this decrease is not enough to combat the negative health effects of excessive particulate matter emissions and to implement the European air quality limit values.
- (36) According to the Dutch authorities, of the overall domestic particulate matter emissions, around a third comes from traffic, another third from industry and approximately a quarter from agriculture. Particles from exhaust gases are among the most harmful of all particulate matter. Traffic subjects people to major exposure, due to its emissions occurring in close proximity to residential areas and other sensitive land uses.
- (37) In the documents titled 'Environmental balance 2005' (Milieubalans 2005) and 'Particulate matter: a closer look' (Fijn stof nader bekeken) annexed to their notification, the Dutch authorities stress that concentrations of particulate matter in the air exceed European air quality standards to a considerable extent across wide areas of the Netherlands. The Dutch authorities note that the daily air quality limits for particulate matter will still be exceeded on a large scale in 2010. On the contrary, breaches of the annually averaged standard for particulate matter occur hardly at all. The Dutch authorities note that violations of the limit values laid down in Directive 99/30/EC have been observed in nearly all European cities. However, the violations in the Netherlands, Belgium, the Ruhr district of Germany and the industrialised area of northern Italy take place over a larger geographical area than in other Member States.
- (38) The Dutch authorities note that it is impossible to draw far-reaching conclusions from this information without considering the exact situation and size of the zones in the various countries. The Dutch authorities also note that determination of air quality in the Netherlands takes place with a high level of detail by employing detailed planning modelling alongside the prescribed measurements. However, only a limited number of EU
- ⁽⁸⁾ 'Health aspects of Air Pollution with Particulate Matter, Ozone and Nitrogen Dioxide', Report on a WHO Working Group, 2003.
- ⁽⁹⁾ Meta-analysis of time-series studies and panel studies of Particulate matter (PM) and Ozone (O₃), WHO Regional office for Europe, 2004.

countries also use models; most countries on the contrary, only use measurements of air quality. It is also possible that some of the differences can be explained by differences in the correction factors used. The Netherlands, for example, increases the measured result by a factor of 1.33. According to the Dutch authorities, a number of countries follow the indications provided by the European Commission and use a correction factor of 1.3. Most countries use lower correction factors or no correction factor at all. Moreover, not all countries model their air quality down to street levels. According to the Dutch authorities, the number of hotspots in the countries that do not model their air quality at the street level is possibly underestimated.

(39) Finally, the Dutch authorities point to their specific legal situation. The Air Quality Decree, which entered into force in 2001, has put in place a legal regime whereby construction and expansion plans can be blocked or modifications to the plans can be required if these are likely to have detrimental effects on air quality. Following the implementation of this regime, more than 40 objections to spatial developments plans have been lodged with various judicial authorities, including the Council of State, due to possible conflicts with the Air Quality Decree. In one third of these cases, the Council of State nullified the plan.

(40) The Commission notes that the percentage contribution of transboundary transport of particulate matter in the Netherlands is high though not higher than in other Benelux countries⁽¹⁰⁾. The Commission also notes that the Netherlands is characterised, in comparison to other Member States, by considerably higher particulate matter emissions derived from inland waterway shipping and maritime transport⁽¹¹⁾. It should also be noted that the large port at Rotterdam is not a predominant source of particulate matter, but has a significant influence on activities and transport in and around the Netherlands⁽¹⁰⁾.

(41) The annual reports under Council Directive 96/62/EC indicate that the Netherlands had no especially high exceedance problems in 2003 compared to other Member States (such as Belgium, Austria, Greece, the Czech Republic, Lithuania, Slovenia and Slovakia). Since the Netherlands has not submitted official data yet for 2004, it is not possible to compare the air quality situation in the Netherlands with that in other Member States in 2004. Moreover, the Commission notes that very recently (March 2006) the Netherlands Environmental Assessment Agency NMP has published a re-evaluation of the PM₁₀ levels, indicating that the levels of PM₁₀ are 10-15 % lower than previously assumed. This decrease depends on the location in the Netherlands, and tends to be larger in rural areas than in cities. According to the NMP report, the number of areas

where the air quality limit values will be exceeded will be halved in 2010 in comparison with 2005 and in 2015 in comparison to 2010.

(42) Based on the annual reports for 2003 and taking into account the new information transmitted by the Dutch government and contained in the NMP report, it would seem that there is considerable doubt as to the existence of a specific problem in the Netherlands compared to other Member States in the compliance with the limit values laid down in the Air Quality Directive. In particular, the level of total emissions of particles (PM₁₀ and PM_{2.5}) per square kilometre in the Netherlands is only half of that in Belgium⁽¹¹⁾.

(43) More specifically, it is doubtful whether there is a specific problem with regard to Directive 98/69/EC. As stated in section 40 above, the Netherlands is characterised by considerably higher than average particulate matter emission derived from inland waterway shipping and maritime transport. Moreover, the share of diesel vehicles in the Netherlands is considerably lower (25 % of new sales) than the EU average (around 50 % of new sales). It is therefore questionable whether there is a specific problem with regard to particulate matter emission derived from motor vehicles covered by Directive 98/69/EC.

(44) The Commission therefore considers that the Netherlands has failed to show the existence of a specific problem with regard to Directive 98/69/EC.

3. Assessment of the conditions under Article 95(6) of the EC Treaty

(45) Article 95(6) of the EC Treaty obliges the Commission to verify that the notified national provisions are not a means of arbitrary discrimination or a disguised restriction on trade between Member States and that they do not constitute an obstacle to the functioning of the internal market.

(46) The last condition cannot be interpreted in such a way that it prohibits the approval of any national measure likely to affect the functioning of the internal market. In fact, any national measure derogating from a harmonisation measure aiming at the establishment and operation of the internal market constitutes in substance a measure that is likely to affect the internal market. Consequently, to preserve the usefulness of the procedure for derogation provided for by Article 95 of the EC Treaty, the Commission considers that, in the context of Article 95(6), the concept of obstacle to the functioning of the internal market has to be understood as a disproportionate effect in relation to the pursued objective.

⁽¹⁰⁾ See TNO report, p. 5.

⁽¹¹⁾ See TNO report, p. 31.

- (47) The Dutch authorities consider that the measure is necessary to improve the quality of the environment and thus protect human health. They also consider that the draft measure is neither a means of arbitrary discrimination nor a disguised restriction on trade between Member States. Furthermore, they believe that, in view of the risks which the emissions of soot particles entail both for the environment and human health, and considering the specific exposure situation in densely populated regions such as the Netherlands, the measure is proportionate to the aim pursued. Furthermore, according to the Dutch authorities, all models of vehicles with any significant share in diesel car sales are already available with particulate traps or will shortly be available. Thus the notified measure would not force car manufacturers to make (radical) modifications to their production process.
- (48) The French and Italian governments have submitted comments on the Dutch notification within the deadline. They have both stressed the negative impacts the notified measure would have on the internal market for vehicles, by distorting the market. They have pointed to the possibility for the Dutch authorities to encourage early uptake of cars meeting the particulate matter emission level of 5 mg/km by fiscal incentives, which would allow for an early implementation of the future European emission standards while, at the same time, not hindering the internal market for vehicles.
- (49) As mentioned above (see Section 46), in the context of Article 95(6) the concept of obstacle to the functioning of the internal market has to be understood as a disproportionate effect in relation to the pursued objective. The Commission will therefore focus its assessment of the conditions under Article 95(6) of the EC Treaty on the proportionality of the national provisions which have been notified. Making this assessment will imply a judgement on whether the notified measure exceeds the limits of what is appropriate and necessary to achieve the stated aim of environmental and health protection. The assessment will be made on the understanding that, where there are a number of appropriate measures that could be taken, the choice should fall to the least restricting of them.
- (50) As a preliminary remark, the Commission would like to point out that the necessity to further improve the performance of vehicles regarding the emissions of atmospheric pollutants is well recognised by the Commission. This is the reason why, as already mentioned, the Euro 5 proposal has recently been made. According to the proposal the emission limits for particulate matter from new diesel passenger cars and the smallest light-duty vehicles will be reduced by 80 %. In establishing the Euro 5 proposal, the Commission attempted to strike a balance between the need for further improvements in environmental performance and the need to provide car manufacturers with the necessary time to design vehicles and plan production activities. This consideration is reflected in particular in the provisions on the entry into force of the regulation. By bringing forward the application of the particulate matter emission limits set out in the Euro 5 proposal, the measure notified by the Dutch authorities would dramatically reduce the proposed lead time for implementation. This would have a significant impact on vehicle manufacturers, by obliging them to adapt their production to the requirements of the Dutch legislation or requiring them to restrict the models offered in the Dutch market. It should be noted in this regard that, at present, not all types of vehicles in the categories M₁ and N₁, class I, are available with a particulate filter. The Dutch authorities have informed the Commission that several types of diesel passenger cars with diesel particulate filter are already available or will soon be available in the Dutch market. However the Commission notes that, on the basis of the information available to the Commission (as of December 2005), there are at least 240 different types of passenger cars out of ca. 710 that are not available in the Dutch market with a particulate filter and that therefore would be excluded from that market if the notified measure were adopted. As for some models it is the bigger engines that are equipped with particulate filters, the Dutch measure could risk excluding the smaller, more fuel efficient engines of those models from the Dutch market which would run counter to the EU's established policy of limiting CO₂ emissions.
- (51) The Dutch authorities have informed the Commission that the envisaged measure is part of a package of measures (Budget Day Set of Measures) aimed at improving air quality in the Netherlands. This package of measures centres on traffic measures since the particles from exhaust gases are among the most harmful of all particulate matter. It includes, among other measures, subsidies for particulate filter on new and older diesel cars, incentives for clean local traffic, freight transport and shipping, incentives for clean fuels. Research has also begun into the cost effectiveness of a subsidy for scrapping older (diesel) cars. In addition, the package of measures includes other generic traffic measures and measures covering industry and agriculture. Local measures affecting the national infrastructure will also be taken, such as reductions in the maximum speed on certain roads. Finally, the package of measures also seeks to take action at local level, such as through the implementation of municipal air quality plans, additional money to encourage less polluting local transport in municipalities and provinces and a measure based on reimbursing a substantial proportion of the additional costs of low-pollution technologies such as particulate traps. Alongside that, there is support for municipalities limiting access to (inner) cities to low-polluting or silent vehicles.

- (52) The Dutch authorities have provided an overview of all the measures they intend to put in place with an assessment of the related costs and benefits. It has to be noted that some of the envisaged measures which form part of the Budget Day Set of Measures are qualified as 'hard measures', others as 'soft measures'. The 'hard measures' are concrete actions that have already been specified, their financing has been arranged and they fall under the competence of the Central Government. Soft measures will be decided later or by other institutions (such as the European Union), the instrument and financing is often not defined or the competences do not lie with the Central Government.
- (53) In order to assess whether the notified measure is proportionate to the stated objectives, the Commission considers that it should be evaluated whether alternative measures could be taken by the Dutch authorities that would generate the same benefits in terms of particulate matter reduction (in particular ultrafine particles), but at the same time would be less disruptive to the internal market. The first step of this analysis implies an evaluation of the possible benefits that could derive from the implementation of the notified measure.
- (54) According to the Dutch authorities, the implementation of an obligation to fit particulate traps as of 1 January 2007 on diesel vehicles in the categories M₁ and N₁, class I, would generate a particulate matter reduction of approximately 0.4 to 0.5 kilotonnes (kt) in 2010 which represents approximately 50 % of the reduction to be achieved by the overall Dutch package of traffic measures. These figures are based on the fact that at the moment of the notification the proportion of diesel vehicles with a particulate trap was 10 % of all cars and on the assumption that the Euro 5 regulation will be mandatory as of 1 July 2008 at the earliest for new types of vehicles and as of 1 January 2010 for new vehicles.
- (55) The Commission acknowledges that the Dutch authorities have implemented since 1 June 2005 a fiscal incentive scheme for fitting new diesel cars with particulate filters. The Commission notes that in the document 'Assessment of the Budget Day Set of Measures tackling air quality 2005' (Beoordeling van het prinsjesdagpakket — Aanpak Luchtkwaliteit 2005), the Dutch authorities assess the impact of this incentive scheme. They assume that, as a result of this measure and assuming that the Euro 5 standard will enter into force at the earliest on 1 July 2008 for new types of vehicles and on 1 January 2010 for new vehicles, in 2008 70-90 % of the new diesel cars sold in the Netherlands will have a particulate filter. The corresponding figures for the previous years are 40-60 % for 2006 and 60-80 % for 2007. The Commission therefore concludes that the additional benefits of the introduction of the notified provisions, in comparison with a baseline scenario where the incentive scheme for new diesel cars is in force, and taking into account the autonomous trend in Europe of equipping diesel vehicles with particulate filters, would be considerably lower than the estimated benefits of 0.4 to 0.5 kt reduction in particulate matter in 2010. The Commission estimates that the impact would possibly be in the range of 0.05 kt ⁽¹²⁾. It should also be noted that the impact of the existing fiscal incentives scheme could be further enhanced by combining this measure with other complementary measures, such as selective circulation bans in accordance with Community law in defined areas for diesel vehicles not complying with a certain particulate matter emission level. The experience of other Member States shows that often the announcement of such selective bans is sufficient to influence purchase decisions in favour of a diesel vehicle with a particulate filter or a non-diesel vehicle.
- (56) The Dutch authorities consider that no other national measure with a lower impact on trade would have the same result as the notified measure. However, the Commission notes that in the document 'Assessment of the Budget Day Set of Measures tackling air quality 2005' (Beoordeling van het prinsjesdagpakket — Aanpak Luchtkwaliteit 2005), the Dutch authorities clearly state that there would be alternative more cost-effective options to the measures considered under the Budget Day Set of Measures. In particular, they consider that the most cost-effective way to lower the concentrations on a Dutch scale, both regional and local, would be an additional pricing policy for the transport sector. The total benefits to society associated with this option would outweigh the costs. According to the estimations made by the Dutch authorities, varying the car taxes and the introduction of road pricing would reduce the emissions in 2010 by approximately as much as the measures proposed under the Budget Day Set of Measures. This means that such a policy could deliver reductions in particulate matter emissions 4 to 10 times higher than the notified measure ⁽¹²⁾.
- (57) The Dutch authorities note that short term benefits associated to road pricing varying according to time and place do not differ significantly from the benefits associated to the Budget Day measures. However, the Budget Day measures score less well as regards the effects on air quality in 2020. They conclude that while road pricing varying according to time and place costs the government more than the Budget Day measures, it would generate substantial welfare benefits (EUR 1-1.5 billion per year). Moreover, other social problems such as noise nuisance, poor traffic safety and congestion would also be reduced with the implementation of road pricing. Finally, they acknowledge that the measures proposed under the Budget Day measures constitute a 'second best' solution compared to the implementation of an additional pricing policy for the transport sector.

⁽¹²⁾ See TNO report, p. 38.

- (58) Based on the information provided by the Dutch authorities, the Commission notes that a road pricing policy for the transport sector appears to be more cost-effective than the notified measure and would deliver higher benefits in terms of reduction of ultrafine particulate matter emissions while, in principle, not creating obstacles to the functioning of the internal market. The effectiveness of this measure would be enhanced by its combination with the existing fiscal incentives scheme and could be further enhanced, as mentioned above, if other complementary measures, such as circulation bans for older more polluting vehicles, were implemented by local authorities. The Commission notes that this latter kind of measures has been effectively and extensively adopted by local authorities in other Member States facing air quality problems similar to those experienced by the Netherlands.
- (59) Moreover, in the Commission's view, the Dutch authorities could also consider strengthening some of the 'hard measures' included in the Budget Day measures. For example, retrofitting of diesel vehicles with particulate filter could lead to higher emission reductions than those estimated by the Dutch authorities, if the budget allocated to this measure was increased and if particulate filters were installed in particular in vehicles with a high urban mileage (e.g. taxis). The costs of retrofitting ships with diesel particulate filters are estimated by the Dutch authorities to be lower than other retrofitting measures (in a range of EUR 10 to EUR 60 per kg of particulate matter reduction⁽¹³⁾) and would be lower than the health costs associated with particulate matter concentrations, as calculated by the Dutch authorities (i.e. EUR 340 per kg in urban environment and EUR 80 per kg in rural environment). It should be noted in this regard that, according to the projections from the RAINS models, while the relative importance of particulate emissions from light-duty vehicles will decrease in the next years, the importance of the emissions from inland shipping and maritime transport is going to increase.
- (60) The Dutch authorities could also consider an earlier implementation of some of the 'soft measures' included in the Budget Day measures falling under the competence of the Dutch government. In this context, it is noted that the estimated particulate matter reduction potential of the total package of 'soft measures' of the Budget day proposal is higher than that of the 'hard measures'. In particular, according to the estimation from the Dutch authorities, the introduction of combined 'air washing systems' in intensive stock farming would yield a particulate matter reduction in 2010 of 4.4 kt. This reduction is considerably higher than the expected particulate matter reduction which would be generated by the implementation of the notified measure (0,05 kt, see section 55 above). This measure would probably have a bigger effect on less populated areas than in the cities. However, given the expected order of magnitude of reduction of the background concentration of particulate matter, and its favourable effect in terms of the protection of public health, it would probably be worth considering earlier implementation.
- (61) The Commission considers that the information provided by the Dutch authorities clearly indicate that less restrictive measures than the notified measure could be taken by the Dutch authorities to reach the stated objectives of environment and health protection. While the notified measure would constitute a breach of the EC type-approval system for vehicles, the alternative measures would not, in principle, imply a derogation to existing EC harmonisation measures. The reasons why such measures have not been finally proposed, even though contemplated by the Dutch authorities and despite the fact that they could yield at least the same amount of particulate matter reduction than the notified measure, do not clearly emerge from the documents submitted by the Netherlands. The Commission would like to stress in this respect that among the different options capable of reaching the pursued objective of health and environmental protection, Member States are obliged to choose those which are less disruptive to the internal market.
- (62) In conclusion, the Commission believes that there is evidence indicating that the envisaged national measure is not the least restrictive measure to achieve the stated aim of environmental and health protection and that, once adopted, it will constitute a disproportionate obstacle to the functioning of the internal market.
- (63) The Commission would like to set out some considerations about the international context of the envisaged measure. By Council 97/836/EC Decision of 27 November 1997 with a view to accession by the European Community to the Agreement of the United Nations Economic Commission for Europe concerning the adoption of uniform technical prescriptions for wheeled vehicles, equipment and parts which can be fitted to and/or be used on wheeled vehicles and the conditions for reciprocal recognition of approvals

4. International context

⁽¹³⁾ See TNO report, p. 41.

granted on the basis of these prescriptions ('Revised 1958 Agreement')⁽¹⁴⁾, the European Community acceded to UN/ECE Regulation 83⁽¹⁵⁾ adopted under the Agreement of the United Nations Economic Commission for Europe concerning the adoption of uniform technical prescriptions for wheeled vehicles, equipment and parts which can be fitted to and/or be used on wheeled vehicles and the conditions for reciprocal recognition of approvals granted on the basis of these prescriptions ('Revised 1958 Agreement'). This Regulation sets the same emission limit values and has the same scope of application as Directive 70/220/EC, as lastly amended by Directive 98/69/EC. According to Article 3 of the 1958 Agreement, 'Wheeled vehicles, equipment or parts for which type approvals have been issued by a Contracting Party in accordance with Article 2 of this Agreement and manufactured either in the territory of a Contracting Party applying the Regulation concerned, or in such other country as is designated by the Contracting Party which has duly approved the types of wheeled vehicles, equipment or parts concerned shall be held to be in conformity with the legislation of all the Contracting Parties applying the said Regulation through type-approval'.

- (64) The measure notified by the Dutch authorities does not contain any provision allowing the use of vehicles for which type-approvals have been issued in accordance with UN/ECE Regulation 83. Thus, the measure would prevent vehicles from other Contracting Parties that fulfil the requirements of Regulation 83 from entering the Dutch market. If adopted, the measure would therefore constitute an infringement of the 1958 Agreement. Following the case-law of the Court of Justice, Community law has to be interpreted, as far as possible, in conformity with the Community's international obligations. Thus, the Commission needs to ensure that the Community fulfils its obligations under the 1958 Agreement. This implies that the Netherlands has to comply with UN/ECE Regulation 83. Failure to do so could undermine the recognition of EU type-approvals by the other Contracting Parties and would thus have clearly disproportionate repercussions on the EC's vehicle exports to those countries.

IV. CONCLUSION

- (65) In light of the elements which it had available to assess the merits of the justifications put forward for the

national measures notified, and in light of the considerations set out above, the Commission considers that the request of the Kingdom of the Netherlands for introducing national provisions derogating from Directive 98/69/EC, submitted on 2 November 2005:

- is admissible,
- does not fulfil all the conditions set out in Article 95 of the EC Treaty. The Netherlands has failed to prove the existence of a specific problem with regard to Directive 98/69/EC. Even if it was admitted that the Netherlands has proved the existence of a specific problem with regard to Directive 98/69/EC the Commission considers that the notified measure is not proportionate to the objectives pursued.

- (66) The Commission therefore has grounds to consider that the national provisions notified cannot be approved in accordance with Article 95 (6) of the EC Treaty,

HAS ADOPTED THIS DECISION:

Article 1

The national provisions imposing a mandatory limit value for the emissions of particulate matter of 5 mg per kilometre on commercial vehicles with a maximum permissible weight of 1 305 kg (N₁ vehicles, class I) and passenger cars (M₁ vehicles) notified by the Kingdom of the Netherlands pursuant to Article 95(5) of the EC Treaty are rejected.

Article 2

This Decision is addressed to the Kingdom of the Netherlands.

Done at Brussels, 3 May 2006.

For the Commission

Günter VERHEUGEN

Vice-President

⁽¹⁴⁾ OJ L 346, 17.12.1997, p. 78.

⁽¹⁵⁾ UN/ECE Regulation 83 on 'Uniform provisions concerning the approval of vehicles with regard to the emission of pollutants according to engine fuel requirements'.

COMMISSION DECISION

of 11 May 2006

on the allocation of import quotas for controlled substances for the period 1 January to 31 December 2006 under Regulation (EC) No 2037/2000 of the European Parliament and of the Council

(notified under document number C(2006) 1819)

(Only the Dutch, English, French, German, Greek, Hungarian, Italian, Polish, Slovenian and Spanish texts are authentic)

(2006/373/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

(4) Article 4(4)(i) allows a derogation from Article 4(2) if methyl bromide is imported for destruction or if it is imported for feedstock use.

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 2037/2000 of the European Parliament and of the Council on 'Substances that Deplete the Ozone Layer' ⁽¹⁾, and in particular to Article 7 thereof,

(5) Article 4(3)(i)(e) sets out the total calculated level of hydrochlorofluorocarbons which producers and importers may place on the market or use for their own account in the period 1 January to 31 December 2006.

Whereas:

(6) The Commission has published a notice to importers in the Community of controlled substances that deplete the ozone layer ⁽²⁾ and has thereby received declarations on intended imports in 2006.

(1) The quantitative limits for the placing on the market in the Community of controlled substances are set out in Article 4 and Annex III of the Regulation.

(2) Article 4(2)(i)(d) prohibits each producer and importer placing any methyl bromide on the market or using any for their own account after 31 December 2004. Article 4(4)(i)(b) allows a derogation from this prohibition if methyl bromide is used to meet the licensed requests for critical uses of those users identified as described in Article 3(2)(ii). The quantity of methyl bromide licensed for critical uses for the period 1 January to 31 December 2006 will be published in a separate Commission decision.

(7) For hydrochlorofluorocarbons the allocation of quotas to producers and importers is in accordance with the provisions of Commission Decision 2005/103/EC of 5 February 2005 determining a mechanism for the allocation of quotas to producers and importers for hydrochlorofluorocarbons for the years 2003 to 2009 under Regulation (EC) No 2037/2000 ⁽³⁾.

(3) Article 4(2)(iii) allows a derogation from Article 4(2)(i)(d) if methyl bromide is imported or produced for quarantine and pre-shipment (QPS) applications. The amount of methyl bromide that can be imported or produced for these purposes in 2006 must not exceed the average of the calculated level of methyl bromide which a producer or importer placed on the market or used for its own account for QPS in the years 1996, 1997 and 1998.

(8) For the purpose of ensuring that operators and companies benefit from allocated import quotas in due time and thereby ensure the necessary continuity of their operations, it is appropriate that the present Decision shall apply from 1 January 2006.

(9) The measures provided for in this Decision are in accordance with the opinion of the Committee established by Article 18(2) of Regulation (EC) No 2037/2000,

⁽¹⁾ OJ L 244, 29.9.2000, p. 1. Regulation as last amended by Commission Regulation (EC) No 2077/2004 (OJ L 359, 4.12.2004, p. 28).

⁽²⁾ OJ C 168, 8.7.2005, p. 33.

⁽³⁾ OJ L 33, 5.2.2005, p. 65.

HAS ADOPTED THIS DECISION:

Article 1

1. The quantity of controlled substances of group I (chlorofluorocarbons 11, 12, 113, 114 and 115) and group II (other fully halogenated chlorofluorocarbons) subject to Regulation (EC) No 2037/2000 which may be released for free circulation in the Community in 2006 from sources outside the Community shall be 6 140 000 ozone depleting potential (ODP) kilograms.

2. The quantity of controlled substances of group III (halons) subject to Regulation (EC) No 2037/2000 that may be released for free circulation in the Community in 2006 from sources outside the Community shall be 9 211 000 ODP kilograms.

3. The quantity of controlled substances of group IV (carbon tetrachloride) subject to Regulation (EC) No 2037/2000 that may be released for free circulation in the Community in 2006 from sources outside the Community shall be 12 099 230 ODP kilograms.

4. The quantity of controlled substances of group V (1,1,1-trichloroethane) subject to Regulation (EC) No 2037/2000 that may be released for free circulation in the Community in 2006 from sources outside the Community shall be 400 060 ODP kilograms.

5. The quantity of controlled substances of group VI (methyl bromide) subject to Regulation (EC) No 2037/2000 which may be released for free circulation in the Community in 2006 from sources outside the Community for quarantine and pre-shipment uses shall be 502 606 ODP kilograms.

6. The quantity of controlled substances of group VI (methyl bromide) subject to Regulation (EC) No 2037/2000 for feedstock and destruction which may be released for free circulation in the Community in 2006 from sources outside the Community shall be 1 503 720 ODP kilograms.

7. The quantity of controlled substances of group VIII (hydrochlorofluorocarbons) subject to Regulation (EC) No 2037/2000 that may be released for free circulation in the Community in 2006 from sources outside the Community shall be 3 078 519,812 ODP kilograms.

8. The quantity of controlled substances of group IX (bromochloromethane) subject to Regulation (EC) No 2037/2000 that may be released for free circulation in the Community in 2006 from sources outside the Community shall be 162 612 ODP kilograms.

Article 2

1. The allocation of import quotas for chlorofluorocarbons 11, 12, 113, 114 and 115 and other fully halogenated chlorofluorocarbons during the period 1 January to 31 December 2006 shall be for the purposes indicated and to the companies indicated in Annex I hereto.

2. The allocation of import quotas for halons during the period 1 January to 31 December 2006 shall be for the purposes indicated and to the companies indicated in Annex II hereto.

3. The allocation of import quotas for carbon tetrachloride during the period 1 January to 31 December 2006 shall be for the purposes indicated and to the companies indicated in Annex III hereto.

4. The allocation of import quotas for 1,1,1-trichloroethane during the period 1 January to 31 December 2006 shall be for the purposes indicated and to the companies indicated in Annex IV hereto.

5. The allocation of import quotas for methyl bromide during the period 1 January to 31 December 2006 shall be for the purposes indicated and to the companies indicated in Annex V hereto.

6. The allocation of import quotas for hydrochlorofluorocarbons during the period 1 January to 31 December 2006 shall be for the purposes indicated and to the companies indicated in Annex VI hereto.

7. The allocation of import quotas for bromochloromethane during the period 1 January to 31 December 2006 shall be for the purposes indicated and to the companies indicated in Annex VII hereto.

8. The import quotas for chlorofluorocarbons 11, 12, 113, 114 and 115, other fully halogenated chlorofluorocarbons, halons, carbon tetrachloride, 1,1,1-trichloroethane, methyl bromide, hydrobromofluorocarbons, hydrochlorofluorocarbons and bromochloromethane during the period 1 January to 31 December 2006 shall be as set out in Annex VIII hereto.

Article 3

This Decision shall apply from 1 January 2006 and shall expire on 31 December 2006.

Article 4

This Decision is addressed to the following undertakings:

Agropest S.A. 91-765 Łódź, PL-Górnica 12/14	Albemarle Chemicals Étang de la Gaffette Boulevard Maritime, BP 28 F-13521 Port-de-Bouc
Albemarle Chemicals Parc Scientifique Einstein Rue du Bosquet 9 B-1348 Louvain-la-Neuve	Alcobre S.A. C/Luis I, Nave 6-B Polígono Industrial Vallecás E-28031 Madrid
Άλφα Γεωργικά Εφόδια ΑΕ Οδός Εθνικής Αντιστάσεως 73, GR-152 31 Χαλάνδρι, Αθήνα	Arkema S.A. Cours Michelet — La Défense 10 F-92091 Paris La Défense
Asahi Glass Europe B.V. World Trade Center Strawinskylaan 1525 NL-1077 XX Amsterdam Nederland	Avantec S.A. Bld Henri Cahn, BP 27 F-94363 Bry-sur-Marne Cedex
BaySystems Iberia C/ Pau Clarís 196 E-08037 Barcelona	Bromotirrena Via Torino, 4 I-04022 Fondi (LT)
Calorie S.A. 503 Rue Hélène Boucher Z.I. Buc — BP 33 F-78534 Buc Cedex	Caraïbes Froid SARL BP 6033 Ste Thérèse, Route du Lamentin F-97219 Fort-de-France, Martinique
Cleanaway Ltd Airborne Close, Leigh-on-Sea Essex SS9 4EL United Kingdom	Dow Deutschland Buetzflethersand D-21683 Stade
DuPont de Nemours (Nederland) B.V. Baanhoekweg 22 3313 LA Dordrecht Nederland	Dyneon GmbH D-84504 Burgkirchen
Empor d.o.o. Leskoškova 9a SI-1000 Ljubljana, Slovenia	Etis d.o.o. Trzaska 333 SI-1000 Ljubljana, Slovenia
Eurobrom B. V. Postbus 158 2280 AD Rijswijk Nederland	Fenner-Dunlop b.v. Oliemolenstraat 2 Drachten Nederland
Fujifilm Electronic Materials Europe Keetberglaan 1A Haven 1061 B-2070 Zwijndrecht	G.A.L Cycle-Air Ltd Οδός Σινώπης 3, Στρόβολος PO Box 28385, Λευκωσία Κύπρος
Galco S.A. Avenue Carton de Wiart 79 B-1090 Brussels	Galex S.A. BP 128 F-13321 Marseille Cedex 16
Great Lakes Chemical (Europe) Ltd Halebank, Widnes Cheshire WA8 8NS United Kingdom	Harp International Ltd Gellihiirion Industrial Estate Rhondda Cynon Taff Pontypridd CF37 5SX United Kingdom

Honeywell Fluorine Products Europe B.V. Kempenweg 90 Postbus 264 6000 AG Weert Nederland	Ineos Fluor Ltd PO Box 13, The Heath Runcorn, Cheshire WA7 4QF United Kingdom
Laboratorios Miret SA (LAMIRSA) Geminis 4, Pol. Ind. Can Parellada E-08228 Les Fonts de Terrassa, Barcelona	Matero PO Box 51744 3508 Λεμεσός Κύπρος
Mebrom NV Assenedestraat 4 B-9940 Rieme Ertvelde	Βιομηχανία Φωσφορικών Λιπασμάτων Α.Ε. Εργοστάσιο Θεσσαλονίκης, Ταχ. Θυρίδα 10183 GR-54110 Θεσσαλονίκη
Poz Pliszka (PL) 45, Szczecińska St., PL-80-392 Gdańsk, Poland	P.U.P.H. SOLFUM Sp. z o.o ul. Wojska Polskiego 83 PL-91-755 Łódź
Refrigerant Products Ltd N9 Central Park Estate Westinghouse Road Trafford Park Manchester M17 1PG United Kingdom	Rhodia Organique Fine Ltd PO Box 46 St Andrews Road, Avonmouth Bristol BS11 9YF United Kingdom
Sigma Aldrich Logistik GmbH Kappelweg 1 D-91625 Schnellendorf	Sigma Aldrich Chimie SARL 80, rue de Luzais L'isle d'Abeau Chesnes, F-38297 St Quentin Fallavier
Sigma Aldrich Company Ltd The Old Brickyard New Road Gillingham SP8 4XT United Kingdom	SJB Chemical Products B.V. Wellerondom 11 3230 AG Brielle Nederland
Solquimia Iberia, S.L. C/Duque de Alba Nº 3, 1º, E-28012 Madrid	Solvay Organics GmbH Hans-Böckler-Allee 20 D-30173 Hannover
Solvay Solexis SpA Viale Lombardia 20 I-20021 Bollate (MI)	Syngenta Crop Protection Surrey Research Park 30 Priestly Road, Guildford Surrey GU2 7YH United Kingdom
Synthesia Española s.a Conde Borrell, 62 E-08015 Barcelona	Tazzetti Fluids S.r.l. Ms Micaela Brero Corso Europa n. 600/a Volpiano (TO)
Unitor ASA Willembarendzstraat, 50 3165 AB Rotterdam/ Albrandswaard Nederland	Wigmors ul. Irysowa 5 51-117 Wrocław Poland
Zephyr Kereskedelmi és Szolgáltató Kft. 6000 Kecskemét Tatár sor 18. Hungary	

Done at Brussels, 11 May 2006.

For the Commission
Stavros DIMAS
Member of the Commission

ANNEX I

GROUPS I and II

Import quotas for chlorofluorocarbons 11, 12, 113, 114 and 115 and other fully halogenated chlorofluorocarbons allocated to importers in accordance with Regulation (EC) No 2037/2000 for feedstock uses and for destruction during the period 1 January to 31 December 2006.

Company

Cleanaway Ltd (UK)
Honeywell Fluorine Products Europe (NL)
Solvay Organics GmbH (DE)
Solvay Solexis SpA (IT)
Syngenta Crop Protection (UK)
Tazzetti Fluids S.r.l. (IT)
Unitor ASA (NL)

ANNEX II

GROUP III

Import quotas for halons allocated to importers in accordance with Regulation (EC) No 2037/2000 for critical uses and for destruction during the period 1 January to 31 December 2006.

Company

Cleanaway Ltd (UK)
Poz Pliszka (PL)
Unitor SAS (NL)

ANNEX III

GROUP IV

Import quotas for carbon tetrachloride allocated to importers in accordance with Regulation (EC) No 2037/2000 for feedstock uses and for destruction for the period 1 January to 31 December 2006.

Company

Dow Deutschland (DE)

Fenner-Dunlop b.v. (NL)

Phosphoric Fertilisers Industry (EL)

ANNEX IV

GROUP V

Import quotas for 1,1,1-trichloroethane allocated to importers in accordance with Regulation (EC) No 2037/2000 for feedstock uses and for destruction for the period 1 January to 31 December 2006.

Company

Fujifilm Electronic Materials Europe (BE)

Arkema SA (FR)

ANNEX V

GROUP VI

Import quotas for methyl bromide allocated to importers in accordance with Regulation (EC) No 2037/2000 for quarantine and pre-shipment applications, for feedstock uses and for destruction for the period 1 January to 31 December 2006.

Company

Agropest (PL)
Albemarle Chemicals (FR)
Albemarle Europe (BE)
Alfa Agricultural Supplies (EL)
Bromotirrena (IT)
Cleanaway Ltd (UK)
Eurobrom B.V. (NL)
Great Lakes Chemicals (UK)
Mebrom N.V. (BE)
PUPH Solfum (PL)
Sigma Aldrich Logistik (DE)
Zephyr Kereskedelmi (HU)

ANNEX VI

GROUP VIII

Import quotas for hydrochlorofluorocarbons allocated to producers and importers in accordance with Regulation (EC) No 2037/2000 and in accordance with the provisions of Commission Decision 2005/103/EC for feedstock uses, process agents, for reclamation, for destruction and other applications allowed under Article 5 of Regulation (EC) No 2037/2000 for the period 1 January to 31 December 2006.

Producer

Arkema SA (FR)
DuPont de Nemours (NL)
Honeywell Fluorine Products (NL)
Ineos Fluor Ltd (UK)
Rhodia Organique (UK)
Solvay Organics GmbH (DE)
Solvay Solexis SpA (IT)

Importer

Alcobre (ES)	HARP International (UK)
Asahi Glass (NL)	Matero (CY)
Avantec S.A. (FR)	Mebrom (BE)
BaySystems Iberia (ES)	Refrigerant Products (UK)
Calorie S.A. (FR)	Sigma Aldrich Chimie (FR)
Caraïbes Froid SARL (FR)	Sigma Aldrich Company (UK)
Dyneon (DE)	SJB Chemical Products (NL)
Etis d.o.o. (SI)	Solquimia Iberia, SL (ES)
Empor d.o.o. (SI)	Synthesia Espanola (ES)
Galco S.A. (BE)	Unitor ASA (NL)
Galex S.A. (FR)	Tazzetti Fluids S.r.l (IT)
G.AL. Cycle Air Ltd (CY)	Wigmors (PL)

ANNEX VII

GROUP IX

Import quotas for bromochloromethane allocated to importers in accordance with Regulation (EC) No 2037/2000 for feedstock uses during the period 1 January to 31 December 2006.

Company
Albemarle Europe (BE)
Eurobrom B.V. (NL)
Laboratorios Miret S.A. (LAMIRSA) (ES)
Sigma Aldrich Logistik (DE)

ANNEX VIII

(This Annex is not published because it contains confidential commercial information).

COMMISSION DECISION**of 22 May 2006****amending Decision 2004/370/EC authorising methods for grading pig carcasses in the United Kingdom***(notified under document number C(2006) 1988)***(Only the English text is authentic)***(2006/374/EC)*

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 3220/84 of 13 November 1984 determining the Community scale for grading pig carcasses ⁽¹⁾, and in particular Article 5(2) thereof,

Whereas:

- (1) Article 2(1) and (2) of Commission Regulation (EEC) No 2967/85 of 24 October 1985 laying down detailed rules for the application of the Community scale for grading pig carcasses ⁽²⁾ provides for a method for calculating the weight of the cold carcase from the warm weight.
- (2) In accordance with Article 2(3) of Regulation (EEC) No 2967/85 and by way of derogation from Article 2(1) and (2) thereof, the United Kingdom was authorised by Commission Decision 2004/370/EC ⁽³⁾ to calculate the weight of the cold carcase by reference to pre-determined scales of absolute weight reductions.
- (3) Due to technical adaptations, the United Kingdom has requested the Commission to withdraw this derogation and to apply the method for calculating the weight of the cold carcase as referred to in Article 2(1) and (2) of Regulation (EEC) No 2967/85.

(4) Decision 2004/370/EC should therefore be amended accordingly.

(5) The measures provided for in this Decision are in accordance with the opinion of the Management Committee for Pigmeat,

HAS ADOPTED THIS DECISION:

Article 1

Decision 2004/370/EC is amended as follows:

1. Article 5 is deleted.
2. Annex III is deleted.

Article 2

This Decision is addressed to the United Kingdom of Great Britain and Northern Ireland.

Done at Brussels, 22 May 2006.

For the Commission

Mariann FISCHER BOEL

Member of the Commission

⁽¹⁾ OJ L 301, 20.11.1984, p. 1. Regulation last amended by Regulation (EC) No 3513/93 (OJ L 320, 22.12.1993, p. 5).

⁽²⁾ OJ L 285, 25.10.1985, p. 39. Regulation amended by Regulation (EC) No 3127/94 (OJ L 330, 21.12.1994, p. 43).

⁽³⁾ OJ L 116, 22.4.2004, p. 32. Decision amended by Decision 2006/99/EC (OJ L 46, 16.2.2006, p. 34).

COMMISSION DECISION

of 23 May 2006

derogation from certain provisions of Directive 2003/54/EC concerning the archipelago of Madeira

(notified under document number C(2006) 2008)

(Only the Portuguese text is authentic)

(2006/375/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 2003/54/EC of the European Parliament and of the Council of 26 June 2003 concerning common rules for the internal market in electricity and repealing Directive 96/92/EC ⁽¹⁾, and in particular Article 26(1) thereof,

Whereas:

- (1) Article 26(1) of Directive 2003/54/EC provides that Member States which can demonstrate, after the Directive has been brought into force, that there are substantial problems for the operation of their small isolated systems, may apply for derogations from the relevant provisions of Chapters IV, V, VI, VII, as well as Chapter III, in the case of micro isolated systems, as far as refurbishing, upgrading and expansion of existing capacity are concerned, which may be granted to them by the Commission.
- (2) Portugal submitted to the Commission on 18 August 2005 an application for derogation for an indefinite period of time from the provisions of Chapters III, IV, V, VI, VII under Article 26(1) of Directive 2003/54/EC concerning the archipelago of Madeira.
- (3) The archipelago of Madeira qualifies as a 'micro isolated system' as defined in Article 2(27) of Directive 2003/54/EC.
- (4) The archipelago of Madeira's peculiar characteristics of remoteness, insularity, small size, difficult topography and climate, have been acknowledged in Article 299(2) of the EC Treaty.

- (5) The documents annexed to the Portuguese application give sufficient evidence that the objective of a competitive market in electricity is impossible or impractical to achieve given the very small level of production and the fact that the islands are also isolated from one another. In such a very small system, it is often not possible to have more than one generating facility per island, which makes the presence of competing generators very impractical. The size of the market will hardly stimulate the application for authorisations or bids for tenders; in addition the level of consumption fluctuates widely: the infrastructures need to be sized according to the maximum demand, which is much higher than the average one. In other words in such peculiar electric systems, security and quality of supply issues have absolute priority. Finally, there is no high voltage transmission system, and without competition in production the Directive's requirements regarding the unbundling of distribution systems lose their justification. The same considerations are valid concerning third party access to the system.

- (6) The Commission, having examined the justification of Portugal's request, is satisfied that the derogation and the conditions for its application will not prejudice the achievement of the objectives of the Directive.
- (7) However, possible technological developments in the medium and long term that may bring about substantial changes need to be taken into account.
- (8) The Commission has consulted all Member States as prescribed in Article 26(1) of Directive 2003/54/EC,

HAS ADOPTED THIS DECISION:

Article 1

A derogation from the relevant provisions of Chapters IV, V, VI, VII, as well as Chapter III, as far as refurbishing, upgrading and expansion of existing capacity are concerned, is granted to the Republic of Portugal for the isles of the archipelago of Madeira.

⁽¹⁾ OJ L 176, 15.7.2003, p. 37.

Article 2

The Portuguese national authorities shall monitor the evolution of the electricity sector of Madeira and report to the Commission any substantial change therein that may require the review of the granted derogation. A first report shall be submitted four years after the date of this decision and a second one nine years after that date.

Article 3

This derogation is valid for an indefinite period of time. It can be reviewed by the Commission if substantial changes occur in the electricity sector of Madeira.

Article 4

This Decision is addressed to the Republic of Portugal.

Done at Brussels, 23 May 2006.

For the Commission

Andris PIEBALGS

Member of the Commission
