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Legislation

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Contents

[1] Text with EEA relevance

(Continued overleaf)

EN

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

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

II *Acts adopted under the EC Treaty/Euratom Treaty whose publication is not obligatory*

EN

[1] Text with EEA relevance

I

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

REGULATIONS

COMMISSION REGULATION (EC) No 836/2009

of 14 September 2009

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

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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

Having regard to Commission Regulation (EC) No 1580/2007 of 21 December 2007 laying down implementing rules for Council Regulations (EC) No 2200/96, (EC) No 2201/96 and (EC) No 1182/2007 in the fruit and vegetable sector [2], and in particular Article 138(1) thereof,

Whereas:

Regulation (EC) No 1580/2007 lays down, pursuant to the outcome of the Uruguay Round multilateral trade negotiations, the criteria whereby the Commission fixes the standard values for imports from third countries, in respect of the products and periods stipulated in Annex XV, Part A thereto,

HAS ADOPTED THIS REGULATION:

Article 1

The standard import values referred to in Article 138 of Regulation (EC) No 1580/2007 are fixed in the Annex hereto.

Article 2

This Regulation shall enter into force on 15 September 2009.

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

Done at Brussels, 14 September 2009.

For the Commission
Jean-Luc DEMARTY
Director-General for Agriculture and Rural Development

[1] OJ L 299, 16.11.2007, p. 1.
[2] OJ L 350, 31.12.2007, p. 1.

ANNEX

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

(EUR/100 kg)

CN code	Third country code (1)	Standard import value
0702 00 00	MK	34,5
	ZZ	34,5
0707 00 05	MK	19,1
	TR	111,0
	ZZ	65,1
0709 90 70	TR	101,8
	ZZ	101,8
0805 50 10	AR	102,8
	CL	137,4
	UY	117,8
	ZA	95,3
	ZZ	113,3
0806 10 10	EG	137,1
	IL	227,0
	TR	98,6
	ZZ	154,2
0808 10 80	AR	123,6
	BR	68,1
	CL	76,3
	NZ	82,6
	US	85,9
	ZA	77,4
	ZZ	85,7
0808 20 50	AR	160,8
	CN	61,6
	TR	116,9
	ZA	69,7
	ZZ	102,3
0809 30	TR	114,2
	US	228,1
	ZZ	171,2
0809 40 05	IL	126,2
	TR	113,9
	ZZ	120,1

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

DIRECTIVES

COMMISSION DIRECTIVE 2009/120/EC

of 14 September 2009

amending Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use as regards advanced therapy medicinal products

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [1], and in particular Article 120 thereof,

Whereas:

(1) Medicinal products for human use may only be placed on the market if a marketing authorisation has been delivered by a competent authority on the basis of an application dossier containing the results of tests and trials carried out on the products concerned.

(2) Annex I to Directive 2001/83/EC lays down detailed scientific and technical requirements regarding the testing of medicinal products for human use against which the quality, safety and efficacy of the medicinal product should be assessed. Those detailed scientific and technical requirements should be regularly adapted to take account of scientific and technical progress.

(3) Due to scientific and technical progress in the field of advanced therapies, as reflected in Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 [2], it is appropriate to adapt Annex I. The definitions and detailed scientific and technical requirements for gene therapy medicinal products and somatic cell therapy medicinal products should be updated. Moreover, detailed scientific and technical requirements should be established for tissue engineered products, as well as for advanced therapy medicinal product containing devices and combined advanced therapy medicinal products.

(4) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee for Medicinal Products for Human Use,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Part IV of Annex I to Directive 2001/83/EC is 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 5 April 2010 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, 14 September 2009.

For the Commission
Günter VERHEUGEN
Vice-President

[1] OJ L 311, 28.11.2001, p. 67.
[2] OJ L 324, 10.12.2007, p. 121.

ANNEX

'PART IV

ADVANCED THERAPY MEDICINAL PRODUCTS

1. INTRODUCTION

Marketing authorisation applications for advanced therapy medicinal products, as defined in point (a) of Article 2(1) of Regulation (EC) No 1394/2007, shall follow the format requirements (Modules 1, 2, 3, 4 and 5) described in Part I of this Annex.

The technical requirements for Modules 3, 4 and 5 for biological medicinal products, as described in Part I of this Annex, shall apply. The specific requirements for advanced therapy medicinal products described in sections 3, 4 and 5 of this part explain how the requirements in Part I apply to advanced therapy medicinal products. In addition, where appropriate and taking into account the specificities of advanced therapy medicinal products, additional requirements have been set.

Due to the specific nature of advanced therapy medicinal products, a risk-based approach may be applied to determine the extent of quality, non-clinical and clinical data to be included in the marketing authorisation application, in accordance with the scientific guidelines relating to the quality, safety and efficacy of medicinal products referred to in point 4 of the "Introduction and general principles".

The risk analysis may cover the entire development. Risk factors that may be considered include: the origin of the cells (autologous, allogeneic, xenogeneic), the ability to proliferate and/or differentiate and to initiate an immune response, the level of cell manipulation, the combination of cells with bioactive molecules or structural materials, the nature of the gene therapy medicinal products, the extent of replication competence of viruses or micro-organisms used *in vivo*, the level of integration of nucleic acids sequences or genes into the genome, the long time functionality, the risk of oncogenicity and the mode of administration or use.

Relevant available non-clinical and clinical data or experience with other, related advanced therapy medicinal products may also be considered in the risk analysis.

Any deviation from the requirements of this Annex shall be scientifically justified in Module 2 of the application dossier. The risk analysis described above, when applied, shall also be included and described in Module 2. In this case, the methodology followed, the nature of the identified risks and the implications of the risk based approach for the development and evaluation program shall be discussed and any deviations from the requirements of this Annex resulting from the risk analysis shall be described.

2. DEFINITIONS

For the purposes of this Annex, in addition to the definitions laid down in Regulation (EC) No 1394/2007, the definitions set out in sections 2.1 and 2.2 shall apply.

2.1. **Gene therapy medicinal product**

Gene therapy medicinal product means a biological medicinal product which has the following characteristics:

(a) it contains an active substance which contains or consists of a recombinant nucleic acid used in or administered to human beings with a view to regulating, repairing, replacing, adding or deleting a genetic sequence;

(b) its therapeutic, prophylactic or diagnostic effect relates directly to the recombinant nucleic acid sequence it contains, or to the product of genetic expression of this sequence.

Gene therapy medicinal products shall not include vaccines against infectious diseases.

2.2. **Somatic cell therapy medicinal product**

Somatic cell therapy medicinal product means a biological medicinal product which has the following characteristics:

(a) contains or consists of cells or tissues that have been subject to substantial manipulation so that biological characteristics, physiological functions or structural properties relevant for the intended clinical use have been altered, or of cells or tissues that are not intended to be used for the same essential function(s) in the recipient and the donor;

(b) is presented as having properties for, or is used in or administered to human beings with a view to treating, preventing or diagnosing a disease through the pharmacological, immunological or metabolic action of its cells or tissues.

For the purposes of point (a), the manipulations listed in Annex I to Regulation (EC) No 1394/2007, in particular, shall not be considered as substantial manipulations.

3. SPECIFIC REQUIREMENTS REGARDING MODULE 3

3.1. **Specific requirements for all advanced therapy medicinal products**

A description of the traceability system that the marketing authorisation holder intends to establish and maintain to ensure that the individual product and its starting and raw materials, including all substances coming into contact with the cells or tissues it may contain, can be traced through the sourcing, manufacturing, packaging, storage, transport and delivery to the hospital, institution or private practice where the product is used, shall be provided.

The traceability system shall be complementary to, and compatible with, the requirements established in Directive 2004/23/EC of the European Parliament and of the Council (*), as regards human cells and tissues other than blood cells, and Directive 2002/98/EC, as regards human blood cells.

3.2. **Specific requirements for gene therapy medicinal products**

3.2.1. *Introduction: finished product, active substance and starting materials*

3.2.1.1. Gene therapy medicinal product containing recombinant nucleic acid sequence(s) or genetically modified micro-organism(s) or virus(es)

The finished medicinal product shall consist of nucleic acid sequence(s) or genetically modified microorganism(s) or virus(es) formulated in their final immediate container for the intended medical use. The finished medicinal product may be combined with a medical device or active implantable medical device.

The active substance shall consist of nucleic acid sequence(s) or genetically modified microorganism(s) or virus(es).

3.2.1.2. Gene therapy medicinal product containing genetically modified cells

The finished medicinal product shall consist of genetically modified cells formulated in the final immediate container for the intended medical use. The finished medicinal product may be combined with a medical device or active implantable medical device.

The active substance shall consist of cells genetically modified by one of the products described in section 3.2.1.1 above.

3.2.1.3. In the case of products consisting of viruses or viral vectors, the starting materials shall be the components from which the viral vector is obtained, i.e. the master virus vector seed or the plasmids used to transfect the packaging cells and the master cell bank of the packaging cell line.

3.2.1.4. In the case of products consisting of plasmids, non-viral vectors and genetically modified microorganism(s) other than viruses or viral vectors, the starting materials shall be the components used to generate the producing cell, i.e. the plasmid, the host bacteria and the master cell bank of recombinant microbial cells.

3.2.1.5. In the case of genetically modified cells, the starting materials shall be the components used to obtain the genetically modified cells, i.e. the starting materials to produce the vector, the vector and the human or animal cells. The principles of good manufacturing practice shall apply from the bank system used to produce the vector onwards.

3.2.2. *Specific requirements*

In addition to the requirements set out in sections 3.2.1 and 3.2.2 of Part I of this Annex, the following requirements shall apply:

(a) information shall be provided on all the starting materials used for the manufacture of the active substance, including the products necessary for the genetic modification of human or animal cells and, as applicable, subsequent culture and preservation of the genetically modified cells, taking into consideration the possible absence of purification steps;

(b) for products containing a microorganism or a virus, data on the genetic modification, sequence analysis, attenuation of virulence, tropism for specific tissues and cell types, cell cycle dependence of the micro-organism or virus, pathogenicity and characteristics of the parental strain shall be provided;

(c) process-related impurities and product-related impurities shall be described in the relevant sections of the dossier, and in particular replication competent virus contaminants if the vector is designed to be replication incompetent;

(d) for plasmids, quantification of the different plasmid forms shall be undertaken throughout the shelf life of the product;

(e) for genetically modified cells, the characteristics of the cells before and after the genetic modification, as well as before and after any subsequent freezing/storage procedures, shall be tested.

For genetically modified cells, in addition to the specific requirements for gene therapy medicinal products, the quality requirements for somatic cell therapy medicinal products and tissue engineered products (see section 3.3) shall apply.

3.3. **Specific requirements for somatic cell therapy medicinal products and tissue engineered products**

3.3.1. *Introduction: finished product, active substance and starting materials*

The finished medicinal product shall consist of the active substance formulated in its immediate container for the intended medical use, and in its final combination for combined advanced therapy medicinal products.

The active substance shall be composed of the engineered cells and/or tissues.

Additional substances (e.g. scaffolds, matrices, devices, biomaterials, biomolecules and/or other components) which are combined with manipulated cells of which they form an integral part shall be considered as starting materials, even if not of biological origin.

Materials used during the manufacture of the active substance (e.g. culture media, growth factors) and that are not intended to form part of the active substance shall be considered as raw materials.

3.3.2. *Specific requirements*

In addition to the requirements set out in sections 3.2.1 and 3.2.2 of Part I of this Annex, the following requirements shall apply:

3.3.2.1. Starting materials

(a) Summary information shall be provided on donation, procurement and testing of the human tissue and cells used as starting materials and made in accordance with Directive 2004/23/EC. If non-healthy cells or tissues (e.g. cancer tissue) are used as starting materials, their use shall be justified.

(b) If allogeneic cell populations are being pooled, the pooling strategies and measures to ensure traceability shall be described.

(c) The potential variability introduced through the human or animal tissues and cells shall be addressed as part of the validation of the manufacturing process, characterisation of the active substance and the finished product, development of assays, setting of specifications and stability.

(d) For xenogeneic cell-based products, information on the source of animals (such as geographical origin, animal husbandry, age), specific acceptance criteria, measures to prevent and monitor infections in the source/donor animals, testing of the animals for infectious agents, including vertically transmitted micro-organisms and viruses, and evidence of the suitability of the animal facilities shall be provided.

(e) For cell-based products derived from genetically modified animals, the specific characteristics of the cells related to the genetic modification shall be described. A detailed description of the method of creation and the characterisation of the transgenic animal shall be provided.

(f) For the genetic modification of the cells, the technical requirements specified in section 3.2 shall apply.

(g) The testing regimen of any additional substance (scaffolds, matrices, devices, biomaterials, biomolecules or other components), which are combined with engineered cells of which they form an integral part, shall be described and justified.

(h) For scaffolds, matrices and devices that fall under the definition of a medical device or active implantable medical device, the information required under section 3.4 for the evaluation of the combined advanced therapy medicinal product shall be provided.

3.3.2.2. Manufacturing process

(a) The manufacturing process shall be validated to ensure batch and process consistency, functional integrity of the cells throughout manufacturing and transport up to the moment of application or administration, and proper differentiation state.

(b) If cells are grown directly inside or on a matrix, scaffold or device, information shall be provided on the validation of the cell culture process with respect to cell-growth, function and integrity of the combination.

3.3.2.3. Characterisation and control strategy

(a) Relevant information shall be provided on the characterisation of the cell population or cell mixture in terms of identity, purity (e.g. adventitious microbial agents and cellular contaminants), viability, potency, karyology, tumourigenicity and suitability for the intended medicinal use. The genetic stability of the cells shall be demonstrated.

(b) Qualitative and, where possible, quantitative information on product- and process-related impurities, as well as on any material capable of introducing degradation products during production, shall be provided. The extent of the determination of impurities shall be justified.

(c) If certain release tests cannot be performed on the active substance or finished product, but only on key intermediates and/or as in-process testing, this shall be justified.

(d) Where biologically active molecules (such as growth factors, cytokines) are present as components of the cell-based product, their impact and interaction with other components of the active substance shall be characterised.

(e) Where a three-dimensional structure is part of the intended function, the differentiation state, structural and functional organisation of the cells and, where applicable, the extracellular matrix generated shall be part of the characterisation for these cell-based products. Where needed, non-clinical investigations shall complement the physicochemical characterisation.

3.3.2.4. Excipients

For excipient(s) used in cell or tissue-based medicinal products (e.g. the components of the transport medium), the requirements for novel excipients, as laid down in Part I of this Annex, shall apply, unless data exists on the interactions between the cells or tissues and the excipients.

3.3.2.5. Developmental studies

The description of the development program shall address the choice of materials and processes. In particular, the integrity of the cell population as in the final formulation shall be discussed.

3.3.2.6. Reference materials

A reference standard, relevant and specific for the active substance and/or the finished product, shall be documented and characterised.

3.4. **Specific requirements for advanced therapy medicinal products containing devices**

3.4.1. *Advanced therapy medicinal product containing devices as referred to in Article 7 of Regulation (EC) No 1394/2007*

A description of the physical characteristics and performance of the product and a description of the product design methods shall be provided.

The interaction and compatibility between genes, cells and/or tissues and the structural components shall be described.

3.4.2. *Combined advanced therapy medicinal products as defined in Article 2(1)(d) of Regulation (EC) No 1394/2007*

For the cellular or tissue part of the combined advanced therapy medicinal product, the specific requirements for somatic cell therapy medicinal products and tissue engineered products set out in section 3.3 shall apply and, in the case of genetically modified cells, the specific requirements for gene therapy medicinal products set out in section 3.2 shall apply.

The medical device or the active implantable medical device may be an integral part of the active substance. Where the medical device or active implantable medical device is combined with the cells at the time of the manufacture or application or administration of the finished products, they shall be considered as an integral part of the finished product.

Information related to the medical device or the active implantable medical device (which is an integral part of the active substance or of the finished product) which is relevant for the evaluation of the combined advanced therapy medicinal product shall be provided. This information shall include:

(a) information on the choice and intended function of the medical device or implantable medical device and demonstration of compatibility of the device with other components of the product;

(b) evidence of conformity of the medical device part with the essential requirements laid down in Annex I to Council Directive 93/42/EEC (**), or of conformity of the active implantable device part with the essential requirements laid down in Annex 1 to Council Directive 90/385/EEC (***);

(c) where applicable, evidence of compliance of the medical device or implantable medical device with the BSE/TSE requirements laid down in Commission Directive 2003/32/EC (****);

(d) where available, the results of any assessment of the medical device part or the active implantable medical device part by a notified body in accordance with Directive 93/42/EEC or Directive 90/385/EEC.

The notified body which has carried out the assessment referred to in point (d) of this section shall make available on request of the competent authority assessing the application, any information related to the results of the assessment in accordance with Directive 93/42/EEC or Directive 90/385/EEC. This may include information and documents contained in the conformity assessment application concerned, where necessary for the evaluation of the combined advanced therapy medicinal product as a whole.

4. SPECIFIC REQUIREMENTS REGARDING MODULE 4

4.1. **Specific requirements for all advanced therapy medicinal products**

The requirements of Part I, Module 4 of this Annex on the pharmacological and toxicological testing of medicinal products may not always be appropriate due to unique and diverse structural and biological properties of advanced therapy medicinal products. The technical requirements in sections 4.1, 4.2 and 4.3 below explain how the requirements in Part I of this Annex apply to advanced therapy medicinal products. Where appropriate and taking into account the specificities of advanced therapy medicinal products, additional requirements have been set.

The rationale for the non-clinical development and the criteria used to choose the relevant species and models (*in vitro* and *in vivo*) shall be discussed and justified in the non-clinical overview. The chosen animal model(s) may include immuno-compromised, knockout, humanised or transgenic animals. The use of homologous models (e.g. mouse cells analysed in mice) or disease mimicking models shall be considered, especially for immunogenicity and immunotoxicity studies.

In addition to the requirements of Part I, the safety, suitability and biocompatibility of all structural components (such as matrices, scaffolds and devices) and any additional substances (such as cellular products, biomolecules, biomaterials, and chemical substances), which are present in the finished product, shall be provided. Their physical, mechanical, chemical and biological properties shall be taken into account.

4.2. **Specific requirements for gene therapy medicinal products**

In order to determine the extent and type of non-clinical studies necessary to determine the appropriate level of non-clinical safety data, the design and type of the gene therapy medicinal product shall be taken into account.

4.2.1. *Pharmacology*

(a) *In vitro* and *in vivo* studies of actions relating to the proposed therapeutic use (i.e. pharmacodynamic "proof of concept" studies) shall be provided using models and relevant animal species designed to show that the nucleic acid sequence reaches its intended target (target organ or cells) and provides its intended function (level of expression and functional activity). The duration of the nucleic acid sequence function and the proposed dosing regimen in the clinical studies shall be provided.

(b) Target selectivity: When the gene therapy medicinal product is intended to have a selective or target-restricted functionality, studies to confirm the specificity and duration of functionality and activity in target cells and tissues shall be provided.

4.2.2. *Pharmacokinetics*

(a) Biodistribution studies shall include investigations on persistence, clearance and mobilisation. Biodistribution studies shall additionally address the risk of germline transmission.

(b) Investigations of shedding and risk of transmission to third parties shall be provided with the environmental risk assessment, unless otherwise duly justified in the application on the basis of the type of product concerned.

4.2.3. *Toxicology*

(a) Toxicity of the finished gene therapy medicinal product shall be assessed. In addition, depending on the type of product, individual testing of active substance and excipients shall be taken into consideration, the *in vivo* effect of expressed nucleic acid sequence-related products which are not intended for the physiological function shall be evaluated.

(b) Single-dose toxicity studies may be combined with safety pharmacology and pharmacokinetic studies, e.g. to investigate persistence.

(c) Repeated dose toxicity studies shall be provided when multiple dosing of human subjects is intended. The mode and scheme of administration shall closely reflect the planned clinical dosing. For those cases where single dosing may result in prolonged functionality of the nucleic acid sequence in humans, repeated toxicity studies shall be considered. The duration of the studies may be longer than in standard toxicity studies depending on the persistence of the gene therapy medicinal product and the anticipated potential risks. A justification for the duration shall be provided.

(d) Genotoxicity shall be studied. However, standard genotoxicity studies shall only be conducted when they are necessary for testing a specific impurity or a component of the delivery system.

(e) Carcinogenicity shall be studied. Standard lifetime rodent carcinogenicity studies shall not be required. However, depending on the type of product, the tumourigenic potential shall be evaluated in relevant *in vivo*/*in vitro* models.

(f) Reproductive and developmental toxicity: Studies on the effects on fertility and general reproductive function shall be provided. Embryo-foetal and perinatal toxicity studies and germline transmission studies shall be provided, unless otherwise duly justified in the application on the basis of the type of product concerned.

(g) *Additional toxicity studies*

— Integration studies: integration studies shall be provided for any gene therapy medicinal product, unless the lack of these studies is scientifically justified, e.g. because nucleic acid sequences will not enter into the cell nucleus. For gene therapy medicinal products not expected to be capable of integration, integration studies shall be performed, if biodistribution data indicate a risk for germline transmission.

— Immunogenicity and immunotoxicity: potential immunogenic and immunotoxic effects shall be studied.

4.3. **Specific requirements for somatic cell therapy medicinal products and tissue engineered products**

4.3.1. *Pharmacology*

(a) The primary pharmacological studies shall be adequate to demonstrate the proof of concept. The interaction of the cell-based products with the surrounding tissue shall be studied.

(b) The amount of product needed to achieve the desired effect/the effective dose, and, depending on the type of product, the frequency of dosing shall be determined.

(c) Secondary pharmacological studies shall be taken into account to evaluate potential physiological effects that are not related to the desired therapeutic effect of the somatic cell therapy medicinal product, of the tissue engineered product or of additional substances, as biologically active molecules besides the protein(s) of interest might be secreted or the protein(s) of interest could have unwanted target sites.

4.3.2. *Pharmacokinetics*

(a) Conventional pharmacokinetic studies to investigate absorption, distribution, metabolism and excretion shall not be required. However, parameters such as viability, longevity, distribution, growth, differentiation and migration shall be investigated, unless otherwise duly justified in the application on the basis of the type of product concerned.

(b) For somatic cell therapy medicinal products and tissue engineered products, producing systemically active biomolecules, the distribution, duration and amount of expression of these molecules shall be studied.

4.3.3. *Toxicology*

(a) The toxicity of the finished product shall be assessed. Individual testing of active substance(s), excipients, additional substances and any process-related impurities shall be taken into consideration.

(b) The duration of observations may be longer than in standard toxicity studies and the anticipated lifespan of the medicinal product, together with its pharmacodynamic and pharmacokinetic profile, shall be taken into consideration. A justification of the duration shall be provided.

(c) Conventional carcinogenicity and genotoxicity studies shall not be required, except with regard to the tumourigenic potential of the product.

(d) Potential immunogenic and immunotoxic effects shall be studied.

(e) In the case of cell-based products containing animal cells, the associated specific safety concerns such as transmission to humans of xenogeneic pathogens shall be addressed.

5. SPECIFIC REQUIREMENTS REGARDING MODULE 5

5.1. **Specific requirements for all advanced therapy medicinal products**

5.1.1. The specific requirements in this section of Part IV are additional requirements to those set in Module 5 in Part I of this Annex.

5.1.2. Where the clinical application of advanced therapy medicinal products requires specific concomitant therapy and involve surgical procedures, the therapeutic procedure as a whole shall be investigated and described. Information on the standardisation and optimisation of those procedures during clinical development shall be provided.

Where medical devices used during the surgical procedures for application, implantation or administration of the advanced therapy medicinal product may have an impact on the efficacy or safety of the advanced therapy product, information on these devices shall be provided.

Specific expertise required to carry out the application, implantation, administration or follow-up activities shall be defined. Where necessary, the training plan of health care professionals on the use, application, implantation or administration procedures of these products shall be provided.

5.1.3. Given that, due to the nature of advanced therapy medicinal products, their manufacturing process may change during clinical development, additional studies to demonstrate comparability may be required.

5.1.4. During clinical development, risks arising from potential infectious agents or the use of material derived from animal sources and measures taken to reduce such risk shall be addressed.

5.1.5. Dose selection and schedule of use shall be defined by dose-finding studies.

5.1.6. The efficacy of the proposed indications shall be supported by relevant results from clinical studies using clinically meaningful endpoints for the intended use. In certain clinical conditions, evidence of long-term efficacy may be required. The strategy to evaluate long-term efficacy shall be provided.

5.1.7. A strategy for the long-term follow-up of safety and efficacy shall be included in the risk management plan.

5.1.8. For combined advanced therapy medicinal products, the safety and efficacy studies shall be designed for and performed on the combined product as a whole.

5.2. **Specific requirements for gene therapy medicinal products**

5.2.1. *Human pharmacokinetic studies*

Human pharmacokinetic studies shall include the following aspects:

(a) shedding studies to address the excretion of the gene therapy medicinal products;

(b) biodistribution studies;

(c) pharmacokinetic studies of the medicinal product and the gene expression moieties (e.g. expressed proteins or genomic signatures).

5.2.2. *Human pharmacodynamic studies*

Human pharmacodynamic studies shall address the expression and function of the nucleic acid sequence following administration of the gene therapy medicinal product.

5.2.3. *Safety studies*

Safety studies shall address the following aspects:

(a) emergence of replication competent vector;

(b) emergence of new strains;

(c) reassortment of existing genomic sequences;

(d) neoplastic proliferation due to insertional mutagenicity.

5.3. **Specific requirements for somatic cell therapy medicinal products**

5.3.1. *Somatic cell therapy medicinal products where the mode of action is based on the production of defined active biomolecule(s)*

For somatic cell therapy medicinal products where the mode of action is based on the production of defined active biomolecule(s), the pharmacokinetic profile (in particular distribution, duration and amount of expression) of those molecules shall be addressed, if feasible.

5.3.2. *Biodistribution, persistence and long-term engraftment of the somatic cell therapy medicinal product components*

The biodistribution, persistence and long-term engraftment of the somatic cell therapy medicinal product components shall be addressed during the clinical development.

5.3.3. *Safety studies*

Safety studies shall address the following aspects:

(a) distribution and engrafting following administration;

(b) ectopic engraftment;

(c) oncogenic transformation and cell/tissue lineage fidelity.

5.4. **Specific requirements for tissue engineered products**

5.4.1. *Pharmacokinetic studies*

Where conventional pharmacokinetic studies are not relevant for tissue engineered products, the biodistribution, persistence and degradation of the tissue engineered product components shall be addressed during the clinical development.

5.4.2. *Pharmacodynamic studies*

Pharmacodynamic studies shall be designed and tailored to the specificities of tissue engineered products. The evidence for the "proof of concept" and the kinetics of the product to obtain the intended regeneration, repairing or replacement shall be provided. Suitable pharmacodynamic markers, related to the intended function(s) and structure shall be taken into account.

5.4.3. *Safety studies*

Section 5.3.3 shall apply.

(*) OJ L 102, 7.4.2004, p. 48.
(**) OJ L 169, 12.7.1993, p. 1.
(***) OJ L 189, 20.7.1990, p. 17.
(****) OJ L 105, 26.4.2003, p. 18.'

COMMISSION DIRECTIVE 2009/121/EC

of 14 September 2009

amending, for the purposes of their adaptation to technical progress, Annexes I and V to Directive 2008/121/EC of the European Parliament and of the Council on textile names

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 2008/121/EC of the European Parliament and of the Council of 14 January 2009 on textile names [1], and in particular Article 15(1) thereof,

Whereas:

(1) Directive 2008/121/EC lays down rules governing the labelling or marking of products as regards their textile fibre content, in order to ensure that consumer interests are thereby protected. Textile products may be placed on the market within the Community only if they comply with the provisions of that Directive.

(2) In view of recent findings by a technical working group, it is necessary, for the purposes of adapting Directive 2008/121/EC to technical progress, to add the fibre melamine to the list of fibres set out in the Annexes I and V to that Directive.

(3) Directive 2008/121/EC should therefore be amended accordingly

(4) The measures provided for in this Directive are in accordance with the opinion of the Committee for Directives relating to Textile Names and Labelling,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 2008/121/EC is amended as follows:

1. in Annex I the following row 48 is added:

'48	melamine	fibre formed of at least 85 % by mass of cross-linked macromolecules made up of melamine derivatives';

2. in Annex V the following entry 48 is added:

'48	Melamine	7,00'.

Article 2

Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 15 September 2010 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, 14 September 2009.

For the Commission
Günter VERHEUGEN
Vice-President

[1] OJ L 19, 23.1.2009, p. 29.

COMMISSION DIRECTIVE 2009/122/EC

of 14 September 2009

amending, for the purposes of its adaptation to technical progress, Annex II to Directive 96/73/EC of the European Parliament and of the Council on certain methods for quantitative analysis of binary textile fibre mixtures

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 96/73/EC of the European Parliament and of the Council of 16 December 1996 on certain methods for quantitative analysis of binary textile fibre mixtures [1], and in particular Article 5 thereof,

Whereas:

(1) Directive 2008/121/EC of the European Parliament and the Council of 14 January 2009 on textile names [2] requires labelling to indicate the fibre composition of textile products, with checks being carried out by analysis on the conformity of these products with indications given on the label.

(2) Uniform methods for quantitative analysis of binary textile fibre mixtures are provided for in Directive 96/73/EC.

(3) On the basis of recent findings by the technical working group, Directive 2008/121/EC was adapted to technical progress, by adding the fibre melamine to the list of fibres set out in Annexes I and V to that Directive.

(4) It is therefore, necessary to define uniform test methods for melamine.

(5) Directive 96/73/EC should therefore be amended accordingly.

(6) The measures provided for in this Directive are in accordance with the opinion of the Committee for Directives relating to Textile Names and Labelling,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex II to Directive 96/73/EC is amended in accordance with the Annex to this Directive.

Article 2

Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 15 September 2010 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, 14 September 2009.

For the Commission
Günter VERHEUGEN
Vice-President

[1] OJ L 32, 3.2.1997, p. 1.
[2] OJ L 19, 23.1.2009, p. 29.

ANNEX

Chapter 2 of Annex II to Directive 96/73/EC is amended as follows:

(a) the Special Methods — Summary Table is replaced by the following:

'SUMMARY TABLE

Method	Field of application		Reagent
	Soluble component	Insoluble component	
1.	Acetate	Certain other fibres	Acetone
2.	Certain protein fibres	Certain other fibres	Hypochlorite
3.	Viscose, cupro or certain types of modal	Cotton, elastolefin or melamine	Formic acid and zinc chloride
4.	Polyamide or nylon	Certain other fibres	Formic acid, 80 % m/m
5.	Acetate	Triacetate, elastolefin or melamine	Benzyl alcohol
6.	Triacetate or polylactide	Certain other fibres	Dichloromethane
7.	Certain cellulose fibres	Polyester, elastomultiester or elastolefin	Sulphuric acid, 75 % m/m
8.	Acrylics, certain modacrylics or certain chlorofibres	Certain other fibres	Dimethylformamide
9.	Certain chlorofibres	Certain other fibres	Carbon disulphide/acetone, 55,5/44,5 v/v
10.	Acetate	Certain chlorofibres, elastolefin or melamine	Glacial acetic acid
11.	Silk	Wool, hair, elastolefin or melamine	Sulphuric acid, 75 % m/m
12.	Jute	Certain animal fibres	Nitrogen content method
13.	Polypropylene	Certain other fibres	Xylene
14.	Certain other fibres	Chlorofibres (homopolymers of vinyl chloride), elastolefin or melamine	Concentrated sulphuric acid method
15.	Chlorofibres, certain modacrylics, certain elastanes, acetates, triacetates	Certain other fibres	Cyclohexanone
16.	Melamine	Cotton or aramid	Hot formic acid 90 % m/m'

(b) method No 1 is amended as follows:

(i) point 1.2 is replaced by the following:

'2. wool (1), animal hair (2 and 3), silk (4), cotton (5), flax (7) true hemp (8), jute (9), abaca (10), alfa (11), coir (12), broom (13), ramie (14), sisal (15), cupro (21), modal (22), protein (23), viscose (25), acrylic (26), polyamide or nylon (30), polyester (35) elastomultiester (46), elastolefin (47) and melamine (48).

In no circumstances is the method applicable to acetate fibres which have been deacetylated on the surface.';

(ii) point 5 is replaced by the following:

'5. CALCULATION AND EXPRESSION OF RESULTS

Calculate the results as described in the general instructions. The value of "d" is 1,00, except for melamine, for which "d" = 1,01.';

(c) method No 2 is amended as follows:

(i) point 1.2 is replaced by the following:

'2. cotton (5), cupro (21), viscose (25), acrylic (26), chlorofibres (27), polyamide or nylon (30), polyester (35), polypropylene (37), elastane (43), glass fibre (44) elastomultiester (46), elastolefin (47) and melamine (48).

If different protein fibres are present, the method gives the total of their amounts but not their individual quantities.';

(ii) point 5 is replaced by the following:

'5. CALCULATION AND EXPRESSION OF RESULTS

Calculate the results as described in the general instructions. The value of "d" is 1,00, except for cotton, viscose, modal and melamine, for which "d" = 1,01, and unbleached cotton, for which "d" = 1,03.';

(d) method No 3 is amended as follows:

(i) point 1.2 is replaced by the following:

'2. cotton (5), elastolefin (47) and melamine (48).

If a modal fibre is found to be present, a preliminary test shall be carried out to see whether it is soluble in the reagent.

This method is not applicable to mixtures in which the cotton has suffered extensive chemical degradation nor when the viscose or cupro is rendered incompletely soluble by the presence of certain dyes or finishes that cannot be removed completely.';

(ii) point 5 is replaced by the following:

'5. CALCULATION AND EXPRESSION OF RESULTS

Calculate the results as described in the general instructions. The value of "d" is 1,02 for cotton, 1,01 for melamine and 1,00 for elastolefin.';

(e) method No 4 is amended as follows:

(i) point 1.2 is replaced by the following:

'2. wool (1), animal hair (2 and 3), cotton (5), cupro (21), modal (22), viscose (25), acrylic (26), chlorofibre (27), polyester (35), polypropylene (37), glass fibre (44), elastomultiester (46), elastolefin (47) and melamine (48).

As mentioned above, this method is also applicable to mixtures with wool, but when the wool content exceeds 25 %, method No 2 shall be applied (dissolving wool in a solution of alkaline sodium hypochlorite).';

(ii) point 5 is replaced by the following:

'5. CALCULATION AND EXPRESSION OF RESULTS

Calculate the results as described in the general instructions. The value of "d" is 1,00, except for melamine, for which "d" = 1,01.';

(f) method No 5 is amended as follows:

(i) point 1 is replaced by the following:

'1. FIELD OF APPLICATION

This method is applicable, after removal of non-fibrous matter, to binary mixtures of:

1. acetate (19)

with

2. triacetate (24), elastolefin (47) and melamine (48).';

(ii) point 5 is replaced by the following:

'5. CALCULATION AND EXPRESSION OF RESULTS

Calculate the results as described in the general instructions. The value of "d" is 1,00, except for melamine, for which "d" = 1,01.';

(g) method No 6 is amended as follows:

(i) point 1.2 is replaced by the following:

'2. wool (1), animal hair (2 and 3), silk (4), cotton (5), cupro (21), modal (22), viscose (25), acrylic (26), polyamide or nylon (30), polyester (35), glass fibre (44) elastomultiester (46), elastolefin (47) and melamine (48).

Note: Triacetate fibres which have received a finish leading to partial hydrolysis cease to be completely soluble in the reagent. In such cases, the method is not applicable.';

(ii) point 5 is replaced by the following:

'5. CALCULATION AND EXPRESSION OF RESULTS

Calculate the results as described in the general instructions. The value of "d" is 1,00, except in the case of polyester, elastomultiester, elastolefin and melamine, for which the value of "d" is 1,01.';

(h) method No 8 is amended as follows:

(i) point 1.2 is replaced by the following:

'2. wool (1), animal hair (2 and 3), silk (4), cotton (5), cupro (21), modal (22), viscose (25), polyamide or nylon (30), polyester (35), elastomultiester (46), elastolefin (47) and melamine (48).

It is equally applicable to acrylics, and certain modacrylics, treated with pre-metallised dyes, but not to those dyed with afterchrome dyes.';

(ii) point 5 is replaced by the following:

'5. CALCULATION AND EXPRESSION OF RESULTS

Calculate the results as described in the general instructions. The value of "d" is 1,00, except in the case of wool, cotton, cupro, modal, polyester, elastomultiester, and melamine, for which the value of "d" is 1,01.';

(i) method No 9 is amended as follows:

(i) point 1.2 is replaced by the following:

'2. wool (1), animal hair (2 and 3), silk (4), cotton (5), cupro (21), modal (22), viscose (25), acrylic (26), polyamide or nylon (30), polyester (35), glass fibre (44), elastomultiester (46) and melamine (48).

When the wool or silk content of the mixture exceeds 25 %, method No 2 shall be used.

When the polyamide or nylon content of the mixture exceeds 25 %, method No 4 shall be used.';

(ii) point 5 is replaced by the following:

'5. CALCULATION AND EXPRESSION OF RESULTS

Calculate the results as described in the general instructions. The value of "d" is 1,00, except for melamine, for which "d" = 1,01.';

(j) point 1.2 of method No 10 is replaced by the following:

'2. certain chlorofibres (27) namely polyvinyl chloride fibres, whether after-chlorinated or not, elastolefin (47) and melamine (48).';

(k) method No 11 is amended as follows:

(i) point 1.2 is replaced by the following:

'2. wool (1), animal hair (2 and 3), elastolefin (47) and melamine (48).';

(ii) point 5 is replaced by the following:

'5. CALCULATION AND EXPRESSION OF RESULTS

Calculate the results as described in the general instructions. The value of "d" is 0,985 for wool, 1,00 for elastolefin and 1,01 for melamine.';

(l) method No 13 is amended as follows:

(i) point 1.2 is replaced by the following:

'2. wool (1), animal hair (2 and 3), silk (4), cotton (5), acetate (19), cupro (21), modal (22), triacetate (24), viscose (25), acrylic (26), polyamide or nylon (30), polyester (35), glass fibre (44), elastomultiester (46) and melamine (48).';

(ii) point 5 is replaced by the following:

'5. CALCULATION AND EXPRESSION OF RESULTS

Calculate the results as described in the general instructions. The value of "d" is 1,00, except for melamine, for which "d" = 1,01.';

(m) method No 14 is amended as follows:

(i) point 1 is replaced by the following:

'1. FIELD OF APPLICATION

This method is applicable, after removal of non-fibrous matter, to binary mixtures of:

1. cotton (5), acetate (19), cupro (21), modal (22), triacetate (24), viscose (25), certain acrylics (26), certain modacrylics (29), polyamide or nylon (30), polyester (35) and elastomultiester (46)

with

2. chlorofibres (27) based on homopolymers of vinyl chloride, whether after-chlorinated or not, elastolefin (47) and melamine (48).

The modacrylics concerned are those which give a limpid solution when immersed in concentrated sulphuric acid (relative density 1,84 at 20 °C).

This method can be used in place of method Nos 8 and 9.';

(ii) point 2 is replaced by the following:

'2. PRINCIPLE

The constituent other than the chlorofibre, elastolefin or melamine (i.e. the fibres mentioned in paragraph 1.1) is dissolved out from a known dry mass of the mixture with concentrated sulphuric acid (relative density 1,84 at 20 °C). The residue, consisting of the chlorofibre, elastolefin or melamine, is collected, washed, dried and weighed; its mass, corrected if necessary, is expressed as a percentage of the dry mass of the mixture. The percentage of the second constituents is obtained by difference.';

(iii) point 5 is replaced by the following:

'5. CALCULATION AND EXPRESSION OF RESULTS

Calculate the results as described in the general instructions. The value of "d" is 1,00, except for melamine, for which "d" = 1,01.';

(n) method No 15 is amended as follows:

(i) point 1 is replaced by the following:

'1. FIELD OF APPLICATION

This method is applicable, after removal of non-fibrous matter, to binary mixtures of:

1. acetate (19), triacetate (24), chlorofibre (27), certain modacrylics (29), certain elastanes (43)

with

2. wool (1), animal hair (2 and 3), silk (4), cotton (5), cupro (21), modal (22), viscose (25), polyamide or nylon (30), acrylic (26), glass fibre (44) and melamine (48).

Where modacrylics or elastanes are present a preliminary test must first be carried out to determine whether the fibre is completely soluble in the reagent.

It is also possible to analyse mixtures containing chlorofibres by using method No 9 or 14.';

(ii) point 5 is replaced by the following:

'5. CALCULATION AND EXPRESSION OF RESULTS

Calculate the results as described in the general instructions. The value of "d" is 1,00 with the following exceptions:

silk and melamine	1,01;
acrylic	0,98.';

(o) method No 16 is inserted after method No 15:

'METHOD No 16

MELAMINE AND CERTAIN OTHER FIBRES

(Method using hot formic acid)

1. FIELD OF APPLICATION

This method is applicable, after removal of non-fibrous matter, to binary mixtures of:

1. melamine (48)

with

2. cotton (5) and aramid (31).

2. PRINCIPLE

The melamine is dissolved out from a known dry mass of the mixture with hot formic acid (90 % by mass).

The residue is collected, washed, dried and weighed; its mass, corrected if necessary, is expressed as a percentage of the dry mass of the mixture. The percentage of the second constituents is obtained by difference.

Note: Keep strictly the recommended temperature range because the solubility of melamine is very much dependent on temperature.

3. APPARATUS AND REAGENTS (other than those specified in the general instructions)

3.1. **Apparatus**

(i) Glass-stoppered conical flask of at least 200 ml capacity.

(ii) Shaking water bath or other apparatus to shake and maintain the flask at 90 ± 2 °C.

3.2. **Reagents**

(i) Formic acid (90 % m/m, relative density at 20 °C: 1,204 g/ml). Dilute 890 ml of 98 to 100 % m/m formic acid (relative density at 20 °C: 1,220 g/ml) to 1 liter with water.

Hot formic acid is very corrosive and must be handled with care.

(ii) Ammonia, dilute solution: dilute 80 ml of concentrated ammonia solution (relative density at 20 °C: 0,880) to 1 litre with water.

4. TEST PROCEDURE

Follow the procedure described in the general instructions, then proceed as follows:

To the specimen contained in the glass-stoppered conical flask of at least 200 ml capacity, add 100 ml of formic acid per gram of specimen. Insert the stopper and shake the flask to wet out the specimen. Maintain the flask in a shaking water bath at 90 ± 2 °C for 1 hour, shaking it vigorously. Cool the flask to room temperature. Decant the liquid through the weighed filter crucible. Add 50 ml of formic acid to the flask containing the residue, shake manually and filter the contents of the flask through the filter crucible. Transfer any residual fibres to the crucible by washing out the flask with a little more formic acid reagent. Drain the crucible with suction and wash the residue with formic acid reagent, hot water, dilute ammonia solution, and finally cold water, draining the crucible with suction after each addition. Do not apply suction until each washing liquor has drained under gravity. Finally, drain the crucible with suction, dry the crucible and residue, and cool and weigh them.

Note: Temperature has a very strong influence on solubility properties of melamine and should be carefully controlled.

5. CALCULATION AND EXPRESSION OF RESULTS

Calculate the results as described in the general instructions. The value of "d" for cotton and aramid is 1,02.

6. PRECISION

On a homogeneous mixture of textile materials, the confidence limits of results obtained by this method are not greater than ± 2 for a confidence level of 95 %.'

II

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

DECISIONS

COMMISSION

COMMISSION DECISION

of 11 February 2009

concerning the State aid C 55/07 (ex NN 63/07, CP 106/06) implemented by the United Kingdom of Great Britain and Northern Ireland — Crown guarantee to BT

(notified under document C(2009) 685)

(Only the English text is authentic)

(Text with EEA relevance)

(2009/703/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

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

Having regard to the Agreement on the European Economic Area, and in particular Article 62(1)(a) thereof,

Having called on interested parties to submit their comments pursuant to those provisions [1] and having regard to their comments,

Whereas:

(1) This case concerns State aid put into effect by the United Kingdom of Great Britain and Northern Ireland (hereinafter the United Kingdom) in favour of BT plc (hereinafter BT, unless otherwise stated). BT is a public limited company registered in England and Wales. British Telecommunications plc is a wholly owned subsidiary of BT Group plc and encompasses virtually all the businesses and assets of the BT group. The successor to the statutory corporation British Telecommunications, it was incorporated in England and Wales as a public limited company, wholly owned by the Government of the United Kingdom, as a result of the Telecommunications Act 1984. Between November 1984 and July 1993, the Government of the United Kingdom sold all of its shareholding in British Telecommunications plc in three public offerings.

[1] OJ C 15, 22.1.2008, p. 8.

1. PROCEDURAL ASPECTS

(2) On 26 April 2006, one of BT's competitors, which requested confidentiality, lodged a complaint against a guarantee granted to BT by the Minister of the Crown (Crown guarantee). By e-mails dated 24 May 2006 and 22 June 2006, this competitor provided further information on the scheme to the Commission.

(3) On 18 May 2006, the Commission sent a request for information to the authorities of the United Kingdom, who replied by letter dated 18 July 2006.

(4) On 21 December 2006, the Commission sent a further request for information. After an extension of the deadline, the authorities of the United Kingdom responded by letter dated 27 February 2007.

(5) On 26 March 2007, a meeting was held with the lawyers representing the trustees of the BT Pension Scheme (BTPS) at the request of the United Kingdom authorities. Further information was submitted by e-mail dated 10 May 2007.

(6) On 10 May 2007, the Commission sent a request for information to the authorities of the United Kingdom. After an extension of the deadline and a meeting which took place on 11 June 2007, the authorities of the United Kingdom responded by letter dated 19 June 2007.

(7) By letter dated 3 August 2007, the Commission requested further information. After an extension of the deadline, the authorities of the United Kingdom responded by letter dated 3 October 2007.

(8) On 28 November 2007, the Commission adopted and notified to the United Kingdom a decision concluding that the Crown guarantee, as far as it concerns BT pension liabilities in case of insolvency, did not constitute State aid within the meaning of Article 87(1) of the EC Treaty, and at the same opened the formal investigation procedure on certain measures linked to the Crown guarantee granted to BTPS.

(9) By e-mail dated 30 January 2008, the authorities of the United Kingdom sent their comments on that decision.

(10) Following the publication of the decision of 28 November 2007, the Commission received comments from the following interested parties: UK Competitive Telecommunications Association (UKCTA), a trade association representing telecommunication operators competing with BT, the original anonymous complainant, BT and BTPS. Their observations were sent to the authorities of the United Kingdom on 25 March 2008.

(11) By e-mail dated 25 April 2008, the authorities of the United Kingdom sought authorisation to submit the third parties' comments to BT. After consultation and agreement of the parties concerned, the Commission authorised disclosure of non-confidential versions of these documents to BT.

(12) By e-mail dated 30 May 2008, the Commission received the comments of the authorities of the United Kingdom on the third parties' submissions. By e-mail dated 3 June 2008, the Commission received BT's comments on the third parties' observations.

(13) On 22 July 2008, the Commission held a meeting with the authorities of the United Kingdom, which was followed by new clarifications provided by e-mail on 19 September 2008.

(14) The lawyers of BT and BTPS, at their request, met with the Commission on 6 August 2008 and 28 October 2008.

2. DESCRIPTION OF THE MEASURES

(15) The relevant measures under examination concern the provisions by which the Government of the United Kingdom guarantees the payment of certain liabilities, in particular pension liabilities, of BT under the Crown guarantee, and relieves BT from obligations laid down in the legal framework which applies to pension schemes in the United Kingdom.

2.1. **The Crown guarantee**

(16) By virtue of the Telecommunications Act 1981, the telecommunications operation which had formerly formed part of the Post Office was transferred to a new public corporation, British Telecommunications. The Telecommunications Act 1984 provided for the privatisation of British Telecommunications.

(17) Under section 60 of the Telecommunications Act 1984, the property, rights and liabilities of the public corporation were transferred to the privatised successor company, British Telecommunications plc. Included in the transfer were any liabilities of the public corporation in respect of its employees' pension scheme, which at the time was showing a deficit of GBP 626 million revealed by the 1983 actuarial valuation of the scheme.

(18) Section 68 of the Telecommunications Act 1984 laid down the Crown guarantee:

'(1) This section applies where

(a) a resolution has been passed, in accordance with the [Insolvency Act 1986], for the voluntary winding up of the successor company, otherwise than merely for the purpose of reconstruction or amalgamation with another company; or

(b) without any such resolution having been passed beforehand, an order has been made for the winding up of the successor company by the court under that Act.

(2) The Secretary of State shall become liable on the commencement of the winding up to discharge any outstanding liability of the successor company which vested in that company by virtue of section 60 above.

(…)

(4) Where the Secretary of State makes a payment to any person in discharge of what appears to him to be a liability imposed on him by this section, he shall thereupon become a creditor of the successor company to the extent of the amount paid, his claim being treated for the purposes of the winding up as a claim in respect of the original liability.'

(19) The Crown guarantee covered all outstanding liabilities of the corporation transferred to BT in 1984. Although the authorities of the United Kingdom state that they do not have complete information on the total amount of liabilities that were covered other than pension liabilities, they note that the 1983/1984 financial statements of British Telecom provide some information as to the position on 31 March 1984:

— short-term liabilities falling due within one year totalled GBP 1 909 million. They comprised short term borrowings, trade creditors, value added tax and payroll taxes, other creditors, accruals and deferred income,

— long-term liabilities totalled GBP 458 million in foreign loans, which were reimbursed 10 years later.

(20) The Communication Act 2003 repealed section 60 and amended section 68(2) of the Telecommunications Act 1984, which now provides that 'the Secretary of State shall become liable on the commencement of the winding up to discharge any outstanding liability of the successor company for the payment of pensions which vested in that company by virtue of section 60 above' (emphasis added).

(21) The Crown guarantee requires the Government of the United Kingdom to discharge any liability of the public corporation for payments of pensions transferred to BT in respect of employees who were members of the public corporation's employee pension scheme before 6 August 1984, provided BT is insolvent and is being wound up and only if the liability is wholly or partly outstanding at the beginning of the winding up. This presupposes that the assets of BT's pension scheme are insufficient to cover its liabilities regarding the rights accrued to those employees. Although the Telecommunications Act 1984 is not clear on this point, the authorities of the United Kingdom are of the opinion that the Crown guarantee covers not only the pension rights acquired by these employees before the privatisation but also those acquired after it.

(22) Prior to the privatisation and given its status as public corporation, BT could not be wound up except by an Act of Parliament. As far as pension liabilities are concerned, the Crown guarantee was allegedly provided to allay the concerns of the public corporation's employees who would no longer enjoy State protection for their pensions. They were particularly worried about what would happen if the privatised successor company were to become insolvent leaving the pension scheme with a deficit. According to the authorities of the United Kingdom, the Crown guarantee issued in 1984 responded to these concerns, which were exacerbated by the actuarial deficit of the pension scheme revealed in 1983.

(23) According to the explanations provided by the authorities of the United Kingdom, if BT became insolvent, the Government of the United Kingdom would become liable immediately — on commencement of liquidation — for any of BT's outstanding liabilities relating to the pension scheme for staff transferred to BT at privatisation. The Secretary of State would make payment to BTPS in respect of these outstanding liabilities and would become an unsecured creditor of BT for that amount. BTPS would also be an unsecured creditor of the insolvent BT for any liabilities related to staff not covered by the Crown guarantee since the law does not give any special preference to pension scheme trustees.

(24) The authorities of the United Kingdom indicate that they are unable to specify the value of the liabilities that would be covered by the guarantee. Indeed, the outstanding liabilities would depend on the number of members to be covered and on the assets of the BT pension scheme if and when BT became insolvent and was wound up.

2.2. **BT Pension Scheme**

(25) Until 1969, employees of the Post Office were civil servants. In that year, they became employees of the Post Office public corporation, which ended their status as members of the civil service. The Post Office was assigned general responsibility for the payment of staff pensions, with the establishment of the Post Office Staff Superannuation Scheme (POSSS), to which the accrued pension rights of Post Office employees were transferred.

(26) In 1983, the British Telecommunications Staff Superannuation Scheme (BTSSS), the terms of which were closely modelled on those of the POSSS, was established. As of 31 March 1986, BT established a further pension scheme for new employees called the British Telecommunications plc New Pension Scheme (BTNPS). The BTSSS was closed to new members from that date. Both these schemes were merged and renamed the BT Pension Scheme (BTPS) in 1993.

(27) The objective of BTPS is to ensure that over the long term, the scheme will always have enough money to meet the cost of the pension benefits to be paid. Under the Rules of the BTPS, BT must contribute regular employment contributions to the scheme, as determined by the scheme actuary, to meet the benefits under and the costs and expenses of the scheme. BT's regular employer contributions amounted to GBP 395 million in the financial year 2006/2007. The scheme actuary is also required to make an actuarial valuation of the assets and the liabilities (namely, future pension benefits and other costs and expenses) of the scheme at intervals not exceeding three years and report the position to BTPS' trustees and to BT. BT must also make further contributions as required to repair any deficit between the scheme assets and liabilities reported on the actuarial valuation under a recovery plan to return the BTPS to full funding […] (*).

(28) For instance, the triennial valuation of the BTPS as at 31 December 2002 concluded that there was a funding deficit, which BT agreed to repay at GBP 232 million per annum over 15 years, in addition to regular employer contributions. The results of the most recent valuation were announced in December 2006 and disclosed liabilities of GBP 37,8 billion and assets of GBP 34,4 billion, which resulted in a deficit of GBP 3,4 billion. According to the recovery plan, the scheme should return to full funding by 2015. BT agreed to pay GBP 280 million per annum for 10 years, which, combined with investment returns, is anticipated to fully pay off the deficit. Should the next actuarial

(*) Business secret.

valuation reveal that the scheme will not return to full funding as planned, a new recovery plan and amended additional contributions will have to be agreed.

2.3. **Main developments of pension legislation in the United Kingdom since 1984**

(29) Pension law in the United Kingdom has undergone several changes since 1984. According to the information available, the Pensions Acts 1995 and the Pensions Acts 2004 introduced the main modifications to the general pension regulatory framework.

2.3.1. *The Pensions Act 1995: Minimum funding requirements*

(30) Section 56 of the Pensions Act 1995 introduced a minimum funding requirement that the value of the assets of the scheme is not less than the amount of the liabilities of the scheme. However, the Occupational Pension Schemes (Minimum Funding Requirement and Actuarial Valuations) Regulations 1996 provide that:

'Section 56 (minimum funding requirement) does not apply to […] any occupational pension scheme in respect of which any Minister of the Crown has given a guarantee or made any other arrangements for the purpose of securing that the assets of the scheme are sufficient to meet its liabilities. […] Where such a guarantee has been given in respect of part only of a scheme, sections 56 to 60 and these Regulations shall apply as if that part and the other part of the scheme were separate schemes' (emphasis added).

(31) Furthermore, section 75 of the Pensions Act 1995 provides that if at the time of insolvency the value of the assets of the scheme is less than the amount of the liabilities of the scheme, an amount equal to the difference shall be treated as a debt due from the employer to the trustees or managers of the scheme. However, the Occupational Pension Schemes (Deficiency on Winding up) Regulations 1996 provide that:

'Section 75 does not apply […] to any occupational pension scheme in respect of which any Minister of the Crown has given a guarantee or made any other arrangements for the purpose of securing that the assets of the scheme are sufficient to meet its liabilities' (emphasis added).

2.3.2. *The Pensions Act 2004: Pension Protection Fund and Statutory Funding Objectives*

(32) Part 2 of the Pensions Act 2004 introduced the Pension Protection Fund as a result of intense political pressure at the time, after thousands of workers lost large amounts of their pension benefits following the bankruptcy of their sponsoring companies. The Pension Protection Fund was created in April 2005. Its function is to pay compensation to members of eligible pension schemes whose sponsor employers have suffered insolvency leaving insufficient assets in the scheme to provide their members with protection equivalent to the level of compensation payable by the Pension Protection Fund.

(33) The Pension Protection Fund is financed partly by the assets transferred from schemes from which it has assumed responsibility and partly by an annual levy raised on eligible pension schemes. This levy includes an administration levy and a risk levy which incorporates two elements: a risk-based element that takes into account the scheme's under-funding risk and the employer insolvency risk (80 % of the levy) and a scheme-based element on the basis of the size of the scheme's liabilities (20 % of the levy). The amount of the initial levy for 2005/2006 was set without taking into consideration the risk-based element.

(34) The Pension Protection Fund (Entry Rules) Regulations 2005 specify that 'a scheme in respect of which a relevant public authority has given a guarantee or made any other arrangements for the purposes of securing that the assets of the scheme are sufficient to meet its liabilities' is exempted from the Pension Protection Fund. Where part of a scheme is guaranteed by the Crown, the guaranteed and non-guaranteed parts of the scheme should be considered as separate schemes.

(35) Finally, part 3 of the Pensions Act 2004 introduced new scheme funding requirements (Statutory funding objectives) which replaced the 1995 minimum funding requirements. Section 222 of the Act provides that schemes are subject to a requirement to hold sufficient and appropriate assets to cover their technical provisions. The Occupational Pension Schemes (Scheme Funding) Regulations 2005 exempt a scheme which is guaranteed by a public authority. Again, if a part of a scheme is guaranteed by the Crown, the guaranteed and non-guaranteed parts of the scheme should be considered as separate schemes.

3. **COMMISSION DECISION ON THE FORMAL INVESTIGATION PROCEDURE**

(36) In its decision of 28 November 2007 initiating the formal investigation, the Commission set out its preliminary assessment and doubts as to the compatibility of the measures at hand with the common market. The measures in question were:

— the Crown guarantee to BT on BT's pension liabilities in 1984,

— the exemption of BTPS from the application of the minimum funding requirements introduced by the Pensions Act 1995 and the Pensions Act 2004 to the BTPS' pension liabilities covered by the Crown guarantee,

— the exemption of BTPS under the Pension Protection Fund (Entry Rules) Regulations 2005 from the requirement laid down in part 2 of the Pensions Act 2004 to contribute an annual levy to the Pension Protection Fund corresponding to its pension liabilities covered by the Crown guarantee.

(37) In that decision, the Commission held the view that, on its own, the Crown guarantee on BT's pension liabilities in case of BT's insolvency after being wound up is of benefit only to employees and therefore does not confer any advantage to BT since it does not affect the credit rating, investment, or employment policy of BT. The Commission therefore concluded that the Crown guarantee, as far as it concerns BT pension liabilities in case of insolvency, did not confer any specific additional advantage to BT, viewed in isolation from the changes in the legal framework introduced in 1995 and 2004, and therefore did not constitute State aid within the meaning of Article 87(1) EC ([1]).

(38) However, the Commission reached a different conclusion with regard to the pension legal framework introduced in 1995 and 2004 in connection with the Crown guarantee. Whilst expressing its preliminary doubts on the compatibility of possible State aid with the common market, the Commission called on the United Kingdom to provide explanations, in particular, as to the following:

— clear evidence that BTPS did not avail itself of the exemption from the minimum funding requirements provided for in the 1995 and 2004 Pension Acts, and reasons for this decision. In this connection, the Commission noted that the BTPS still had a GBP 3,4 billion deficit in 2006, despite the requirements of the 1995 Pension Act that the assets of the scheme had to match its liabilities,

— full explanations as to why the exemption from the contribution to the Pension Protection Fund does not constitute State aid within the meaning of Article 87(1) EC,

— full explanations as to why these measures can be found to be compatible with State aid rules, and in particular under Article 87(3)(c) EC, should the Commission conclude that they constitute State aid.

4. COMMENTS FROM THE PARTIES INVOLVED

4.1. Position of the authorities of the United Kingdom

(39) The observations of the United Kingdom relate to the issues raised in the decision of 28 November 2007 as concerns minimum funding requirement and the exemption from payment of levies to the Pension Protection Fund.

4.1.1. *Minimum funding requirement*

(40) The United Kingdom claims that BT and the BTPS did not avail themselves of the exemption from the application of the minimum funding requirements.

(41) The minimum funding requirement provided for in section 56 of the Pensions Act 1995, which was in force until 2004, imposed a requirement that the value of the assets of the pension fund should not be less than the amount of liabilities. The United Kingdom stresses that the basis for calculations of pension liabilities pursuant to section 56(3) of the Pensions Act 1995 differed from those generally used by pension schemes in the course of their regular ongoing valuations. As a result, the different methodology produced different values for liabilities.

(42) The differences between the valuations under the methodology of the minimum funding requirement (MFR) and the BTPS ongoing valuations are detailed in the table below:

Date of valuation	Assets	Liabilities (MFR basis)	Ratio assets/liabilities (MFR basis)	Liabilities (ongoing basis)	Ratio assets/liabilities (ongoing basis)
31.12.2002	GBP 22,8 billion	GBP 22,5 billion	101,1 %	GBP 24,9 billion	91,6 %
31.12.1999	GBP 29,9 billion	GBP 26,5 billion	112,7 %	GBP 30,9 billion	96,8 %

(43) These figures show that, in the case of the two valuations of BTPS carried out during the period in which the 1995 minimum funding requirement was in force, namely, the 1999 and 2002 valuation, its funding position calculated on the basis of the minimum funding requirement methodology exceeded 100 % even though its ongoing valuation under a different methodology showed a deficit. In that respect, the United Kingdom stresses that the minimum funding requirement imposed no requirement on schemes for their assets to exceed the liabilities calculated in the course of their ongoing valuations. Moreover, even a deficit under minimum funding requirement did not need to be corrected immediately but within a prescribed period of no more than 10 years to reach a funding position of 100 % ratio assets/liabilities.

([1]) See Commission Decision of 28 November 2007, paragraphs 42-60.

(44) The Pensions Act 2004 replaced the 1995 minimum funding requirement with a new scheme funding regime, which obliges pension funds' trustees to agree with the sponsor company on a plan to restore any funding deficit. The authorities of the United Kingdom underlined that under the Occupational Pension Schemes Regulations, only pension schemes that benefit from a Crown guarantee and that are established by enactment (by law) can be exempted from the application of the mandatory funding requirement. In this respect, it should be noted that BTPS was not established by enactment.

(45) The authorities of the United Kingdom further underlined that this mandatory funding requirement has been fully respected by the BTPS, as illustrated by the statements prepared by the BTPS trustees indicating that the 2004 funding requirement had been fully applied in respect of the recovery plan associated with the 2005 valuation. The authorities of the United Kingdom also indicated that the pensions regulator was satisfied that the guarantee was not used to extend the recovery period or affect the key assumptions in the actuarial valuation or recovery plan.

4.1.2. *Exemption of the payment of the levy to the Pension Protection Fund*

(46) With regard to the exemption of the payment of the levy to the Pension Protection Fund, the authorities of the United Kingdom recall that the Pension Protection Fund was part of a package introduced under the Pensions Act 2004 with a view to improving the protection offered to members of pension schemes in case of employer insolvency. The Pension Protection Fund was specifically created to strengthen the protection for members in the event of schemes' winding-up where they were under-funded, and where appropriate arrangements were not yet in place. In the view of the authorities of the United Kingdom, since the obligation to pay levies is directly linked to the receipt of protection from the Pension Protection Fund, schemes with appropriate arrangements such as a Crown guarantee are not eligible for the Pension Protection Fund under the regulations, since the protection afforded by the Pension Protection Fund is not relevant.

(47) Therefore, the BTPS is outside the scope of the Pension Protection Fund system for employees covered by a Crown guarantee. Indeed, for these employees, the BTPS does not need or gain any protection from the Pension Protection Fund and therefore a levy is not paid. To categorise this as an exemption is, in the view of the authorities of the United Kingdom, inconsistent with the whole logic of the Pension Protection Fund system. On the contrary, the payment of a full Pension Protection Fund levy by the BTPS would deliver a windfall gain to schemes that are eligible for and benefit from the protection of the Pension Protection Fund.

4.2. **Position of BT and BTPS' trustees**

(48) In their joint submission to the decision of 28 November 2007, BT and BTPS underline that the Crown guarantee is only part of a package that was introduced at the time of privatisation of BT in 1984 and was intended to protect the civil service-style pension rights of the pre-privatisation employees of BT. In contrast to the benefit of the Crown guarantee for pre-privatisation employees, this package included a series of additional burdens which are not normally included in the budget of an undertaking:

— civil service-style enhanced benefits, such as retirement age at 60,

— enhanced early retirement terms on redundancy,

— restrictions on BT's ability to amend these obligations, cease employer contribution […], and

— inheritance by BT of the net deficit of the scheme at privatisation.

(49) BT further notes that the non-applicability of the Pension Protection Fund levy is the logical consequence of the Crown guarantee since the latter already offers separate pension protection. It argues that these two measures (Crown guarantee and the resulting exemption from the Pension Protection Fund levy) are intrinsically linked to the 1984 pension package. This package has imposed a considerable financial burden on BT. An expert actuary has determined the net present value of the additional pension liabilities transferred to BT to be GBP […], a sum not normally borne by companies in the private sector. Since that burden far outweighs any amount that would be due to the Pension Protection Fund in the absence of the Crown guarantee, allegedly, there is no overall advantage granted to BT, and therefore no State aid.

(50) BT also argues that it would be contrary to State aid law to characterise as State aid a measure such as the Crown guarantee that was not aid at the time it was granted as a result of an exogenous event such as the creation of the Pension Protection Fund twenty years later which has not altered the provisions of the initial measure. In any event, there is allegedly no transfer of State resources involved.

4.3. **The complainant and other interested parties**

(51) To the extent that the comments of third parties challenge the Commission conclusion set out in the Commission Decision of 28 November 2007 opening the procedure that the Crown guarantee did not, in itself, confer any specific additional advantage on BT, such comments are not related to the object of the present decision and shall not be addressed in this decision.

(52) The complainant points out that, to the extent that the guarantee has an effect on the funding of the pension liabilities, this effect on BT is very substantial since the size of the BTPS' deficit — GBP 3,4 billion in 2006 — is material in comparison to BT's net worth of GBP 1,55 billion at the same time. If the scheme deficit were taken to the balance sheet, this would have affected BT's ratios, ability to borrow and the terms on which it could do so. The different funding requirements of the BTPS allowed by the Crown guarantee would thus procure benefits to BT alone without any need to resort to actual insolvency, on the top of the benefits of protection to beneficiaries of the BTPS.

(53) UKCTA holds the view that the exemption from the minimum funding requirements and the payment of the Pension Protection Fund levy give BT an advantage, which is not justified by the logic of the system. Whilst no protection to beneficiaries of pension schemes under the general regulatory provisions governing occupational pension schemes such as BTPS was available in 1984 when the guarantee was issued, the object of the 1995 and 2004 reforms was to provide efficient protection to beneficiaries which made the Crown guarantee redundant. To exempt a specific company of the general obligation that companies are themselves responsible to set up or participate in arrangements for protection is openly contradictory to the logic of the system.

(54) In particular, as to minimum funding requirements, UKCTA stresses that, by exempting schemes which are covered by the Crown guarantee from the 1995 and 2004 regulatory requirements, the United Kingdom deliberately renounced the possibility to reduce its exposure under the Crown guarantee. Moreover, in that respect, the unilateral decision of BT to contribute to the BTPS beyond what would be required does not have any effect on the liability of the State. A measure does not cease being State aid because it has not yet been used.

5. **ASSESSMENT**

5.1. **Qualification of the measures as State aid**

(55) Article 87(1) of the EC Treaty states:

'Save as otherwise provided in this Treaty, any aid granted by a Member State or through State resources in any form whatsoever which distorts or threatens to distort competition by favouring certain undertakings or the production of certain goods shall, in so far as it affects trade between Member States, be incompatible with the common market.'

(56) In order for Article 87(1) EC to be applicable, there needs to be an aid measure imputable to the State which is granted by State resources, affects trade between Member States and distorts competition in the common market by conferring a selective economic advantage to certain undertakings.

5.1.1. *Aid granted by a Member State or through State resources*

(57) The exemption from the minimum funding requirements laid down in the Pensions Act 1995 and the Pensions Act 2004 and the exemption from the payment of levy to the Pension Protection Fund corresponding to the pension liabilities covered by the Crown guarantee set out in the Pensions Act 2004 result from provisions adopted by the legislative bodies of the United Kingdom. It should be noted that the same is also true with respect to the Crown guarantee. As a result, any aid contained in those measures is granted by the United Kingdom. Furthermore, the exemptions involve State resources because they are the consequence of the Crown guarantee, which involves State resources of the United Kingdom.

(58) Pursuant to the Telecommunications Act 1984, the United Kingdom will discharge any outstanding liability of the successor company which vested in the public corporation BT if BT is wound up. This liability has been limited since 2003 to any outstanding liability for the payment of pensions. If BT is wound up and insolvent that commitment imposes an obligation to pay the relevant part of pension liabilities in relation to the BTPS. In that case, the resources of the United Kingdom would be called to make good any outstanding liability that BT would have otherwise had to pay.

(59) Not only are the financial resources of the United Kingdom committed if BT becomes insolvent, but that commitment is granted for free since it does not concomitantly trigger the regular or deferred payment by BT to the public budget of competent financial bodies of the United Kingdom of any fee or financial compensation whatsoever. It follows that the United Kingdom foregoes the possible revenues and, hence, the State resources which it could obtain from granting the benefit of the Crown guarantee.

(60) The exemption from the minimum funding requirements laid down in the Pensions Act 1995 and the Pensions Act 2005 by virtue of the Crown guarantee and the exemption from the payment of levy to the Pension Protection Fund corresponding to the pension liabilities covered by the Crown guarantee set out in the Pensions Act 2004 are triggered by the existence of a Crown guarantee which involves resources of the United Kingdom. It follows that these exemptions are dependent on and thus involve resources of the United Kingdom within the meaning of Article 87(1) EC.

5.1.2. *(Selective) economic advantage to BT*

(61) Following the comments of the parties on the opening decision, it is necessary to examine whether the exemption from the minimum funding requirements laid down in the Pensions Acts 1995 and the Pensions Act 2004 or the exemption from the payment for a levy to the Pension Protection Fund set out in the Pensions Act 2004 corresponding to the pension liabilities covered by the Crown guarantee have procured an economic advantage to BT.

5.1.2.1. The exemption from the minimum funding requirements laid down in the Pensions Act 1995 and the Pensions Act 2004

(62) The Pensions Act 1995 introduced a minimum funding requirement that the value of the assets of the scheme must not be less than the amounts of the liabilities of the scheme based on a prescribed actuarial methodology for valuation. Pension funds which enjoy a Crown guarantee were exempted from that funding requirement. Part 3 of the Pensions Act 2004 modified the 1995 Act in that it introduced a new scheme of funding requirements and actuarial valuations, from which pension funds with a Crown guarantee are also exempted, provided that they are established by enactment.

(63) Concerning compliance with the minimum funding requirements introduced by the Pensions Act 2004, it follows from the information submitted by the authorities of the United Kingdom that BTPS does not fulfil one of the conditions for exemption, since it was not established by enactment. It follows that BTPS is subject to the minimum funding requirements laid down in the Pensions Act 2004 notwithstanding the existence of the benefit of the Crown guarantee. As a result, BT cannot avail itself from any exemption therein and must meet the requirements of that Act as long as they are in force.

(64) In that respect, the content of the latest BTPS recovery plan, agreed between BT and BTPS trustee in December 2005, was subject to the Pension Regulator's scrutiny. The Pension Regulator is an independent authority set by the Pensions Act 2004 and is in charge of the regulation of pension schemes. The authorities of the United Kingdom formally confirmed that the Pension Regulator was satisfied that the Crown guarantee was not being used to extend the recovery period or affect any of the key assumptions in the actuarial valuation or recovery plan of BTPS.

(65) However, it is necessary to assess whether, by virtue of the Crown guarantee, the exemption from the funding requirements contained in the Pensions Act 1995, which was not subject to the condition of the pension scheme in question having been established by enactment, procured an economic advantage to BT or to BTPS. Any possible advantage would have been present between 1995 and 2004, when those requirements were in force.

(66) Those requirements were defined in particular as to the methodology to be followed for the actuarial valuation of the schemes' position and as to the 10-year period within which any reported deficit had to be made good. The exemption could have, in principle, provided an economic advantage to employer companies like BT whose liabilities in relation to their pension fund are covered by the Crown guarantee. Those companies could have followed more lenient requirements, if at all, as to (i) the obligation to correct any deficit; (ii) the methodology followed to assess the schemes' position as to assets and liabilities; and (iii) the conditions and period for doing so. Indeed, the funds released from not following those requirements could have been used for other economic activities.

(67) In respect of the funding obligation, the rules of BTPS between 1995 and 2004 placed BT under an obligation to correct any deficit identified by the scheme actuary. Although BT could have availed itself of the exemption from the Pensions Act 1995, it did not do so as concerns the obligation of return to full funding.

(68) In respect of the methodology, the authorities of the United Kingdom provided all BTPS' Statement of investment principles since 1996 to the Commission. They always state that the investment policy of BTPS had regard to the minimum funding requirements laid down in the Pensions Act 1995. The authorities of the United Kingdom claim that, in effect, BT funded BTPS as if the minimum funding requirements laid down in the Pensions Act 1995 and the Pensions Act 2004 fully applied to it. The authorities of the United Kingdom have also shown that those requirements were complied with in the valuations carried out in 1999 and 2002, notwithstanding the deficit established according to a different, ongoing valuation, basis. As a matter of fact, BTPS' funding position resulting from the valuations carried out in 1999 and 2002, when the minimum funding requirements of the Pensions Act 1995 were in force, does not disclose any deficit which BT would have been forced to make good in application of those requirements. Although BT could have availed itself of the exemption from the Pensions Act 1995 as concerns the prescribed methodology, it did not do so and actually applied a methodology which placed more stringent obligations on the funding of BTPS' deficit.

(69) In respect of the prescribed period for return to full funding, had a deficit existed under the minimum funding requirements set out in the Pensions Act 1995, the correction needed not to be immediate but could be carried forward within prescribed periods of 10 years or less. It is true that BT was, and still is, obliged under the rules of BTPS to repair any deficit between the scheme assets and liabilities reported on an actuarial valuation, […]. However, in the absence of any deficit of the BTPS under the methodology prescribed by the Pensions Act 1995, the longer period within which BT could have corrected it as compared with the Act does not appear to have provided an actual economic advantage to BT.

(70) The Commission notes the argument made by third parties that a measure does not cease being State aid because it has not yet been used. However, in the current circumstances, the measure in question is no longer in force and there is no evidence of an economic benefit having accrued to BP between 1995 and 2004.

(71) In these circumstances, the Commission considers that it is not established that the exemption from the minimum funding requirements laid down in the Pensions Act 1995 and, even less so, the rules contained in the Pensions Act 2004 have procured or still procure an economic advantage to BT. There is therefore no State aid in this respect since the cumulative conditions laid down by Article 87(1) of the EC Treaty are not fulfilled.

5.1.2.2. The exemption from the payment of levy to the Pension Protection Fund corresponding to the pension liabilities covered by the Crown guarantee set out in the Pensions Act 2004

(72) The Pensions Act 2004 created the Pension Protection Fund, to which pension funds generally have to contribute by paying an annual levy, unless they benefit from a Crown guarantee and are as a result exempted from this payment. As from 2004, the Pension Protection Fund general system has been established and occupational pension schemes, and indirectly employers, have to make contributions to the Pension Protection Fund, which guarantees the employees of any contributor scheme. In other words, the general system is that additional protection must be paid by the employers in the form of the payment of a full levy.

(73) Under the Pension Protection Fund entry rules regulations, the section of BTPS for the part of its employees' pension rights guaranteed by the Crown is exempted. Therefore, BTPS levy is calculated by the Pension Protection Fund excluding all members of the scheme who joined before privatisation on the understanding that section 68 of the 1984 Act guarantees the liability of BT to make contributions to BTPS in respect of these members. As a result, there is a difference between the Pension Protection Fund levy which the BTPS actually paid since 2005 and the levy which the BTPS would have paid had the existence of the Crown guarantee been ignored.

(74) For instance, the levy which BTPS paid in 2005/2006 was GBP […] whilst the putative levy payable without the Crown guarantee would have been GBP […] In other words, the fee actually paid amounted to less than […] of the amount which the BTPS would have had to pay without the Crown guarantee. For subsequent years, the fee payable if the existence of the Crown guarantee had been ignored would have been GBP […] in 2006/2007 and GBP […] in 2007/2008.

(75) The Commission does not consider that the reduction of the levy to be paid to the Pension Protection Fund is justified 'by the logic of the system'. The Commission considers that the 'system' set out in the United Kingdom for the protection of pension rights cannot be regarded as constituted by the Pension Protection Fund alone. Rather, all measures established in order to achieve protection of pensions must be taken into consideration. In case BT becomes insolvent and its pension fund is in deficit, the pensions of the pre-privatisation employees concerned will be paid by the State, rather than by the privately funded Pension Protection Fund, as would be the case if the normal rules had applied. As indicated above, the BTPS obtains the protection of the Crown guarantee without any payment. The only 'logic' apparent in this case is that where State resources are made available for the protection of an undertaking's pension scheme, private provision becomes superfluous.

(76) The argument put forward by the authorities of the United Kingdom to the effect that the protection system set out by the Pension Protection Fund only applies in the absence of other adequate protection arrangements being put in place, such as a Crown guarantee, disregards the fact that the protective arrangements from which the BTPS benefits are made available at no cost to BT. Even if one were to admit that the Pension Protection Fund is as a 'safety net' intended only for pension schemes not benefiting from adequate protection in case of insolvency of the employer, the fact remains that BT does not pay for such protection as concerns the pension rights of pre-privatisation employees and has been supplemented by the State for the provision of the adequate protection which the United Kingdom deems it necessary to put in place for other employees of occupational pension schemes. Indeed, as concerns its post-privatisation employees whose rights are not covered by the Crown guarantee, BTPS benefits from and contributes to the Pension Protection Fund.

(77) Nor does the Commission share the view put forward by BT and BTPS that a measure which was allegedly not aid in 1984 when it was granted cannot be characterised as aid 20 years later as a result of exogenous events. The Commission firstly points out that it does not find the guarantee to be, in itself, an aid to BT. As the Commission noted in its decision of 28 November 2007, the Crown guarantee on pension liabilities was made for the benefit of the said employees and did not confer an economic advantage directly to BT. The guarantee does however now constitute the underlying reason why BT receives an advantage in the form of the derogation from the full levy to finance the Pension Protection Fund which was introduced by the Pensions Act 2004, which BT pays only as far as its post-privatisation employees are concerned. That derogation could not exist at the time when the Crown guarantee was issued because there was no obligation to contribute to the same or a similar fund, but the guarantee is recognised by the Pensions Act 2004 as justification for the derogation.

(78) The allegation by BT and BTPS that the creation of the obligation to contribute is exogenous to the Crown guarantee disregards the fact that the nature of the benefit and the beneficiary are not the same in 1984 and in 2004. The coverage of pension rights in case of BT insolvency is a benefit for pre-privatisation employees in that it guarantees the payment of the rights which accrue to them. However, the exemption from the Pension Protection Fund and the payment of the full levy is a benefit for BT insofar as it diminishes the levy which would otherwise be due and that exemption owes to the existence of the Crown guarantee.

(79) The Commission also rejects the argument that no advantage is present on the grounds that this guarantee has already been paid by BT's shareholders in the overall price that they paid for the company in 1984. As explained in the decision of 28 November 2007, the Commission concluded on the basis of the information available that the Crown guarantee in itself, as far as it covers BT's pension liabilities, did not confer any advantage to BT at the time it was granted and there is therefore no reason to assume that BT's shareholders paid a premium for an advantage for certain employees that would only materialise in the event of BT's insolvency. It did not imply any advantage until 2004, when its implications were substantially changed by the legislation. At the time of the privatisation, the Crown guarantee on pension liabilities had no discernible value for BT's shareholders in view of subsequent and unforeseeable modifications to pension legislation. In 1984, it was not possible to anticipate any obligation for BT to contribute to the Pension Protection Fund established in 2004, nor the potential economic advantage resulting from the exemption from these obligations by virtue of a Crown guarantee.

(80) BTPS also argues that the potential advantage deriving from the lower levies to the Pension Protection Fund is more than compensated by extra liabilities and financial burdens of GBP […] borne by BT and BTPS because of the special nature of BTPS. The Commission does not consider that the alleged disadvantages could be used to offset this advantage:

— first, the benefit secured to employees in case of BT bankruptcy was of little interest, if any, to BT shareholders,

— secondly, there is no temporal link between these alleged disadvantages and the advantage resulting from a reduced contribution to the Pension Protection Fund, which materialised 20 years later and for which there is no indication in the law that it was intended to offset the alleged disadvantages. Nor is there a discernable substantive link between the alleged burdens placed on BT and the liabilities covered by the Crown guarantee which in 1984 also included, inter alia, short-term borrowings, trade creditors, value added tax and payroll taxes and foreign long-term loans,

— thirdly, BT refers to the burdens of extra liabilities of civil servant-like rights. One cannot, however, exclude that those rights have, in turn, triggered benefits for BT such as increased loyalty or acceptance of different salary and working conditions by the employees concerned than if those rights had not existed.

(81) Contrary to other undertakings in the electronic communications and other sectors which are not given the benefit of the exemption from the payment of levy to the Pension Protection Fund set out in the 2004 Pension Act and corresponding to the pension liabilities covered by the Crown guarantee, BT obtains an economic advantage in that it pays a greatly reduced levy to the Pension Protection Fund. As a result, BT can use these financial resources to finance its economic activities on the markets where it is active.

(82) In conclusion, an economic advantage financed by the State appears to have been granted to BT from the entry into force of the Pension Protection Fund (Entry Rules) Regulations 2005.

5.1.3. *Undertaking benefiting from selective measures*

(83) As concerns the beneficiary of the measures at hand, it must be underlined that BTPS and BT are two different legal entities. The exemption from payment of an adequate Pension Protection Fund levy directly concerns BTPS, whose trustees have responsibility for the payment. For instance, the 2005/2006 fee payable by BTPS was allegedly funded from the assets of the scheme. However, BT must contribute to cover any deficit and administrative costs of its pension scheme as long as it is solvent. Even if BT is not itself invoiced and does not disburse the amount of the pension protection levy when it becomes due, a lower levy decreases the costs of BTPS and is to the benefit of the assets of BTPS, thus diminishing BT's own liabilities towards BTPS. It follows that any economic advantage for BTPS resulting from the measure at hand is entirely transferred to BT.

(84) Moreover, the measure is selective in that the provision in the Pension Protection Fund (Entry Rules) Regulations 2005 implementing the Pensions Act 2004 granting an exemption from the Pension Protection Fund levy is selective because it resulted from having the benefit of the Crown guarantee, laid down in the 1984 Act which addressed liabilities vested on BT only. Those measures, when read together, introduced derogations from the general obligations imposed by the Pension Acts on other undertakings not having such a benefit and are therefore selective.

5.1.4. *Distortion of competition affecting trade between Member States*

(85) BT, through various subsidiaries, is significantly active in the provision of electronic communication services in several Member States including Germany, Italy, Spain, The Netherlands, France and, not least, in the United Kingdom ([1]). The provision of electronic communication services inherently entails communication of content between networks across borders within the common market, whether such services are supplied on a local, national or cross-border basis.

(86) Particularly in the United Kingdom, the regulatory authority for electronic communications OFCOM has identified BT as holding significant market power within the meaning of the EU regulatory framework on electronic communication services and networks on a number of retail and wholesale service markets. Those markets include all or parts of the markets for fixed narrowband retail services, fixed narrowband wholesale exchange lines, call origination and conveyance, wholesale broadband access, wholesale local access and leased lines ([2]). On all these service markets in the United Kingdom, BT competes with significantly weaker competitors, which do not enjoy the economic advantage to their contribution to the Pension Protection Fund which the Crown guarantee confers on BT. Competition between those undertakings and BT, which is weakened as a result of the significant market power which BT holds, is thereby further distorted by the measure at stake.

(87) Given BT's activities and position in national and international markets for electronic communications, this advantage may affect competition and trade between Member States within the meaning of Article 87(1) of the EC Treaty.

(88) In conclusion, the exemption from the payment of a levy to the Pension Protection Fund corresponding to the pension liabilities covered by the Crown guarantee conferred on BT's pension liabilities confers an economic advantage on BT through the use of State resources imputable to the United Kingdom. This advantage is liable to affect competition and trade between Member States within the meaning of Article 87(1) of the EC Treaty.

5.1.5. *Lawfulness of the measure*

(89) Since the enactment of the Pensions Act 2004 and the Pension Protection Fund (Entry Rules) Regulations 2005, an advantage is granted to BT in the form of an exemption from the full contribution to the Pension Protection Fund.

(90) This exemption constitutes State aid within the meaning of Article 87(1) of the EC Treaty and has not been notified to the Commission pursuant to Article 88(3) of the EC Treaty. As a result, this measure is unlawful.

5.2. **Assessment of compatibility of the measures**

(91) Since the presence of State aid in the form of an exemption from full contribution to the Pension Protection Fund levy is confirmed, it is necessary to consider the compatibility of such State aid under Community rules. In that respect, neither the United Kingdom nor BT or BTPS have argued that the measures at hand can be found to be compatible with the common market.

5.2.1. *Article 86(2) EC*

(92) Although BT is entrusted with certain obligations of general economic interest, within the meaning of Article 86(2) EC, the aid is not confined or otherwise connected to the fulfilment of those obligations and, therefore, benefits the entirety of its activities. Nor do the authorities of the United Kingdom or BT argue that the payment of a full levy to the Pension Protection Fund would obstruct the performance of the tasks of general interest assigned to BT. In those circumstances, the derogation provided for Article 86(2) of the EC Treaty is not applicable.

5.2.2. *Articles 87(2) and 87(3) EC*

(93) The measure involved does not appear to be compatible under Article 87(2) of the EC Treaty either. In particular, Article 87(2)(a) of the EC Treaty concerns aid with a social character granted to individual consumers. The State aid discussed benefits BT itself. Consequently, such aid would not fall within the scope of Article 87(2)(a) of the EC Treaty.

([1]) See http://www.btplc.com/Report/Report08/pdf/AnnualReport2008.pdf

([2]) See http://www.btplc.com/Report/Report08/pdf/AnnualReport2008.pdf. See also, OFCOM Notice under section 155(1) of the Enterprise Act 2002 of 30 June 2005, at http://www.ofcom.org.uk/consult/condocs/sec155/sec155.pdf and Final statements on the strategic review of telecommunications, and undertakings in lieu of a reference under the Enterprise Act 2002, 22 September 2005, at: http://www.ofcom.org.uk/consult/condocs/statement_tsr/statement.pdf

(94) Furthermore, the Commission considers that Article 87(3)(a), 87(3)(b) and 87(3)(d) of the EC Treaty are manifestly not applicable and neither the authorities of the United Kingdom nor BT or the BTPS have put forward arguments in this respect.

(95) The only possible basis for compatibility for the measure at stake would at this stage appear to be Article 87(3)(c) of the EC Treaty. However, the measure involved does not appear to comply with any of the rules concerning the application of that sub-paragraph that the Commission has promulgated to date in the form of guidelines and communications. Consequently, the compatibility of this measure, would have to be assessed directly on the basis of Article 87(3)(c) of the EC Treaty, which states that: 'aid to facilitate the development of certain economic activities or of certain economic areas, where such aid does not adversely affect trading conditions to an extent contrary to the common interest' may be considered to be compatible with the common market.

(96) In order to be compatible under Article 87(3)(c) of the EC Treaty, an aid must pursue an objective of common interest in a necessary and proportionate way. In this regard, the Commission considers it appropriate to assess the following questions:

1. Is the aid measure aimed at a well-defined objective of common interest (namely, does the proposed aid address a market failure or other objective)?

2. Is the aid well designed to deliver the objective of common interest? In particular:

   — is the aid measure an appropriate instrument?

   — is there an incentive effect, namely, does the aid change the behaviour of firms?

   — is the aid measure proportional, that is, could the same change in behaviour be obtained with less aid?

3. Are the distortions of competition and the effect on trade limited, so that the overall balance is positive?

(97) The United Kingdom has not indicated that the measure at stake was designed to deliver a particular objective of common interest. Furthermore, there are no discernible indications or grounds showing that the provision of the State aid at hand is an adequate and proportionate instrument which provides any suitable incentive effect for the development of the economic activities in which BT, among other competitors, is engaged. As indicated above, the measure at hand is neither related to nor confined to the fulfilment of the mission of general economic interest entrusted to BT.

(98) Therefore, the only discernable objective of common interest which could be pursued by the relevant provisions of the pension legislation appears to be the supplementary protection of pension rights of workers in case of insolvency of their employer. The additional guarantee that retired workers will effectively enjoy financial well-being which is commensurate with their labour during their working life is in the common interest of the general and socially balanced development of economic activities. However, by establishing a derogation on the levy payable by BTPS, the aid measure does not contribute to fulfilling those objectives.

(99) Likewise, according to the United Kingdom, the pension protection measures may offer protection only where that other alternative and adequate protection does not exist. In that case, the Pensions Act 2004 could also be seen as providing an incentive to companies putting in place on their own, and at their own cost, alternative arrangements or mechanisms that would exclude the contribution of a levy to and reliance on the general Pension Protection Fund. However, the aid measure without any countervailing payment eliminates any incentive for BT putting in place any alternative arrangements. On the contrary, if the aid was suppressed, BT would be incentivised to do so or, at the very least, would rely on the privately funded Pension Protection Fund to guarantee the pension rights of its pre-privatisation employees.

(100) It follows that the aid measure is not an appropriate instrument in pursuing the objective of common interest which can be identified in the pension legislation of the United Kingdom. On the contrary, the aid relieves BTPS and, hence, BT, of the operating costs which the pursuance of such objective should normally trigger for them. As a result, the negative effects of the operating aid measure in trade between Member States and competition are not outweighed by other positive effects in other respects, so that the balance is, overall, negative.

(101) The Commission therefore concludes that the exemption from full contribution to the Pension Protection Fund levy cannot be declared compatible with the common market pursuant to Article 86(2) of the EC Treaty or Article 87(3) of the EC Treaty.

6. **CONCLUSION**

(102) In the light of the foregoing, the Commission concludes that the exemption from the payment of a levy to the Pension Protection Fund corresponding to the pension liabilities covered by the Crown guarantee conferred on BT's pension liabilities constitutes State aid within the meaning of Article 87(1) EC, which cannot be declared compatible with the common market.

7. **RECOVERY**

(103) According to Article 14(1) of Council Regulation (EC) No 659/1999 ([1]), where negative decisions are taken in cases of unlawful aid, the Commission shall decide that the Member State concerned shall take all necessary measures to recover the aid from the beneficiary. Only aid which is incompatible with the common market shall be recovered.

(104) The purpose of recovery is to restore the situation that existed prior to the granting of the aid. This is achieved once the incompatible aid is repaid by BT, which therefore forfeits the advantage which it enjoyed over its competitors in the market since BTPS has not paid a full levy to the Pension Protection Fund since 2005. The amount to be recovered should be such as to eliminate the economic advantage given to BT which, for the reasons set out above at recital 83, is the beneficiary of the measure.

(105) Since the incompatible aid to BT is equal to the difference between the levy to the Pension Protection Fund due in the absence of the Crown guarantee since the establishment of the fund in 2005 and the fee which BTPS effectively paid, that difference constitutes the amount to be recovered, plus the recovery interest effectively accrued on that amount, which cannot be lower than as calculated pursuant to Article 9 of Commission Regulation (EC) No 794/2004 of 21 April 2004 implementing Council Regulation (EC) No 659/1999 ([2]).

(106) It should be noted that according to the information supplied by the United Kingdom on 29 March 2007, the Board of the Pension Protection Fund, BT and BTPS trustee entered into an escrow arrangement to the effect of blocking into an escrow account the difference between the sum which BTPS would have had to pay in 2005/2006 had the Crown guarantee not been taken into account, and the amount actually paid by BTPS. In subsequent years, BTPS has been due to pay into the escrow account the sum which BTPS would have had to pay had the Crown guarantee not been taken into account. Those amounts attract interest at […], which, according to the United Kingdom, is […].

(107) According to the provisions of the escrow agreement, these arrangements continue until the Commission concludes its investigation into whether the reduction in the Pension Protection Fund levies constitutes an incompatible aid or decides not to pursue the matter any further. In the former case, the final amount invoiced by the Pension Protection Fund for the pension protection levies shall also include the interest accrued on the amounts paid into the escrow account. […] shall therefore accrue to the Pension Protection Fund in case the Commission adopts an incompatible aid decision and not to the BTPS or to BT. This should ensure that the interest accrued on the escrow account does not further increase the economic advantage which BT has been granted,

HAS ADOPTED THIS DECISION:

Article 1

The State aid unlawfully put into effect by the United Kingdom of Great Britain and Northern Ireland for BT plc, the beneficiary, in the form of an exemption for the BT Pension Fund contribution to the Pension Protection Fund as concerns the beneficiary's pension liabilities covered by section 68(2) of the Telecommunications Act 1984 as amended, is incompatible with the common market within the meaning of Article 87(1) of the EC Treaty.

The United Kingdom of Great Britain and Northern Ireland shall cease the incompatible State aid to BT plc.

Article 2

The United Kingdom of Great Britain and Northern Ireland shall recover the aid referred to in Article 1 from the beneficiary.

The sum to be recovered shall bear interest for the entire period running from the date it was put into effect until the date of its recovery.

The interest shall be calculated as capitalised interest in conformity with Chapter V of Regulation (EC) No 794/2004.

Article 3

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

The United Kingdom of Great Britain and Northern Ireland shall ensure that this Decision is implemented within four months of the date of its notification.

Article 4

Within two months following notification of this Decision, the United Kingdom of Great Britain and Northern Ireland shall submit the following information to the Commission:

([1]) Council Regulation (EC) No 659/1999 of 22 March 1999 laying down detailed rules for the application of Article 93 (now Article 88) of the EC Treaty (OJ L 83, 27.3.1999, p. 1).

([2]) OJ L 140, 30.4.2004, p. 1.

(a) the total amount to be recovered from the beneficiary;

(b) a detailed description of the measures already taken and planned to comply with this Decision; and

(c) documentary evidence that the beneficiary has been ordered to repay the aid.

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

Article 5

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

Done at Brussels, 11 February 2009.

For the Commission

Neelie KROES

Member of the Commission

CORRIGENDA

Corrigendum to Commission Regulation (EC) No 734/2009 of 11 August 2009 initiating an investigation concerning the possible circumvention of anti-dumping measures imposed by Council Regulation (EC) No 1858/2005 on imports of steel ropes and cables originating in the People's Republic of China by imports of steel ropes and cables consigned from the Republic of Korea and Malaysia, whether declared as originating in the Republic of Korea and Malaysia or not, and making such imports subject to registration

(Official Journal of the European Union L 208 of 12 August 2009)

On page 9, Article 1:

for: 'consigned from the Republic of Korea and Malaysia or not, whether declared as originating in the Republic of Korea and Malaysia or not',

read: 'consigned from the Republic of Korea and Malaysia, whether declared as originating in the Republic of Korea and Malaysia or not'.

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