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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.

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EN

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

REGULATIONS

**REGULATION (EC) No 1069/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 21 October 2009**

laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 152(4)(b) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee ⁽¹⁾,

Having consulted the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty ⁽²⁾,

Whereas:

(1) Animal by-products not intended for human consumption are a potential source of risks to public and animal health. Past crises related to outbreaks of foot-and-mouth disease, the spread of transmissible spongiform encephalopathies such as bovine spongiform encephalopathy (BSE) and the occurrence of dioxins in feedingstuffs have shown the consequences of the improper use of certain animal by-products for public and animal health, the safety of the food and feed chain and consumer confidence. In addition, such crises may also have a wider adverse impact on society as a whole, by their impact on the socioeconomic situation of the farmers and of the industrial sectors concerned and on consumer confidence in the safety of products of animal origin. Disease outbreaks could also have negative consequences for the environment, not only due to the disposal problems posed, but also as regards biodiversity.

(2) Animal by-products arise mainly during the slaughter of animals for human consumption, during the production of products of animal origin such as dairy products, and in the course of the disposal of dead animals and during disease control measures. Regardless of their source, they pose a potential risk to public and animal health and the environment. This risk needs to be adequately controlled, either by directing such products towards safe means of disposal or by using them for different purposes, provided that strict conditions are applied which minimise the health risks involved.

(3) The disposal of all animal by-products is not a realistic option, as it would lead to unsustainable costs and risks for the environment. Conversely, there is a clear interest for all citizens that, provided the health risks are minimised, a wide range of animal by-products are safely used for various applications in a sustainable manner. A wide range of animal by-products are indeed commonly used in important productive sectors, such as the pharmaceutical, feed and leather industries.

(4) New technologies have widened the possible use of animal by-products or derived products to a large number of productive sectors, in particular for the generation of energy. However, the use of those new technologies might pose health risks that must also be minimised.

(5) Community health rules for collection, transport, handling, treatment, transformation, processing, storage, placing on the market, distribution, use or disposal of animal by-products should be laid down in a coherent and comprehensive framework.

(6) Those general rules should be proportionate to the risk to public and animal health which animal by-products pose when they are dealt with by operators at different stages of

⁽¹⁾ OJ C 100, 30.4.2009, p. 133.

⁽²⁾ Opinion of the European Parliament of 24 April 2009 (not yet published in the Official Journal) and Council Decision of 7 September 2009.

the chain from collection to their use or disposal. The rules should also take into account the risks for the environment posed during those operations. The Community framework should include health rules on the placing on the market, including intra-Community trade and import, of animal by-products, where appropriate.

- (7) In Regulation (EC) No 1774/2002 ⁽¹⁾, the European Parliament and the Council laid down Community health rules concerning animal by-products not intended for human consumption. Based on scientific advice and as an action under the Commission White Paper of 12 January 2000 on Food Safety, that Regulation introduced a set of rules aimed at protecting the safety of the food and feed chain, which is complementary to Community legislation on food and feed. Those rules have significantly improved the level of protection in the Community against the risks posed by animal by-products.
- (8) Regulation (EC) No 1774/2002 introduced the classification of animal by-products into three categories according to the degree of risk involved. It requires operators to keep animal by-products of different categories separate from each other if they wish to make use of animal by-products which do not pose a significant risk to public or animal health, in particular if such products are derived from material fit for human consumption. That Regulation also introduced the principle that high-risk material should not be fed to farmed animals, and that material derived from animals is not to be fed to animals of the species from which it is derived. Pursuant to that Regulation, only material from animals which have undergone veterinary inspection is to enter the feed chain. In addition, it lays down rules for processing standards which ensure the reduction of risks.
- (9) Under Article 35(2) of Regulation (EC) No 1774/2002, the Commission is to submit a report to the European Parliament and to the Council on the measures taken by the Member States to ensure compliance with that Regulation. The report is to be accompanied, if appropriate, by legislative proposals. The report was submitted on 21 October 2005 and emphasised that the principles of Regulation (EC) No 1774/2002 should be maintained. In addition, it highlighted the areas where amendments to that Regulation were considered necessary, in particular clarifications as regards the applicability of the rules to finished products, the relationship with other Community legislation and the classification of certain material. The findings of a series of fact-finding missions carried out in the Member States by the Food and Veterinary Office of the Commission (FVO) in 2004 and 2005 support those conclusions. According to the FVO, improvements are necessary as regards the traceability of the flow of animal by-products and the effectiveness and harmonisation of official controls.
- (10) The Scientific Steering Committee, which was superseded by the European Food Safety Authority (EFSA) in 2002, has adopted a number of opinions concerning animal by-products. Those opinions demonstrate the need to maintain the main principles of Regulation (EC) No 1774/2002; in particular that animal by-products derived from animals shown not to be fit for human consumption as a result of a health inspection should not enter the feed chain. However, those animal by-products may be recovered and used for the production of technical or industrial products under specified health conditions.
- (11) The conclusions of the Presidency of the Council on the Commission report of 21 October 2005 which were adopted in December 2005, and the subsequent consultations carried out by the Commission, have highlighted that the rules laid down in Regulation (EC) No 1774/2002 should be improved. The chief objectives of the rules on animal by-products, namely the control of risks to public and animal health and the protection of the safety of the food and feed chain, should be clearly laid down. The provisions of this Regulation should permit the achievement of those objectives.
- (12) The rules on animal by-products laid down in this Regulation should apply to products that may not be used for human consumption under Community legislation, in particular where they do not comply with food hygiene legislation or where they may not be placed on the market as food since they are unsafe either because they are injurious to health or unfit for human consumption (animal by-products 'by law'). Those rules should, however, also apply to products of animal origin which do comply with certain rules regarding their possible use for human consumption, or which are raw materials for the production of products for human consumption, even if they are eventually destined for other purposes (animal by-products 'by choice').
- (13) In addition, in order to prevent risks arising from wild animals, bodies or parts of bodies of such animals suspected of being infected with a transmissible disease should be subject to the rules laid down in this Regulation. This inclusion should not imply an obligation to collect and dispose of bodies of wild animals that have died or that are hunted in their natural habitat. If good hunting practices are observed, intestines and other body parts of wild game may be disposed of safely on site. Such practices for the mitigation of risks are well-established in Member States and are in some cases based on cultural traditions or on national legislation which regulates the activities of hunters. Community legislation, in particular Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin ⁽²⁾, lays down rules for handling of meat and animal by-products from wild game. Those rules

⁽¹⁾ OJ L 273, 10.10.2002, p. 1.

⁽²⁾ OJ L 139, 30.4.2004, p. 55.

- also place the responsibility for the prevention of risks on trained persons such as hunters. In view of the potential risks for the food chain, animal by-products from killed wild game should only be subject to this Regulation in so far as food hygiene legislation applies to the placing on the market of such game and involves operations carried out by game-handling establishments. In addition, animal by-products for the preparation of game trophies should be covered by this Regulation in order to prevent animal health risks arising from such by-products.
- (14) The rules laid down in this Regulation should apply to animal by-products derived from aquatic animals, other than material from vessels operating under Community food hygiene legislation. However, risk-proportionate measures should be adopted as regards the handling and disposal of material which arises on board fishing vessels from the evisceration of fish and which shows signs of disease. Such measures for the implementation of this Regulation should be adopted on the basis of a risk assessment carried out by the appropriate scientific institution in view of the available evidence regarding the effectiveness of certain measures to combat the spread of diseases communicable to humans, in particular of certain parasites.
- (15) Due to the limited risks arising from materials used as raw pet food on farm or supplied to end users by food businesses, certain activities related to such raw pet food should not be covered by the rules laid down in this Regulation.
- (16) It is appropriate to clarify in this Regulation which animals are to be classified as pet animals, so that by-products derived from such animals are not used in feed for farmed animals. In particular, animals kept for purposes other than farming, such as for companionship, should be classified as pet animals.
- (17) For the sake of consistency of Community legislation, certain definitions set out in Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies ⁽¹⁾ and in Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste ⁽²⁾ should be used in this Regulation. The reference to Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes ⁽³⁾ should be clarified.
- (18) For the sake of consistency of Community legislation, the definition of 'aquatic animal' as laid down in Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals ⁽⁴⁾ should be used in this Regulation. At the same time, aquatic invertebrates which are not covered by that definition and which pose no risk of disease transmission should be subject to the same requirements as aquatic animals.
- (19) Council Directive 1999/31/EC of 26 April 1999 on the landfill of waste ⁽⁵⁾ specifies the conditions for the issuing of a permit for a landfill. This Regulation should provide for the disposal of animal by-products on landfills for which such a permit has been issued.
- (20) The primary responsibility for carrying out operations in accordance with this Regulation should rest with operators. At the same time, the public interest in preventing risks to public and animal health requires that a collection and disposal system is in place to ensure the safe use or the safe disposal of animal by-products which may not be used, or which are not used for economic reasons. The scope of the collection and disposal system should take into account the actual amount of animal by-products which accrue in the particular Member State. It should also reflect, on a precautionary basis, the need for extended disposal capacities in the event of major outbreaks of transmissible diseases or of temporary technical failures in an existing disposal facility. Member States should be permitted to cooperate with each other and third countries provided that the objectives of this Regulation are met.
- (21) It is important to determine the starting point in the life cycle of animal by-products from which the requirements of this Regulation should apply. Once a product has become an animal by-product, it should not re-enter the food chain. Special circumstances apply for the handling of certain raw materials, such as hides, handled in establishments or plants integrated at the same time into the food chain and the animal by-products chain. In those cases, the necessary measures should be taken by means of segregation to mitigate potential risks for the food chain which can arise from cross-contamination. For other establishments, risk-based conditions should be determined to prevent cross-contamination, in particular through separation between the animal by-products chain and the food chain.
- (22) For reasons of legal certainty and proper control of potential risks, an end point in the manufacturing chain should be determined for products which no longer have direct

⁽¹⁾ OJ L 147, 31.5.2001, p. 1.

⁽²⁾ OJ L 312, 22.11.2008, p. 3.

⁽³⁾ OJ L 358, 18.12.1986, p. 1.

⁽⁴⁾ OJ L 328, 24.11.2006, p. 14.

⁽⁵⁾ OJ L 182, 16.7.1999, p. 1.

relevance for the safety of the feed chain. For certain products regulated under other Community legislation, such an end point should be determined at the stage of manufacturing. Products which have reached this end point should be exempt from controls under this Regulation. In particular, products beyond the end point should be allowed to be placed on the market without restriction under this Regulation and to be handled and transported by operators which have not been approved or registered in accordance with this Regulation.

- (23) However, it should be possible to modify such an end point, particularly in the case of newly emerging risks. Regulation (EC) No 1774/2002 exempts certain products, notably guano, certain hides to which particular forms of treatment such as tanning have been applied, and certain game trophies from its requirements. Similar exemptions should be provided for in the implementing measures to be adopted under this Regulation for products such as oleochemical products and the end products resulting from the production of biodiesel, under appropriate conditions.
- (24) In order to ensure a high level of protection of public and animal health, Member States should continue to take the necessary measures to prevent the dispatch of animal by-products from restricted areas or establishments, in particular in the event of an outbreak of a disease listed in Council Directive 92/119/EEC of 17 December 1992 introducing general Community measures for the control of certain animal diseases and specific measures relating to swine vesicular disease ⁽¹⁾.
- (25) Operations with animal by-products which give rise to a considerable degree of risk to public and animal health should only be carried out in establishments or plants which have been approved in advance for such operations by the competent authority. That condition should apply in particular to processing establishments or plants and other establishments or plants which handle or store animal by-products with a direct relevance for the safety of the feed chain. It should be permitted for animal by-products of more than one category to be handled in the same establishment or plant provided cross-contamination is prevented. It should further be permitted to amend those conditions if the amount of material for disposal and processing rises due to a major outbreak of disease, provided it is ensured that the temporary use under such amended conditions does not lead to the propagation of disease risks.
- (26) However, such approvals should not be necessary for establishments or plants which process or handle certain safe materials, such as products processed to such an extent that they no longer pose a risk to public and animal health.

Such establishments or plants should be registered so as to permit official control over the flow of material and ensure their traceability. That registration requirement should apply also to operators who transport animal by-products or derived products, unless they are no longer subject to any control since an end point in the chain has been determined.

- (27) Establishments or plants should be approved following the submission of information to the competent authority and following a visit carried out on site which demonstrates that the requirements of this Regulation for the infrastructure and equipment of the establishment or plant will be met, so that any risks to public and animal health arising from the process used will be adequately contained. It should be possible to grant the approvals conditionally in order to allow operators to rectify deficiencies before the establishment or plant obtains full approval.
- (28) Establishments or plants whose operations have already been approved in accordance with Community legislation on food hygiene should not be required to be approved or registered under this Regulation, as approvals or registrations under that Community legislation already take into account the objectives of this Regulation. However, establishments or plants which have been approved or registered under hygiene legislation should be obliged to comply with the requirements of this Regulation and subject to official controls carried out for the purposes of verifying compliance with the requirements of this Regulation.
- (29) Animal by-products and derived products should be classified into three categories which reflect the degree of risk that they pose to public and animal health, on the basis of risk assessments. While animal by-products and derived products posing a high risk should only be used for purposes outside the feed chain, their use posing a lower risk should be permitted under safe conditions.
- (30) Progress in science and technology may lead to the development of processes which eliminate or minimise the risks to public and animal health. Amendments to the lists of animal by-products set out in this Regulation should be possible, in order to take account of such progress. Prior to any such amendments, and in accordance with the general principles of Community legislation aimed at ensuring a high level of protection of public and animal health, a risk assessment should be carried out by the appropriate scientific institution, such as EFSA, the European Medicines Agency or the Scientific Committee for Consumer Products, depending on the type of animal by-products for which risks are to be assessed. However, it should be clear that once animal by-products of different categories are mixed, the mixture should be handled in accordance with the standards laid down for the proportion of the mixture belonging to the highest risk category.

⁽¹⁾ OJ L 62, 15.3.1993, p. 69.

- (31) Due to the high risk to public health, animal by-products giving rise to a risk of transmissible spongiform encephalopathy (TSE) should, in particular, not be used for feed. This restriction should also apply to wild animals through which a communicable disease may be transmitted. The restriction on the feeding of animal by-products giving rise to a TSE risk should be without prejudice to the feeding rules laid down in Regulation (EC) No 999/2001.
- (32) Animal by-products from animals used for experiments as defined in Directive 86/609/EEC should also be excluded from use in feed, due to the potential risks arising from those animal by-products. However, Member States may allow the use of animal by-products from animals which have been used for experiments to test new feed additives, in accordance with Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ⁽¹⁾.
- (33) The use of certain substances and products is unlawful under Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in food stuffs of animal origin ⁽²⁾ and Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of β agonists ⁽³⁾. In addition, Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products ⁽⁴⁾ lays down further rules on the monitoring of certain substances and residues thereof in live animals and animal products. Directive 96/23/EC also lays down rules which apply where the presence of residues of authorised substances or contaminants exceeding certain permitted levels has been established. In order to ensure the coherence of Community legislation, products of animal origin in which substances are detected in breach of Regulation (EEC) No 2377/90 and Directives 96/22/EC and 96/23/EC should be classified as Category 1 or Category 2 material, as appropriate, in view of the risk they pose to the food and feed chain.
- (34) Manure and digestive tract content should not need to be disposed of, provided that proper treatment ensures that diseases are not transmitted during their application to land. Animal by-products from animals that die on farm and animals killed for the eradication of diseases should not be used in the feed chain. This restriction should also apply to imported animal by-products which are allowed into the Community, where they do not comply with Community legislation upon inspection at the Community border post, and to products which do not comply with the applicable requirements during checks carried out within the Community. Non-compliance with Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs ⁽⁵⁾ and with Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed ⁽⁶⁾ should not result in the exclusion from the feed chain of products presented for border inspection.
- (35) Since the date of entry into force of Regulation (EC) No 1774/2002, the classification of certain animal by-products by default as Category 2 material limits their possible uses severely, while not necessarily being proportionate to the risks involved. Accordingly those animal by-products should be reclassified as Category 3 material, so as to allow their use for certain feeding purposes. For any other animal by-products which are not listed under one of the three categories, the categorisation by default as Category 2 material should be maintained for precautionary reasons, in particular to reinforce the general exclusion of such material from the feed chain for farmed animals, other than fur animals.
- (36) Other legislation which has entered into force following the adoption of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety ⁽⁷⁾, namely Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs ⁽⁸⁾, Regulation (EC) No 853/2004 and Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene ⁽⁹⁾, and to which Regulation (EC) No 1774/2002 is complementary, places the primary duty of complying with Community legislation, aimed at protecting public and animal health, on the food and feed business operators. In line with that legislation, operators carrying out activities under this Regulation should also be primarily responsible for ensuring compliance with this Regulation. That obligation should be further clarified and specified as regards the means by which traceability is ensured, such as separate collection and channelling of animal by-products. Established systems ensuring traceability for products exclusively circulating at national level by

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ OJ L 224, 18.8.1990, p. 1.

⁽³⁾ OJ L 125, 23.5.1996, p. 3.

⁽⁴⁾ OJ L 125, 23.5.1996, p. 10.

⁽⁵⁾ OJ L 109, 6.5.2000, p. 29.

⁽⁶⁾ OJ L 229, 1.9.2009, p. 1.

⁽⁷⁾ OJ L 31, 1.2.2002, p. 1.

⁽⁸⁾ OJ L 139, 30.4.2004, p. 1.

⁽⁹⁾ OJ L 35, 8.2.2005, p. 1.

other means should continue to operate, if they provide equivalent information. Every effort should be made to promote the use of electronic and other means of documentation which do not involve paper records, as long as they ensure full traceability.

- (37) A system of own checks is necessary to ensure that, within an establishment or plant, the requirements of this Regulation are fulfilled. During official controls the competent authorities should take into account the performance of own checks. In certain establishments or plants own checks should be carried out through a system based on the hazard analysis and critical control points (HACCP) principles. The HACCP principles should be based on the experience of their implementation under Community legislation on food and feed hygiene. In this respect, national guides to good practice could serve as a useful tool to facilitate the practical implementation of the HACCP principles, and of other aspects of this Regulation.
- (38) Animal by-products should only be used if the risks to public and animal health are minimised in the course of their processing and the placing on the market of derived products manufactured on the basis of animal by-products. If this option is not available, the animal by-products should be disposed of under safe conditions. The options available for the use of animal by-products of the different categories should be clarified in coherence with other Community legislation. In general, the options for a higher risk category should be available for the lower risk categories as well, unless special considerations apply in view of the risk attached to certain animal by-products.
- (39) Disposal of animal by-products and derived products should take place in accordance with environmental legislation regarding landfilling and waste incineration. In order to ensure consistency, incineration should take place in accordance with Directive 2000/76/EC of the European Parliament and of the Council of 4 December 2000 on the incineration of waste ⁽¹⁾. Co-incineration of waste – either as a recovery or disposal operation – is subject to similar conditions regarding approval and operation to those regarding waste incineration, in particular as to air emission limit values, waste water and residue discharge, control and monitoring and measurement requirements. Consequently, direct co-incineration, without prior processing, of all three categories of materials should be permitted. In addition, specific provisions should be enacted for the approval of low and high-capacity incineration plants.
- (40) The use of animal by-products or derived products as a fuel in the combustion process should be authorised and

should not be considered as a waste disposal operation. However, such use should take place under conditions which ensure the protection of public and animal health, as well as the appropriate environmental standards.

- (41) This Regulation should provide for the possibility to lay down parameters for processing methods regarding time, temperature and pressure for animal by-products, in particular for the methods currently referred to as methods 2 to 7 under Regulation (EC) No 1774/2002.
- (42) Shells from shellfish from which the soft tissue or flesh have been removed, should be excluded from the scope of the Regulation. Due to the various practices in the Community regarding the removal of such soft tissue or flesh from shells, it should be possible to use shells from which the entire soft tissue or flesh has not been removed, provided such use does not lead to a risk arising to public and animal health. National guides to good practice could assist in the dissemination of knowledge regarding proper conditions under which such use would be possible.
- (43) In view of the limited risk to public or animal health arising from such products, the competent authority should be able to authorise the preparation and application to land of biodynamic preparations, on the basis of Category 2 and Category 3 materials, as referred to in Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products ⁽²⁾.
- (44) Novel technologies which are being developed offer advantageous ways of generating energy on the basis of animal by-products or of providing for the safe disposal of such products. Safe disposal may take place through a combination of methods for the safe containment of animal by-products on site with established disposal methods, and through a combination of authorised processing parameters with new standards which have been favourably assessed. In order to take account of the related progress in science and technology, such technologies should be authorised as alternative methods for the disposal or use of animal by-products throughout the Community. If a technological process has been developed by an individual, an application checked by the competent authority should be examined by EFSA before such authorisation is granted, in order to ensure that an assessment of the risk reduction potential of the process is carried out and that the rights of individuals, including the confidentiality of business information, is preserved. In order to provide advice to applicants a standard format for application should be adopted. Since that document is intended only to be indicative it should be adopted in accordance with the advisory procedure in collaboration with EFSA.
- (45) It is appropriate to clarify the requirements applicable to the placing on the market of animal by-products and

⁽¹⁾ OJ L 332, 28.12.2000, p. 91.

⁽²⁾ OJ L 189, 20.7.2007, p. 1.

derived products intended for feeding purposes and of organic fertilisers and soil improvers, so as to ensure the protection of the food and feed chain. Only Category 3 material should be used for feeding farmed animals other than fur animals. Fertilisers produced on the basis of animal by-products may affect the safety of the feed and food chain. Where they have been manufactured from meat-and-bone meal derived from Category 2 material or from processed animal protein, a component, such as an inorganic or an indigestible substance, should be added in order to prevent their direct use for feeding purposes. Such mixing should not be required if the composition or packaging of products, in particular of products destined for use by the final consumer, prevents the misuse of the product for feeding purposes. When determining the components, different circumstances regarding climate and soil and the objective for the use of particular fertilisers should be taken into account.

- (46) Regulation (EC) No 1523/2007 of the European Parliament and of the Council of 11 December 2007 banning the placing on the market and the import to, or export from, the Community of cat and dog fur, and products containing such fur ⁽¹⁾ lays down a general prohibition on the placing on the market and the import and export of cat and dog fur and products containing such fur. However, that prohibition should not affect the obligation under this Regulation to dispose of animal by-products from cats and dogs, including fur.
- (47) The promotion of science and research, and artistic activities may require the use of animal by-products or derived products of all categories, sometimes in quantities below the scale of commercial exchanges. In order to facilitate the import and use of such animal by-products or derived products, the competent authority should be able to fix the conditions for such operations on a case-specific basis. Harmonised conditions should be laid down where action at a Community level is necessary.
- (48) Regulation (EC) No 1774/2002 contains detailed provisions which allow, by way of derogation, the feeding of Category 2 and Category 3 materials to zoo animals. Similar provisions should be laid down in this Regulation and the feeding of certain Category 1 material should be allowed and complemented by the possibility to lay down detailed rules to control any possible risks arising to public or animal health.
- (49) Regulation (EC) No 1774/2002 allows for the feeding of Category 1 material to endangered or protected species of necrophagous birds and other species living in their natural habitat, for the promotion of biodiversity. In order to provide an adequate tool for the preservation of those species, that feeding practice should continue to be permitted

under this Regulation, in accordance with conditions laid down to prevent the spread of diseases. At the same time, health conditions should be laid down in the implementing measures permitting the use of such Category 1 material for feeding purposes in extensive grazing systems and for feeding to other carnivore species, such as bears and wolves. It is important that such health conditions take into account the natural consumption patterns of the species concerned as well as Community objectives for the promotion of biodiversity as referred to in the Communication from the Commission of 22 May 2006 entitled 'Halting the loss of biodiversity by 2010 – and beyond'.

- (50) Burial and burning of animal by-products, in particular of dead animals may be justified in specific situations, in particular in remote areas, or in disease control situations requiring the emergency disposal of the animals killed as a measure to control an outbreak of a serious transmissible disease. In particular, disposal on site should be allowed under special circumstances, since the available rendering or incinerator capacity within a region or a Member State could otherwise be a limiting factor in the control of a disease.
- (51) The current derogation concerning burial and burning of animal by-products should be extended to areas where access is not practically possible or presents a risk to the health and safety of the collection personnel. Experience gained with the application of Regulation (EC) No 1774/2002 and with natural disasters such as forest fires and floods in certain Member States has shown that under such exceptional circumstances, disposal by burial or burning on site can be justified so as to ensure the swift disposal of animals and to avoid the propagation of disease risks. The overall size of remote areas in a Member State should be limited, on the basis of the experience gained with the application of Regulation (EC) No 999/2001 so as to ensure that the general obligation to have in place a proper disposal system which complies with the rules laid down in this Regulation is fulfilled.
- (52) Certain establishments or plants which handle only small quantities of animal by-products which do not pose a risk to public and animal health should be allowed to dispose of such by-products by means other than disposal in accordance with this Regulation, under official supervision. However, the criteria for such exceptional circumstances should be laid down at Community level, so as to ensure their uniform application, based on the actual situation of certain sectors and the availability of other disposal systems in certain Member States.
- (53) The possible courses of action which the competent authority can take when carrying out official controls should be specified in order to ensure legal certainty, in particular regarding the suspension or permanent

⁽¹⁾ OJ L 343, 27.12.2007, p. 1.

prohibition of operations or the imposition of conditions to ensure the proper application of this Regulation. These official controls should be carried out in the framework of multi-annual control plans under Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules ⁽¹⁾.

- (54) In order to ensure that Member States may control the quantity of material which is introduced for disposal into their territory, the competent authority should authorise the receipt of such material to its territory.
- (55) Pressure sterilisation and auxiliary transport conditions may be imposed so as to ensure the control of possible risks. In order to ensure traceability and cooperation between the competent authorities of Member States controlling the dispatch of animal by-products or derived products, the Traces system introduced by Commission Decision 2004/292/EC ⁽²⁾ should be used to provide information on the dispatch of Category 1 and Category 2 materials and meat-and-bone meal or animal fat derived from Category 1 and Category 2 materials, and processed animal protein derived from Category 3 material. For materials typically sent in small quantities for research, educational, artistic or diagnostic use, special conditions should be laid down to facilitate the movement of such materials within the Community. Bilateral arrangements facilitating the control of materials moved between the Member States sharing a common border should be permitted under special circumstances.
- (56) In order to facilitate the transport of consignments through third countries neighbouring more than one Member State, a special regime for the dispatch of consignments from the territory of one Member State to another through the territory of a third country should be introduced in order to ensure, in particular, that consignments re-entering Community territory are subject to veterinary checks in accordance with Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market ⁽³⁾.
- (57) For the sake of coherence of Community legislation, it is necessary to clarify the relationship between the rules laid down in this Regulation and Community legislation on

waste. In particular, consistency should be ensured with the prohibitions on waste exports laid down in Regulation (EC) No 1013/2006 of the European Parliament and of the Council of 14 June 2006 on shipments of waste ⁽⁴⁾. In order to prevent potentially detrimental effects for the environment, the export of animal by-products and derived products destined for disposal by incineration and by landfill should be prohibited. The export of animal by-products and derived products should also be prevented where the objective is to use them in a biogas or composting plant to third countries which are not members of the Organisation for Economic Cooperation and Development (OECD), in order to prevent potentially adverse environmental impacts and risks to public and animal health. When applying the provisions to derogate from the export ban, the Commission is obliged to fully respect in its decisions the Basel Convention on the control of transboundary movements of hazardous waste and their disposal, as concluded, on behalf of the Community, by Council Decision 93/98/EEC ⁽⁵⁾, and the amendment to this Convention laid down in Decision III/1 of the Conference of the Parties, as approved, on behalf of the Community, by Council Decision 97/640/EC ⁽⁶⁾, and implemented by Regulation (EC) No 1013/2006.

- (58) In addition, it should be ensured that animal by-products mixed or contaminated with hazardous waste, as listed in Commission Decision 2000/532/EC of 3 May 2000 replacing Decision 94/3/EC establishing a list of wastes pursuant to Article 1(a) of Council Directive 75/442/EEC on waste and Council Decision 94/904/EC establishing a list of hazardous waste pursuant to Article 1(4) of Council Directive 91/689/EEC on hazardous waste ⁽⁷⁾ are only imported, exported or dispatched between Member States in accordance with Regulation (EC) No 1013/2006. It is also necessary to lay down rules concerning the dispatch of such material within a Member State.
- (59) The Commission should be able to carry out controls in Member States. Community controls in third countries should be carried out in accordance with Regulation (EC) No 882/2004.
- (60) The import of animal by-products and derived products into the Community and the transit of such material should take place in accordance with rules which are at least as strict as those applicable within the Community. Alternatively, the rules applicable to animal by-products and derived products in third countries may be recognised to be equivalent to the rules laid down in Community legislation. Due to the potential risk arising from them, a simplified set of import rules should be applicable to products which are destined for uses outside the feed chain.

⁽¹⁾ OJ L 165, 30.4.2004, p. 1.

⁽²⁾ OJ L 94, 31.3.2004, p. 63.

⁽³⁾ OJ L 395, 30.12.1989, p. 13.

⁽⁴⁾ OJ L 190, 12.7.2006, p. 1.

⁽⁵⁾ OJ L 39, 16.2.1993, p. 1.

⁽⁶⁾ OJ L 272, 4.10.1997, p. 45.

⁽⁷⁾ OJ L 226, 6.9.2000, p. 3.

- (61) Community legislation on the manufacture of derived products intended for use as cosmetic products, medicinal products or medical devices comprises a comprehensive framework for the placing on the market of such products: Council Directive 76/768/EEC of 27 July 1976 on the approximation of laws of the Member States relating to cosmetic products ⁽¹⁾, 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 ⁽²⁾, Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products ⁽³⁾, Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices ⁽⁴⁾, Council Directive 93/42/EEC of 14 June 1993 concerning medical devices ⁽⁵⁾ and Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices ⁽⁶⁾ (the specific Directives). However, the specific Directives on cosmetic products and medical devices do not provide for protection against risks to animal health. In such cases, this Regulation should apply to those risks and recourse to safeguard measures in accordance with Regulation (EC) No 178/2002 should be possible.
- (62) Animal by-products or derived products that are supplied as material or ingredients for the manufacture of such derived products should also be subject to the requirements of the specific Directives, in so far as they lay down rules controlling risks to public and animal health. Those specific Directives already regulate starting material of animal origin which may be used for the manufacture of the derived products referred to and impose certain conditions to ensure the protection of public or animal health. In particular, Directive 76/768/EEC excludes Category 1 and Category 2 materials as part of the composition of a cosmetic product and obliges manufacturers to apply good manufacturing practices. Commission Directive 2003/32/EC ⁽⁷⁾ introduces detailed specifications with respect to medical devices manufactured utilising tissues of animal origin.
- (63) However, where those conditions have not yet been laid down in the specific Directives or where they do not cover certain risks to public and animal health, this Regulation should apply, and recourse to safeguard measures in accordance with Regulation (EC) No 178/2002 should be possible.
- (64) Certain derived products do not enter the feed chain or are not applied to land which is grazed by farmed animals or from which herbage for feed is cut. Such derived products include products for technical uses, such as treated hides for leather production, processed wool for the textile industry, bone products for glue and processed material destined for petfood. Operators should be permitted to place such products on the market provided that they are either derived from raw material requiring no treatment or the treatment or the end use of the treated material ensures adequate risk control.
- (65) Certain failures to comply with the rules laid down in Regulation (EC) No 1774/2002 have been revealed in a number of Member States. Accordingly, in addition to the strict enforcement of those rules, criminal and other sanctions against operators which do not comply with those rules are needed. Therefore, it is necessary that Member States lay down rules on penalties applicable to infringements of this Regulation.
- (66) Since the objective of this Regulation, namely to lay down public and animal health rules for animal by-products and derived products in order to prevent and minimise risks to public and animal health arising from those products and, in particular, to protect the safety of the food and feed chain, cannot be sufficiently achieved by the Member States and can therefore be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.
- (67) In order to enhance legal certainty and in the light of the Commission's general objective to simplify Community legislation, a coherent framework of rules should be laid down in this Regulation, taking into account the rules laid down in Regulation (EC) No 1774/2002, as well as the experience gained and progress made since the date of entry into force of that Regulation. Regulation (EC) No 1774/2002 should therefore be repealed and replaced by this Regulation.
- (68) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission ⁽⁸⁾.
- (69) In order to improve coherence and clarity of Community legislation, the technical rules concerning specific operations involving animal by-products, which are currently

⁽¹⁾ OJ L 262, 27.9.1976, p. 169.

⁽²⁾ OJ L 311, 28.11.2001, p. 67.

⁽³⁾ OJ L 311, 28.11.2001, p. 1.

⁽⁴⁾ OJ L 189, 20.7.1990, p. 17.

⁽⁵⁾ OJ L 169, 12.7.1993, p. 1.

⁽⁶⁾ OJ L 331, 7.12.1998, p. 1.

⁽⁷⁾ OJ L 105, 26.4.2003, p. 18.

⁽⁸⁾ OJ L 184, 17.7.1999, p. 23.

laid down in the Annexes to Regulation (EC) No 1774/2002, as well as in implementing measures adopted by the Commission on the basis of that Regulation⁽¹⁾, should be laid down in separate implementing acts. Consultation and information of consumers and socio-professional circles concerned with issues related to this Regulation should be carried out in accordance with Commission Decision 2004/613/EC of 6 August 2004 concerning the creation of an advisory group on the food chain and animal and plant health⁽²⁾.

(70) In particular, the Commission should be empowered to adopt rules modifying the end point in the manufacturing chain of certain derived products and establishing such an end point for certain other derived products, rules in regard to serious transmissible diseases in the presence of which the dispatch of animal by-products and derived products should not be allowed and/or the conditions allowing such a dispatch, measures changing the categorisation of animal by-products and derived products, measures regarding restrictions on the use and disposal of animal by-products and derived products, measures laying down conditions for the application of certain derogations regarding the use, collection and disposal of animal by-products and derived products and measures authorising or rejecting a particular alternative method for the use and disposal of animal by-products and derived products.

(71) In addition, the Commission should be empowered to adopt more specific rules concerning collection and transport of animal by-products and derived products, the infrastructure, equipment and hygiene requirements for establishments or plants handling animal by-products and derived products, the conditions and technical requirements for the handling of animal by-products and derived products, including the evidence to be presented for the purpose of validation of such treatment, conditions for the placing on the market of animal by-products and derived products, requirements related to safe sourcing, safe treatment and safe end uses, conditions for the import, transit and export of animal by-products and derived products, detailed arrangements for implementing official controls

⁽¹⁾ Regulation (EC) No 811/2003 on the intra-species recycling ban for fish, and the burial and burning of certain animal by-products (OJ L 117, 13.5.2003, p. 14); Decision 2003/322/EC on the feeding of certain necrophagous birds with certain Category 1 materials (OJ L 117, 13.5.2003, p. 32); Decision 2003/324/EC on a derogation from the intra-species recycling ban for fur animals (OJ L 117, 13.5.2003, p. 37); Regulation (EC) No 92/2005 on means of disposal or uses (OJ L 19, 21.1.2005, p. 27); Regulation (EC) No 181/2006 on organic fertilisers and soil improvers other than manure (OJ L 29, 2.2.2006, p. 31); Regulation (EC) No 1192/2006 on lists of approved plants (OJ L 215, 5.8.2006, p. 10); Regulation (EC) No 2007/2006 on the importation and transit of certain intermediate products derived from Category 3 material (OJ L 379, 28.12.2006, p. 98).

⁽²⁾ OJ L 275, 25.8.2004, p. 17.

including rules concerning the reference methods for microbiological analyses as well as conditions for the control of the dispatch of certain animal by-products and derived products between Member States. Since those measures are of general scope and are designed to amend non-essential elements of this Regulation, inter alia, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

(72) On grounds of efficiency, the normal time-limits for the regulatory procedure with scrutiny should be curtailed for the adoption of measures specifying the conditions for the dispatch of animal by-products from restricted holdings, plants or zones. On grounds of urgency, it is necessary to apply the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adoption of measures modifying the end point in the manufacturing chain for certain products,

HAVE ADOPTED THIS REGULATION:

TITLE I

GENERAL PROVISIONS

CHAPTER I

Common provisions

Section 1

Subject matter, scope and definitions

Article 1

Subject matter

This Regulation lays down public health and animal health rules for animal by-products and derived products, in order to prevent and minimise risks to public and animal health arising from those products, and in particular to protect the safety of the food and feed chain.

Article 2

Scope

1. This Regulation shall apply to:
 - (a) animal by-products and derived products which are excluded from human consumption under Community legislation; and

- (b) the following products which pursuant to a decision by an operator, which shall be irreversible, are destined for purposes other than human consumption:
- (i) products of animal origin which may be destined for human consumption under Community legislation;
 - (ii) raw materials for the production of products of animal origin.

2. This Regulation shall not apply to the following animal by-products:

- (a) entire bodies or parts of wild animals, other than wild game, which are not suspected of being infected or affected with a disease communicable to humans or animals, except for aquatic animals landed for commercial purposes;
- (b) entire bodies or parts of wild game which are not collected after killing, in accordance with good hunting practice, without prejudice to Regulation (EC) No 853/2004;
- (c) animal by-products from wild game and from wild game meat referred to in Article 1(3)(e) of Regulation (EC) No 853/2004;
- (d) oocytes, embryos and semen destined for breeding purposes;
- (e) raw milk, colostrum and products derived therefrom which are obtained, kept, disposed of or used on the farm of origin;
- (f) shells from shellfish with the soft tissue and flesh removed;
- (g) catering waste, except if it:
 - (i) originates from means of transport operating internationally;
 - (ii) is destined for feeding purposes;
 - (iii) is destined for processing by pressure sterilisation or for processing by methods referred to in point (b) of the first subparagraph of Article 15(1) or for transformation into biogas or for composting;
- (h) without prejudice to Community environmental legislation, material from vessels complying with Regulations (EC) No 852/2004 and (EC) No 853/2004, which has arisen in the course of their fishing operations and is disposed of at sea, except material derived from on-board evisceration of fish showing signs of disease, including parasites, that are communicable to humans;
- (i) raw pet food originating from retail shops, where the cutting and storage are performed solely for the purpose of supplying the consumer directly on the spot;
- (j) raw pet food derived from animals which are slaughtered on the farm of origin for private domestic consumption; and

- (k) excrement and urine other than manure and non-mineralised guano.

3. This Regulation shall be without prejudice to Community veterinary legislation having as its objective the control and eradication of animal diseases.

Article 3

Definitions

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

1. 'animal by-products' means entire bodies or parts of animals, products of animal origin or other products obtained from animals, which are not intended for human consumption, including oocytes, embryos and semen;
2. 'derived products' means products obtained from one or more treatments, transformations or steps of processing of animal by-products;
3. 'products of animal origin' means products of animal origin as defined in point 8.1 of Annex I to Regulation (EC) No 853/2004;
4. 'carcase' means carcase as defined in point 1.9 of Annex I to Regulation (EC) No 853/2004;
5. 'animal' means any invertebrate or vertebrate animal;
6. 'farmed animal' means:
 - (a) any animal that is kept, fattened or bred by humans and used for the production of food, wool, fur, feathers, hides and skins or any other product obtained from animals or for other farming purposes;
 - (b) equidae;
7. 'wild animal' means any animal not kept by humans;
8. 'pet animal' means any animal belonging to species normally nourished and kept but not consumed, by humans for purposes other than farming;
9. 'aquatic animals' means aquatic animals as defined in Article 3(1)(e) of Directive 2006/88/EC;
10. 'competent authority' means the central authority of a Member State competent to ensure compliance with the requirements of this Regulation or any authority to which that competence has been delegated; it also includes, where appropriate, the corresponding authority of a third country;
11. 'operator' means the natural or legal persons having an animal by-product or derived product under their actual control, including carriers, traders and users;

12. 'user' means the natural or legal persons using animal by-products and derived products for special feeding purposes, for research or for other specific purposes;
13. 'establishment' or 'plant' means any place where any operation involving the handling of animal by-products or derived products is carried out, other than a fishing vessel;
14. 'placing on the market' means any operation the purpose of which is to sell animal by-products or derived products to a third party in the Community or any other form of supply against payment or free of charge to such a third party or storage with a view to supply to such a third party;
15. 'transit' means movement through the Community from the territory of a third country to the territory of another third country, other than by sea or by air;
16. 'export' means movement from the Community to a third country;
17. 'transmissible spongiform encephalopathies (TSEs)' means all transmissible spongiform encephalopathies as defined in Article 3(1)(a) of Regulation (EC) No 999/2001;
18. 'specified risk material' means specified risk material as defined in Article 3(1)(g) of Regulation (EC) No 999/2001;
19. 'pressure sterilisation' means the processing of animal by-products, after reduction in particle size to not more than 50 mm, to a core temperature of more than 133 °C for at least 20 minutes without interruption at an absolute pressure of at least 3 bar;
20. 'manure' means any excrement and/or urine of farmed animals other than farmed fish, with or without litter;
21. 'authorised landfill' means a landfill for which a permit has been issued in accordance with Directive 1999/31/EC;
22. 'organic fertiliser' and 'soil improver' means materials of animal origin used to maintain or improve plant nutrition and the physical and chemical properties and biological activities of soils, either separately or together; they may include manure, non-mineralised guano, digestive tract content, compost and digestion residues;
23. 'remote area' means an area where the animal population is so small, and where disposal establishments or plants are so far away that the arrangements necessary for the collection and transport of animal by-products would be unacceptably onerous compared to local disposal;
24. 'food' or 'foodstuff' means food or foodstuff as defined in Article 2 of Regulation (EC) No 178/2002;
25. 'feed' or 'feedingstuff' means feed or feedingstuff as defined in Article 3(4) of Regulation (EC) No 178/2002;
26. 'centrifuge or separator sludge' means material collected as a by-product after purification of raw milk and separation of skimmed milk and cream from raw milk;
27. 'waste' means waste as defined in point 1 of Article 3 of Directive 2008/98/EC.

Section 2

Obligations

Article 4

Starting point in the manufacturing chain and obligations

1. As soon as operators generate animal by-products or derived products falling within the scope of this Regulation, they shall identify them and ensure that they are dealt with in accordance with this Regulation (starting point).
2. Operators shall ensure at all stages of collection, transport, handling, treatment, transformation, processing, storage, placing on the market, distribution, use and disposal within the businesses under their control that animal by-products and derived products satisfy the requirements of this Regulation which are relevant to their activities.
3. Member States shall monitor and verify that the relevant requirements of this Regulation are fulfilled by operators along the entire chain of animal by-products and derived products as referred to in paragraph 2. For that purpose, they shall maintain a system of official controls in accordance with relevant Community legislation.
4. Member States shall ensure that an adequate system is in place on their territory ensuring that animal by-products are:
 - (a) collected, identified and transported without undue delay; and
 - (b) treated, used or disposed of in accordance with this Regulation.
5. Member States may fulfil their obligations under paragraph 4 in cooperation with other Member States or third countries.

Article 5

End point in the manufacturing chain

1. Derived products referred to in Article 33 which have reached the stage of manufacturing regulated by the Community legislation referred to in that Article shall be regarded as having reached the end point in the manufacturing chain, beyond which they are no longer subject to the requirements of this Regulation.

Those derived products may subsequently be placed on the market without restrictions under this Regulation and shall no longer be subject to official controls in accordance with this Regulation.

The end point in the manufacturing chain may be modified:

- (a) for products referred to in Article 33(a) to (d), in case of risks to animal health;
- (b) for products referred to in Article 33(e) and (f), in case of risks to public or animal health.

Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 52(6).

2. For derived products referred to in Articles 35 and 36 which no longer pose any significant risk to public or animal health, an end point in the manufacturing chain may be determined, beyond which they are no longer subject to the requirements of this Regulation.

Those derived products may subsequently be placed on the market without restrictions under this Regulation and shall no longer be subject to official controls in accordance with this Regulation.

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 52(5).

3. In the event of risks to public or animal health, Articles 53 and 54 of Regulation (EC) No 178/2002 concerning emergency measures shall apply *mutatis mutandis* to the derived products referred to in Articles 33 and 36 of this Regulation.

Section 3

Animal health restrictions

Article 6

General animal health restrictions

1. Animal by-products and derived products from susceptible species shall not be dispatched from holdings, establishments, plants or zones which are subject to restrictions:

- (a) pursuant to Community veterinary legislation; or
- (b) due to the presence of a serious transmissible disease:
 - (i) listed in Annex I to Directive 92/119/EEC; or
 - (ii) laid down in accordance with the second subparagraph.

The measures referred to in point (b)(ii) of the first subparagraph, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 52(4).

2. Paragraph 1 shall not apply where animal by-products and derived products are dispatched under conditions designed to prevent the spread of diseases transmissible to humans or animals.

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 52(5).

Section 4

Categorisation

Article 7

Categorisation of animal by-products and derived products

1. Animal by-products shall be categorised into specific categories which reflect the level of risk to public and animal health arising from those animal by-products, in accordance with the lists laid down in Articles 8, 9 and 10.

2. Derived products shall be subject to the rules for the specific category of animal by-products from which they have been derived, unless otherwise specified in this Regulation, or provided for in measures for the implementation of this Regulation which may specify the conditions under which derived products are not subject to those rules adopted by the Commission.

3. Articles 8, 9 and 10 may be amended in order to take into account scientific progress as regards the assessment of the level of risk, provided such progress can be identified on the basis of a risk assessment carried out by the appropriate scientific institution. However, no animal by-products listed in those Articles may be removed from those lists, only changes of categorisation or additions may be made.

4. The measures referred to in paragraphs 2 and 3, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 52(4).

Article 8

Category 1 material

Category 1 material shall comprise the following animal by-products:

- (a) entire bodies and all body parts, including hides and skins, of the following animals:
 - (i) animals suspected of being infected by a TSE in accordance with Regulation (EC) No 999/2001 or in which the presence of a TSE has been officially confirmed;
 - (ii) animals killed in the context of TSE eradication measures;
 - (iii) animals other than farmed and wild animals, including in particular pet animals, zoo animals and circus animals;

- (iv) animals used for experiments as defined by Article 2(d) of Directive 86/609/EEC without prejudice to Article 3(2) of Regulation (EC) No 1831/2003;
- (v) wild animals, when suspected of being infected with diseases communicable to humans or animals;
- (b) the following material:
- (i) specified risk material;
- (ii) entire bodies or parts of dead animals containing specified risk material at the time of disposal;
- (c) animal by-products derived from animals which have been submitted to illegal treatment as defined in Article 1(2)(d) of Directive 96/22/EC or Article 2(b) of Directive 96/23/EC;
- (d) animal by-products containing residues of other substances and environmental contaminants listed in Group B(3) of Annex I to Directive 96/23/EC, if such residues exceed the permitted level laid down by Community legislation or, in the absence thereof, by national legislation;
- (e) animal by-products collected during the treatment of waste water required by implementing rules adopted under point (c) of the first paragraph of Article 27:
- (i) from establishments or plants processing Category 1 material; or
- (ii) from other establishments or plants where specified risk material is being removed;
- (f) catering waste from means of transport operating internationally;
- (g) mixtures of Category 1 material with either Category 2 material or Category 3 material or both.
- (ii) from slaughterhouses other than those covered by Article 8(e);
- (c) animal by-products containing residues of authorised substances or contaminants exceeding the permitted levels as referred to in Article 15(3) of Directive 96/23/EC;
- (d) products of animal origin which have been declared unfit for human consumption due to the presence of foreign bodies in those products;
- (e) products of animal origin, other than Category 1 material, that are:
- (i) imported or introduced from a third country and fail to comply with Community veterinary legislation for their import or introduction into the Community except where Community legislation allows their import or introduction subject to specific restrictions or their return to the third country;
- (ii) dispatched to another Member State and fail to comply with requirements laid down or authorised by Community legislation except where they are returned with the authorisation of the competent authority of the Member State of origin;
- (f) animals and parts of animals, other than those referred to in Article 8 or Article 10,
- (i) that died other than by being slaughtered or killed for human consumption, including animals killed for disease control purposes;
- (ii) foetuses;
- (iii) oocytes, embryos and semen which are not destined for breeding purposes; and
- (iv) dead-in-shell poultry;
- (g) mixtures of Category 2 material with Category 3 material;
- (h) animal by-products other than Category 1 material or Category 3 material.

Article 9

Category 2 material

Category 2 material shall comprise the following animal by-products:

- (a) manure, non-mineralised guano and digestive tract content;
- (b) animal by-products collected during the treatment of waste water required by implementing rules adopted under point (c) of the first paragraph of Article 27:
- (i) from establishments or plants processing Category 2 material; or

Article 10

Category 3 material

Category 3 material shall comprise the following animal by-products:

- (a) carcasses and parts of animals slaughtered or, in the case of game, bodies or parts of animals killed, and which are fit for human consumption in accordance with Community legislation, but are not intended for human consumption for commercial reasons;

- (b) carcasses and the following parts originating either from animals that have been slaughtered in a slaughterhouse and were considered fit for slaughter for human consumption following an ante-mortem inspection or bodies and the following parts of animals from game killed for human consumption in accordance with Community legislation:
- (i) carcasses or bodies and parts of animals which are rejected as unfit for human consumption in accordance with Community legislation, but which did not show any signs of disease communicable to humans or animals;
 - (ii) heads of poultry;
 - (iii) hides and skins, including trimmings and splitting thereof, horns and feet, including the phalanges and the carpus and metacarpus bones, tarsus and metatarsus bones, of:
 - animals, other than ruminants requiring TSE testing, and
 - ruminants which have been tested with a negative result in accordance with Article 6(1) of Regulation (EC) No 999/2001;
 - (iv) pig bristles;
 - (v) feathers;
- (c) animal by-products from poultry and lagomorphs slaughtered on the farm as referred to in Article 1(3)(d) of Regulation (EC) No 853/2004, which did not show any signs of disease communicable to humans or animals;
- (d) blood of animals which did not show any signs of disease communicable through blood to humans or animals obtained from the following animals that have been slaughtered in a slaughterhouse after having been considered fit for slaughter for human consumption following an ante-mortem inspection in accordance with Community legislation:
- (i) animals other than ruminants requiring TSE testing; and
 - (ii) ruminants which have been tested with a negative result in accordance with Article 6(1) of Regulation (EC) No 999/2001;
- (e) animal by-products arising from the production of products intended for human consumption, including degreased bones, greaves and centrifuge or separator sludge from milk processing;
- (f) products of animal origin, or foodstuffs containing products of animal origin, which are no longer intended for human consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects from which no risk to public or animal health arise;
- (g) petfood and feedingstuffs of animal origin, or feedingstuffs containing animal by-products or derived products, which are no longer intended for feeding for commercial reasons or due to problems of manufacturing or packaging defects or other defects from which no risk to public or animal health arises;
- (h) blood, placenta, wool, feathers, hair, horns, hoof cuts and raw milk originating from live animals that did not show any signs of disease communicable through that product to humans or animals;
- (i) aquatic animals, and parts of such animals, except sea mammals, which did not show any signs of disease communicable to humans or animals;
- (j) animal by-products from aquatic animals originating from establishments or plants manufacturing products for human consumption;
- (k) the following material originating from animals which did not show any signs of disease communicable through that material to humans or animals:
- (i) shells from shellfish with soft tissue or flesh;
 - (ii) the following originating from terrestrial animals:
 - hatchery by-products,
 - eggs,
 - egg by-products, including egg shells,
 - (iii) day-old chicks killed for commercial reasons;
- (l) aquatic and terrestrial invertebrates other than species pathogenic to humans or animals;
- (m) animals and parts thereof of the zoological orders of Rodentia and Lagomorpha, except Category 1 material as referred to in Article 8(a)(iii), (iv) and (v) and Category 2 material as referred to in Article 9(a) to (g);
- (n) hides and skins, hooves, feathers, wool, horns, hair and fur originating from dead animals that did not show any signs of disease communicable through that product to humans or animals, other than those referred to in point (b) of this Article;
- (o) adipose tissue from animals which did not show any signs of disease communicable through that material to humans or animals, which were slaughtered in a slaughterhouse and which were considered fit for slaughter for human consumption following an ante-mortem inspection in accordance with Community legislation;
- (p) catering waste other than as referred to in Article 8(f).

CHAPTER II

Disposal and use of animal by-products and derived products

Section 1

Restrictions on use

Article 11

Restrictions on use

1. The following uses of animal by-products and derived products shall be prohibited:

- (a) the feeding of terrestrial animals of a given species other than fur animals with processed animal protein derived from the bodies or parts of bodies of animals of the same species;
- (b) the feeding of farmed animals other than fur animals with catering waste or feed material containing or derived from catering waste;
- (c) the feeding of farmed animals with herbage, either directly by grazing or by feeding with cut herbage, from land to which organic fertilisers or soil improvers, other than manure, have been applied unless the cutting or grazing takes place after the expiry of a waiting period which ensures adequate control of risks to public and animal health and is at least 21 days; and
- (d) the feeding of farmed fish with processed animal protein derived from the bodies or parts of bodies of farmed fish of the same species.

2. Measures relating to the following may be laid down:

- (a) the checks and controls to be carried out to ensure the application of the prohibitions referred to in paragraph 1, including detection methods and tests to be used to verify the presence of materials originating from certain species and thresholds for insignificant amounts of processed animal proteins referred to in points (a) and (d) of paragraph 1 which are caused by adventitious and technically unavoidable contamination;
- (b) the conditions for the feeding of fur animals with processed animal protein derived from bodies or parts of bodies of animals of the same species; and
- (c) the conditions for the feeding of farmed animals with herbage from land to which organic fertilisers or soil improvers have been applied, in particular a modification of the waiting period as referred to in paragraph 1(c).

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 52(4).

Section 2

Disposal and use

Article 12

Disposal and use of Category 1 material

Category 1 material shall be:

- (a) disposed of as waste by incineration:
 - (i) directly without prior processing; or
 - (ii) following processing, by pressure sterilisation if the competent authority so requires, and permanent marking of the resulting material;
- (b) recovered or disposed of by co-incineration, if the Category 1 material is waste:
 - (i) directly without prior processing; or
 - (ii) following processing, by pressure sterilisation if the competent authority so requires, and permanent marking of the resulting material;
- (c) in the case of Category 1 material other than material referred to in Article 8(a)(i) and (ii), disposed of by processing by pressure sterilisation, permanent marking of the resulting material and burial in an authorised landfill;
- (d) in the case of Category 1 material referred to in Article 8(f), disposed of by burial in an authorised landfill;
- (e) used as a fuel for combustion with or without prior processing; or
- (f) used for the manufacture of derived products referred to in Articles 33, 34 and 36 and placed on the market in accordance with those Articles.

Article 13

Disposal and use of Category 2 material

Category 2 material shall be:

- (a) disposed of as waste by incineration:
 - (i) directly without prior processing; or
 - (ii) following processing, by pressure sterilisation if the competent authority so requires, and permanent marking of the resulting material;

- (b) recovered or disposed of by co-incineration, if the Category 2 material is waste:
- (i) directly without prior processing; or
 - (ii) following processing, by pressure sterilisation if the competent authority so requires, and permanent marking of the resulting material;
- (c) disposed of in an authorised landfill, following processing by pressure sterilisation and permanent marking of the resulting material;
- (d) used for the manufacturing of organic fertilisers or soil improvers to be placed on the market in accordance with Article 32 following processing by pressure sterilisation, when applicable, and permanent marking of the resulting material;
- (e) composted or transformed into biogas:
- (i) following processing by pressure sterilisation and permanent marking of the resulting material; or
 - (ii) in the case of manure, digestive tract and its content, milk, milk-based products, colostrum, eggs and egg products which the competent authority does not consider to present a risk for the spread of any serious transmissible disease, following or without prior processing;
- (f) applied to land without processing, in the case of manure, digestive tract content separated from the digestive tract, milk, milk-based products and colostrum which the competent authority does not consider to present a risk for the spread of any serious transmissible disease;
- (g) in the case of material originating from aquatic animals, ensiled, composted or transformed into biogas;
- (h) used as a fuel for combustion with or without prior processing; or
- (i) used for the manufacture of derived products referred to in Articles 33, 34 and 36 and placed on the market in accordance with those Articles.
- (d) processed, except in the case of Category 3 material which has changed through decomposition or spoilage so as to present an unacceptable risk to public or animal health, through that product, and used:
- (i) for the manufacturing of feed for farmed animals other than fur animals, to be placed on the market in accordance with Article 31, except in the case of material referred to in Article 10(n), (o) and (p);
 - (ii) for the manufacturing of feed for fur animals, to be placed on the market in accordance with Article 36;
 - (iii) for the manufacturing of pet food, to be placed on the market in accordance with Article 35; or
 - (iv) for the manufacturing of organic fertilisers or soil improvers, to be placed on the market in accordance with Article 32;
- (e) used for the production of raw petfood, to be placed on the market in accordance with Article 35;
- (f) composted or transformed into biogas;
- (g) in the case of material originating from aquatic animals, ensiled, composted or transformed into biogas;
- (h) in the case of shells from shellfish, other than those referred to in Article 2(2)(f), and egg shells, used under conditions determined by the competent authority which prevent risks arising to public and animal health;
- (i) used as a fuel for combustion with or without prior processing;
- (j) used for the manufacture of derived products referred to in Articles 33, 34 and 36 and placed on the market in accordance with those Articles;
- (k) in the case of catering waste referred to in Article 10(p) processed by pressure sterilisation or by processing methods referred to in point (b) of the first subparagraph of Article 15(1) or composted or transformed into biogas; or
- (l) applied to land without processing, in the case of raw milk, colostrum and products derived therefrom, which the competent authority does not consider to present a risk of any disease communicable through those products to humans or animals.

Article 14

Disposal and use of Category 3 material

Category 3 material shall be:

- (a) disposed of as waste by incineration, with or without prior processing;
- (b) recovered or disposed of by co-incineration, with or without prior processing, if the Category 3 material is waste;
- (c) disposed of in an authorised landfill, following processing;

Article 15

Implementing measures

1. Measures for the implementation of this Section may be laid down relating to the following:
 - (a) special conditions for the on-board handling and the disposal of material derived from on-board evisceration of fish showing signs of disease, including parasites, that are communicable to humans;

- (b) processing methods for animal by-products other than pressure sterilisation, in particular as regards the parameters to be applied for those processing methods, in particular the time, temperature, pressure and size of particles;
- (c) parameters for the transformation of animal by-products, including catering waste, into biogas or compost;
- (d) conditions for the incineration and co-incineration of animal by-products and derived products;
- (e) conditions for the combustion of animal by-products and derived products;
- (f) conditions for the generation and handling of animal by-products referred to in Article 10(c);
- (g) ensilage of material originating from aquatic animals;
- (h) permanent marking of animal by-products;
- (i) the application to land of certain animal by-products, organic fertilisers and soil improvers;
- (j) the use of certain animal by-products for feeding to farmed animals; and
- (k) the level of risk to public or animal health with respect to certain material which is considered as unacceptable as referred to in Article 14(d).

Those measures designed to amend non-essential elements of this Regulation, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 52(4).

2. Pending the adoption of rules referred to:

- (a) in points (c), (f) and (g) of the first subparagraph of paragraph 1, Member States may adopt or maintain national rules for:
 - (i) the generation and handling of animal by-products referred to in Article 10(c);
 - (ii) the transformation of animal by-products referred to in Article 10(p); and
 - (iii) for the ensilage of material originating from aquatic animals;
- (b) in point (a) of the first subparagraph of paragraph 1, animal by-products referred to therein may be disposed of at sea, without prejudice to Community environmental legislation.

Section 3

Derogations

Article 16

Derogations

By way of derogation from Articles 12, 13 and 14, animal by-products may be:

- (a) in the case of animal by-products referred to in point (a) of the first subparagraph of Article 15(1), handled and disposed of in accordance with special conditions laid down pursuant to that point;
- (b) used for research and other specific purposes in accordance with Article 17;
- (c) in the case of animal by-products referred to in Article 18, used for special feeding purposes in accordance with that Article;
- (d) in the case of animal by-products referred to in Article 19, disposed of in accordance with that Article;
- (e) disposed of or used in accordance with alternative methods which have been authorised in accordance with Article 20, based on parameters which may include pressure sterilisation or other requirements of this Regulation or the implementing measures thereof;
- (f) in the case of Category 2 and Category 3 materials and if authorised by the competent authority, used for the preparation and application to land of bio-dynamic preparations as referred to in Article 12(1)(c) of Regulation (EC) No 834/2007;
- (g) in the case of Category 3 material and, if authorised by the competent authority, used for feeding to pet animals;
- (h) in the case of animal by-products, except for Category 1 material, which arise in the course of surgical intervention on live animals or during birth of animals on farm and, if authorised by the competent authority, disposed of on that farm.

Article 17

Research and other specific purposes

1. The competent authority may, by way of derogation from Articles 12, 13 and 14, authorise the use of animal by-products and derived products for exhibitions, artistic activities, and for diagnostic, educational or research purposes under conditions which ensure the control of risks to public and animal health.

Such conditions shall include:

- (a) the prohibition of any subsequent use of the animal by-products or derived products for other purposes; and

- (b) the obligation to dispose of the animal by-products or derived products safely, or to re-dispatch them to their place of origin, if appropriate.

2. In the case of risks to public and animal health which require the adoption of measures for the whole territory of the Community, in particular in the case of newly emerging risks, harmonised conditions for the import and use of the animal by-products and derived products referred to in paragraph 1 may be laid down. Such conditions may include requirements regarding storage, packaging, identification, transport and disposal.

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 52(4).

Article 18

Special feeding purposes

1. The competent authority may, by way of derogation from Articles 13 and 14, authorise, under conditions which ensure the control of risks to public and animal health, the collection and use of Category 2 material, provided that it comes from animals which were not killed or did not die as a result of the presence or suspected presence of a disease communicable to humans or animals, and of Category 3 material for feeding to:

- (a) zoo animals;
- (b) circus animals;
- (c) reptiles and birds of prey other than zoo or circus animals;
- (d) fur animals;
- (e) wild animals;
- (f) dogs from recognised kennels or packs of hounds;
- (g) dogs and cats in shelters;
- (h) maggots and worms for fishing bait.

2. The competent authority may authorise, by way of derogation from Article 12, and in accordance with the conditions laid down pursuant to paragraph 3 of this Article:

- (a) the feeding of the Category 1 material referred to in Article 8(b)(ii) and of material derived from zoo animals for feeding to zoo animals; and
- (b) the feeding of the Category 1 material referred to in Article 8(b)(ii) to endangered or protected species of necrophagous birds and other species living in their natural habitat, for the promotion of biodiversity.

3. Measures for the implementation of this Article may be laid down relating to the following:

- (a) conditions under which the collection and use as referred to in paragraph 1 may be authorised with respect to the movement, storage and use of Category 2 material and of Category 3 material for feeding, including in the case of newly emerging risks; and
- (b) conditions under which, in certain cases by way of derogation from the obligation laid down in Article 21(1), the feeding of Category 1 material as referred to in paragraph 2 of this Article may be authorised, including:
 - (i) the endangered or protected species of necrophagous birds and other species in certain Member States to which such material may be fed;
 - (ii) measures to prevent risks to public and animal health.

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 52(4).

Article 19

Collection, transport and disposal

1. The competent authority may, by way of derogation from Articles 12, 13, 14 and 21, authorise the disposal:

- (a) by burial of dead pet animals and equidae;
- (b) by burning or burial on site or by other means under official supervision which prevent the transmission of risks to public and animal health of Category 1 material referred to in Article 8(a)(v) and (b)(ii), Category 2 and Category 3 materials in remote areas;
- (c) by burning or burial on site or by other means under official supervision which prevent the transmission of risks to public and animal health of Category 1 material referred to in Article 8(b)(ii), Category 2 and Category 3 materials in areas where access is practically impossible or where access would only be possible under circumstances, related to geographical or climatic reasons or due to a natural disaster, which would pose a risk to the health and safety of the personnel carrying out the collection or where access would necessitate the use of disproportionate means of collection;
- (d) by means other than burning or burial on site, under official supervision, in the case of Category 2 and Category 3 materials which do not pose a risk to public and animal health, when the amounts of materials do not exceed a particular volume per week, this volume being determined in relation to the nature of the activities carried out and the species of origin of the animal by-products concerned;

(e) by burning or burial on site, under conditions which prevent the transmission of risks to public and animal health, of animal by-products other than Category 1 material referred to in Article 8(a)(i) in the event of an outbreak of a notifiable disease, if transport to the nearest plant approved for processing or disposal of the animal by-products would increase the danger of propagation of health risks or, in case of a widespread outbreak of an epizootic disease, would mean that the disposal capacities of such plants were exceeded; and

(f) by burning or burial on site, under conditions which prevent the transmission of risks to public and animal health, of bees and apiculture by-products.

2. The animal population of a particular species in the remote areas referred to in paragraph 1(b) shall not exceed a maximum percentage of the animal population of this species in the Member State concerned.

3. Member States shall make available to the Commission information on:

(a) the areas that they categorise as remote areas for the purpose of applying paragraph 1(b) and the reasons for that categorisation, and updated information concerning any change to such categorisation; and

(b) the use they make of the authorisations provided for in points (c) and (d) of paragraph 1 with respect to Category 1 and Category 2 materials.

4. Measures for the implementation of this Article shall be laid down relating to the following:

(a) conditions aimed at ensuring control of risks to public and animal health in the event of burning and burial on site;

(b) the maximum percentage of the animal population as referred to in paragraph 2;

(c) the volume of animal by-products, in relation to the nature of activities and the species of origin, as referred to in paragraph 1(d); and

(d) the list of diseases referred to in paragraph 1(e).

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 52(4).

Section 4

Alternative methods

Article 20

Authorisation of alternative methods

1. The procedure for authorisation of an alternative method of use or disposal of animal by-products or derived products may be initiated either by the Commission or, following an application, by a Member State or by an interested party, which may represent several interested parties.

2. Interested parties shall send their applications to the competent authority of the Member State where they intend to use the alternative method.

The competent authority shall evaluate, within a period of two months following receipt of a complete application, whether the application complies with the standard format for applications referred to in paragraph 10.

3. The competent authority shall communicate the applications of the Member States and interested parties, together with a report on its evaluation to the European Food Safety Authority (EFSA) and inform the Commission thereof.

4. When the Commission initiates the procedure for authorisation, it shall send a report on its evaluation to EFSA.

5. EFSA shall assess, within six months following receipt of a complete application, whether the method submitted ensures that risks to public or animal health are:

(a) controlled in a manner which prevents their proliferation before disposal in accordance with this Regulation or the implementing measures thereof; or

(b) reduced to a degree which is at least equivalent, for the relevant category of animal by-products, to the processing methods laid down pursuant to point (b) of the first subparagraph of Article 15(1).

EFSA shall issue an opinion on the application submitted.

6. In duly justified cases where EFSA requests additional information from applicants, the period provided for in paragraph 5 may be extended.

After consulting the Commission or the applicant, EFSA shall decide on a period within which that information shall be provided to it and inform the Commission and the applicant as appropriate of the additional period needed.

7. Where applicants wish to submit additional information on their own initiative, they shall send it directly to EFSA.

In that case the period provided for in paragraph 5 shall not be extended by an additional period.

8. EFSA shall forward its opinion to the Commission, the applicant and the competent authority of the Member State concerned.

9. Within three months following receipt of the opinion of EFSA and taking account of that opinion, the Commission shall inform the applicant of the proposed measure to be adopted in accordance with paragraph 11.

10. A standard format for applications for alternative methods shall be adopted in accordance with the advisory procedure referred to in Article 52(2).

11. Following receipt of the opinion of EFSA, the following shall be adopted:

- (a) either a measure authorising an alternative method of use or disposal of animal by-products or derived products; or
- (b) a measure rejecting the authorisation of such an alternative method.

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 52(4).

TITLE II

OBLIGATIONS OF OPERATORS

CHAPTER I

General obligations

Section 1

Collection, transport and traceability

Article 21

Collection and identification as regards category and transport

1. Operators shall collect, identify and transport animal by-products without undue delay under conditions which prevent risks arising to public and animal health.

2. Operators shall ensure that animal by-products and derived products are accompanied during transport by a commercial document or, when required by this Regulation or by a measure adopted in accordance with paragraph 6, by a health certificate.

By way of derogation from the first subparagraph, the competent authority may authorise the transport of manure between two points located on the same farm or between farms and users of manure within the same Member State without a commercial document or health certificate.

3. Commercial documents and health certificates accompanying animal by-products or derived products during transport shall at least include information on the origin, the destination and the quantity of such products, and a description of the animal by-products or derived products and their marking, when such marking is required by this Regulation.

However, for animal by-products and derived products transported within the territory of a Member State, the competent authority of the Member State concerned may authorise transmission of the information referred to in the first subparagraph by way of an alternative system.

4. Operators shall collect, transport and dispose of Category 3 catering waste, in accordance with national measures foreseen in Article 13 of Directive 2008/98/EC.

5. The following shall be adopted in accordance with the regulatory procedure referred to in Article 52(3):

- (a) models for commercial documents which are required to accompany animal by-products during transport; and
- (b) models for health certificates and the conditions governing the way they must accompany animal by-products and derived products during transport.

6. Measures for the implementation of this Article may be laid down relating to the following:

- (a) cases where a health certificate is required, having regard to the level of risk to public and animal health arising from certain derived products;
- (b) cases where, by way of derogation from the first subparagraph of paragraph 2 and having regard to the low level of risk to public and animal health arising from certain animal by-products or derived products, transport of derived products may take place without the documents or certificates referred to in that paragraph;
- (c) requirements for the identification, including labelling, and for the separation of different categories of animal by-products during transport; and
- (d) conditions to prevent risks to public and animal health arising during the collection and transport of animal by-products, including conditions for the safe transport of those products with respect to containers, vehicles and packaging material.

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 52(4).

Article 22

Traceability

1. Operators consigning, transporting or receiving animal by-products or derived products shall keep a record of consignments and related commercial documents or health certificates.

However, the first subparagraph shall not apply when an authorisation to transport animal by-products or derived products without commercial documents or health certificates has been granted in accordance with the second subparagraph of Article 21(2) or in accordance with implementing measures adopted under Article 21(6)(b).

2. The operators referred to in paragraph 1 shall have in place systems and procedures to identify:

- (a) the other operators to which their animal by-products or derived products have been supplied; and
- (b) the operators from whom they have been supplied.

This information shall be made available to the competent authorities on request.

3. Measures for the implementation of this Article may be adopted in accordance with the regulatory procedure referred to in Article 52(3), in particular on:

- (a) the information to be made available to the competent authorities;
- (b) the period of time during which this information must be kept.

Section 2

Registration and approval

Article 23

Registration of operators, establishments or plants

1. With a view to registration, operators shall:
 - (a) before commencing operations, notify the competent authority of any establishments or plants under their control which are active at any stage of the generation, transport, handling, processing, storage, placing on the market, distribution, use or disposal of animal by-products and derived products;
 - (b) provide the competent authority with information on:
 - (i) the category of animal by-products or derived products under their control;
 - (ii) the nature of the operations performed using animal by-products or derived products as starting material.
2. Operators shall provide the competent authority with up-to-date information on any establishments or plants under their control as referred to in point (a) of paragraph 1, including any significant change in activities such as any closure of an existing establishment or plant.
3. Detailed rules regarding registration as referred to in paragraph 1 may be adopted in accordance with the regulatory procedure referred to in Article 52(3).
4. By way of derogation from paragraph 1, no notification with a view to registration shall be required for activities with respect to which establishments generating animal by-products have already been approved or registered in accordance with Regulation (EC) No 852/2004 or Regulation (EC) No 853/2004; and for activities with respect to which establishments or plants have already been approved in accordance with Article 24 of this Regulation.

The same derogation shall apply for the activities involving the generation of animal by-products on site only, which are carried out on farms or other premises where animals are kept, bred or taken care of.

Article 24

Approval of establishments or plants

1. Operators shall ensure that establishments or plants under their control are approved by the competent authority, where such establishments or plants carry out one or more of the following activities:

- (a) processing of animal by-products by pressure sterilisation, by processing methods referred to in point (b) of the first subparagraph of Article 15(1) or by alternative methods authorised in accordance with Article 20;
- (b) disposal, as waste, by incineration of animal by-products and derived products, excluding establishments or plants which have a permit to operate in accordance with Directive 2000/76/EC;
- (c) disposal or recovery of animal by-products and derived products, if they are waste, by co-incineration, excluding establishments or plants which have a permit to operate in accordance with Directive 2000/76/EC;
- (d) use of animal by-products and derived products as fuel for combustion;
- (e) manufacturing of pet food;
- (f) manufacturing of organic fertilisers and soil improvers;
- (g) transformation of animal by-products and/or derived products into biogas or compost;
- (h) handling of animal by-products after their collection, by way of operations such as sorting, cutting, chilling, freezing, salting, removal of hides and skins or of specified risk material;
- (i) storage of animal by-products;
- (j) storage of derived products intended to be:
 - (i) disposed of by landfill or incineration or intended to be recovered or disposed of by co-incineration;
 - (ii) used as fuel for combustion;
 - (iii) used as feed, excluding establishments or plants approved or registered in accordance with Regulation (EC) No 1831/2003;
 - (iv) used as organic fertilisers and soil improvers, excluding storage at a place of direct application.

2. The approval referred to in paragraph 1 shall specify if the establishment or plant is approved for operations with animal by-products and/or derived products of:

- (a) a particular category referred to in Articles 8, 9 or 10; or
- (b) more than one category referred to in Articles 8, 9 or 10, indicating if such operations are carried out:
 - (i) permanently under conditions of strict separation which prevent any risk to public and animal health; or
 - (ii) temporarily under conditions which prevent contamination, in response to a shortage of capacity for such products arising due to:
 - a widespread outbreak of an epizootic disease, or
 - other extraordinary and unforeseen circumstances.

Article 25

General hygiene requirements

1. Operators shall ensure that establishments or plants under their control carrying out the activities referred to in Article 24(1)(a) and (h):

- (a) are constructed in a way permitting their effective cleaning and disinfection and where appropriate the construction of floors facilitates the draining of liquids;
- (b) have access to adequate facilities for personal hygiene such as lavatories, changing rooms and washbasins for staff;
- (c) have appropriate arrangements for protection against pests, such as insects, rodents and birds;
- (d) keep installations and equipment in good condition and ensure that measuring equipment is calibrated regularly; and
- (e) have appropriate arrangements for the cleaning and the disinfection of containers and vehicles in place to avoid risks of contamination.

2. Any person working in the establishment or plant referred to in paragraph 1 shall wear suitable, clean and, where necessary, protective clothing.

Where appropriate in a particular establishment or plant:

- (a) persons working in the unclean sector shall not enter the clean sector without first changing their work clothes and shoes or without having disinfected them;

(b) equipment and machinery shall not be moved from the unclean to the clean sector without first being cleaned and disinfected; and

(c) the operator shall establish a procedure relating to the movements of persons in order to monitor their movements and describe the correct use of footbaths and wheel baths.

3. In establishments or plants carrying out the activities referred to in Article 24(1)(a):

- (a) animal by-products shall be handled in such a way as to avoid risks of contamination;
- (b) animal by-products shall be processed as soon as possible. After processing, derived products shall be handled and stored in such a way as to avoid risks of contamination;
- (c) where appropriate, during any processing applied to animal by-products and derived products every part of the animal by-product and derived products shall be treated to a given temperature for a given period of time and risks of re-contamination shall be prevented;
- (d) the operators shall check regularly the applicable parameters, particularly temperature, pressure, time, size of particles, where appropriate by automatic devices;
- (e) cleaning procedures shall be established and documented for all parts of the establishments or plants.

Article 26

Handling of animal by-products within food businesses

1. The treatment, processing or storage of animal by-products in establishments or plants approved or registered in accordance with Article 4 of Regulation (EC) No 853/2004 or in accordance with Article 6 of Regulation (EC) No 852/2004 shall be carried out under conditions which prevent cross-contamination and if appropriate in a dedicated part of the establishment or plant.

2. Raw materials for the production of gelatine and collagen not intended for human consumption may be stored, treated or processed in the establishments specifically authorised in accordance with Regulation (EC) No 853/2004, Annex III, Section XIV, Chapter I, point 5, and Section XV, Chapter I, point 5, provided the transmission of disease risk is prevented by segregation of such raw materials from the raw materials for the production of products of animal origin.

3. Paragraphs 1 and 2 shall apply without prejudice to more specific requirements laid down in Community veterinary legislation.

Article 27

Implementing measures

Measures for the implementation of this Section and Section 1 of this Chapter shall be laid down relating to the following:

- (a) infrastructure and equipment requirements applicable within establishments or plants;

- (b) hygiene requirements applicable to all types of handling of animal by-products and derived products, including measures modifying hygiene requirements for establishments or plants referred to in Article 25(1);
- (c) conditions and technical requirements for the handling, treatment, transformation, processing and storage of animal by-products or derived products and conditions for treatment of waste water;
- (d) evidence to be presented by the operator for the purpose of validation of the treatment, transformation and processing of animal by-products or derived products, on their ability to prevent public and animal health risks;
- (e) conditions for the handling of animal by-products or derived products of more than one category referred to in Articles 8, 9 or 10 in the same establishment or plant:
 - (i) where such operations are carried out separately;
 - (ii) where such operations are carried out temporarily in certain circumstances;
- (f) conditions for the prevention of cross-contamination when animal by-products are stored, treated or processed in a dedicated part of an establishment or plant referred to in Article 26;
- (g) standard transformation parameters for biogas and composting plants;
- (h) requirements applicable to the incineration or co-incineration in plants of high and low capacity as referred to in Article 24(1)(b) and (c); and
- (i) requirements applicable to the combustion of animal by-products and derived products as referred to in Article 24(1)(d).

Those measures, designed to amend non-essential elements of this Regulation by supplementing it shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 52(4).

Section 3

Own checks and hazard analysis and critical control points

Article 28

Own checks

Operators shall put in place, implement and maintain own checks in their establishments or plants in order to monitor compliance with this Regulation. They shall ensure that no animal by-products or derived products suspected or discovered not to comply with this Regulation leave the establishment or plant, unless destined for disposal.

Article 29

Hazard analysis and critical control points

1. Operators carrying out one of the following activities shall put in place, implement and maintain a permanent written procedure or procedures based on the hazard analysis and critical control points (HACCP) principles for the:

- (a) processing of animal by-products;
- (b) transformation of animal by-products into biogas and compost;
- (c) handling and storage of more than one category of animal by-products or derived products in the same establishment or plant;
- (d) manufacturing of pet food.

2. Operators as specified in paragraph 1 shall in particular:

- (a) identify any hazards that must be prevented, eliminated or reduced to acceptable levels;
- (b) identify the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or reduce it to acceptable levels;
- (c) establish critical limits at critical control points which separate acceptability from unacceptability, for the prevention, elimination or reduction of identified hazards;
- (d) establish and implement effective monitoring procedures at critical control points;
- (e) establish corrective action when monitoring indicates that a critical control point is not under control;
- (f) establish procedures to verify that the measures outlined in points (a) to (e) are complete and working effectively. Verification procedures shall be carried out regularly;
- (g) establish documents and records commensurate with the nature and size of the businesses to demonstrate the effective application of the measures set out in points (a) to (f).

3. When any modification is made to a product, process or any stage of production, processing, storage or distribution, operators shall review their procedures and make the necessary changes.

4. Measures to facilitate the implementation of this Article may be adopted in accordance with the regulatory procedure referred to in Article 52(3).

Article 30

National guides to good practice

1. Where necessary, competent authorities shall encourage the development, dissemination and voluntary use of national guides to good practice in particular for the application of HACCP principles as referred to in Article 29. Operators may use such guides on a voluntary basis.

2. The competent authority shall assess national guides to ensure that:

- (a) they have been developed in consultation with representatives of parties whose interests may be substantially affected, and have been disseminated by sectors of operators; and
- (b) their contents are practicable for the sectors to which they refer.

CHAPTER II

Placing on the market

Section 1

Animal by-products and derived products for feeding to farmed animals excluding fur animals

Article 31

Placing on the market

1. Animal by-products and derived products destined for feeding to farmed animals, excluding fur animals, may only be placed on the market provided:

- (a) they are or they are derived from Category 3 material other than material referred to in Article 10(n), (o) and (p);
- (b) they have been collected or processed, as applicable, in accordance with the conditions for pressure sterilisation or other conditions to prevent risks arising to public and animal health in accordance with measures adopted pursuant to Article 15 and any measures which have been laid down in accordance with paragraph 2 of this Article; and
- (c) they come from approved or registered establishments or plants, as applicable for the animal by-product or derived product concerned.

2. Measures for the implementation of this Article may be laid down relating to the public and animal health conditions for the collection, processing and treatment of animal by-products and derived products referred to in paragraph 1.

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 52(4).

Section 2

Organic fertilisers and soil improvers

Article 32

Placing on the market and use

1. Organic fertilisers and soil improvers may be placed on the market and used provided:

- (a) they are derived from Category 2 or Category 3 material;
- (b) they have been produced in accordance with the conditions for pressure sterilisation or with other conditions to prevent risks arising to public and animal health, in accordance with the requirements laid down pursuant to Article 15 and any measures which have been laid down in accordance with paragraph 3 of this Article;
- (c) they come from approved or registered establishments or plants, as applicable; and
- (d) in the case of meat-and-bone meal derived from Category 2 material and processed animal proteins intended to be used as or in organic fertilisers and soil improvers, they have been mixed with a component to exclude the subsequent use of the mixture for feeding purposes and marked when required by measures adopted under paragraph 3.

In addition, digestion residues from transformation into biogas or compost may be placed on the market and used as organic fertilisers or soil improvers.

Member States may adopt or maintain national rules imposing additional conditions for or restricting the use of organic fertilisers and soil improvers, provided that such rules are justified on grounds of the protection of public and animal health.

2. By way of derogation from point (d) of paragraph 1, mixing shall not be required for materials whose use for feeding purposes is excluded due to their composition or packaging.

3. Measures for the implementation of this Article may be laid down relating to the following:

- (a) public and animal health conditions for the production and use of organic fertilisers and soil improvers;
- (b) components or substances for the marking of organic fertilisers or soil improvers;
- (c) components to be mixed with organic fertilisers or soil improvers;
- (d) supplementary conditions, such as the methods to be used for marking and the minimum proportions to be observed when preparing the mixture, in order to exclude the use of such fertilisers or soil improvers for feeding purposes; and

- (e) cases where the composition or packaging allows the materials to be exempted from the mixing requirement.

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 52(4).

Section 3

Derived products regulated by certain other Community legislation

Article 33

Placing on the market

Operators may place on the market the following derived products:

- (a) cosmetic products as defined in Article 1(1) of Directive 76/768/EEC;
- (b) active implantable medical devices as defined in Article 1(2)(c) of Directive 90/385/EEC;
- (c) medical devices as defined in Article 1(2)(a) of Directive 93/42/EEC;
- (d) in vitro diagnostic medical devices as defined in Article 1(2)(b) of Directive 98/79/EC;
- (e) veterinary medicinal products as defined in Article 1(2) of Directive 2001/82/EC;
- (f) medicinal products as defined in Article 1(2) of Directive 2001/83/EC.

Article 34

Manufacture

1. The import, collection and movement of animal by-products and derived products destined for establishments or plants for the manufacture of the derived products referred to in Article 33 and the manufacture of those derived products shall be carried out in accordance with the Community legislation referred to in that Article.

Unused material from such establishments or plants shall be disposed of in accordance with that legislation.

2. However, this Regulation shall apply where the Community legislation referred to in Article 33 does not provide for conditions controlling potential risks to public and animal health in accordance with the objectives of this Regulation.

Section 4

Other derived products

Article 35

Placing on the market of pet food

Operators may place pet food on the market provided:

- (a) the products are derived:
 - (i) from Category 3 material, other than material referred to in Article 10(n), (o) and (p);
 - (ii) in the case of imported pet food or of pet food produced from imported materials, from Category 1 material referred to in Article 8(c), subject to conditions laid down pursuant to point (a) of the first paragraph of Article 40; or
 - (iii) in the case of raw petfood, from material referred to in Article 10(a) and (b)(i) and (ii); and
- (b) they ensure the control of risks to public and animal health by safe treatment in accordance with Article 38, where safe sourcing in accordance with Article 37 does not ensure sufficient control.

Article 36

Placing on the market of other derived products

Operators may place on the market derived products, other than the products referred to in Articles 31, 32, 33 and 35, provided:

- (a) those products are:
 - (i) not intended for use for the feeding to farmed animals or for application to land from which such animals are to be fed; or
 - (ii) intended for feeding to fur animals; and
- (b) they ensure the control of risks to public and animal health by:
 - (i) safe sourcing in accordance with Article 37;
 - (ii) safe treatment in accordance with Article 38, where safe sourcing does not ensure sufficient control; or
 - (iii) verifying that the products are only used for safe end uses in accordance with Article 39 where safe treatment does not ensure sufficient control.

*Article 37***Safe sourcing**

1. Safe sourcing shall include the use of material:
 - (a) from which no unacceptable risks to public and animal health arise;
 - (b) which has been collected and transported from the point of collection to the manufacturing establishment or plant under conditions which exclude risks to public and animal health; or
 - (c) which has been imported into the Community and transported from the point of first entry to the manufacturing establishment or plant under conditions which exclude risks to public and animal health.
2. For the purpose of safe sourcing, operators shall provide documentation of the requirements of paragraph 1, including, where necessary, proof of the safety of bio-security measures taken in order to exclude risks arising to public and animal health from starting material.

Such documentation shall be kept available to the competent authority upon request.

In the case referred to in point (c) of paragraph 1, the consignments shall be accompanied by a health certificate corresponding to a model adopted in accordance with the regulatory procedure referred to in Article 52(3).

*Article 38***Safe treatment**

Safe treatment shall include application of a manufacturing process to the material used which reduces to an acceptable level risks to public and animal health arising from the material used or from other substances resulting from the manufacturing process.

It shall be ensured that the derived product poses no unacceptable risks to public and animal health, in particular by means of testing of the end product.

*Article 39***Safe end uses**

Safe end uses shall include the use of derived products:

- (a) under conditions which pose no unacceptable risks to public and animal health; or
- (b) which may pose a risk to public and animal health, for specific purposes provided that such use is justified by objectives set out in Community legislation, in particular for the protection of public and animal health.

*Article 40***Implementing measures**

Measures for the implementation of this Section may be laid down relating to the following:

- (a) conditions for the placing on the market of imported pet food or of pet food produced from imported materials, from Category 1 material referred to in Article 8(c);
- (b) conditions for the safe sourcing and movement of material to be used under conditions which exclude risks to public and animal health;
- (c) documentation as referred to in the first subparagraph of Article 37(2);
- (d) parameters for the manufacturing process as referred to in the first paragraph of Article 38, in particular as regards the application of physical or chemical treatments to the material used;
- (e) testing requirements applicable to the end product; and
- (f) conditions for the safe use of derived products which pose a risk to public or animal health.

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 52(4).

*CHAPTER III***Import, transit and export***Article 41***Import and transit**

1. Animal by-products and derived products shall be imported into, or sent in transit through, the Community in accordance with:
 - (a) the relevant requirements of this Regulation and the implementing measures thereof for the particular animal by-product or derived product which are at least as stringent as those applicable to the production and marketing of such animal by-products or derived products within the Community;
 - (b) conditions recognised to be at least equivalent to the requirements applicable to the production and marketing of such animal by-products or derived products under Community legislation; or
 - (c) in the case of animal by-products and derived products referred to in Articles 33, 35 and 36, the requirements set out in those Articles.

The measures referred to in point (b) of the first subparagraph, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 52(4).

2. By way of derogation from paragraph 1, the import and transit of:

- (a) specified risk material shall take place only in accordance with Regulation (EC) No 999/2001;
- (b) animal by-products or derived products mixed or contaminated with any waste listed as hazardous in Decision 2000/532/EC shall take place only subject to the requirements of Regulation (EC) No 1013/2006;
- (c) Category 1 material, Category 2 material and products derived therefrom which are not intended for the manufacture of derived products referred to in Articles 33, 35 and 36, shall only take place provided that rules for their import have been adopted in accordance with Article 42(2)(a);
- (d) animal by-products and derived products destined for the purposes referred to in Article 17(1) shall take place in accordance with national measures which ensure the control of risks to public and animal health, pending the adoption of harmonised conditions referred to in Article 17(2).

3. In the case of import and transit of Category 3 material and products derived therefrom, the relevant requirements as referred to in point (a) of the first subparagraph of paragraph 1 shall be laid down.

Those requirements may specify that consignments:

- (a) must come from a third country or part of a third country listed in accordance with paragraph 4;
- (b) must come from establishments or plants approved or registered by the competent authority of the third country of origin and listed by that authority for that purpose; and
- (c) must be accompanied at the point of entry into the Community where the veterinary checks take place by documentation such as a commercial document or a health certificate and where appropriate by a declaration, which corresponds to a model laid down pursuant to point (d) of the first subparagraph of Article 42(2).

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 52(4).

Pending the adoption of the requirements referred to in points (a) and (c) of the second subparagraph, the Member States shall specify those requirements in national measures.

4. Lists of third countries or parts of third countries from which animal by-products or derived products may be imported or transit through the Community shall be drawn up in accordance with the regulatory procedure referred to in Article 52(3), taking into account in particular:

- (a) the legislation of the third country;
- (b) the organisation of the competent authority and its inspection services in the third country, the powers of those services, the supervision to which they are subject, and their authority to monitor effectively the application of their legislation;
- (c) the actual health conditions applied to the production, manufacture, handling, storage and dispatch of products of animal origin intended for the Community;
- (d) the assurances the third country can give regarding compliance with the relevant health conditions;
- (e) experience of marketing the product from the third country and the results of import checks carried out;
- (f) the result of any Community inspections in the third country;
- (g) the health status of the livestock, other domestic animals and wildlife in the third country, having particular regard to exotic animal diseases and any aspects of the general health situation in the country which might pose a risk to public or animal health in the Community;
- (h) the regularity and speed with which the third country supplies information about the existence of infectious animal diseases in its territory, in particular the diseases listed in the Terrestrial Animal Health Code and the Aquatic Animal Health Code of the World Organisation for Animal Health;
- (i) the regulations on the prevention and control of infectious animal diseases in force in the third country and their implementation, including rules on imports from other third countries.

The lists of establishments or plants referred to in point (b) of the second subparagraph of paragraph 3 shall be kept up to date and communicated to the Commission and the Member States and made available to the public.

Article 42

Implementing measures

1. Measures for the implementation of Article 41 which may exclude animal by-products or derived products manufactured in certain establishments or plants from import or transit in order to protect public or animal health shall be adopted in accordance with the regulatory procedure referred to in Article 52(3).

2. Other measures for the implementation of Article 41 shall be laid down relating to the following:

- (a) conditions for the import and transit of Category 1 and Category 2 materials and for products derived therefrom;
- (b) restrictions regarding public or animal health applicable to imported Category 3 material or products derived therefrom which may be laid down by reference to Community lists of third countries or parts of third countries drawn up in accordance with Article 41(4) or for other public or animal health purposes;
- (c) conditions for the manufacture of animal by-products or derived products in establishments or plants in third countries; such conditions may include the arrangements for controls of such establishments or plants by the competent authority concerned and may exempt certain types of establishments or plants handling animal by-products or derived products from approval or registration as referred to in point (b) of the second subparagraph of Article 41(3); and
- (d) models for health certificates, commercial documents and declarations which are to accompany consignments, specifying the conditions under which it can be stated that the animal by-products or derived products concerned have been collected or manufactured in accordance with the requirements of this Regulation.

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 52(4).

Article 43

Export

1. The export of animal by-products and derived products destined for incineration or landfill shall be prohibited.
2. The export of animal by-products and derived products to third countries which are not members of the OECD for use in a biogas or composting plant shall be prohibited.
3. Category 1 material, Category 2 material and products derived therefrom shall only be exported for purposes other than those referred to in paragraphs 1 and 2 provided that rules for their export have been laid down.

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 52(4).

4. Article 12 of Regulation (EC) No 178/2002 concerning food and feed exported from the Community shall apply *mutatis mutandis* to the export of Category 3 material or products derived therefrom in compliance with this Regulation.

5. By way of derogation from paragraphs 3 and 4, the export of:

- (a) specified risk material shall take place only in accordance with Regulation (EC) No 999/2001;
- (b) animal by-products or derived products mixed or contaminated with any waste listed as hazardous in Decision 2000/532/EC shall take place only subject to the requirements of Regulation (EC) No 1013/2006.

TITLE III

OFFICIAL CONTROLS AND FINAL PROVISIONS

CHAPTER I

Official controls

Article 44

Procedure for approval

1. The competent authority shall approve establishments or plants only where an on site visit, prior to start-up of any activity, has demonstrated that they meet the relevant requirements laid down in accordance with Article 27.
2. The competent authority may grant conditional approval if it appears, from the on site visit, that the establishment or plant meets all the infrastructure and equipment requirements with a view to ensuring the application of the operational procedures in compliance with this Regulation. It shall grant full approval only if it appears, from another on site visit carried out within three months of granting conditional approval, that the establishment or plant meets the other requirements referred to in paragraph 1. If clear progress has been made, but the establishment or plant still does not meet all of these requirements, the competent authority may extend conditional approval. However, conditional approval shall not exceed a total of six months.
3. Operators shall ensure that an establishment or plant ceases to operate if the competent authority withdraws its approval or in the case of conditional approval fails to extend it or to grant full approval.

Article 45

Official controls

1. Without prejudice to Article 5, the competent authority shall at regular intervals carry out official controls and supervision of the handling of animal by-products and derived products falling within the scope of this Regulation.
2. Articles 41 and 42 of Regulation (EC) No 882/2004 shall apply *mutatis mutandis* to official controls carried out to verify compliance with this Regulation.

3. The competent authority may take into account adherence to guides to good practice, when carrying out its official controls.

4. Detailed arrangements for implementing this Article, including rules concerning the reference methods for microbiological analyses, may be laid down.

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 52(4).

Article 46

Suspensions, withdrawals and prohibitions on operations

1. If the official controls and supervision carried out by the competent authority reveal that one or more of the requirements of this Regulation are not met, it shall take appropriate action.

The competent authority shall in particular, as appropriate to the nature and to the gravity of the deficiencies and to the potential risks for public and animal health:

- (a) suspend approvals of establishments or plants approved pursuant to this Regulation, if:
 - (i) the conditions for approving or operating the establishment or plant are no longer fulfilled;
 - (ii) the operator can be expected to remedy the deficiencies within a reasonable period of time; and
 - (iii) the potential risks to public and animal health do not require action in accordance with point (b);
- (b) withdraw approvals of establishments or plants approved pursuant to this Regulation, if:
 - (i) the conditions for approving or operating the establishment or plant are no longer fulfilled; and
 - (ii) the operator cannot be expected to remedy the deficiencies within a reasonable period of time:
 - for reasons relating to the infrastructure of the establishment or plant,
 - for reasons relating to the personal capacity of the operator or the staff under his supervision, or
 - because of serious risks to public and animal health requiring major adjustments to the operation of the establishment or plant before the operator may apply for re-approval;
- (c) impose specific conditions on establishments or plants in order to rectify existing deficiencies.

2. The competent authority shall, as appropriate to the nature and to the gravity of the deficiencies and to the potential risks for public and animal health, temporarily or permanently prohibit operators referred to in Articles 23(1) and (3) and Article 24(1) from carrying out operations under this Regulation, as appropriate, following receipt of information indicating:

- (a) that the requirements of Community legislation are not met; and
- (b) potential risks to public or animal health arising from such operations.

Article 47

Lists

1. Each Member State shall draw up a list of establishments, plants and operators which have been approved or registered in accordance with this Regulation within its territory.

It shall assign an official number to each approved or registered establishment, plant or operator, which identifies the establishment, plant or operator with respect to the nature of its activities.

Member States shall indicate, if applicable, an official number which has been assigned to the establishment, plant or operator under other Community legislation.

Member States shall make the lists of approved or registered establishments, plants and operators available to the Commission and other Member States.

Member States shall keep up-to-date the lists of approved or registered establishments, plants and operators and make them available to other Member States and to the public.

2. Measures for the implementation of this Article may be laid down in accordance with the regulatory procedure referred to in Article 52(3), in particular on:

- (a) the format for the lists referred to in paragraph 1; and
- (b) the procedure for making the lists referred to in paragraph 1 available.

Article 48

Controls for dispatch to other Member States

1. Where an operator intends to dispatch Category 1 material, Category 2 material and meat-and-bone meal or animal fat derived from Category 1 and Category 2 materials to another Member State, it shall inform the competent authority of the Member State of origin and the competent authority of the Member State of destination.

The competent authority of the Member State of destination shall decide upon application by the operator, within a specified time period:

- (a) to refuse receipt of the consignment;
- (b) to accept the consignment unconditionally; or

- (c) to make receipt of the consignment subject to the following conditions:
- (i) if the derived products have not undergone pressure sterilisation, it must undergo such treatment; or
 - (ii) the animal by-products or derived products must comply with any conditions for the dispatch of the consignment which are justified for the protection of public and animal health in order to ensure that animal by-products and derived products are handled in accordance with this Regulation.

2. Formats for applications by operators referred to in paragraph 1 may be adopted in accordance with the regulatory procedure referred to in Article 52(3).

3. The competent authority of the Member State of origin shall inform the competent authority of the Member State of destination, by means of the Traces system in accordance with Decision 2004/292/EC, of the dispatch of each consignment sent to the Member State of destination, of

- (a) animal by-products or derived products referred to in paragraph 1;
- (b) processed animal protein derived from Category 3 material.

When informed of the dispatch, the competent authority of the Member State of destination shall inform the competent authority of the Member State of origin of the arrival of each consignment by means of the Traces system.

4. Category 1 and Category 2 materials, meat-and-bone meal and animal fat referred to in paragraph 1 shall be transported directly to the establishment or plant of destination, which must have been registered or approved in accordance with Articles 23, 24 and 44 or, in the case of manure, to the farm of destination.

5. When animal by-products or derived products are sent to other Member States via the territory of a third country, they shall be sent in consignments which have been sealed in the Member State of origin and shall be accompanied by a health certificate.

The sealed consignments shall re-enter the Community only via a border inspection post, in accordance with Article 6 of Directive 89/662/EEC.

6. By way of derogation from paragraphs 1 to 5, animal by-products or derived products referred to therein which have been mixed or contaminated with any waste listed as hazardous in Decision 2000/532/EC shall be sent to other Member States only subject to the requirements of Regulation (EC) No 1013/2006.

7. Measures for the implementation of this Article may be adopted relating to the following:

- (a) a specified time period for the decision of the competent authority as referred to in paragraph 1;
- (b) supplementary conditions for the dispatch of animal by-products or derived products referred to in paragraph 4;

- (c) models for the health certificates which have to accompany consignments sent in accordance with paragraph 5; and
- (d) conditions under which animal by-products or derived products intended to be used for exhibitions, artistic activities, for diagnostic, educational or research purposes may be sent to other Member States, by way of derogation from paragraph 1 to 5 of this Article.

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 52(4).

8. Measures for the implementation of this Article may specify the conditions subject to which, by way of derogation from paragraphs 1 to 4, the competent authorities may allow:

- (a) the dispatch of manure transported between two points located on the same farm or between farms located in the border regions of Member States sharing a common border;
- (b) the dispatch of other animal by-products transported between establishments or plants located in the border regions of Member States sharing a common border; and
- (c) the transport of a dead pet animal for incineration to an establishment or plant located in the border region of another Member State sharing a common border.

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 52(4).

Article 49

Community controls in Member States

1. Experts from the Commission may make on-the-spot checks, in cooperation with the competent authorities of Member States, in so far as is necessary for the uniform application of this Regulation.

The Member State on whose territory the checks are made shall provide the experts with all the assistance necessary for carrying out their duties.

The Commission shall inform the competent authority of the results of the checks made.

2. Measures for the implementation of this Article may be adopted in accordance with the regulatory procedure referred to in Article 52(3), in particular on the procedure for the cooperation with national authorities.

*Article 50***Application of Regulation (EC) No 882/2004 for the purposes of certain controls**

1. Article 46 of Regulation (EC) No 882/2004 shall apply *mutatis mutandis* to Community controls in third countries carried out to verify compliance with this Regulation.
2. Article 50(1)(a) of Regulation (EC) No 882/2004 shall apply *mutatis mutandis* to the phased introduction of the requirements of Article 41(3) of this Regulation.
3. Article 52 of Regulation (EC) No 882/2004 shall apply *mutatis mutandis* to third-country controls in Member States related to operations under this Regulation.

CHAPTER II

Final provisions*Article 51***National provisions**

Member States shall communicate to the Commission the text of the provisions of national law they adopt in areas under their competence which directly concern the proper implementation of this Regulation.

*Article 52***Committee procedure**

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health established by Article 58(1) of Regulation (EC) No 178/2002.
2. Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.
3. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

4. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

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

Done at Strasbourg, 21 October 2009.

For the European Parliament
The President
J. BUZEK

For the Council
The President
C. MALMSTRÖM

5. Where reference is made to this paragraph, Article 5a(1) to (4) and (5)(b) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The time limits laid down in Article 5a(3)(c), (4)(b) and (4)(e) of Decision 1999/468/EC shall be two months, one month and two months respectively.

6. Where reference is made to this paragraph, Article 5a(1), (2), (4) and (6) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

*Article 53***Penalties**

The Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission by 4 June 2011 and shall notify it without delay of any subsequent amendment affecting them.

*Article 54***Repeal**

Regulation (EC) No 1774/2002 shall be repealed with effect from 4 March 2011.

References to Regulation (EC) No 1774/2002 shall be construed as references to this Regulation and shall be read in accordance with the correlation table laid down in the Annex.

*Article 55***Transitional measure**

Establishments, plants and users approved or registered in accordance with Regulation (EC) No 1774/2002 before 4 March 2011 shall be deemed to be approved or registered, as required, in accordance with this Regulation.

*Article 56***Entry into force**

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

It shall apply from 4 March 2011.

ANNEX

CORRELATION TABLE

Regulation (EC) No 1774/2002	This Regulation
Article 1	Articles 1 and 2
Article 2	Article 3
Article 3(1)	Article 4(1) and(2)
Article 3(2)	Article 41(3), fourth subparagraph
Article 3(3)	Article 4(3), (4) and (5)
Article 4(1)	Article 8
Article 4(2)	Articles 12, 15 and 16
Article 4(3)	Article 24(h), (i) and (j)
Article 4(4)	Article 41(2)(c), Article 43(3) and (5)(a)
Article 5(1)	Article 9
Article 5(2)	Articles 13, 15 and 16
Article 5(3)	Article 24(h), (i) and (j)
Article 5(4)	Article 41(2)(c) and Article 43(3)
Article 6(1)	Article 10
Article 6(2)	Articles 14, 15 and 16
Article 6(3)	Article 24(h), (i) and (j)
Article 7	Article 21
Article 8	Article 48
Article 9	Article 22
Articles 10 to 15, 17 and 18	Articles 23, 24, 27 and 44
Article 16	Article 6
Article 19	Article 31
Article 20(1)	Articles 35 and 36
Article 20(2)	Article 32
Article 20(3)	Article 36
Article 21	—
Article 22	Article 11
Article 23	Articles 17 and 18
Article 24	Article 19
Article 25	Articles 28 and 29
Article 26	Articles 45, 46 and 47
Article 27	Article 49
Article 28	Article 35(a)(ii) and Article 41(1)
Article 29	Articles 41 and 42
Article 30	Article 41(1)(b)
Article 31	Article 50(1)
Article 32	—
Article 33	Article 52
Article 34	—
Article 35	Article 15(2) and Article 51
Article 36	—
Article 37	Article 54
Article 38	Article 56

REGULATION (EC) No 1070/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 21 October 2009

amending Regulations (EC) No 549/2004, (EC) No 550/2004, (EC) No 551/2004 and (EC) No 552/2004
in order to improve the performance and sustainability of the European aviation system

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 80(2) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee ⁽¹⁾,

Having regard to the opinion of the Committee of the Regions ⁽²⁾,

Acting in accordance with the procedure laid down in Article 251 of the Treaty ⁽³⁾,

Whereas:

- (1) Implementation of the common transport policy requires an efficient air transport system allowing the safe, regular and sustainable operation of air transport services, optimising capacity and facilitating the free movement of goods, persons and services.
- (2) The adoption by the European Parliament and the Council of the first package of the single European sky legislation, namely, Regulation (EC) No 549/2004 of 10 March 2004 laying down the framework for the creation of the single European sky (the framework Regulation) ⁽⁴⁾, Regulation (EC) No 550/2004 of 10 March 2004 on the provision of air navigation services in the single European sky (the service provision Regulation) ⁽⁵⁾, Regulation (EC) No 551/2004 of 10 March 2004 on the organisation and use of the airspace in the single European sky (the airspace Regulation) ⁽⁶⁾, and Regulation (EC) No 552/2004 of 10 March 2004 on the interoperability of the European air traffic management network (the interoperability Regulation) ⁽⁷⁾ laid down a firm legal basis for a seamless, interoperable and safe air traffic management (ATM) system.

- (3) In response to strong demand from industry, Member States and other stakeholders to simplify and increase the effectiveness of the regulatory framework for aviation in Europe, a high level group on the future of the European aviation regulatory framework (the High Level Group) was established in November 2006. The High Level Group, made up of representatives of the majority of stakeholders, submitted a report in July 2007 containing recommendations on how to improve the performance and governance of the European aviation system. The High Level Group recommended according the environment the same importance as safety and efficiency in the aviation system and insisted that industry and regulators should work together to ensure that ATM contributes as much as possible to sustainability.

- (4) At its meeting of 7 April 2008 the Council invited the Commission to develop, in accordance with the recommendations of the High Level Group, an overall system approach in line with the gate-to-gate concept to enhance safety, improve ATM and to increase cost efficiency.

- (5) In order to complete the creation of the single European sky, it is necessary to adopt additional measures at Community level, in particular, to improve the performance of the European aviation system in key areas such as the environment, capacity and cost-efficiency, all having regard to the overriding safety objectives. It is also necessary to adapt the single European sky legislation to technical progress.

- (6) Council Regulation (EC) No 219/2007 of 27 February 2007 on the establishment of a Joint Undertaking to develop the new generation European air traffic management system (SESAR) ⁽⁸⁾ calls for the development and implementation of an ATM Master Plan. The implementation of the ATM Master Plan requires regulatory measures to support the development, introduction and financing of new concepts and technologies. It should result in a system composed of fully harmonised and interoperable components, which guarantee high performance air transport activities in Europe. The schedule for implementation of the single European sky should take into consideration the timescale foreseen for the development and deployment phases of the SESAR programme as a part of the single European sky. Both processes should be closely coordinated.

⁽¹⁾ OJ C 182, 4.8.2009, p. 50.

⁽²⁾ OJ C 120, 28.5.2009, p. 52.

⁽³⁾ Opinion of the European Parliament of 25 March 2009 (not yet published in the Official Journal) and Council Decision of 7 September 2009.

⁽⁴⁾ OJ L 96, 31.3.2004, p. 1.

⁽⁵⁾ OJ L 96, 31.3.2004, p. 10.

⁽⁶⁾ OJ L 96, 31.3.2004, p. 20.

⁽⁷⁾ OJ L 96, 31.3.2004, p. 26.

⁽⁸⁾ OJ L 64, 2.3.2007, p. 1.

- (7) The concept of common projects, aimed at assisting airspace users and/or air navigation service providers to improve collective air navigation infrastructure, the provision of air navigation services and the use of airspace, in particular those that may be required for the implementation of the ATM Master Plan, should not prejudice pre-existing projects decided by one or several Member States with similar objectives. The provisions on financing of the deployment of common projects should not prejudice the manner in which these common projects are set up. The Commission may propose that funding, such as Trans-European Network or European Investment Bank funding, may be used in support of common projects, in particular to speed up the deployment of the SESAR programme, within the multiannual financial framework. Without prejudice to access to that funding, Member States should be free to decide how revenues generated by the auctioning of aviation sector allowances under the Emissions Trading Scheme are to be used and to consider in this context whether a share of such revenues might be used to finance common projects at the level of functional airspace blocks.
- (8) In particular where common projects are deployed, care should be taken, *inter alia*, through the application of comprehensive and transparent accounting, to ensure that airspace users are not double-charged. Common projects should be deployed to the benefit of all stakeholders and should ensure equal treatment thereof.
- (9) To ensure the consistent and sound oversight of service provision across Europe, the national supervisory authorities should be guaranteed sufficient independence and resources. This independence should not prevent those authorities from exercising their tasks within an administrative framework.
- (10) National supervisory authorities have a key role to play in the implementation of the single European sky and the Commission should therefore facilitate cooperation among them in order to enable the exchange of best practices and to develop a common approach, including through enhanced cooperation at regional level. This cooperation should take place on a regular basis.
- (11) The social partners should be better informed and consulted on all measures having significant social implications. At Community level, the Sectoral Dialogue Committee set up under Commission Decision 98/500/EC ⁽¹⁾ should also be consulted.
- (12) To drive improved performance of ATM and air navigation services (ANS), it is necessary to establish a framework for the definition, implementation and enforcement of binding performance targets in key performance areas in line with the policies of the International Civil Aviation Organisation (ICAO). An indispensable feature of such a framework should be an appropriate mechanism for reporting, examining, evaluating and disseminating performance data of ATM and ANS along with a relevant incentive scheme to encourage achievement of the targets.
- (13) National supervisory authorities should have the flexibility to reflect specific national or regional circumstances when formulating their national and regional plans. When approving or adopting national plans, Member States should be entitled to make appropriate modifications.
- (14) When establishing charges for air navigation services the Commission and Member States should endeavour to use common forecasts. Some flexibility should be permitted in those cases where traffic diverges significantly from forecasts, in particular by using appropriate alert mechanisms.
- (15) The costs determined by the Member States at national level or at the level of a functional airspace block which are intended to be shared among airspace users should take account of performance targets.
- (16) For the cross-border provision of services, Member States should ensure that the designation of an air traffic service provider is not prohibited by any national legal system on the grounds that it is established in another Member State or is owned by nationals of that Member State.
- (17) The national supervisory authorities should take appropriate measures to ensure a high level of safety including the possibility of issuing an individual certificate for each type of air navigation service, while respecting the need for cost-efficiency and consistency and avoiding duplication.
- (18) The functional airspace blocks are key enablers for enhancing cooperation between air navigation service providers in order to improve performance and create synergies. Member States should establish functional airspace blocks within a reasonable time-frame. For that purpose and in order to optimise the interface of functional airspace blocks in the single European sky, the Member States concerned should cooperate with each other and where appropriate they should also cooperate with third countries.
- (19) When Member States establish a functional airspace block, other Member States, the Commission and other interested parties have an opportunity to submit their observations with the aim of facilitating an exchange of views. Those observations should be merely of an advisory nature for the Member State(s) concerned.

(¹) OJ L 225, 12.8.1998, p. 27.

- (20) In case of difficulties in the negotiation process with regard to the setting up of functional airspace blocks, the Commission may designate a Functional Airspace Blocks System Coordinator (the Coordinator). The tasks of the Coordinator should aim at providing assistance in overcoming such difficulties without interfering with the sovereignty of the Member State(s) concerned and, where appropriate, that of third countries taking part in the same functional airspace block. Costs incurred for the activities of the Coordinator should not have any impact on Member States' national budgets.
- (21) The reports of the Eurocontrol Performance Review Commission and the final report of the High Level Group confirm that the route network and airspace structure cannot be developed in isolation, as each individual Member State is an integral element of the European Air Traffic Management Network (EATMN), both inside and outside the Community. A progressively more integrated operating airspace should therefore be established for general air traffic.
- (22) In view of the creation of functional airspace blocks and the setting up of the performance scheme, the Commission should determine and take into account the necessary conditions for the Community to create a Single European Flight Information Region (SEFIR), to be requested by the Member States from the ICAO in accordance with both the established procedures of that organisation and the rights, obligations and responsibilities of Member States under the Convention on International Civil Aviation, signed in Chicago on 7 December 1944 (the Chicago Convention). By encompassing the airspace under the responsibility of the Member States, the SEFIR should facilitate common planning and integrated operations in order to overcome regional bottlenecks. Such a SEFIR should include the necessary flexibility to reflect specific needs such as traffic density and the level of complexity required.
- (23) Airspace users face disparate conditions of access to, and freedom of movement within, Community airspace. This is due to the lack of harmonised Community rules of the air, and, in particular, the lack of a harmonised classification of airspace. The Commission should therefore harmonise such rules on the basis of ICAO standards.
- (24) The EATMN should be designed and implemented with a view to achieving the safety, environmental sustainability, capacity enhancement and improved cost-efficiency of the whole air transport network. As highlighted in the Eurocontrol performance review Commission's report entitled 'Evaluation of functional airspace block initiatives and their contribution to performance improvement' of 31 October 2008, this could be best ensured through coordinated air transport network management at Community level.
- (25) In line with the Statement by the Member States on military issues related to the single European sky accompanying Regulation (EC) No 549/2004, civil-military cooperation and coordination should play a fundamental role in the implementation of the single European sky, in order to move towards an enhanced flexible use of airspace for the achievement of the single European sky performance objectives, having due regard to military mission effectiveness.
- (26) It is essential to achieve a common, harmonised airspace structure in terms of routes, to base the present and future organisation of airspace on common principles, to ensure the progressive implementation of the ATM Master Plan, to optimise the use of scarce resources to avoid unnecessary equipage costs, and to design and manage airspace in accordance with harmonised rules. To this end, the Commission should be responsible for adopting the necessary rules and implementing decisions with legally binding effect.
- (27) The list of functions for network management and design should be amended to integrate, if necessary, future network functions defined by the ATM Master Plan. In doing so, the Commission should make the best possible use of the expertise of Eurocontrol.
- (28) The High Level Group has recommended building new or enhanced functions upon existing foundations and enhancing the role of Eurocontrol, while positioning the Community as the single regulator and respecting the principle of separation of regulation from service provision. Accordingly, the Commission should entrust a reformed Eurocontrol, which has new governance arrangements in place, with the execution of tasks related to various functions, which do not involve the adoption of binding measures of a general scope or the exercise of political discretion. The execution of these tasks by Eurocontrol should be done in an impartial and cost-effective manner and with the full involvement of the airspace users and air navigation service providers.
- (29) Adequate measures should be introduced to improve the effectiveness of air traffic flow management in order to assist existing operational units, including the Eurocontrol Central Flow Management Unit, to ensure efficient flight operations. Furthermore, the Commission communication on an action plan for airport capacity, efficiency and safety in Europe highlights the need to ensure operational consistency between flight plans and airport slots. In addition, the Community Observatory on Airport Capacity could help in providing Member States with objective information in order to align airport capacity with ATM capacity, without prejudice to their competences in this area.

- (30) The provision of modern, complete, high-quality and timely aeronautical information has a significant impact on safety and on facilitating access to Community airspace and freedom of movement within it. Taking account of the ATM Master Plan, the Community should take the initiative to modernise this sector in cooperation with Eurocontrol and ensure that users are able to access those data through a single public point of access, providing a modern, user-friendly and validated integrated briefing.
- (31) For the electronic portal on meteorological information, the Commission should take into account the various sources of information including from designated service providers, where relevant.
- (32) To avoid unnecessary administrative burden and overlapping verification procedures, certificates issued in accordance with Regulation (EC) No 216/2008 of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency ⁽¹⁾ should be accepted for the purposes of this Regulation, where they apply to constituents or systems.
- (33) A certificate issued in accordance with Regulation (EC) No 216/2008 and used to demonstrate an alternative means of compliance with the essential requirements of Regulation (EC) No 552/2004, should be accompanied by a technical file as required for the purposes of certification by the European Aviation Safety Agency (EASA).
- (34) Certain requirements of Regulation (EC) No 552/2004 should not apply to systems put into operation before 20 October 2005. National supervisory authorities and air navigation service providers should have the freedom to agree, at national level, the procedures and documentation required to demonstrate compliance of ATM systems in operation before 20 October 2005 with the essential requirements of Regulation (EC) No 552/2004. Implementing rules and Community specifications adopted after the adoption of this Regulation should take account of this arrangement and this should not result in a retroactive requirement for documentary evidence.
- (35) The High Level Group recommended in its final report to the Commission that the SESAR programme should address specifically the definition of interoperable procedures, systems and information exchange within Europe and with the rest of the world. This should also include the development of relevant standards and the identification of new implementing rules or Community specifications in the context of the single European sky.
- (36) When adopting implementing measures including standards laid down by Eurocontrol, the Commission should ensure that the measures include all necessary improvements to the original standards and take full account of the need to avoid double regulation.
- (37) The simultaneous pursuit of the goals of augmentation of air traffic safety standards and improvement of the overall performance of ATM and ANS for general air traffic in Europe require that the human factor be taken into account. Therefore the Member States should consider the introduction of 'just culture' principles.
- (38) In view of the proposed extension of the competences of the EASA to include air traffic management safety, consistency should be ensured between Regulations (EC) No 549/2004, (EC) No 550/2004, (EC) No 551/2004, (EC) No 552/2004 and (EC) No 216/2008.
- (39) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission ⁽²⁾. Those measures should be adopted within a suitable time-frame in order to meet the deadlines set out in this Regulation and Regulations (EC) No 549/2004, (EC) No 550/2004, (EC) No 551/2004, (EC) No 552/2004 and (EC) No 216/2008.
- (40) In particular, the Commission should be empowered to update measures due to technical or operational developments as well as to lay down the basic criteria and procedures for the exercise of certain network management functions. Since those measures are of a general scope and are designed to amend non-essential elements of Regulations (EC) No 549/2004, (EC) No 550/2004, (EC) No 551/2004 and (EC) No 552/2004 by supplementing them with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.
- (41) When on imperative grounds of urgency the normal time limits for the regulatory procedure with scrutiny cannot be complied with, the Commission should be able to use the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC.
- (42) The Ministerial Statement on Gibraltar Airport, agreed in Córdoba on 18 September 2006 (the Ministerial Statement), during the first Ministerial meeting of the Forum of Dialogue on Gibraltar, will replace the Joint Declaration on the Airport made in London on 2 December 1987, and the full compliance with that Statement will be deemed to constitute compliance with the 1987 Declaration.

(¹) OJ L 79, 19.3.2008, p. 1.

(²) OJ L 184, 17.7.1999, p. 23.

- (43) This Regulation applies in full to Gibraltar Airport in the context and by virtue of the Ministerial Statement. Without prejudice to the Ministerial Statement the application to Gibraltar Airport and all the measures related to its implementation shall conform fully with that Statement and all the arrangements contained therein.
- (44) Regulations (EC) No 549/2004, (EC) No 550/2004, (EC) No 551/2004 and (EC) No 552/2004 should therefore be amended accordingly,

HAVE ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 549/2004 shall be amended as follows:

1. Article 1 is replaced by the following:

'Article 1

Objective and scope

1. The objective of the single European sky initiative is to enhance current air traffic safety standards, to contribute to the sustainable development of the air transport system and to improve the overall performance of air traffic management (ATM) and air navigation services (ANS) for general air traffic in Europe, with a view to meeting the requirements of all airspace users. This single European sky shall comprise a coherent pan-European network of routes, network management and air traffic management systems based only on safety, efficiency and technical considerations, for the benefit of all airspace users. In pursuit of this objective, this Regulation establishes a harmonised regulatory framework for the creation of the single European sky.

2. The application of this Regulation and of the measures referred to in Article 3 shall be without prejudice to Member States' sovereignty over their airspace and to the requirements of the Member States relating to public order, public security and defence matters, as set out in Article 13. This Regulation and the measures referred to in Article 3 do not cover military operations and training.

3. The application of this Regulation and of the measures referred to in Article 3 shall be without prejudice to the rights and duties of Member States under the 1944 Chicago Convention on International Civil Aviation (the Chicago Convention). In this context, an additional objective of this Regulation is, in the fields it covers, to assist Member States in fulfilling their obligations under the Chicago Convention, by providing a basis for a common interpretation and uniform implementation of its provisions, and by ensuring that these provisions are duly taken into account in this Regulation and in the rules drawn up for its implementation.

4. The application of this Regulation to the airport of Gibraltar is understood to be without prejudice to the respective legal positions of the Kingdom of Spain and the United Kingdom of Great Britain and Northern Ireland with regard to the dispute over sovereignty over the territory in which the airport is situated.;

2. Article 2 is amended as follows:

- (a) point 8 is replaced by the following:

'8. "airspace users" means operators of aircraft operated as general air traffic;';

- (b) point 10 is replaced by the following:

'10. "air traffic management (ATM)" means the aggregation of the airborne and ground-based functions (air traffic services, airspace management and air traffic flow management) required to ensure the safe and efficient movement of aircraft during all phases of operations;';

- (c) the following point is inserted:

'13a. "ATM Master Plan" means the plan endorsed by Council Decision 2009/320/EC (*), in accordance with Article 1(2) of Council Regulation (EC) No 219/2007 of 27 February 2007 on the establishment of a Joint Undertaking to develop the new generation European air traffic management system (SESAR) (**);

(*) OJ L 95, 9.4.2009, p. 41.

(**) OJ L 64, 2.3.2007, p. 1.;

- (d) point 15 is replaced by the following:

'15. "certificate" means a document issued by a national supervisory authority in any form complying with national law, which confirms that an air navigation service provider meets the requirements for providing a specific service;';

- (e) point 21 is deleted;

- (f) point 22 is replaced by the following:

'22. "flexible use of airspace" means an airspace management concept applied in the European Civil Aviation Conference area on the basis of the "Airspace management handbook for the application of the concept of the flexible use of airspace" issued by Eurocontrol;';

(g) the following points are inserted:

‘23a. “flight information service” means a service provided for the purpose of giving advice and information useful for the safe and efficient conduct of flights;

23b. “alerting service” means a service provided to notify relevant organisations regarding aircraft in need of search and rescue aid, and to assist such organisations as required;’

(h) point 25 is replaced by the following:

‘25. “functional airspace block” means an airspace block based on operational requirements and established regardless of State boundaries, where the provision of air navigation services and related functions are performance-driven and optimised with a view to introducing, in each functional airspace block, enhanced cooperation among air navigation service providers or, where appropriate, an integrated provider;’

(i) point 37 is deleted;

(j) the following point is added:

‘41. “cross-border services” means any situation where air navigation services are provided in one Member State by a service provider certified in another Member State.’;

3. Article 4 is replaced by the following:

‘Article 4

National supervisory authorities

1. Member States shall, jointly or individually, either nominate or establish a body or bodies as their national supervisory authority in order to assume the tasks assigned to such authority under this Regulation and under the measures referred to in Article 3.

2. The national supervisory authorities shall be independent of air navigation service providers. This independence shall be achieved through adequate separation, at the functional level at least, between the national supervisory authorities and such providers.

3. National supervisory authorities shall exercise their powers impartially, independently and transparently. This shall be achieved by applying appropriate management and control mechanisms, including within the administration of a Member State. However, this shall not prevent the national supervisory authorities from exercising their tasks within the rules of organisation of national civil aviation authorities or any other public bodies.

4. Member States shall ensure that national supervisory authorities have the necessary resources and capabilities to carry out the tasks assigned to them under this Regulation in an efficient and timely manner.

5. Member States shall notify the Commission of the names and addresses of the national supervisory authorities, as well as changes thereto, and of the measures taken to ensure compliance with paragraphs 2, 3 and 4.’;

4. Article 5(4) is replaced by the following:

‘4. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

5. Where reference is made to this paragraph, Article 5a(1), (2), (4),(6) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.’;

5. Articles 6 to 11 are replaced by the following:

‘Article 6

Industry consultation body

Without prejudice to the role of the Committee and of Eurocontrol, the Commission shall establish an “industry consultation body”, to which air navigation service providers, associations of airspace users, airport operators, the manufacturing industry and professional staff representative bodies shall belong. The role of this body shall solely be to advise the Commission on the implementation of the single European sky.

Article 7

Relations with European third countries

The Community and its Member States shall aim at and support the extension of the single European sky to countries which are not members of the European Union. To that end, they shall endeavour, either in the framework of agreements concluded with neighbouring third countries or in the context of agreements on functional airspace blocks, to extend the application of this Regulation, and of the measures referred to in Article 3, to those countries.

Article 8

Implementing rules

1. For the development of implementing rules the Commission may issue mandates to Eurocontrol or, where appropriate, to another body, setting out the tasks to be performed and the timetable for this and taking into account the relevant deadlines laid down in this Regulation. The Commission shall act in accordance with the advisory procedure referred to in Article 5(2).

2. When the Commission intends to issue a mandate in accordance with paragraph 1 it shall endeavour to make the best use of existing arrangements for the involvement and consultation of all interested parties, where these arrangements correspond to Commission practices on transparency and consultation procedures and do not conflict with its institutional obligations.

Article 9

Penalties

The penalties that Member States shall lay down for infringements of this Regulation and of the measures referred to in Article 3 in particular by airspace users and service providers shall be effective, proportionate and dissuasive.

Article 10

Consultation of stakeholders

1. The Member States, acting in accordance with their national legislation, shall establish consultation mechanisms for appropriate involvement of stakeholders, including professional staff representative bodies, in the implementation of the single European sky.

2. The Commission shall establish a consultation mechanism at Community level. The specific Sectoral Dialogue Committee set up under Decision 98/500/EC shall be involved in the consultation.

3. Consultation of stakeholders shall cover, in particular, the development and introduction of new concepts and technologies in the EATMN.

The stakeholders may include:

- air navigation service providers,
- airport operators,
- relevant airspace users or relevant groups representing airspace users,
- military authorities,
- manufacturing industry, and,
- professional staff representative bodies.

Article 11

Performance scheme

1. To improve the performance of air navigation services and network functions in the single European sky, a performance scheme for air navigation services and network functions shall be set up. It shall include:

- (a) Community-wide performance targets on the key performance areas of safety, the environment, capacity and cost-efficiency;

- (b) national plans or plans for functional airspace blocks, including performance targets, ensuring consistency with the Community-wide performance targets; and

- (c) periodic review, monitoring and benchmarking of the performance of air navigation services and network functions.

2. In accordance with the regulatory procedure referred to in Article 5(3), the Commission may designate Eurocontrol or another impartial and competent body to act as a “performance review body”. The role of the performance review body shall be to assist the Commission, in coordination with the national supervisory authorities, and to assist the national supervisory authorities on request in the implementation of the performance scheme referred to in paragraph 1. The Commission shall ensure that the performance review body acts independently when carrying out the tasks entrusted to it by the Commission.

3. (a) The Community-wide performance targets for the air traffic management network shall be adopted by the Commission in accordance with the regulatory procedure referred to in Article 5(3), after taking into account the relevant inputs from national supervisory authorities at national level or at the level of functional airspace blocks.

- (b) The national or functional airspace block plans referred to in point (b) of paragraph 1 shall be drawn up by national supervisory authorities and adopted by the Member State(s). These plans shall include binding national targets or targets at the level of functional airspace blocks and an appropriate incentive scheme as adopted by the Member State(s). Drafting of the plans shall be subject to consultation with air navigation service providers, airspace users’ representatives, and, where relevant, airport operators and airport coordinators.

- (c) The consistency of the national or functional airspace block targets with the Community-wide performance targets shall be assessed by the Commission using the assessment criteria referred to in point (d) of paragraph 6.

In the event that the Commission identifies that one or more national or functional airspace block targets do not meet the assessment criteria, it may decide, in accordance with the advisory procedure referred to in Article 5(2), to issue a recommendation that the national supervisory authorities concerned propose revised performance target(s). The Member State(s) concerned shall adopt revised performance targets and appropriate measures which shall be notified to the Commission in due time.

Where the Commission finds that the revised performance targets and appropriate measures are not adequate, it may decide, in accordance with the regulatory procedure referred to in Article 5(3), that the Member States concerned shall take corrective measures.

Alternatively, the Commission may decide, with adequate supporting evidence, to revise the Community-wide performance targets in accordance with the regulatory procedure referred to in Article 5(3).

- (d) The reference period for the performance scheme shall cover a minimum of three years and a maximum of five years. During this period, in the event that the national or functional airspace block targets are not met, the Member States and/or the national supervisory authorities shall apply the appropriate measures they have defined. The first reference period shall cover the first three years following the adoption of the implementing rules referred to in paragraph 6.
- (e) The Commission shall carry out regular assessments of the achievement of the performance targets and present the results to the Single Sky Committee.

4. The following procedures shall apply to the performance scheme referred to in paragraph 1:

- (a) collection, validation, examination, evaluation and dissemination of relevant data related to the performance of air navigation services and network functions from all relevant parties, including air navigation service providers, airspace users, airport operators, national supervisory authorities, Member States and Eurocontrol;
- (b) selection of appropriate key performance areas on the basis of ICAO Document No 9854 'Global air traffic management operational concept', and consistent with those identified in the Performance Framework of the ATM Master Plan, including safety, the environment, capacity and cost-efficiency areas, adapted where necessary in order to take into account the specific needs of the single European sky and relevant objectives for these areas and definition of a limited set of key performance indicators for measuring performance;
- (c) establishment of Community-wide performance targets that shall be defined taking into consideration inputs identified at national level or at the level of functional airspace blocks;
- (d) assessment of the national or functional airspace block performance targets on the basis of the national or functional airspace block plan; and

- (e) monitoring of the national or functional airspace block performance plans, including appropriate alert mechanisms.

The Commission may add to the list of procedures referred to in this paragraph. These measures designed to amend non-essential elements of this Regulation, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 5(4).

5. The establishment of the performance scheme shall take into account that en route services, terminal services and network functions are different and should be treated accordingly, if necessary also for performance-measuring purposes.

6. For the detailed functioning of the performance scheme, the Commission shall by 4 December 2011 and within a suitable time-frame with a view to meeting the relevant deadlines laid down in this Regulation, adopt implementing rules in accordance with the regulatory procedure referred to in Article 5(3). These implementing rules shall cover the following:

- (a) the content and timetable of the procedures referred to in paragraph 4;
- (b) the reference period and intervals for the assessment of the achievement of performance targets and setting of new targets;
- (c) criteria for the setting up by the national supervisory authorities of the national or functional airspace block performance plans, containing the national or functional airspace block performance targets and the incentive scheme. The performance plans shall:
 - (i) be based on the business plans of the air navigation service providers;
 - (ii) address all cost components of the national or functional airspace block cost base;
 - (iii) include binding performance targets consistent with the Community-wide performance targets;
- (d) criteria to assess whether the national or functional airspace block targets are consistent with the Community-wide performance targets during the reference period and to support alert mechanisms;
- (e) general principles for the setting up by Member States of the incentive scheme;
- (f) principles for the application of a transitional mechanism necessary for the adaptation to the functioning of the performance scheme not exceeding 12 months following the adoption of the implementing rules.;

6. Article 12 is amended as follows:

(a) paragraph 2 is replaced by the following:

'2. The Commission shall periodically review the application of this Regulation and of the measures referred to in Article 3, and shall firstly report to the European Parliament and to the Council by 4 June 2011, and at the end of each reference period referred to in Article 11(3)(d) thereafter. When justified for this purpose, the Commission may request from the Member States information additional to the information contained in the reports submitted by them in accordance with paragraph 1 of this Article.;

(b) paragraph 4 is replaced by the following:

'4. The reports shall contain an evaluation of the results achieved by the actions taken pursuant to this Regulation including appropriate information about developments in the sector, in particular concerning economic, social, environmental, employment and technological aspects, as well as about quality of service, in the light of the original objectives and with a view to future needs.;

7. the following Article is inserted:

'Article 13a

European Aviation Safety Agency

When implementing this Regulation and Regulations (EC) No 550/2004, (EC) No 551/2004, (EC) No 552/2004 and Regulation (EC) No 216/2008 of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency (*), Member States and the Commission, in accordance with their respective roles as provided for by this Regulation, shall coordinate as appropriate with the European Aviation Safety Agency to ensure that all safety aspects are properly addressed.

(*) OJ L 79, 19.3.2008, p. 1.'

Article 2

Regulation (EC) No 550/2004 shall be amended as follows:

1. Articles 2 to 4 are replaced by the following:

'Article 2

Tasks of the national supervisory authorities

1. The national supervisory authorities referred to in Article 4 of the framework Regulation shall ensure the appropriate supervision of the application of this Regulation, in particular with regard to the safe and efficient operation of air

navigation service providers which provide services relating to the airspace falling under the responsibility of the Member State which nominated or established the relevant authority.

2. To this end, each national supervisory authority shall organise proper inspections and surveys to verify compliance with the requirements of this Regulation, including human resources requirements for the provision of air navigation services. The air navigation service provider concerned shall facilitate such work.

3. In respect of functional airspace blocks that extend across the airspace falling under the responsibility of more than one Member State, the Member States concerned shall conclude an agreement on the supervision provided for in this Article with regard to the air navigation service providers providing services relating to those blocks.

4. National supervisory authorities shall cooperate closely to ensure adequate supervision of air navigation service providers holding a valid certificate from one Member State that also provide services relating to the airspace falling under the responsibility of another Member State. Such cooperation shall include arrangements for the handling of cases involving non-compliance with the applicable common requirements set out in Article 6 or with the conditions set out in Annex II.

5. In the case of cross-border provision of air navigation services, such arrangements shall include an agreement on the mutual recognition of the supervisory tasks set out in paragraphs 1 and 2 and of the results of these tasks. This mutual recognition shall apply also where arrangements for recognition between national supervisory authorities are made for the certification process of service providers.

6. If permitted by national law and with a view to regional cooperation, national supervisory authorities may also conclude agreements regarding the division of responsibilities regarding supervisory tasks.

Article 3

Qualified entities

1. National supervisory authorities may decide to delegate in full or in part the inspections and surveys referred to in Article 2(2) to qualified entities that fulfil the requirements set out in Annex I.

2. Such a delegation granted by a national supervisory authority shall be valid within the Community for a renewable period of three years. National supervisory authorities may instruct any of the qualified entities located in the Community to undertake these inspections and surveys.

*Article 4***Safety requirements**

The Commission shall, in accordance with the regulatory procedure referred to in Article 5(3) of the framework Regulation, adopt implementing rules incorporating the relevant provisions of the Eurocontrol safety regulatory requirements (ESARRs) and subsequent amendments to those requirements falling within the scope of this Regulation, where necessary with appropriate adaptations.;

2. Article 5 is deleted;
3. in Article 7, paragraphs 6 and 7 are replaced by the following:

'6. Without prejudice to Articles 8 and 9, the issue of certificates shall confer on air navigation service providers the possibility of offering their services to Member States, other air navigation service providers, airspace users and airports within the Community.

7. National supervisory authorities shall monitor compliance with the common requirements and with the conditions attached to the certificates. Details of such monitoring shall be included in the annual reports to be submitted by Member States pursuant to Article 12(1) of the framework Regulation. If a national supervisory authority finds that the holder of a certificate no longer satisfies such requirements or conditions, it shall take appropriate measures while ensuring continuity of services on condition that safety is not compromised. Such measures may include the revocation of the certificate.;

4. Article 8 is replaced by the following:

*'Article 8***Designation of air traffic service providers**

1. Member States shall ensure the provision of air traffic services on an exclusive basis within specific airspace blocks in respect of the airspace under their responsibility. For this purpose, Member States shall designate an air traffic service provider holding a valid certificate in the Community.

2. For the provision of cross-border services, Member States shall ensure that compliance with this Article and Article 10(3) is not prevented by their national legal system requiring that air traffic service providers providing services in the airspace under the responsibility of that Member State:

- (a) be owned directly or through a majority holding by that Member State or its nationals;
- (b) have their principal place of operation or registered office in the territory of that Member State; or

- (c) use only facilities in that Member State.

3. Member States shall define the rights and obligations to be met by the designated air traffic service providers. The obligations may include conditions for the timely supply of relevant information enabling all aircraft movements in the airspace under their responsibility to be identified.

4. Member States shall have discretionary powers in choosing an air traffic service provider, on condition that the latter fulfils the requirements and conditions referred to in Articles 6 and 7.

5. In respect of functional airspace blocks established in accordance with Article 9a that extend across the airspace under the responsibility of more than one Member State, the Member States concerned shall jointly designate, in accordance with paragraph 1 of this Article, one or more air traffic service providers, at least one month before implementation of the airspace block.

6. Member States shall inform the Commission and other Member States immediately of any decision within the framework of this Article regarding the designation of air traffic service providers within specific airspace blocks in respect of the airspace under their responsibility.;

5. the following Articles are inserted:

*'Article 9a***Functional airspace blocks**

1. By 4 December 2012, Member States shall take all necessary measures in order to ensure the implementation of functional airspace blocks with a view to achieving the required capacity and efficiency of the air traffic management network within the single European sky and maintaining a high level of safety and contributing to the overall performance of the air transport system and a reduced environmental impact. Member States shall cooperate to the fullest extent possible with each other, in particular Member States establishing neighbouring functional airspace blocks, in order to ensure compliance with this provision. Where relevant, cooperation may also include third countries taking part in functional airspace blocks.

2. Functional airspace blocks shall, in particular:

- (a) be supported by a safety case;
- (b) enable optimum use of airspace, taking into account air traffic flows;
- (c) ensure consistency with the European route network established in accordance with Article 6 of the airspace Regulation;

- (d) be justified by their overall added value, including optimal use of technical and human resources, on the basis of cost-benefit analyses;
- (e) ensure a smooth and flexible transfer of responsibility for air traffic control between air traffic service units;
- (f) ensure compatibility between the different airspace configurations, optimising, inter alia, the current flight information regions;
- (g) comply with conditions stemming from regional agreements concluded within the ICAO;
- (h) respect regional agreements in existence on the date of entry into force of this Regulation, in particular those involving European third countries; and
- (i) facilitate consistency with Community-wide performance targets.

3. A functional airspace block shall only be established by mutual agreement between all the Member States and, where appropriate, third countries who have responsibility for any part of the airspace included in the functional airspace block. Before notifying the Commission of the establishment of a functional airspace block, the Member State(s) concerned shall provide the Commission, the other Member States and other interested parties with adequate information and give them an opportunity to submit their observations.

4. Where a functional airspace block relates to airspace that is wholly or partly under the responsibility of two or more Member States, the agreement by which the functional airspace block is established shall contain the necessary provisions concerning the way in which the block can be modified and the way in which a Member State can withdraw from the block, including transitional arrangements.

5. Where difficulties arise between two or more Member States with regard to a cross-border functional airspace block that concerns airspace under their responsibility, the Member States concerned may jointly bring the matter to the Single Sky Committee for an opinion. The opinion shall be addressed to the Member States concerned. Without prejudice to paragraph 3, the Member States shall take that opinion into account in order to find a solution.

6. After having received the notifications by Member States of the agreements and declarations referred to in paragraphs 3 and 4 the Commission shall assess the fulfilment by each functional airspace block of the requirements set out in paragraph 2 and present the results to the Single Sky Committee for discussion. If the Commission finds that one or more functional airspace blocks do not fulfil the requirements it shall engage in a dialogue with the Member States concerned with the aim of reaching a consensus on the measures necessary to rectify the situation.

7. Without prejudice to paragraph 6, the agreements and declarations referred to in paragraphs 3 and 4 shall be notified to the Commission for publication in the *Official Journal of the European Union*. Such publication shall specify the date of entry into force of the relevant decision.

8. Guidance material for the establishment and modification of functional airspace blocks shall be developed by 4 December 2010 in accordance with the advisory procedure referred to in Article 5(2) of the framework Regulation.

9. The Commission shall, by 4 December 2011 and in accordance with the regulatory procedure referred to in Article 5(3) of the framework Regulation, adopt implementing rules regarding the information to be provided by the Member State(s) concerned before establishing and modifying a functional airspace block in accordance with paragraph 3 of this Article.

Article 9b

Functional airspace blocks system coordinator

1. In order to facilitate the establishment of the functional airspace blocks, the Commission may designate a natural person as functional airspace blocks system coordinator (the Coordinator). The Commission shall act in accordance with the regulatory procedure referred to in Article 5(3) of the framework Regulation.

2. Without prejudice to Article 9a(5) the Coordinator shall facilitate at the request of all Member States concerned and, where appropriate, third countries taking part in the same functional airspace block, overcoming of difficulties in their negotiation process in order to speed up the establishment of functional airspace blocks. The Coordinator shall act on the basis of a mandate from all Member States concerned and, where appropriate, third countries taking part in the same functional airspace block.

3. The Coordinator shall act impartially in particular with regard to Member States, third countries, the Commission and the stakeholders.

4. The Coordinator shall not disclose any information obtained whilst performing his function except where authorised to do so by the Member State(s) and, where appropriate, third countries concerned.

5. The Coordinator shall report to the Commission, to the Single Sky Committee and to the European Parliament every three months after his designation. The report shall include a summary of negotiations and their results.

6. The remit of the Coordinator shall expire when the last functional airspace block agreement is signed but no later than 4 December 2012;

6. Article 11 is replaced by the following:

'Article 11

Relations with military authorities

Member States shall, within the context of the common transport policy, take the necessary steps to ensure that written agreements between the competent civil and military authorities or equivalent legal arrangements are established or renewed in respect of the management of specific airspace blocks.;

7. Article 12(3) is replaced by the following:

'3. When providing a bundle of services, air navigation service providers shall identify and disclose the costs and income deriving from air navigation services, broken down in accordance with the charging scheme for air navigation services referred to in Article 14 and, where appropriate, shall keep consolidated accounts for other, non-air-navigation services, as they would be required to do if the services in question were provided by separate undertakings.;

8. Article 14 is replaced by the following:

'Article 14

General

In accordance with the requirements of Articles 15 and 16, the charging scheme for air navigation services shall contribute to greater transparency in the determination, imposition and enforcement of charges to airspace users and shall contribute to the cost efficiency of providing air navigation services and to efficiency of flights, while maintaining an optimum safety level. This scheme shall also be consistent with Article 15 of the 1944 Chicago Convention on International Civil Aviation and with Eurocontrol's charging system for en-route charges.;

9. Article 15 is replaced by the following:

'Article 15

Principles

1. The charging scheme shall be based on the account of costs for air navigation services incurred by service providers for the benefit of airspace users. The scheme shall allocate these costs among categories of users.

2. The following principles shall be applied when establishing the cost-base for charges:

- (a) the cost to be shared among airspace users shall be the determined cost of providing air navigation services, including appropriate amounts for interest on capital investment and depreciation of assets, as well as the costs of maintenance, operation, management and administration. Determined costs shall be the costs determined

by the Member State at national level or at the level of functional airspace blocks either at the beginning of the reference period for each calendar year of the reference period referred to in Article 11 of the framework Regulation, or during the reference period, following appropriate adjustments applying the alert mechanisms set out in Article 11 of the framework Regulation;

- (b) the costs to be taken into account in this context shall be those assessed in relation to the facilities and services provided for and implemented under the ICAO Regional Air Navigation Plan, European Region. They may also include costs incurred by national supervisory authorities and/or qualified entities, as well as other costs incurred by the relevant Member State and service provider in relation to the provision of air navigation services. They shall not include the costs of penalties imposed by Member States according to Article 9 of the framework Regulation nor the costs of any corrective measures imposed by Member States according to Article 11 of the framework Regulation;
- (c) in respect of the functional airspace blocks and as part of their respective framework agreements, Member States shall make reasonable efforts to agree on common principles for charging policy;
- (d) the cost of different air navigation services shall be identified separately, as provided for in Article 12(3);
- (e) cross-subsidy shall not be allowed between en-route services and terminal services. Costs that pertain to both terminal services and en-route services shall be allocated in a proportional way between en-route services and terminal services on the basis of a transparent methodology. Cross-subsidy shall be allowed between different air navigation services in either one of those two categories only when justified for objective reasons, subject to clear identification;
- (f) transparency of the cost-base for charges shall be guaranteed. Implementing rules for the provision of information by the service providers shall be adopted in order to permit reviews of the provider's forecasts, actual costs and revenues. Information shall be regularly exchanged between the national supervisory authorities, service providers, airspace users, the Commission and Eurocontrol.
3. Member States shall comply with the following principles when setting charges in accordance with paragraph 2:
- (a) charges shall be set for the availability of air navigation services under non-discriminatory conditions. When imposing charges on different airspace users for the use of the same service, no distinction shall be made in relation to the nationality or category of the user;

- (b) exemption of certain users, especially light aircraft and State aircraft, may be permitted, provided that the cost of such exemption is not passed on to other users;
- (c) charges shall be set per calendar year on the basis of the determined costs, or may be set under conditions established by Member States for determining the maximum level of the unit rate or of the revenue for each year over a period not exceeding five years;
- (d) air navigation services may produce sufficient revenues to provide for a reasonable return on assets to contribute towards necessary capital improvements;
- (e) charges shall reflect the cost of air navigation services and facilities made available to airspace users, taking into account the relative productive capacities of the different aircraft types concerned;
- (f) charges shall encourage the safe, efficient, effective and sustainable provision of air navigation services with a view to achieving a high level of safety and cost-efficiency and meeting the performance targets and they shall stimulate integrated service provision, whilst reducing the environmental impact of aviation. To that end, and in relation to the national or functional airspace block performance plans, national supervisory authorities may set up mechanisms, including incentives consisting of financial advantages and disadvantages, to encourage air navigation service providers and/or airspace users to support improvements in the provision of air navigation services such as increased capacity, reduced delays and sustainable development, while maintaining an optimum safety level.

4. The Commission shall adopt detailed implementing rules for this Article in accordance with the regulatory procedure referred to in Article 5(3) of the framework Regulation.;

10. the following Article is inserted:

'Article 15a

Common projects

1. Common projects may assist the successful implementation of the ATM Master Plan. Such projects shall support the objectives of this Regulation to improve the performance of the European aviation system in key areas such as capacity, flight and cost efficiency as well as environmental sustainability, within the overriding safety objectives.

2. The Commission may, in accordance with the regulatory procedure referred to in Article 5(3) of the framework Regulation, develop guidance material concerning the way in which such projects can support the implementation of the ATM Master Plan. Such guidance material shall not prejudice

mechanisms for the deployment of such projects concerning functional airspace blocks as agreed upon by the parties of those blocks.

3. The Commission may also decide, in accordance with the regulatory procedure referred to in Article 5(3) of the framework Regulation, to set up common projects for network-related functions which are of particular importance for the improvement of the overall performance of air traffic management and air navigation services in Europe. Such common projects may be considered eligible for Community funding within the multiannual financial framework. To this end, and without prejudice to Member States' competence to decide on the use of their financial resources, the Commission shall carry out an independent cost-benefit analysis and appropriate consultations with Member States and with relevant stakeholders in accordance with Article 10 of the framework Regulation, exploring all appropriate means for financing the deployment thereof. The eligible costs of deployment of common projects shall be recovered in accordance with the principles of transparency and non-discrimination.;

11. Articles 16 to 18 are replaced by the following:

'Article 16

Review of compliance

1. The Commission shall provide for the ongoing review of compliance with the principles and rules referred to in Articles 14 and 15, acting in cooperation with the Member States. The Commission shall endeavour to establish the necessary mechanisms for making use of Eurocontrol expertise and shall share the results of the review with the Member States, Eurocontrol and the airspace users' representatives.

2. At the request of one or more Member States that consider that the principles and rules referred to in Articles 14 and 15 have not been properly applied, or on its own initiative, the Commission shall carry out an investigation into any allegation of non-compliance or non-application of the principles and/or rules concerned. Without prejudice to Article 18(1), the Commission shall share the results of the investigation with the Member States, Eurocontrol and the airspace users' representatives. Within two months of receipt of a request, after having heard the Member State concerned and after consulting the Single Sky Committee in accordance with the advisory procedure referred to in Article 5(2) of the framework Regulation, the Commission shall take a decision on the application of Articles 14 and 15 of this Regulation and as to whether the practice concerned may continue.

3. The Commission shall address its decision to the Member States and inform the service provider thereof, in so far as it is legally concerned. Any Member State may refer the Commission's decision to the Council within one month. The Council, acting by a qualified majority, may take a different decision within a period of one month.

*Article 17***Revision of Annexes**

Measures, designed to amend non-essential elements of the Annexes in order to take into account technical or operational developments, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 5(4) of the framework Regulation.

On imperative grounds of urgency, the Commission may use the urgency procedure referred to in Article 5(5) of the framework Regulation.

*Article 18***Confidentiality**

1. Neither the national supervisory authorities, acting in accordance with their national legislation, nor the Commission shall disclose information of a confidential nature, in particular information about air navigation service providers, their business relations or their cost components.

2. Paragraph 1 shall be without prejudice to the right of disclosure by national supervisory authorities or the Commission where this is essential for the fulfilment of their duties, in which case such disclosure shall be proportionate and shall have regard to the legitimate interests of air navigation service providers, airspace users, airports or other relevant stakeholders in the protection of their business secrets.

3. Information and data provided pursuant to the charging scheme referred to in Article 14 shall be publicly disclosed.;

12. the following Article is inserted:

*'Article 18a***Review**

The Commission shall submit a study to the European Parliament and to the Council no later than 4 December 2012 evaluating the legal, safety, industrial, economic and social impacts of the application of market principles to the provision of communication, navigation, surveillance and aeronautical information services, compared to existing or alternative organisational principles and taking into account developments in the functional airspace blocks and in available technology.;

13. Annex I is amended as follows:

(a) the title shall be replaced by the following:

'REQUIREMENTS FOR QUALIFIED ENTITIES';

(b) the introductory wording shall be replaced by the following:

'The qualified entities must:'.

Article 3

Regulation (EC) No 551/2004 shall be amended as follows:

1. Article 2 is deleted;
2. Article 3 is replaced by the following:

*'Article 3***European Upper Flight Information Region (EUIR)**

1. The Community and its Member States shall aim at the establishment and recognition by the ICAO of a single EUIR. To that effect, for matters which fall within the competence of the Community, the Commission shall submit a recommendation to the Council in accordance with Article 300 of the Treaty at the latest by 4 December 2011.

2. The EUIR shall be designed to encompass the airspace falling under the responsibility of the Member States in accordance with Article 1(3) and may also include airspace of European third countries.

3. The establishment of the EUIR shall be without prejudice to the responsibility of Member States for the designation of air traffic service providers for the airspace under their responsibility in accordance with Article 8(1) of the service provision Regulation.

4. Member States shall retain their responsibilities towards the ICAO within the geographical limits of the upper flight information regions and flight information regions entrusted to them by the ICAO on the date of entry into force of this Regulation.;

3. the following Article is inserted:

*'Article 3a***Electronic aeronautical information**

1. Without prejudice to the publication by Member States of aeronautical information and in a manner consistent with that publication, the Commission, working in cooperation with Eurocontrol, shall ensure the availability of electronic aeronautical information of high quality, presented in a harmonised way and serving the requirements of all relevant users in terms of data quality and timeliness.

2. For the purpose of paragraph 1, the Commission shall:

- (a) ensure the development of a Community-wide aeronautical information infrastructure in the form of an electronic integrated briefing portal with unrestricted access to interested stakeholders. That infrastructure shall integrate access to and provision of required data elements such as, but not limited to aeronautical information, air traffic services reporting office (ARO) information, meteorological information and flow management information;

- (b) support the modernisation and harmonisation of the provision of aeronautical information in its broadest sense in close cooperation with Eurocontrol and the ICAO.

3. The Commission shall adopt detailed implementing rules for this Article in accordance with the regulatory procedure referred to in Article 5(3) of the framework Regulation.;

4. Article 4 is replaced by the following:

'Article 4

Rules of the air and airspace classification

The Commission shall, in accordance with the regulatory procedure referred to in Article 5(3) of the framework Regulation, adopt implementing rules in order to:

- (a) adopt appropriate provisions on rules of the air based upon ICAO standards and recommended practices;
- (b) harmonise the application of the ICAO airspace classification, with appropriate adaptation, in order to ensure the seamless provision of safe and efficient air traffic services within the single European sky.;

5. Article 5 is deleted;

6. Article 6 is replaced by the following:

'Article 6

Network management and design

1. The air traffic management (ATM) network functions shall allow optimum use of airspace and ensure that airspace users can operate preferred trajectories, while allowing maximum access to airspace and air navigation services. These network functions shall be aimed at supporting initiatives at national level and at the level of functional airspace blocks and shall be executed in a manner which respects the separation of regulatory and operational tasks.

2. In order to achieve the objectives referred to in paragraph 1 and without prejudice to the responsibilities of the Member States with regard to national routes and airspace structures, the Commission shall ensure that the following functions are carried out:

- (a) design of the European route network;
- (b) coordination of scarce resources within aviation frequency bands used by general air traffic, in particular radio frequencies as well as coordination of radar transponder codes.

The functions listed in the first subparagraph shall not involve the adoption of binding measures of a general scope or the exercise of political discretion. They shall take into account proposals established at national level and at the level of functional airspace blocks. They shall be performed in coordination with military authorities in accordance with agreed procedures concerning the flexible use of airspace.

The Commission may, after consultation of the Single Sky Committee and in conformity with the implementing rules referred to in paragraph 4, entrust to Eurocontrol, or another impartial and competent body, the tasks necessary for the execution of the functions listed in the first subparagraph. These tasks shall be executed in an impartial and cost-effective manner and performed on behalf of Member States and stakeholders. They shall be subject to appropriate governance, which recognises the separate accountabilities for service provision and regulation, taking into consideration the needs of the whole ATM network and with the full involvement of the airspace users and air navigation service providers.

3. The Commission may add to the list of the functions in paragraph 2 after proper consultation of industry stakeholders. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 5(4) of the framework Regulation.

4. Detailed rules for the implementation of the measures referred to in this Article, except for those referred to in paragraphs 6 to 9, shall be adopted in accordance with the regulatory procedure referred to in Article 5(3) of the framework Regulation. Those implementing rules shall address in particular:

- (a) the coordination and harmonisation of processes and procedures to enhance the efficiency of aeronautical frequency management including the development of principles and criteria;
- (b) the central function to coordinate the early identification and resolution of frequency needs in the bands allocated to European general air traffic to support the design and operation of European aviation network;
- (c) additional network functions as defined in the ATM Master Plan;
- (d) detailed arrangements for cooperative decision-making between the Member States, the air navigation service providers and the network management function for the tasks referred to in paragraph 2;
- (e) arrangements for consultation of the relevant stakeholders in the decision-making process both at national and European levels; and

(f) within the radio spectrum allocated to general air traffic by the International Telecommunication Union, a division of tasks and responsibilities between the network management function and national frequency managers, ensuring that the national frequency management functions continue to perform those frequency assignments that have no impact on the network. For those cases which do have an impact on the network, the national frequency managers shall cooperate with those responsible for the network management function to optimise the use of frequencies.

5. Aspects of airspace design other than those referred to in paragraph 2 shall be dealt with at national level or at the level of functional airspace blocks. This design process shall take into account traffic demands and complexity, national or functional airspace block performance plans and shall include full consultation of relevant airspace users or relevant groups representing airspace users and military authorities as appropriate.

6. Member States shall entrust Eurocontrol or another impartial and competent body with the performance of air traffic flow management, subject to appropriate oversight arrangements.

7. Implementing rules for air traffic flow management, including the necessary oversight arrangements, shall be developed in accordance with the advisory procedure referred to in Article 5(2) of the framework Regulation and adopted in accordance with the regulatory procedure referred to in Article 5(3) of the framework Regulation, with a view to optimising available capacity in the use of airspace and enhancing air traffic flow management processes. These rules shall be based on transparency and efficiency, ensuring that capacity is provided in a flexible and timely manner, consistent with the recommendations of the ICAO Regional Air Navigation Plan, European Region.

8. The implementing rules for air traffic flow management shall support operational decisions by air navigation service providers, airport operators and airspace users and shall cover the following areas:

- (a) flight planning;
- (b) use of available airspace capacity during all phases of flight, including slot assignment; and
- (c) use of routings by general air traffic, including:
 - the creation of a single publication for route and traffic orientation,
 - options for diversion of general air traffic from congested areas, and

- priority rules regarding access to airspace for general air traffic, particularly during periods of congestion and crisis.

9. When developing and adopting the implementing rules the Commission shall, as appropriate and without prejudice to safety, take into account consistency between flight plans and airport slots and the necessary coordination with adjacent regions.;

7. Article 9 is deleted.

Article 4

Regulation (EC) No 552/2004 shall be amended as follows:

1. the following Article is inserted:

'Article 6a

Alternative verification of compliance

A certificate issued in accordance with Regulation (EC) No 216/2008 of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency (*), where it applies to constituents or systems, shall be considered, for the purposes of Articles 5 and 6 of this Regulation, as an EC declaration of conformity or suitability for use, or as an EC declaration of verification, if it includes a demonstration of compliance with the essential requirements of this Regulation and the relevant implementing rules for interoperability.

(*) OJ L 79, 19.3.2008, p. 1.;

2. Article 9 is replaced by the following:

'Article 9

Revision of Annexes

Measures, designed to amend non-essential elements of the Annexes, in order to take into account technical or operational developments, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 5(4) of the framework Regulation.;

3. in Article 10 the following paragraph is inserted:

'2a. For the purposes of paragraph 2 of this Article, Member States may declare systems and constituents of the EATMN as compliant with the essential requirements and exempt from the provisions of Articles 5 and 6.;

4. Annex II is amended as follows:

- (a) in Part A, the first paragraph of point 2, is replaced by the following:

'The EATMN, its systems and their constituents shall support, on a coordinated basis, new agreed and validated concepts of operation that improve the quality, sustainability and effectiveness of air navigation services, in particular in terms of safety and capacity.;

- (b) Part B is amended as follows:

- (i) the first paragraph of point 3.1.2, is replaced by the following:

'Flight data processing systems shall accommodate the progressive implementation of advanced, agreed and validated concepts of operation for all phases of flight, in particular as envisaged in the ATM Master Plan.;

- (ii) point 3.2.2 is replaced by the following:

'3.2.2. Support for new concepts of operation

Surveillance data processing systems shall accommodate the progressive availability of

new sources of surveillance information in such a way as to improve the overall quality of service, in particular as envisaged in the ATM Master Plan.;

- (iii) point 4.2 is replaced by the following:

'4.2. Support for new concepts of operation

Communication systems shall support the implementation of advanced, agreed and validated concepts of operation for all phases of flight, in particular as envisaged in the ATM Master Plan.'

Article 5

Entry into force

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

Article 6(2) and (6) of Regulation (EC) No 551/2004, as amended by this Regulation, shall apply from the date specified in their respective implementing rules but no later than 4 December 2012.

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

Done at Strasbourg, 21 October 2009.

For the European Parliament
The President
J. BUZEK

For the Council
The President
C. MALMSTRÖM

REGULATION (EC) No 1071/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 21 October 2009
establishing common rules concerning the conditions to be complied with to pursue the occupation
of road transport operator and repealing Council Directive 96/26/EC
 (Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 71(1) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee ⁽¹⁾,

Having regard to the opinion of the European Data Protection Supervisor ⁽²⁾,

After consulting the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty ⁽³⁾,

Whereas:

- (1) The completion of an internal market in road transport with fair conditions of competition requires the uniform application of common rules on admission to the occupation of road haulage operator or road passenger transport operator (the occupation of road transport operator). Such common rules will contribute to the achievement of a higher level of professional qualification for road transport operators, the rationalisation of the market and an improved quality of service, in the interests of road transport operators, their customers and the economy as a whole, together with improvements in road safety. They will also facilitate the effective exercise of the right of establishment by road transport operators.
- (2) Council Directive 96/26/EC of 29 April 1996 on admission to the occupation of road haulage operator and road passenger transport operator and mutual recognition of diplomas, certificates and other evidence of formal qualifications intended to facilitate for these operators the right to freedom of establishment in national and international transport operations ⁽⁴⁾ lays down minimum conditions governing admission to the occupation of road transport

operator and the mutual recognition of the documents required in this connection. However, experience, an impact assessment and various studies show that that Directive is being applied inconsistently by Member States. Such disparities have several adverse consequences, in particular a distortion of competition and a lack of market transparency and of uniform monitoring, as well as the risk that undertakings employing staff with a low level of professional qualification may be negligent in respect of, or less compliant with, the rules on road safety and social welfare, which may harm the image of the sector.

- (3) These consequences are all the more detrimental as they are liable to disturb the smooth functioning of the internal market in road transport, since the market in the transport of international goods and certain cabotage operations is accessible to undertakings throughout the Community. The only condition imposed on such undertakings is that they have a Community licence, which can be obtained provided they satisfy the conditions governing admission to the occupation of road transport operator laid down in Regulation (EC) No 1072/2009 of the European Parliament and of the Council of 21 October 2009 on common rules for access to the international road haulage market ⁽⁵⁾ and Regulation (EC) No 1073/2009 of the European Parliament and of the Council of 21 October 2009 on common rules for access to the international market for coach and bus services ⁽⁶⁾.
- (4) It is therefore appropriate to modernise the existing rules on admission to the occupation of road transport operator in order to ensure that those rules are applied more uniformly and effectively. Since compliance with those rules constitutes the main condition governing access to the Community market, and the applicable Community instruments in this field are Regulations, a Regulation would appear to be the most appropriate instrument to govern admission to the occupation of road transport operator.
- (5) Member States should be allowed to adapt the conditions with which to comply in order to pursue the occupation of road transport operator in the outermost regions referred to in Article 299(2) of the Treaty because of the special characteristics of, and constraints in, those regions. However, the undertakings established in those regions which comply with the conditions to pursue the occupation of road transport operator only as a result of such adaptation should not be able to obtain a Community licence. The adaptation of the conditions to pursue the occupation of road transport operator should not hinder

⁽¹⁾ OJ C 151, 17.6.2008, p. 16.

⁽²⁾ OJ C 14, 19.1.2008, p. 1.

⁽³⁾ Opinion of the European Parliament of 21 May 2008 (not yet published in the Official Journal), Council Common Position of 9 January 2009 (OJ C 62 E, 17.3.2009, p. 1), Position of the European Parliament of 23 April 2009 (not yet published in the Official Journal) and Council Decision of 24 September 2009.

⁽⁴⁾ OJ L 124, 23.5.1996, p. 1.

⁽⁵⁾ See page 72 of this Official Journal.

⁽⁶⁾ See page 88 of this Official Journal.

- undertakings which would have been admitted to the occupation of road transport operator and which comply with the general conditions laid down in this Regulation from carrying out transport operations in the outermost regions.
- (6) In the interests of fair competition, the common rules governing the exercise of the occupation of road transport operator should apply as widely as possible to all undertakings. However, it is unnecessary to include within the scope of this Regulation undertakings which only perform transport operations with a very small impact on the transport market.
- (7) It should be the responsibility of the Member State of establishment to verify that an undertaking satisfies at all times the conditions laid down in this Regulation so that the competent authorities of that Member State are able, if necessary, to decide to suspend or withdraw the authorisations which allow that undertaking to operate on the market. Proper compliance with, and reliable monitoring of, the conditions governing admission to the occupation of road transport operator presuppose that undertakings have an effective and stable establishment.
- (8) Natural persons with the requisite good repute and professional competence should be clearly identified and designated to the competent authorities. Such persons (transport managers), should be resident in a Member State and effectively and continuously manage the transport activities of road transport undertakings. It is therefore appropriate to specify the conditions under which a person is considered to effectively and continuously manage the transport activities of an undertaking.
- (9) The good repute of transport managers is conditional on their not having been convicted of a serious criminal offence or not having incurred a penalty, for a serious infringement, in particular, of Community rules relating to road transport. A conviction or penalty incurred by a transport manager or a road transport undertaking in one or more Member States for the most serious infringements of Community rules should result in the loss of good repute provided that the competent authority has ascertained that a duly completed and documented investigation procedure granting essential procedural rights took place before its final decision and that appropriate rights of appeal were respected.
- (10) It is necessary for road transport undertakings to have a minimum financial standing to ensure their proper launching and administration. A bank guarantee or a professional liability insurance may constitute a simple and cost-efficient method of demonstrating the financial standing of undertakings.
- (11) A high level of professional qualification should increase the socioeconomic efficiency of the road transport sector. It is therefore appropriate that applicants for the post of transport manager should possess high-quality professional knowledge. In order to ensure greater uniformity of examinations and to promote a high quality of training, it is appropriate to provide that Member States may authorise examination and training centres according to criteria to be defined by them. Transport managers should possess the requisite knowledge for managing both national and international transport operations. The list of subjects of which knowledge is required in order to obtain a certificate of professional competence and the procedures for the organisation of examinations are likely to evolve with technical progress, and provision should be made for updating them. It should be possible for Member States to exempt from the examinations persons who can provide proof of continuous experience in managing transport activities.
- (12) Fair competition and road transport that is fully compliant with the rules call for a uniform level of monitoring by Member States. The national authorities responsible for monitoring undertakings and the validity of their authorisations have a crucial role to play in this respect, and it is appropriate to ensure that they take suitable measures if necessary, in particular in the most serious cases by suspending or withdrawing authorisations or declaring as unsuitable transport managers who are repeatedly negligent or who act in bad faith. This must be preceded by due consideration of the measure with respect to the proportionality principle. An undertaking should, however, be warned in advance and should have a reasonable period of time within which to rectify the situation before incurring such penalties.
- (13) Better organised administrative cooperation between Member States would improve the effectiveness of the monitoring of undertakings operating in several Member States and would reduce administrative costs in the future. Electronic registers of undertakings interconnected throughout the Community, which comply with the Community rules on the protection of personal data, would facilitate such cooperation and reduce the costs involved in checks for both undertakings and administrations. National registers already exist in several Member States. Infrastructure has also been set up with a view to promoting interconnection between Member States. A more systematic use of electronic registers could therefore make a significant contribution to reducing the administrative costs of checks and to improving their effectiveness.
- (14) Some data contained in national electronic registers concerning infringements and penalties are personal. Member States should therefore take the measures necessary to ensure compliance with Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data ⁽¹⁾, in particular with regard to the monitoring of the

(¹) OJ L 281, 23.11.1995, p. 31.

- processing of personal data by public authorities, the right of data subjects to be provided with information, their right of access and their right to object. For the purposes of this Regulation, it would appear to be necessary to retain such data for at least 2 years to ensure that disqualified undertakings do not establish themselves in other Member States.
- (15) In order to improve transparency and to allow the client of a transport undertaking to verify whether that undertaking is in possession of the appropriate authorisation, certain data contained in the national electronic register should be made publicly accessible, in so far as the relevant provisions on data protection are complied with.
- (16) It is essential to gradually interconnect national electronic registers so as to enable information to be exchanged rapidly and efficiently between Member States and to guarantee that road transport operators are not tempted to commit, or to take the risk of committing, serious infringements in Member States other than their Member State of establishment. Interconnection of this kind entails the joint definition of the precise format of the data to be exchanged and the technical procedures for the exchange of that data.
- (17) In order to ensure the efficient exchange of information between Member States, national contact points should be designated and certain common procedures relating as a minimum to time limits and the nature of the information to be forwarded, should be specified.
- (18) In order to facilitate freedom of establishment, the production of appropriate documents issued by a competent authority in the Member State where the transport manager used to reside should be accepted as sufficient proof of good repute for admission to the occupation of road transport operator in the Member State of establishment, provided that the persons concerned have not been declared unfit to pursue that occupation in other Member States.
- (19) With regard to professional competence, in order to facilitate freedom of establishment, a single model certificate issued in accordance with this Regulation should be regarded as sufficient proof by the Member State of establishment.
- (20) Closer monitoring of the application of this Regulation at Community level is required. This presupposes the forwarding to the Commission of regular reports, drawn up on the basis of national registers, on the good repute, financial standing and professional competence of undertakings in the road transport sector.
- (21) Member States should provide for penalties applicable to infringements of this Regulation. Such penalties should be effective, proportionate and dissuasive.
- (22) Since the objective of this Regulation, namely the modernisation of the rules governing admission to the occupation of road transport operator in order to ensure that those rules are applied more uniformly and effectively in the Member States, cannot be sufficiently achieved by the Member States and can therefore by reason of the scale and effects of the action be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary to achieve that objective.
- (23) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission ⁽¹⁾.
- (24) In particular, the Commission should be empowered to draw up a list of categories, types and degrees of seriousness of infringements leading to the loss of good repute of road transport operators, to adapt to technical progress Annexes I, II and III to this Regulation concerning the knowledge to be taken into consideration for the recognition of professional competence by the Member States and the model certificate of professional competence, and to draw up a list of infringements which in addition to those set out in Annex IV to this Regulation may lead to the loss of good repute. Since those measures are of general scope and are designed to amend non-essential elements of this Regulation, inter alia, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.
- (25) Directive 96/26/EC should be repealed,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter and scope

1. This Regulation governs admission to, and the pursuit of, the occupation of road transport operator.
2. This Regulation shall apply to all undertakings established in the Community which are engaged in the occupation of road transport operator. It shall also apply to undertakings which intend to engage in the occupation of road transport operator. References to undertakings engaged in the occupation of road transport operator shall, as appropriate, be considered to include a reference to undertakings intending to engage in such occupation.

⁽¹⁾ OJ L 184, 17.7.1999, p. 23.

3. As regards the regions referred to in Article 299(2) of the Treaty, the Member States concerned may adapt the conditions to be complied with in order to pursue the occupation of road transport operator, in so far as operations are fully carried out in those regions by undertakings established there.

4. By way of derogation from paragraph 2, this Regulation shall, unless otherwise provided for in national law, not apply to:

- (a) undertakings engaged in the occupation of road haulage operator solely by means of motor vehicles or combinations of vehicles the permissible laden mass of which does not exceed 3,5 tonnes. Member States may, however, lower this limit for all or some categories of road transport operations;
- (b) undertakings engaged in road passenger transport services exclusively for non-commercial purposes or which have a main occupation other than that of road passenger transport operator;
- (c) undertakings engaged in the occupation of road transport operator solely by means of motor vehicles with a maximum authorised speed not exceeding 40 km/h.

5. Member States may exempt from the application of all or some of the provisions of this Regulation only those road transport operators engaged exclusively in national transport operations having only a minor impact on the transport market because of:

- (a) the nature of the goods carried; or
- (b) the short distances involved.

Article 2

Definitions

For the purposes of this Regulation:

1. 'the occupation of road haulage operator' means the activity of any undertaking transporting goods for hire or reward by means either of motor vehicles or combinations of vehicles;
2. 'the occupation of road passenger transport operator' means the activity of any undertaking operating, by means of motor vehicles so constructed and equipped as to be suitable for carrying more than nine persons, including the driver, and intended for that purpose, passenger transport services for the public or for specific categories of users in return for payment by the person transported or by the transport organiser;
3. 'the occupation of road transport operator' means the occupation of road passenger transport operator or the occupation of road haulage operator;
4. 'undertaking' means any natural person, any legal person, whether profit-making or not, any association or group of persons without legal personality, whether profit-making or not, or any official body, whether having its own legal personality or being dependent upon an authority having such

personality, engaged in the transport of passengers, or any natural or legal person engaged in the transport of freight with a commercial purpose;

5. 'transport manager' means a natural person employed by an undertaking or, if that undertaking is a natural person, that person or, where provided for, another natural person designated by that undertaking by means of a contract, who effectively and continuously manages the transport activities of that undertaking;
6. 'authorisation to pursue the occupation of road transport operator' means an administrative decision which authorises an undertaking which satisfies the conditions laid down in this Regulation to pursue the occupation of road transport operator;
7. 'competent authority' means a national, regional or local authority in a Member State which, for the purpose of authorising the pursuit of the occupation of road transport operator, verifies whether an undertaking satisfies the conditions laid down in this Regulation, and which is empowered to grant, suspend or withdraw an authorisation to pursue the occupation of road transport operator;
8. 'Member State of establishment' means the Member State in which an undertaking is established, regardless of whether its transport manager originates from another country.

Article 3

Requirements for engagement in the occupation of road transport operator

1. Undertakings engaged in the occupation of road transport operator shall:
 - (a) have an effective and stable establishment in a Member State;
 - (b) be of good repute;
 - (c) have appropriate financial standing; and
 - (d) have the requisite professional competence.
2. Member States may decide to impose additional requirements, which shall be proportionate and non-discriminatory, to be satisfied by undertakings in order to engage in the occupation of road transport operator.

Article 4

Transport manager

1. An undertaking which engages in the occupation of road transport operator shall designate at least one natural person, the transport manager, who satisfies the requirements set out in Article 3(1)(b) and (d) and who:
 - (a) effectively and continuously manages the transport activities of the undertaking;

(b) has a genuine link to the undertaking, such as being an employee, director, owner or shareholder or administering it, or, if the undertaking is a natural person, is that person; and

(c) is resident in the Community.

2. If an undertaking does not satisfy the requirement of professional competence laid down in Article 3(1)(d), the competent authority may authorise it to engage in the occupation of road transport operator without a transport manager designated in accordance with paragraph 1 of this Article, provided that:

(a) the undertaking designates a natural person residing in the Community who satisfies the requirements laid down in Article 3(1)(b) and (d), and who is entitled under contract to carry out duties as transport manager on behalf of the undertaking;

(b) the contract linking the undertaking with the person referred to in point (a) specifies the tasks to be performed on an effective and continuous basis by that person, and indicates his or her responsibilities as transport manager. The tasks to be specified shall comprise, in particular, those relating to vehicle maintenance management, verification of transport contracts and documents, basic accounting, the assignment of loads or services to drivers and vehicles, and the verification of safety procedures;

(c) in his or her capacity as transport manager, the person referred to in point (a) may manage the transport activities of up to four different undertakings carried out with a combined maximum total fleet of 50 vehicles. Member States may decide to lower the number of undertakings and/or the size of the total fleet of vehicles which that person may manage; and

(d) the person referred to in point (a) performs the specified tasks solely in the interests of the undertaking and his or her responsibilities are exercised independently of any undertakings for which the undertaking carries out transport operations.

3. Member States may decide that a transport manager designated in accordance with paragraph 1 may not in addition be designated in accordance with paragraph 2, or may only be so designated in respect of a limited number of undertakings or a fleet of vehicles that is smaller than that referred to in paragraph 2(c).

4. The undertaking shall notify the competent authority of the transport manager or managers designated.

CHAPTER II

CONDITIONS TO BE MET TO SATISFY THE REQUIREMENTS LAID DOWN IN ARTICLE 3

Article 5

Conditions relating to the requirement of establishment

In order to satisfy the requirement laid down in Article 3(1)(a), an undertaking shall, in the Member State concerned:

(a) have an establishment situated in that Member State with premises in which it keeps its core business documents, in particular its accounting documents, personnel management documents, documents containing data relating to driving time and rest and any other document to which the competent authority must have access in order to verify compliance with the conditions laid down in this Regulation. Member States may require that establishments on their territory also have other documents available at their premises at any time;

(b) once an authorisation is granted, have at its disposal one or more vehicles which are registered or otherwise put into circulation in conformity with the legislation of that Member State, whether those vehicles are wholly owned or, for example, held under a hire-purchase agreement or a hire or leasing contract;

(c) conduct effectively and continuously with the necessary administrative equipment its operations concerning the vehicles mentioned in point (b) and with the appropriate technical equipment and facilities at an operating centre situated in that Member State.

Article 6

Conditions relating to the requirement of good repute

1. Subject to paragraph 2 of this Article, Member States shall determine the conditions to be met by undertakings and transport managers in order to satisfy the requirement of good repute laid down in Article 3(1)(b).

In determining whether an undertaking has satisfied that requirement, Member States shall consider the conduct of the undertaking, its transport managers and any other relevant person as may be determined by the Member State. Any reference in this Article to convictions, penalties or infringements shall include convictions, penalties or infringements of the undertaking itself, its transport managers and any other relevant person as may be determined by the Member State.

The conditions referred to in the first subparagraph shall include at least the following:

- (a) that there be no compelling grounds for doubting the good repute of the transport manager or the transport undertaking, such as convictions or penalties for any serious infringement of national rules in force in the fields of:
 - (i) commercial law;
 - (ii) insolvency law;
 - (iii) pay and employment conditions in the profession;
 - (iv) road traffic;
 - (v) professional liability;
 - (vi) trafficking in human beings or drugs; and
- (b) that the transport manager or the transport undertaking have not in one or more Member States been convicted of a serious criminal offence or incurred a penalty for a serious infringement of Community rules relating in particular to:
 - (i) the driving time and rest periods of drivers, working time and the installation and use of recording equipment;
 - (ii) the maximum weights and dimensions of commercial vehicles used in international traffic;
 - (iii) the initial qualification and continuous training of drivers;
 - (iv) the roadworthiness of commercial vehicles, including the compulsory technical inspection of motor vehicles;
 - (v) access to the market in international road haulage or, as appropriate, access to the market in road passenger transport;
 - (vi) safety in the carriage of dangerous goods by road;
 - (vii) the installation and use of speed-limiting devices in certain categories of vehicle;
 - (viii) driving licences;
 - (ix) admission to the occupation;
 - (x) animal transport.

2. For the purposes of point (b) of the third subparagraph of paragraph 1:

- (a) where the transport manager or the transport undertaking has in one or more Member States been convicted of a serious criminal offence or incurred a penalty for one of the most serious infringements of Community rules as set out in Annex IV, the competent authority of the Member State

of establishment shall carry out in an appropriate and timely manner a duly completed administrative procedure, which shall include, if appropriate, a check at the premises of the undertaking concerned.

The procedure shall determine whether, due to specific circumstances, the loss of good repute would constitute a disproportionate response in the individual case. Any such finding shall be duly reasoned and justified.

If the competent authority finds that the loss of good repute would constitute a disproportionate response, it may decide that good repute is unaffected. In such case, the reasons shall be recorded in the national register. The number of such decisions shall be indicated in the report referred to in Article 26(1).

If the competent authority does not find that the loss of good repute would constitute a disproportionate response, the conviction or penalty shall lead to the loss of good repute;

- (b) the Commission shall draw up a list of categories, types and degrees of seriousness of serious infringements of Community rules which, in addition to those set out in Annex IV, may lead to the loss of good repute. Member States shall take into account information on those infringements, including information received from other Member States, when setting the priorities for checks pursuant to Article 12(1).

Those measures, designed to amend non-essential elements of this Regulation by supplementing it and which relate to this list, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 25(3).

To this end, the Commission shall:

- (i) lay down the categories and types of infringement which are most frequently encountered;
- (ii) define the degree of seriousness of infringements according to their potential to create a risk of fatalities or serious injuries; and
- (iii) provide the frequency of occurrence beyond which repeated infringements shall be regarded as more serious, by taking into account the number of drivers used for the transport activities managed by the transport manager.

3. The requirement laid down in Article 3(1)(b) shall not be satisfied until a rehabilitation measure or any other measure having an equivalent effect has been taken pursuant to the relevant provisions of national law.

*Article 7***Conditions relating to the requirement of financial standing**

1. In order to satisfy the requirement laid down in Article 3(1)(c), an undertaking shall at all times be able to meet its financial obligations in the course of the annual accounting year. To this end, the undertaking shall demonstrate, on the basis of annual accounts certified by an auditor or a duly accredited person, that, every year, it has at its disposal capital and reserves totalling at least EUR 9 000 when only one vehicle is used and EUR 5 000 for each additional vehicle used.

For the purposes of this Regulation, the value of the euro in the currencies of Member States which do not participate in the third stage of the economic and monetary union shall be fixed every year. The rates to be applied shall be those obtained on the first working day of October and published in the *Official Journal of the European Union*. They shall have effect from 1 January of the following calendar year.

The accounting items referred to in the first subparagraph shall be understood as those defined in Fourth Council Directive 78/660/EEC of 25 July 1978 based on Article 54(3)(g) of the Treaty on the annual accounts of certain types of companies ⁽¹⁾.

2. By way of derogation from paragraph 1, the competent authority may agree or require that an undertaking demonstrate its financial standing by means of a certificate such as a bank guarantee or an insurance, including a professional liability insurance from one or more banks or other financial institutions, including insurance companies, providing a joint and several guarantee for the undertaking in respect of the amounts specified in the first subparagraph of paragraph 1.

3. The annual accounts referred to in paragraph 1, and the guarantee referred to in paragraph 2, which are to be verified, are those of the economic entity established in the Member State in which an authorisation has been applied for and not those of any other entity established in any other Member State.

*Article 8***Conditions relating to the requirement of professional competence**

1. In order to satisfy the requirement laid down in Article 3(1)(d), the person or persons concerned shall possess knowledge corresponding to the level provided for in Part I of Annex I in the subjects listed therein. That knowledge shall be demonstrated by means of a compulsory written examination which, if a Member State so decides, may be supplemented by an oral examination. Those examinations shall be organised in accordance with Part II of Annex I. To this end, Member States may decide to impose training prior to the examination.

2. The persons concerned shall sit the examination in the Member State in which they have their normal residence or the Member State in which they work.

'Normal residence' shall mean the place where a person usually lives, that is for at least 185 days in each calendar year, because of personal ties which show close links between that person and the place where he is living.

However, the normal residence of a person whose occupational ties are in a different place from his personal ties and who, consequently, lives in turn in different places situated in two or more Member States, shall be regarded as being in the place of his personal ties, provided that such person returns there regularly. This last condition shall not be required where the person is living in a Member State in order to carry out a task of a definite duration. Attendance at a university or school shall not imply transfer of normal residence.

3. Only the authorities or bodies duly authorised for this purpose by a Member State, in accordance with criteria defined by it, may organise and certify the written and oral examinations referred to in paragraph 1. Member States shall regularly verify that the conditions under which those authorities or bodies organise the examinations are in accordance with Annex I.

4. Member States may duly authorise, in accordance with criteria defined by them, bodies to provide applicants with high-quality training to prepare them for the examinations and transport managers with continuous training to update their knowledge if they wish to do so. Such Member States shall regularly verify that these bodies at all times fulfil the criteria on the basis of which they were authorised.

5. Member States may promote periodic training on the subjects listed in Annex I at 10-year intervals to ensure that transport managers are aware of developments in the sector.

6. Member States may require persons who possess a certificate of professional competence, but who have not managed a road haulage undertaking or a road passenger transport undertaking in the last 5 years, to undertake retraining in order to update their knowledge regarding the current developments of the legislation referred to in Part I of Annex I.

7. A Member State may exempt the holders of certain higher education qualifications or technical education qualifications issued in that Member State, specifically designated to this end and entailing knowledge of all the subjects listed in Annex I from the examination in the subjects covered by those qualifications. The exemption shall only apply to those sections of Part I of Annex I for which the qualification covers all subjects listed under the heading of each section.

A Member State may exempt from specified parts of the examinations holders of certificates of professional competence valid for national transport operations in that Member State.

⁽¹⁾ OJ L 222, 14.8.1978, p. 11.

8. A certificate issued by the authority or body referred to in paragraph 3 shall be produced as proof of professional competence. That certificate shall not be transferable to any other person. It shall be drawn up in accordance with the security features and the model certificate set out in Annexes II and III and shall bear the seal of the duly authorised authority or body which issued it.

9. The Commission shall adapt Annexes I, II and III to technical progress. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 25(3).

10. The Commission shall encourage and facilitate the exchange of experience and information between Member States, or through any body it may designate, concerning training, examinations and authorisations.

Article 9

Exemption from examination

Member States may decide to exempt from the examinations referred to in Article 8(1) persons who provide proof that they have continuously managed a road haulage undertaking or a road passenger transport undertaking in one or more Member States for the period of 10 years before 4 December 2009.

CHAPTER III

AUTHORISATION AND MONITORING

Article 10

Competent authorities

1. Each Member State shall designate one or more competent authorities to ensure the correct implementation of this Regulation. Those competent authorities shall be empowered to:

- (a) examine applications made by undertakings;
- (b) grant authorisations to engage in the occupation of road transport operator, and suspend or withdraw such authorisations;
- (c) declare a natural person to be unfit to manage the transport activities of an undertaking in the capacity of transport manager;
- (d) carry out the requisite checks to verify whether an undertaking satisfies the requirements laid down in Article 3.

2. The competent authorities shall publish all the conditions laid down pursuant to this Regulation, any other national provisions, the procedures to be followed by interested applicants and the corresponding explanations.

Article 11

Examination and registration of applications

1. A transport undertaking which complies with the requirements laid down in Article 3 shall, upon application, be authorised to engage in the occupation of road transport operator. The competent authority shall ascertain that an undertaking which submits an application satisfies the requirements laid down in that Article.

2. The competent authority shall record in the national electronic register referred to in Article 16 the data relating to undertakings which it authorises and which are referred to in points (a) to (d) of the first subparagraph of Article 16(2).

3. The time limit for the examination of an application for authorisation by a competent authority shall be as short as possible and shall not exceed 3 months from the date on which the competent authority receives all documents necessary to assess the application. The competent authority may extend this time limit for one additional month in duly justified cases.

4. Until 31 December 2012, the competent authority shall verify, in case of any doubt when assessing the good repute of an undertaking, whether at the time of application the designated transport manager or managers are declared, in one of the Member States, unfit to manage the transport activities of an undertaking pursuant to Article 14.

From 1 January 2013, when assessing the good repute of an undertaking, the competent authority shall verify, by accessing the data referred to in point (f) of the first subparagraph of Article 16(2), either by direct secure access to the relevant part of the national registers or by request, whether at the time of the application the designated transport manager or managers are declared, in one of the Member States, unfit to manage the transport activities of an undertaking pursuant to Article 14.

Measures designed to amend non-essential elements of this Regulation and relating to a postponement for a maximum of 3 years of the dates referred to in this paragraph shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 25(3).

5. Undertakings with an authorisation to engage in the occupation of road transport operator shall, within a period of 28 days or less, as determined by the Member State of establishment, notify the competent authority which granted the authorisation of any changes to the data referred to in paragraph 2.

Article 12

Checks

1. Competent authorities shall monitor whether undertakings which they have authorised to engage in the occupation of road transport operator continue to fulfil the requirements laid down in Article 3. To that end, Member States shall carry out checks targeting those undertakings which are classed as posing an increased risk. For that purpose, Member States shall extend the risk classification system established by them pursuant to Article 9 of Directive 2006/22/EC of the European Parliament and of the Council of 15 March 2006 on minimum conditions for the

implementation of Council Regulations (EEC) No 3820/85 and (EEC) No 3821/85 concerning social legislation relating to road transport activities ⁽¹⁾ to cover all infringements specified in Article 6 of this Regulation.

2. Until 31 December 2014, Member States shall carry out checks at least every 5 years to verify that undertakings fulfil the requirements laid down in Article 3.

Measures designed to amend non-essential elements of this Regulation and relating to a postponement of the date referred to in the first subparagraph shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 25(3).

3. Member States shall carry out individual checks to verify whether an undertaking meets the conditions governing admission to the occupation of road transport operator whenever the Commission so requests in duly motivated cases. It shall inform the Commission of the results of such checks and of the measures taken if it is established that the undertaking no longer fulfils the requirements laid down in this Regulation.

Article 13

Procedure for the suspension and withdrawal of authorisations

1. Where a competent authority establishes that an undertaking runs the risk of no longer fulfilling the requirements laid down in Article 3, it shall notify the undertaking thereof. Where a competent authority establishes that one or more of those requirements is no longer satisfied, it may set one of the following time limits for the undertaking to rectify the situation:

- (a) a time limit not exceeding 6 months, which may be extended by 3 months in the event of the death or physical incapacity of the transport manager, for the recruitment of a replacement transport manager where the transport manager no longer satisfies the requirement as to good repute or professional competence;
- (b) a time limit not exceeding 6 months where the undertaking has to rectify the situation by demonstrating that it has an effective and stable establishment;
- (c) a time limit not exceeding 6 months where the requirement of financial standing is not satisfied, in order to demonstrate that that requirement will again be satisfied on a permanent basis.

2. The competent authority may require an undertaking whose authorisation has been suspended or withdrawn to ensure that its transport managers have passed the examinations referred to in Article 8(1) prior to any rehabilitation measure being taken.

3. If the competent authority establishes that the undertaking no longer satisfies one or more of the requirements laid down in Article 3, it shall suspend or withdraw the authorisation to engage in the occupation of road transport operator within the time limits referred to in paragraph 1 of this Article.

⁽¹⁾ OJ L 102, 11.4.2006, p. 35.

Article 14

Declaration of unfitness of the transport manager

1. Where a transport manager loses good repute in accordance with Article 6, the competent authority shall declare that transport manager unfit to manage the transport activities of an undertaking.

2. Unless and until a rehabilitation measure is taken in accordance with the relevant provisions of national law, the certificate of professional competence, referred to in Article 8(8), of the transport manager declared to be unfit, shall no longer be valid in any Member State.

Article 15

Decisions of the competent authorities and appeals

1. Negative decisions taken by the competent authorities of the Member States pursuant to this Regulation, including the rejection of an application, the suspension or withdrawal of an existing authorisation and a declaration of unfitness of a transport manager, shall state the reasons on which they are based.

Such decisions shall take account of available information concerning infringements committed by the undertaking or the transport manager which are such as to detract from the good repute of the undertaking and of any other information at the disposal of the competent authority. They shall specify the rehabilitation measures applicable in the event of the suspension of an authorisation or a declaration of unfitness.

2. Member States shall take steps to ensure that the undertakings and persons concerned have the possibility of appealing the decisions referred to in paragraph 1 to at least one independent and impartial body or a court of law.

CHAPTER IV

SIMPLIFICATION AND ADMINISTRATIVE COOPERATION

Article 16

National electronic registers

1. For the purposes of the implementation of this Regulation, and in particular Articles 11 to 14 and Article 26 thereof, each Member State shall keep a national electronic register of road transport undertakings which have been authorised by a competent authority designated by it to engage in the occupation of road transport operator. The data contained in that register shall be processed under the supervision of a public authority designated for that purpose. The relevant data contained in the national electronic register shall be accessible to all the competent authorities of the Member State in question.

By 31 December 2009, the Commission shall adopt a Decision on minimum requirements for the data to be entered in the national electronic register from the date of its setting-up in order to facilitate the future interconnection of registers. It may recommend the inclusion of the vehicle registration marks in addition to the data referred to in paragraph 2.

2. National electronic registers shall contain at least the following data:

- (a) the name and legal form of the undertaking;
- (b) the address of its establishment;
- (c) the names of the transport managers designated to meet the conditions as to good repute and professional competence or, as appropriate, the name of a legal representative;
- (d) the type of authorisation, the number of vehicles it covers and, where appropriate, the serial number of the Community licence and of the certified copies;
- (e) the number, category and type of serious infringements, as referred to in Article 6(1)(b), which have resulted in a conviction or penalty during the last 2 years;
- (f) the name of any person declared to be unfit to manage the transport activities of an undertaking, as long as the good repute of that person has not been re-established pursuant to Article 6(3), and the rehabilitation measures applicable.

For the purposes of point (e), Member States may, until 31 December 2015, choose to include in the national electronic register only the most serious infringements set out in Annex IV.

Member States may choose to keep the data referred to in points (e) and (f) of the first subparagraph in separate registers. In such a case, the relevant data shall be available upon request or directly accessible to all the competent authorities of the Member State in question. The requested information shall be provided within 30 working days of receipt of the request. The data referred to in points (a) to (d) of the first subparagraph shall be publicly accessible, in accordance with the relevant provisions on personal data protection.

In any case, the data referred to in points (e) and (f) of the first subparagraph shall only be accessible to authorities other than the competent authorities where they are duly endowed with powers relating to supervision and the imposition of penalties in the road transport sector and their officials are sworn to, or otherwise are under a formal obligation of, secrecy.

3. Data concerning an undertaking whose authorisation has been suspended or withdrawn shall remain in the national electronic register for 2 years from the expiry of the suspension or the withdrawal of the licence, and shall thereafter be immediately removed.

Data concerning any person declared to be unfit for the occupation of road transport operator shall remain in the national electronic register as long as the good repute of that person has not been re-established pursuant to Article 6(3). Where such a rehabilitation measure or any other measure having an equivalent effect is taken, the data shall be immediately removed.

The data referred to in the first and second subparagraphs shall specify the reasons for the suspension or withdrawal of the authorisation or the declaration of unfitness, as appropriate, and the corresponding duration.

4. Member States shall take all necessary measures to ensure that all the data contained in the national electronic register is kept up to date and is accurate, in particular the data referred to in points (e) and (f) of the first subparagraph of paragraph 2.

5. Without prejudice to paragraphs 1 and 2, Member States shall take all necessary measures to ensure that the national electronic registers are interconnected and accessible throughout the Community through the national contact points defined in Article 18. Accessibility through national contact points and interconnection shall be implemented by 31 December 2012 in such a way that a competent authority of any Member State is able to consult the national electronic register of any Member State.

6. Common rules concerning the implementation of paragraph 5, such as the format of the data exchanged, the technical procedures for electronic consultation of the national electronic registers of the other Member States and the promotion of the interoperability of these registers with other relevant databases, shall be adopted by the Commission in accordance with the advisory procedure referred to in Article 25(2) and for the first time before 31 December 2010. Those common rules shall determine which authority is responsible for access to data and further use and updating of data after access and, to this effect, shall include rules on data logging and data monitoring.

7. Measures designed to amend non-essential elements of this Regulation and relating to a postponement of the time limits referred to in paragraphs 1 and 5 shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 25(3).

Article 17

Protection of personal data

With regard to the application of Directive 95/46/EC, Member States shall ensure in particular that:

- (a) all persons are informed when data relating to them is recorded or is planned to be forwarded to third parties. The information provided shall specify the identity of the authority responsible for processing the data, the type of data processed and the reasons for such action;
- (b) all persons have a right of access to data relating to them held by the authority responsible for processing those data. That right shall be exercisable without constraint, at reasonable intervals and without excessive delay or cost for the applicant;
- (c) all persons whose data are incomplete or inaccurate have the right to have those data rectified, erased or blocked;

- (d) all persons have the right to oppose, on compelling legitimate grounds, the processing of data relating to them. Where there is justified opposition, the processing may no longer involve those data;
- (e) undertakings comply, where applicable, with the relevant provisions on the protection of personal data.

Article 18

Administrative cooperation between Member States

1. Member States shall designate a national contact point responsible for the exchange of information with the other Member States with regard to the application of this Regulation. Member States shall forward to the Commission the names and addresses of their national contact points by 4 December 2011. The Commission shall draw up a list of all contact points and forward it to the Member States.

2. Member States which exchange information in the framework of this Regulation shall use the national contact points designated pursuant to paragraph 1.

3. Member States which exchange information on the infringements referred to in Article 6(2) or on transport managers declared to be unfit shall comply with the procedure and time limits referred to in Article 13(1) of Regulation (EC) No 1072/2009 or, as appropriate, Article 23(1) of Regulation (EC) No 1073/2009. A Member State which receives notification of a serious infringement which has resulted in a conviction or a penalty in another Member State shall record that infringement in its national electronic register.

CHAPTER V

MUTUAL RECOGNITION OF CERTIFICATES AND OTHER DOCUMENTS

Article 19

Certificates of good repute and equivalent documents

1. Without prejudice to Article 11(4), the Member State of establishment shall accept as sufficient proof of good repute for admission to the occupation of road transport operator the production of an extract from a judicial record or, failing that, an equivalent document issued by a competent judicial or administrative authority in the Member State where the transport manager or any other relevant person used to reside.

2. Where a Member State imposes on its own nationals certain conditions relating to good repute, and proof that these conditions are met cannot be provided by means of the document referred to in paragraph 1, that Member State shall accept as sufficient proof for nationals of other Member States a certificate issued by a competent judicial or administrative authority in the Member State(s) where the transport manager or any other relevant person used to reside stating that these conditions have been met. Such certificate shall relate to the specific information taken into consideration in the Member State of establishment.

3. If the document referred to in paragraph 1 or the certificate referred to in paragraph 2 has not been issued by the Member State(s) where the transport manager or any other relevant person used to reside, that document or certificate may be replaced by a declaration on oath or by a solemn declaration made by the transport manager or any other relevant person before a competent judicial or administrative authority or, where appropriate, before a notary in the Member State where the transport manager or any other relevant person used to reside. Such authority or notary shall issue a certificate authenticating the declaration on oath or the solemn declaration.

4. A document referred to in paragraph 1 and a certificate referred to in paragraph 2 shall not be accepted if produced more than 3 months after their date of issue. This condition shall also apply to a declaration made in accordance with paragraph 3.

Article 20

Certificates relating to financial standing

Where a Member State imposes on its nationals certain conditions relating to financial standing in addition to those set out in Article 7, that Member State shall accept as sufficient proof for nationals of other Member States a certificate issued by a competent authority in the Member State(s) where the transport manager or any other relevant person used to reside stating that these conditions have been met. Such certificate shall relate to the specific information taken into consideration in the new Member State of establishment.

Article 21

Certificates of professional competence

1. Member States shall recognise as sufficient proof of professional competence a certificate which complies with the model certificate set out in Annex III and which is issued by the authority or body duly authorised for that purpose.

2. A certificate issued before 4 December 2011 as proof of professional competence pursuant to the provisions in force until that date shall be deemed to be equivalent to a certificate which complies with the model certificate set out in Annex III and shall be recognised as proof of professional competence in all Member States. Member States may require that holders of certificates of professional competence valid only for national transport pass the examinations, or parts of the examinations, referred to in Article 8(1).

CHAPTER VI

FINAL PROVISIONS

Article 22

Penalties

1. Member States shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation, and shall take all the measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission by 4 December 2011 at the latest and shall notify it without delay of any subsequent amendment affecting them. Member States shall ensure that all such measures are applied without discrimination as to the nationality or place of establishment of the undertaking.

2. The penalties referred to in paragraph 1 shall include, in particular, suspension of the authorisation to engage in the occupation of road transport operator, withdrawal of such authorisation and a declaration of unfitness of the transport manager.

Article 23

Transitional provisions

Undertakings which before 4 December 2009 have an authorisation to engage in the occupation of road transport operator shall comply with the provisions of this Regulation by 4 December 2011.

Article 24

Mutual assistance

The competent authorities of the Member States shall cooperate closely and shall give each other mutual assistance for the purposes of applying this Regulation. They shall exchange information on convictions and penalties for any serious infringements, and other specific information liable to have consequences for the pursuit of the occupation of road transport operator, in compliance with the provisions applicable to the protection of personal data.

Article 25

Committee procedure

1. The Commission shall be assisted by the Committee set up by Article 18(1) of Council Regulation (EEC) No 3821/85 of 20 December 1985 on recording equipment in road transport ⁽¹⁾.

2. Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

Article 26

Reporting

1. Every 2 years, Member States shall draw up a report on the activities of the competent authorities and shall forward it to the Commission. This report shall comprise:

- (a) an overview of the sector with regard to good repute, financial standing and professional competence;
- (b) the number of authorisations granted by year and by type, those suspended, those withdrawn, the number of declarations of unfitness and the reasons on which those decisions were based;
- (c) the number of certificates of professional competence issued each year;
- (d) core statistics relating to the national electronic registers and their use by the competent authorities; and
- (e) an overview of exchanges of information with other Member States pursuant to Article 18(2), including in particular the annual number of established infringements notified to other Member States and the replies received, as well as the annual number of requests and replies received pursuant to Article 18(3).

2. On the basis of the reports referred to in paragraph 1, the Commission shall, every 2 years, submit a report to the European Parliament and to the Council on the pursuit of the occupation of road transport operator. That report shall contain, in particular, an assessment of the operation of the exchange of information between Member States and a review of the functioning and data contained in the national electronic registers. It shall be published at the same time as the report referred to in Article 17 of Regulation (EC) No 561/2006 of the European Parliament and of the Council of 15 March 2006 on the harmonisation of certain social legislation relating to road transport ⁽²⁾.

⁽¹⁾ OJ L 370, 31.12.1985, p. 8.

⁽²⁾ OJ L 102, 11.4.2006, p. 1.

*Article 27***List of competent authorities**

Each Member State shall forward to the Commission by 4 December 2011 a list of competent authorities which it has designated to authorise the pursuit of the occupation of road transport operator and a list of the authorised authorities or bodies responsible for organising the examinations referred to in Article 8(1) and issuing the certificates. A consolidated list of those authorities and bodies throughout the Community shall be published by the Commission in the *Official Journal of the European Union*.

*Article 28***Communication of national measures**

Member States shall communicate to the Commission the text of the laws, regulations and administrative provisions which they adopt

in the field governed by this Regulation no later than 30 days after their date of adoption and for the first time by 4 December 2011.

*Article 29***Repeal**

Directive 96/26/EC is hereby repealed.

*Article 30***Entry into force**

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

It shall apply with effect from 4 December 2011.

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

Done at Strasbourg, 21 October 2009.

For the European Parliament
The President
J. BUZEK

For the Council
The President
C. MALMSTRÖM

ANNEX I

I. LIST OF SUBJECTS REFERRED TO IN ARTICLE 8

The knowledge to be taken into consideration for the official recognition of professional competence by Member States must cover at least the subjects listed below for road haulage and road passenger transport respectively. In relation to these subjects, applicant road haulage and road passenger transport operators must have the levels of knowledge and practical aptitude necessary for the management of a transport undertaking.

The minimum level of knowledge, as indicated below, may not be below level 3 of the training-level structure laid down in the Annex to Council Decision 85/368/EEC ⁽¹⁾, namely the level of knowledge acquired during the course of compulsory education, which is supplemented either by vocational training and supplementary technical training or by secondary school or other technical training.

A. **Civil law**

The applicant must, in particular, in relation to road haulage and passenger transport:

1. be familiar with the main types of contract used in road transport and with the rights and obligations arising therefrom;
2. be capable of negotiating a legally valid transport contract, notably with regard to conditions of carriage;

in relation to road haulage:

3. be able to consider a claim by his principal regarding compensation for loss of or damage to goods during transportation or for their late delivery, and to understand how such a claim affects his contractual liability;
4. be familiar with the rules and obligations arising from the CMR Convention on the Contract for the International Carriage of Goods by Road;

in relation to road passenger transport:

5. be able to consider a claim by his principal regarding compensation for injury to passengers or damage to their baggage caused by an accident during transportation, or regarding compensation for delays, and to understand how such a claim affects his contractual liability.

B. **Commercial law**

The applicant must, in particular, in relation to road haulage and passenger transport:

1. be familiar with the conditions and formalities laid down for plying the trade, the general obligations incumbent upon transport operators (registration, record keeping, etc.) and the consequences of bankruptcy;
2. have appropriate knowledge of the various forms of commercial companies and the rules governing their constitution and operation.

C. **Social law**

The applicant must, in particular, in relation to road haulage and passenger transport, be familiar with the following:

1. the role and function of the various social institutions which are concerned with road transport (trade unions, works councils, shop stewards, labour inspectors, etc.);
2. the employers' social security obligations;

⁽¹⁾ Council Decision 85/368/EEC of 16 July 1985 on the comparability of vocational training qualifications between the Member States of the European Community (OJ L 199, 31.7.1985, p. 56).

3. the rules governing work contracts for the various categories of worker employed by road transport undertakings (form of the contracts, obligations of the parties, working conditions and working hours, paid leave, remuneration, breach of contract, etc.);
4. the rules applicable to driving time, rest periods and working time, and in particular the provisions of Regulation (EEC) No 3821/85, Regulation (EC) No 561/2006, Directive 2002/15/EC of the European Parliament and of the Council ⁽¹⁾ and Directive 2006/22/EC, and the practical measures for applying those provisions; and
5. the rules applicable to the initial qualification and continuous training of drivers, and in particular those deriving from Directive 2003/59/EC of the European Parliament and of the Council ⁽²⁾.

D. Fiscal law

The applicant must, in particular, in relation to road haulage and passenger transport, be familiar with the rules governing:

1. value added tax (VAT) on transport services;
2. motor-vehicle tax;
3. the taxes on certain road haulage vehicles and tolls and infrastructure user charges;
4. income tax.

E. Business and financial management of the undertaking

The applicant must, in particular, in relation to road haulage and passenger transport:

1. be familiar with the laws and practices regarding the use of cheques, bills of exchange, promissory notes, credit cards and other means or methods of payment;
2. be familiar with the various forms of credit (bank credit, documentary credit, guarantee deposits, mortgages, leasing, renting, factoring, etc.) and the charges and obligations arising therefrom;
3. know what a balance sheet is, how it is set out and how to interpret it;
4. be able to read and interpret a profit and loss account;
5. be able to assess the undertaking's profitability and financial position, in particular on the basis of financial ratios;
6. be able to prepare a budget;
7. be familiar with the cost elements of the undertaking (fixed costs, variable costs, working capital, depreciation, etc.), and be able to calculate costs per vehicle, per kilometre, per journey or per tonne;
8. be able to draw up an organisation chart relating to the undertaking's personnel as a whole and to organise work plans, etc.;
9. be familiar with the principles of marketing, publicity and public relations, including transport services, sales promotion and the preparation of customer files, etc.;
10. be familiar with the different types of insurance relating to road transport (liability, accidental injury/life insurance, non-life and luggage insurance) and the guarantees and obligations arising therefrom;
11. be familiar with the applications of electronic data transmission in road transport;

in relation to road haulage:

⁽¹⁾ Directive 2002/15/EC of the European Parliament and of the Council of 11 March 2002 on the organisation of the working time of persons performing mobile road transport activities (OJ L 80, 23.3.2002, p. 35).

⁽²⁾ Directive 2003/59/EC of the European Parliament and of the Council of 15 July 2003 on the initial qualification and periodic training of drivers of certain road vehicles for the carriage of goods or passengers (OJ L 226, 10.9.2003, p. 4).

12. be able to apply the rules governing the invoicing of road haulage services and know the meaning and implications of Incoterms;
13. be familiar with the different categories of transport auxiliaries, their role, their functions and, where appropriate, their status;

in relation to road passenger transport:
14. be able to apply the rules governing fares and pricing in public and private passenger transport;
15. be able to apply the rules governing the invoicing of road passenger transport services.

F. Access to the market

The applicant must, in particular, in relation to road haulage and passenger transport, be familiar with the following:

1. the occupational regulations governing road transport for hire or reward, industrial vehicle rental and subcontracting, and in particular the rules governing the official organisation of the occupation, admission to the occupation, authorisations for intra-Community and extra-Community road transport operations, inspections and penalties;
2. the rules for setting up a road transport undertaking;
3. the various documents required for operating road transport services and the introduction of checking procedures to ensure that the approved documents relating to each transport operation, and in particular those relating to the vehicle, the driver, the goods and luggage are kept both in the vehicle and on the premises of the undertaking;

in relation to road haulage:

4. the rules on the organisation of the market in road haulage services, as well as the rules on freight handling and logistics;
5. border formalities, the role and scope of T documents and TIR carnets, and the obligations and responsibilities arising from their use;

in relation to road passenger transport:

6. the rules on the organisation of the market in road passenger transport;
7. the rules for introducing road passenger transport services and the drawing up of transport plans.

G. Technical standards and technical aspects of operation

The applicant must, in particular, in relation to road haulage and passenger transport:

1. be familiar with the rules concerning the weights and dimensions of vehicles in the Member States and the procedures to be followed in the case of abnormal loads which constitute an exception to these rules;
2. be able to choose vehicles and their components (chassis, engine, transmission system, braking system, etc.) in accordance with the needs of the undertaking;
3. be familiar with the formalities relating to the type approval, registration and technical inspection of these vehicles;
4. understand what measures must be taken to reduce noise and to combat air pollution by motor vehicle exhaust emissions;
5. be able to draw up periodic maintenance plans for the vehicles and their equipment;

in relation to road haulage:

6. be familiar with the different types of cargo-handling and loading devices (tailboards, containers, pallets, etc.) and be able to introduce procedures and issue instructions for loading and unloading goods (load distribution, stacking, stowing, blocking and chocking, etc.);
7. be familiar with the various techniques of 'piggy-back' and roll-on roll-off combined transport;
8. be able to implement procedures to comply with the rules on the carriage of dangerous goods and waste, notably those arising from Directive 2008/68/EC ⁽¹⁾ and Regulation (EC) No 1013/2006 ⁽²⁾;
9. be able to implement procedures to comply with the rules on the carriage of perishable foodstuffs, notably those arising from the Agreement on the International Carriage of Perishable Foodstuffs and on the Special Equipment to be used for such Carriage (ATP);
10. be able to implement procedures to comply with the rules on the transport of live animals.

H. Road safety

The applicant must, in particular, in relation to road haulage and passenger transport:

1. know what qualifications are required for drivers (driving licence, medical certificates, certificates of fitness, etc.);
2. be able to take the necessary steps to ensure that drivers comply with the traffic rules, prohibitions and restrictions in force in different Member States (speed limits, priorities, waiting and parking restrictions, use of lights, road signs, etc.);
3. be able to draw up instructions for drivers to check their compliance with the safety requirements concerning the condition of the vehicles, their equipment and cargo, and concerning preventive measures to be taken;
4. be able to lay down procedures to be followed in the event of an accident and to implement appropriate procedures to prevent the recurrence of accidents or serious traffic offences;
5. be able to implement procedures to properly secure goods and be familiar with the corresponding techniques;

in relation to road passenger transport:
6. have elementary knowledge of the layout of the road network in the Member States.

II. ORGANISATION OF THE EXAMINATION

1. Member States will organise a compulsory written examination which they may supplement by an optional oral examination to establish whether applicant road transport operators have achieved the required level of knowledge in the subjects listed in Part I and in particular their capacity to use the instruments and techniques relating to those subjects and to fulfil the corresponding executive and coordination duties.
 - (a) The compulsory written examination will involve two tests, namely:
 - (i) written questions consisting of either multiple choice questions (each with four possible answers), questions requiring direct answers or a combination of both systems;
 - (ii) written exercises/case studies.The minimum duration of each test will be two hours.
 - (b) Where an oral examination is organised, Member States may stipulate that participation is subject to the successful completion of the written examination.

⁽¹⁾ Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods (OJ L 260, 30.9.2008, p. 13).

⁽²⁾ Regulation (EC) No 1013/2006 of the European Parliament and of the Council of 14 June 2006 on shipments of waste (OJ L 190, 12.7.2006, p. 1).

2. Where Member States also organise an oral examination, they must provide, in respect of each of the three tests, for a weighting of marks of a minimum of 25 % and a maximum of 40 % of the total number of marks to be given.

Where Member States organise only a written examination, they must provide, in respect of each test, for a weighting of marks of a minimum of 40 % and a maximum of 60 % of the total number of marks to be given.

3. With regard to all the tests, applicants must obtain an average of at least 60 % of the total number of marks to be given, achieving in any given test not less than 50 % of the total number of marks possible. In one test only, a Member State may reduce that mark from 50 % to 40 %.
-

ANNEX II

Security features of the certificate of professional competence

The certificate must have at least two of the following security features:

- a hologram,
 - special fibres in the paper which become visible under UV light,
 - at least one microprint line (printing visible only with a magnifying glass and not reproduced by photocopying machines),
 - tactile characters, symbols or patterns,
 - double numbering: serial number and issue number,
 - a security design background with fine guilloche patterns and rainbow printing.
-

ANNEX III

Model of the certificate of professional competence**EUROPEAN COMMUNITY**(Colour Pantone stout fawn, format DIN A 4 cellulose paper 100 g/m² or more)

(Text in the official language(s) or one of the official languages of the Member State issuing the certificate)

Distinguishing sign of the Member State concerned ⁽¹⁾ Name of the authorised authority or body ⁽²⁾**CERTIFICATE OF PROFESSIONAL COMPETENCE IN ROAD HAULAGE/PASSENGER TRANSPORT ⁽³⁾**

No

We

hereby certify that ⁽⁴⁾

born on in

has successfully passed the tests for the examination (year:; session:) ⁽⁵⁾ necessary for the award of the certificate of professional competence in road haulage/passenger transport ⁽³⁾ in accordance with Regulation (EC) No 1071/2009 of the European Parliament and of the Council of 21 October 2009 establishing common rules concerning the conditions to be complied with to pursue the occupation of road transport operator ⁽⁶⁾.

This certificate constitutes the sufficient proof of professional competence referred to in Article 21 of Regulation (EC) No 1071/2009.

Issued at, on ⁽⁷⁾

⁽¹⁾ The distinguishing signs of the Member States are: (B) Belgium, (BG) Bulgaria, (CZ) Czech Republic, (DK) Denmark, (D) Germany, (EST) Estonia, (IRL) Ireland, (GR) Greece, (E) Spain, (F) France, (I) Italy, (CY) Cyprus, (LV) Latvia, (LT) Lithuania, (L) Luxembourg, (H) Hungary, (M) Malta, (NL) Netherlands, (A) Austria, (PL) Poland, (P) Portugal, (RO) Romania, (SLO) Slovenia, (SK) Slovakia, (FIN) Finland, (S) Sweden, (UK) United Kingdom.

⁽²⁾ Authority or body designated in advance for this purpose by each Member State of the European Community to issue this certificate.

⁽³⁾ Delete as appropriate.

⁽⁴⁾ Surname and forename; place and date of birth.

⁽⁵⁾ Identification of the examination.

⁽⁶⁾ OJ L 300, 14.11.2009, p. 51

⁽⁷⁾ Seal and signature of the authorised authority or body issuing the certificate.

ANNEX IV

Most serious infringements for the purposes of Article 6(2)(a)

1. (a) Exceeding the maximum 6-day or fortnightly driving time limits by margins of 25 % or more.
(b) Exceeding, during a daily working period, the maximum daily driving time limit by a margin of 50 % or more without taking a break or without an uninterrupted rest period of at least 4,5 hours.
 2. Not having a tachograph and/or speed limiter, or using a fraudulent device able to modify the records of the recording equipment and/or the speed limiter or falsifying record sheets or data downloaded from the tachograph and/or the driver card.
 3. Driving without a valid roadworthiness certificate if such a document is required under Community law and/or driving with a very serious deficiency of, inter alia, the braking system, the steering linkages, the wheels/tyres, the suspension or chassis that would create such an immediate risk to road safety that it leads to a decision to immobilise the vehicle.
 4. Transporting dangerous goods that are prohibited for transport or transporting such goods in a prohibited or non-approved means of containment or without identifying them on the vehicle as dangerous goods, thus endangering lives or the environment to such extent that it leads to a decision to immobilise the vehicle.
 5. Carrying passengers or goods without holding a valid driving licence or carrying by an undertaking not holding a valid Community licence.
 6. Driving with a driver card that has been falsified, or with a card of which the driver is not the holder, or which has been obtained on the basis of false declarations and/or forged documents.
 7. Carrying goods exceeding the maximum permissible laden mass by 20 % or more for vehicles the permissible laden weight of which exceeds 12 tonnes, and by 25 % or more for vehicles the permissible laden weight of which does not exceed 12 tonnes.
-

REGULATION (EC) No 1072/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 21 October 2009

on common rules for access to the international road haulage market

(recast)

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 71 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee ⁽¹⁾,

After consulting the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty ⁽²⁾,

Whereas:

(1) A number of substantial changes are to be made to Council Regulation (EEC) No 881/92 of 26 March 1992 on access to the market in the carriage of goods by road within the Community to or from the territory of a Member State or passing across the territory of one or more Member States ⁽³⁾, to Council Regulation (EEC) No 3118/93 of 25 October 1993 laying down the conditions under which non-resident carriers may operate national road haulage services within a Member State ⁽⁴⁾, and to Directive 2006/94/EC of the European Parliament and of the Council of 12 December 2006 on the establishment of common rules for certain types of carriage of goods by road ⁽⁵⁾. In the interests of clarity and simplification, those legal acts should be recast and incorporated into one single regulation.

(2) The establishment of a common transport policy entails, inter alia, laying down common rules applicable to access to the market in the international carriage of goods by road within the territory of the Community, as well as laying down the conditions under which non-resident hauliers may operate transport services within a Member State.

Those rules must be laid down in such a way as to contribute to the smooth operation of the internal transport market.

(3) To ensure a coherent framework for international road haulage throughout the Community, this Regulation should apply to all international carriage on Community territory. Carriage from Member States to third countries is still largely covered by bilateral agreements between the Member States and those third countries. Therefore, this Regulation should not apply to that part of the journey within the territory of the Member State of loading or unloading as long as the necessary agreements between the Community and the third countries concerned have not been concluded. It should, however, apply to the territory of a Member State crossed in transit.

(4) The establishment of a common transport policy implies the removal of all restrictions against the person providing transport services on the grounds of nationality or the fact that he is established in a different Member State from the one in which the services are to be provided.

(5) In order to achieve this smoothly and flexibly, provision should be made for a transitional cabotage regime as long as harmonisation of the road haulage market has not yet been completed.

(6) The gradual completion of the single European market should lead to the elimination of restrictions on access to the domestic markets of Member States. Nevertheless, this should take into account the effectiveness of controls and the evolution of employment conditions in the profession, the harmonisation of the rules in the fields of, inter alia, enforcement and road user charges, and social and safety legislation. The Commission should closely monitor the market situation as well as the harmonisation mentioned above and propose, if appropriate, the further opening of domestic road transport markets, including cabotage.

(7) Under Directive 2006/94/EC, a certain number of types of carriage are exempt from Community authorisation and from any other carriage authorisation. Within the framework of the organisation of the market provided for by this Regulation, a system of exemption from the Community licence and from any other carriage authorisation should be maintained for some of those types of carriage, because of their special nature.

⁽¹⁾ OJ C 204, 9.8.2008, p. 31.

⁽²⁾ Opinion of the European Parliament of 21 May 2008 (not yet published in the Official Journal), Council Common Position of 9 January 2009 (OJ C 62 E, 17.3.2009, p. 46), Position of the European Parliament of 23 April 2009 (not yet published in the Official Journal) and Council Decision of 24 September 2009.

⁽³⁾ OJ L 95, 9.4.1992, p. 1.

⁽⁴⁾ OJ L 279, 12.11.1993, p. 1.

⁽⁵⁾ OJ L 374, 27.12.2006, p. 5.

- (8) Under Directive 2006/94/EC, the carriage of goods with vehicles of a maximum laden weight of between 3,5 tonnes and 6 tonnes was exempt from the requirement for a Community licence. Community rules in the field of road transport of goods, however, apply in general to vehicles with a maximum laden mass of more than 3,5 tonnes. Thus, the provisions of this Regulation should be aligned with the general scope of application of Community road transport rules and should only provide for an exemption for vehicles with a maximum laden mass of up to 3,5 tonnes.
- (9) The international carriage of goods by road should be conditional on the possession of a Community licence. Hauliers should be required to carry a certified true copy of the Community licence aboard each of their vehicles in order to facilitate effective controls by enforcement authorities, especially those outside the Member State in which the haulier is established. To this end, it is necessary to lay down more detailed specifications as regards the layout and other features of the Community licence and the certified copies.
- (10) Roadside checks should be carried out without direct or indirect discrimination on grounds of the nationality of the road transport operator or the country of establishment of the road transport operator or of registration of the vehicle.
- (11) The conditions governing the issue and withdrawal of Community licences and the types of carriage to which they apply, their periods of validity and the detailed rules for their use should be determined.
- (12) A driver attestation should also be established in order to allow Member States to check effectively whether drivers from third countries are lawfully employed or at the disposal of the haulier responsible for a given transport operation.
- (13) Hauliers who are holders of Community licences provided for in this Regulation and hauliers authorised to operate certain categories of international haulage service should be permitted to carry out national transport services within a Member State on a temporary basis in conformity with this Regulation, without having a registered office or other establishment therein. When such cabotage operations are performed, they should be subject to Community legislation such as Regulation (EC) No 561/2006 of the European Parliament and of the Council of 15 March 2006 on the harmonisation of certain social legislation relating to road transport ⁽¹⁾ and to national law in force in specified areas in the host Member State.
- (14) Provisions should be adopted to allow action to be taken in the event of serious disturbance of the transport markets affected. For that purpose it is necessary to introduce a suitable decision-making procedure and for the required statistical data to be collected.
- (15) Without prejudice to the provisions of the Treaty on the right of establishment, cabotage operations consist of the provision of services by hauliers within a Member State in which they are not established and should not be prohibited as long as they are not carried out in a way that creates a permanent or continuous activity within that Member State. To assist the enforcement of this requirement, the frequency of cabotage operations and the period in which they can be performed should be more clearly defined. In the past, such national transport services were permitted on a temporary basis. In practice, it has been difficult to ascertain which services are permitted. Clear and easily enforceable rules are thus needed.
- (16) This Regulation is without prejudice to the provisions concerning the incoming or outgoing carriage of goods by road as one leg of a combined transport journey as laid down in Council Directive 92/106/EEC of 7 December 1992 on the establishment of common rules for certain types of combined transport of goods between Member States ⁽²⁾. National journeys by road within a host Member State which are not part of a combined transport operation as laid down in Directive 92/106/EEC fall within the definition of cabotage operations and should accordingly be subject to the requirements of this Regulation.
- (17) The provisions of Directive 96/71/EC of the European Parliament and of the Council of 16 December 1996 concerning the posting of workers in the framework of the provision of services ⁽³⁾ apply to transport undertakings performing a cabotage operation.
- (18) In order to perform efficient controls of cabotage operations, the enforcement authorities of the host Member States should, at least, have access to data from consignment notes and from recording equipment, in accordance with Council Regulation (EEC) No 3821/85 of 20 December 1985 on recording equipment in road transport ⁽⁴⁾.
- (19) Member States should grant each other mutual assistance with a view to the sound application of this Regulation.

⁽¹⁾ OJ L 102, 11.4.2006, p. 1.

⁽²⁾ OJ L 368, 17.12.1992, p. 38.

⁽³⁾ OJ L 18, 21.1.1997, p. 1.

⁽⁴⁾ OJ L 370, 31.12.1985, p. 8.

- (20) Administrative formalities should be reduced as far as possible without abandoning the controls and penalties that guarantee the correct application and effective enforcement of this Regulation. To this end, the existing rules on the withdrawal of the Community licence should be clarified and strengthened. The current rules should be adapted to allow the effective sanctioning of serious infringements committed in a host Member State. Penalties should be non-discriminatory and proportionate to the seriousness of the infringements. It should be possible to lodge an appeal in respect of any penalties imposed.
- (21) Member States should enter in their national electronic register of road transport undertakings all serious infringements committed by hauliers which have led to the imposition of a penalty.
- (22) In order to facilitate and strengthen the exchange of information between national authorities, Member States should exchange the relevant information through the national contact points set up pursuant to Regulation (EC) No 1071/2009 of the European Parliament and of the Council of 21 October 2009 establishing common rules concerning the conditions to be complied with to pursue the occupation of road transport operator ⁽¹⁾.
- (23) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission ⁽²⁾.
- (24) In particular, the Commission should be empowered to adapt Annexes I, II and III to this Regulation to technical progress. Since those measures are of general scope and are designed to amend non-essential elements of this Regulation, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.
- (25) Member States should take the necessary measures to implement this Regulation, in particular as regards effective, proportionate and dissuasive penalties.
- (26) Since the objective of this Regulation, namely to ensure a coherent framework for international road haulage throughout the Community, cannot be sufficiently achieved by the Member States and can therefore, by reason of its scale and effects, be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Scope

1. This Regulation shall apply to the international carriage of goods by road for hire or reward for journeys carried out within the territory of the Community.
2. In the event of carriage from a Member State to a third country and vice versa, this Regulation shall apply to the part of the journey on the territory of any Member State crossed in transit. It shall not apply to that part of the journey on the territory of the Member State of loading or unloading, as long as the necessary agreement between the Community and the third country concerned has not been concluded.
3. Pending the conclusion of the agreements referred to in paragraph 2, this Regulation shall not affect:
 - (a) provisions relating to the carriage from a Member State to a third country and vice versa included in bilateral agreements concluded by Member States with those third countries;
 - (b) provisions relating to the carriage from a Member State to a third country and vice versa included in bilateral agreements concluded between Member States which, under either bilateral authorisations or liberalisation arrangements, allow loading and unloading in a Member State by hauliers not established in that Member State.
4. This Regulation shall apply to the national carriage of goods by road undertaken on a temporary basis by a non-resident haulier as provided for in Chapter III.
5. The following types of carriage and unladen journeys made in conjunction with such carriage shall not require a Community licence and shall be exempt from any carriage authorisation:
 - (a) carriage of mail as a universal service;
 - (b) carriage of vehicles which have suffered damage or breakdown;
 - (c) carriage of goods in motor vehicles the permissible laden mass of which, including that of trailers, does not exceed 3,5 tonnes;
 - (d) carriage of goods in motor vehicles provided the following conditions are fulfilled:
 - (i) the goods carried are the property of the undertaking or have been sold, bought, let out on hire or hired, produced, extracted, processed or repaired by the undertaking;

⁽¹⁾ See page 51 of this Official Journal.

⁽²⁾ OJ L 184, 17.7.1999, p. 23.

- (ii) the purpose of the journey is to carry the goods to or from the undertaking or to move them, either inside or outside the undertaking for its own requirements;
 - (iii) motor vehicles used for such carriage are driven by personnel employed by, or put at the disposal of, the undertaking under a contractual obligation;
 - (iv) the vehicles carrying the goods are owned by the undertaking, have been bought by it on deferred terms or have been hired provided that in the latter case they meet the conditions of Directive 2006/1/EC of the European Parliament and of the Council of 18 January 2006 on the use of vehicles hired without drivers for the carriage of goods by road ⁽¹⁾; and
 - (v) such carriage is no more than ancillary to the overall activities of the undertaking;
- (e) carriage of medicinal products, appliances, equipment and other articles required for medical care in emergency relief, in particular for natural disasters.
- (d) an unladen journey in conjunction with the carriage referred to in points (a), (b) and (c);
3. 'host Member State' means a Member State in which a haulier operates other than the haulier's Member State of establishment;
 4. 'non-resident haulier' means a road haulage undertaking which operates in a host Member State;
 5. 'driver' means any person who drives the vehicle even for a short period, or who is carried in a vehicle as part of his duties to be available for driving if necessary;
 6. 'cabotage operations' means national carriage for hire or reward carried out on a temporary basis in a host Member State, in conformity with this Regulation;
 7. 'serious infringement of Community road transport legislation' means an infringement which may lead to the loss of good repute in accordance with Article 6(1) and (2) of Regulation (EC) No 1071/2009 and/or to the temporary or permanent withdrawal of a Community licence.

Point (d)(iv) of the first subparagraph shall not apply to the use of a replacement vehicle during a short breakdown of the vehicle normally used.

6. The provisions of paragraph 5 shall not affect the conditions under which a Member State authorises its nationals to engage in the activities referred to in that paragraph.

Article 2

Definitions

For the purposes of this Regulation:

1. 'vehicle' means a motor vehicle registered in a Member State, or a coupled combination of vehicles the motor vehicle of which at least is registered in a Member State, used exclusively for the carriage of goods;
2. 'international carriage' means:
 - (a) a laden journey undertaken by a vehicle the point of departure and the point of arrival of which are in two different Member States, with or without transit through one or more Member States or third countries;
 - (b) a laden journey undertaken by a vehicle from a Member State to a third country or vice versa, with or without transit through one or more Member States or third countries;
 - (c) a laden journey undertaken by a vehicle between third countries, with transit through the territory of one or more Member States; or

CHAPTER II

INTERNATIONAL CARRIAGE

Article 3

General principle

International carriage shall be carried out subject to possession of a Community licence and, if the driver is a national of a third country, in conjunction with a driver attestation.

Article 4

Community licence

1. The Community licence shall be issued by a Member State, in accordance with this Regulation, to any haulier carrying goods by road for hire or reward who:
 - (a) is established in that Member State in accordance with Community legislation and the national legislation of that Member State; and
 - (b) is entitled in the Member State of establishment, in accordance with Community legislation and the national legislation of that Member State concerning admission to the occupation of road haulage operator, to carry out the international carriage of goods by road.
2. The Community licence shall be issued by the competent authorities of the Member State of establishment for renewable periods of up to 10 years.

Community licences and certified copies issued before the date of application of this Regulation shall remain valid until their date of expiry.

⁽¹⁾ OJ L 33, 4.2.2006, p. 82.

The Commission shall adapt the period of validity of the Community licence to technical progress, in particular the national electronic registers of road transport undertakings as provided for in Article 16 of Regulation (EC) No 1071/2009. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 15(2).

3. The Member State of establishment shall issue the holder with the original of the Community licence, which shall be kept by the haulier, and the number of certified true copies corresponding to the number of vehicles at the disposal of the holder of the Community licence, whether those vehicles are wholly owned or, for example, held under a hire purchase, hire or leasing contract.

4. The Community licence and the certified true copies shall correspond to the model set out in Annex II, which also lays down the conditions governing its use. They shall contain at least two of the security features listed in Annex I.

The Commission shall adapt Annexes I and II to technical progress. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 15(2).

5. The Community licence and the certified true copies thereof shall bear the seal of the issuing authority as well as a signature and a serial number. The serial numbers of the Community licence and of the certified true copies shall be recorded in the national electronic register of road transport undertakings as part of the data relating to the haulier.

6. The Community licence shall be issued in the name of the haulier and shall be non-transferable. A certified true copy of the Community licence shall be kept in each of the haulier's vehicles and shall be presented at the request of any authorised inspecting officer.

In the case of a coupled combination of vehicles, the certified true copy shall accompany the motor vehicle. It shall cover the coupled combination of vehicles even where the trailer or semi-trailer is not registered or authorised to use the roads in the name of the licence holder or where it is registered or authorised to use the roads in another State.

Article 5

Driver attestation

1. A driver attestation shall be issued by a Member State, in accordance with this Regulation, to any haulier who:

- (a) is the holder of a Community licence; and
- (b) in that Member State, either lawfully employs a driver who is neither a national of a Member State nor a long-term resident within the meaning of Council Directive 2003/109/EC of 25 November 2003 concerning the status of third-country

nationals who are long-term residents⁽¹⁾, or lawfully uses a driver who is neither a national of a Member State nor a long-term resident within the meaning of that Directive and who is put at the disposal of that haulier in accordance with the conditions of employment and of vocational training laid down in that Member State:

- (i) by laws, regulations or administrative provisions; and, as appropriate;
- (ii) by collective agreements, in accordance with the rules applicable in that Member State.

2. The driver attestation shall be issued by the competent authorities of the Member State of establishment of the haulier, at the request of the holder of the Community licence, for each driver who is neither a national of a Member State nor a long-term resident within the meaning of Directive 2003/109/EC whom that haulier lawfully employs, or for each driver who is neither a national of a Member State nor a long-term resident within the meaning of that Directive and who is put at the disposal of the haulier. Each driver attestation shall certify that the driver named therein is employed in accordance with the conditions laid down in paragraph 1.

3. The driver attestation shall correspond to the model set out in Annex III. It shall contain at least two of the security features listed in Annex I.

4. The Commission shall adapt Annex III to technical progress. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 15(2).

5. The driver attestation shall bear the seal of the issuing authority as well as a signature and a serial number. The serial number of the driver attestation may be recorded in the national electronic register of road transport undertakings as part of the data relating to the haulier who puts it at the disposal of the driver designated therein.

6. The driver attestation shall belong to the haulier, who puts it at the disposal of the driver designated therein when that driver drives a vehicle using a Community licence issued to that haulier. A certified true copy of the driver attestation issued by the competent authorities of the haulier's Member State of establishment shall be kept at the haulier's premises. The driver attestation shall be presented at the request of any authorised inspecting officer.

7. A driver attestation shall be issued for a period to be determined by the issuing Member State, subject to a maximum validity of 5 years. Driver attestations issued before the date of application of this Regulation shall remain valid until their date of expiry.

⁽¹⁾ OJ L 16, 23.1.2004, p. 44.

The driver attestation shall be valid only as long as the conditions under which it was issued are satisfied. Member States shall take appropriate measures to ensure that if those conditions are no longer met, the haulier returns the attestation immediately to the issuing authorities.

Article 6

Verification of conditions

1. Whenever an application for a Community licence or an application for renewal of a Community licence in accordance with Article 4(2) is lodged, the competent authorities of the Member State of establishment shall verify whether the haulier satisfies or continues to satisfy the conditions laid down in Article 4(1).

2. The competent authorities of the Member State of establishment shall regularly verify, by carrying out checks each year covering at least 20 % of the valid driver attestations issued in that Member State, whether the conditions, referred to in Article 5(1), under which a driver attestation has been issued are still satisfied.

Article 7

Refusal to issue and withdrawal of Community licence and driver attestation

1. If the conditions laid down in Article 4(1) or those referred to in Article 5(1) are not satisfied, the competent authorities of the Member State of establishment shall reject an application for the issue or renewal of a Community licence or the issue of a driver attestation, by means of a reasoned decision.

2. The competent authorities shall withdraw a Community licence or a driver attestation where the holder:

- (a) no longer satisfies the conditions laid down in Article 4(1) or those referred to in Article 5(1); or
- (b) has supplied incorrect information in relation to an application for a Community licence or for a driver attestation.

CHAPTER III

CABOTAGE

Article 8

General principle

1. Any haulier for hire or reward who is a holder of a Community licence and whose driver, if he is a national of a third country, holds a driver attestation, shall be entitled, under the conditions laid down in this Chapter, to carry out cabotage operations.

2. Once the goods carried in the course of an incoming international carriage have been delivered, hauliers referred to in paragraph 1 shall be permitted to carry out, with the same vehicle, or, in the case of a coupled combination, the motor vehicle of that same vehicle, up to three cabotage operations following the international carriage from another Member State or from a third country

to the host Member State. The last unloading in the course of a cabotage operation before leaving the host Member State shall take place within 7 days from the last unloading in the host Member State in the course of the incoming international carriage.

Within the time limit referred to in the first subparagraph, hauliers may carry out some or all of the cabotage operations permitted under that subparagraph in any Member State under the condition that they are limited to one cabotage operation per Member State within 3 days of the unladen entry into the territory of that Member State.

3. National road haulage services carried out in the host Member State by a non-resident haulier shall only be deemed to conform with this Regulation if the haulier can produce clear evidence of the incoming international carriage and of each consecutive cabotage operation carried out.

Evidence referred to in the first subparagraph shall comprise the following details for each operation:

- (a) the name, address and signature of the sender;
- (b) the name, address and signature of the haulier;
- (c) the name and address of the consignee as well as his signature and the date of delivery once the goods have been delivered;
- (d) the place and the date of taking over of the goods and the place designated for delivery;
- (e) the description in common use of the nature of the goods and the method of packing, and, in the case of dangerous goods, their generally recognised description, as well as the number of packages and their special marks and numbers;
- (f) the gross mass of the goods or their quantity otherwise expressed;
- (g) the number plates of the motor vehicle and trailer.

4. No additional document shall be required in order to prove that the conditions laid down in this Article have been met.

5. Any haulier entitled in the Member State of establishment, in accordance with that Member State's legislation, to carry out the road haulage operations for hire or reward specified in Article 1(5)(a), (b) and (c) shall be permitted, under the conditions set out in this Chapter, to carry out, as the case may be, cabotage operations of the same kind or cabotage operations with vehicles in the same category.

6. Permission to carry out cabotage operations, within the framework of the types of carriage referred to in Article 1(5)(d) and (e), shall be unrestricted.

*Article 9***Rules applicable to cabotage operations**

1. The performance of cabotage operations shall be subject, save as otherwise provided in Community legislation, to the laws, regulations and administrative provisions in force in the host Member State with regard to the following:

- (a) the conditions governing the transport contract;
- (b) the weights and dimensions of road vehicles;
- (c) the requirements relating to the carriage of certain categories of goods, in particular dangerous goods, perishable foodstuffs and live animals;
- (d) the driving time and rest periods;
- (e) the value added tax (VAT) on transport services.

The weights and dimensions referred to in point (b) of the first subparagraph may, where appropriate, exceed those applicable in the haulier's Member State of establishment, but they may under no circumstances exceed the limits set by the host Member State for national traffic or the technical characteristics mentioned in the proofs referred to in Article 6(1) of Council Directive 96/53/EC of 25 July 1996 laying down for certain road vehicles circulating within the Community the maximum authorised dimensions in national and international traffic and the maximum authorised weights in international traffic ⁽¹⁾.

2. The laws, regulations and administrative provisions referred to in paragraph 1 shall be applied to non-resident hauliers under the same conditions as those imposed on hauliers established in the host Member State, so as to prevent any discrimination on grounds of nationality or place of establishment.

*Article 10***Safeguard procedure**

1. In the event of serious disturbance of the national transport market in a given geographical area due to, or aggravated by, cabotage, any Member State may refer the matter to the Commission with a view to the adoption of safeguard measures and shall provide the Commission with the necessary information and notify it of the measures it intends to take as regards resident hauliers.

2. For the purposes of paragraph 1:

'serious disturbance of the national transport market in a given geographical area' means the existence on the market of problems specific to it, such that there is a serious and potentially enduring excess of supply over demand, implying a threat to the financial stability and survival of a significant number of hauliers,

⁽¹⁾ OJ L 235, 17.9.1996, p. 59.

'geographical area' means an area covering all or part of the territory of a Member State or extending to all or part of the territory of other Member States.

3. The Commission shall examine the situation on the basis in particular of the relevant data and, after consulting the committee referred to in Article 15(1), shall decide within 1 month of receipt of the Member State's request whether or not safeguard measures are necessary and shall adopt them if they are necessary.

Such measures may involve the temporary exclusion of the area concerned from the scope of this Regulation.

Measures adopted in accordance with this Article shall remain in force for a period not exceeding 6 months, renewable once within the same limits of validity.

The Commission shall without delay notify the Member States and the Council of any decision taken pursuant to this paragraph.

4. If the Commission decides to adopt safeguard measures concerning one or more Member States, the competent authorities of the Member States involved shall be required to take measures of equivalent scope in respect of resident hauliers and shall inform the Commission thereof. Those measures shall be applied at the latest as from the same date as the safeguard measures adopted by the Commission.

5. Any Member State may refer to the Council a decision taken by the Commission pursuant to paragraph 3 within 30 days of its notification. The Council, acting by a qualified majority may, within 30 days of that referral, or, if there are referrals by several Member States, of the first referral, take a different decision.

The limits of validity laid down in the third subparagraph of paragraph 3 shall apply to the Council's decision. The competent authorities of the Member States concerned shall be required to take measures of equivalent scope in respect of resident hauliers, and shall inform the Commission thereof. If the Council takes no decision within the period referred to in the first subparagraph, the Commission decision shall become final.

6. Where the Commission considers that the measures referred to in paragraph 3 need to be prolonged, it shall submit a proposal to the Council, which shall take a decision by qualified majority.

CHAPTER IV

MUTUAL ASSISTANCE AND PENALTIES*Article 11***Mutual assistance**

Member States shall assist one another in ensuring the application and monitoring of this Regulation. They shall exchange information via the national contact points established pursuant to Article 18 of Regulation (EC) No 1071/2009.

*Article 12***Sanctioning of infringements by the Member State of establishment**

1. In the event of a serious infringement of Community road transport legislation committed or ascertained in any Member State, the competent authorities of the Member State of establishment of the haulier who has committed such infringement shall take the appropriate action which may include a warning, if provided for by national law, to pursue the matter which may lead, inter alia, to the imposition of the following administrative penalties:

- (a) temporary or permanent withdrawal of some or all of the certified true copies of the Community licence;
- (b) temporary or permanent withdrawal of the Community licence.

These penalties may be determined after the final decision on the matter has been taken and shall have regard to the seriousness of the infringement committed by the holder of the Community licence and to the total number of certified true copies of that licence that he holds in respect of international traffic.

2. In the event of a serious infringement regarding any misuse whatsoever of driver attestations, the competent authorities of the Member State of establishment of the haulier who committed such infringement shall impose appropriate penalties, such as:

- (a) suspending the issue of driver attestations;
- (b) withdrawing driver attestations;
- (c) making the issue of driver attestations subject to additional conditions in order to prevent misuse;
- (d) withdrawing, temporarily or permanently, some or all of the certified true copies of the Community licence;
- (e) withdrawing, temporarily or permanently, the Community licence.

These penalties may be determined after the final decision on the matter has been taken and shall have regard to the seriousness of the infringement committed by the holder of the Community licence.

3. The competent authorities of the Member State of establishment shall communicate to the competent authorities of the Member State in which the infringement was ascertained, as soon as possible and at the latest within 6 weeks of their final decision on the matter, which, if any, of the penalties provided for in paragraphs 1 and 2 have been imposed.

If such penalties are not imposed, the competent authorities of the Member State of establishment shall state the reasons therefor.

4. The competent authorities shall ensure that the penalties imposed on the haulier concerned are, as a whole, proportionate to the infringement or infringements which gave rise to such penalties, taking into account any penalty for the same infringement imposed in the Member State in which the infringement was ascertained.

5. The competent authorities of the haulier's Member State of establishment may also, pursuant to national law, bring proceedings against the haulier before a competent national court or tribunal. They shall inform the competent authority of the host Member State of any decisions taken to this effect.

6. Member States shall ensure that hauliers have the right to appeal against any administrative penalty imposed on them pursuant to this Article.

*Article 13***Sanctioning of infringements by the host Member State**

1. Where the competent authorities of a Member State are aware of a serious infringement of this Regulation or of Community road transport legislation attributable to a non-resident haulier, the Member State within the territory of which the infringement is ascertained shall transmit to the competent authorities of the haulier's Member State of establishment, as soon as possible and at the latest within 6 weeks of their final decision on the matter, the following information:

- (a) a description of the infringement and the date and time when it was committed;
- (b) the category, type and seriousness of the infringement; and
- (c) the penalties imposed and the penalties executed.

The competent authorities of the host Member State may request the competent authorities of the Member State of establishment to impose administrative penalties in accordance with Article 12.

2. Without prejudice to any criminal prosecution, the competent authorities of the host Member State shall be empowered to impose penalties on a non-resident haulier who has committed infringements of this Regulation or of national or Community road transport legislation in their territory during a cabotage operation. They shall impose such penalties on a non-discriminatory basis. These penalties may, inter alia, consist of a warning, or, in the event of a serious infringement, a temporary ban on cabotage operations on the territory of the host Member State where the infringement was committed.

3. Member States shall ensure that hauliers have the right to appeal against any administrative penalty imposed on them pursuant to this Article.

*Article 14***Entry in the national electronic registers**

Member States shall ensure that serious infringements of Community road transport legislation committed by hauliers established in their territory, which have led to the imposition of a penalty by any Member State, as well as any temporary or permanent withdrawal of the Community licence or of the certified true copy thereof, are recorded in the national electronic register of road transport undertakings. Entries in the register which concern a temporary or permanent withdrawal of a Community licence shall remain in the database for 2 years from the time of the expiry of the period of withdrawal, in the case of temporary withdrawal, or from the date of withdrawal, in the case of permanent withdrawal.

CHAPTER V

IMPLEMENTATION*Article 15***Committee procedure**

1. The Commission shall be assisted by the committee established by Article 18(1) of Regulation (EEC) No 3821/85.
2. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

*Article 16***Penalties**

Member States shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation, and shall take all the measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission by 4 December 2011, and shall notify it without delay of any subsequent amendment affecting them.

Member States shall ensure that all such measures are taken without discrimination as to the nationality or place of establishment of the haulier.

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

Done at Strasbourg, 21 October 2009.

For the European Parliament
The President
J. BUZEK

*Article 17***Reporting**

1. Every 2 years Member States shall inform the Commission of the number of hauliers possessing Community licences on 31 December of the previous year and of the number of certified true copies corresponding to the vehicles in circulation at that date.
2. Member States shall also inform the Commission of the number of driver attestations issued in the previous calendar year as well as the number of driver attestations in circulation on 31 December of that same year.
3. The Commission shall draw up a report on the state of the Community road transport market by the end of 2013. The report shall contain an analysis of the market situation, including an evaluation of the effectiveness of controls and the evolution of employment conditions in the profession, as well as an assessment as to whether harmonisation of the rules in the fields, inter alia, of enforcement and road user charges, as well as social and safety legislation, has progressed to such an extent that the further opening of domestic road transport markets, including cabotage, could be envisaged.

CHAPTER VI

FINAL PROVISIONS*Article 18***Repeals**

Regulations (EEC) No 881/92 and (EEC) No 3118/93 and Directive 2006/94/EC are hereby repealed.

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

*Article 19***Entry into force**

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

It shall apply from 4 December 2011, with the exception of Articles 8 and 9, which shall apply from 14 May 2010.

For the Council
The President
C. MALMSTRÖM

ANNEX I

Security features of the Community licence and the driver attestation

The Community licence and the driver attestation must have at least two of the following security features:

- a hologram,
 - special fibres in the paper which become visible under UV-light,
 - at least one microprint line (printing visible only with a magnifying glass and not reproduced by photocopying machines),
 - tactile characters, symbols or patterns,
 - double numbering: serial number of the Community licence, of the certified copy thereof or of the driver attestation as well as, in each case, the issue number,
 - a security design background with fine guilloche patterns and rainbow printing.
-

ANNEX II

Community licence model

EUROPEAN COMMUNITY

(a)

(Colour Pantone light blue, format DIN A4 cellulose paper 100 g/m² or more)

(First page of the licence)

(Text in (one of) the official language(s) of the Member State issuing the licence)

Distinguishing sign of the Member State ⁽¹⁾ issuing the licence

Name of the competent authority or body
--

LICENCE No ...

(or)

CERTIFIED TRUE COPY No

for the international carriage of goods by road for hire or reward

This licence entitles ⁽²⁾

.....

.....

to engage in the international carriage of goods by road for hire or reward by any route, for journeys or parts of journeys carried out for hire or reward within the territory of the Community, as laid down in Regulation (EC) No 1072/2009 of the European Parliament and of the Council of 21 October 2009 on common rules for access to the international road haulage market and in accordance with the general provisions of this licence.

Particular remarks:	
.....	
This licence shall be valid from	to
Issued in,	on
..... ⁽³⁾	

⁽¹⁾ The distinguishing signs of the Member States are: (B) Belgium, (BG) Bulgaria, (CZ) Czech Republic, (DK) Denmark, (D) Germany, (EST) Estonia, (IRL) Ireland, (GR) Greece, (E) Spain, (F) France, (I) Italy, (CY) Cyprus, (LV) Latvia, (LT) Lithuania, (L) Luxembourg, (H) Hungary, (MT) Malta, (NL) Netherlands, (A) Austria, (PL) Poland, (P) Portugal, (RO) Romania, (SLO) Slovenia, (SK) Slovakia, (FIN) Finland, (S) Sweden, (UK) United Kingdom.

⁽²⁾ Name or business name and full address of the haulier.

⁽³⁾ Signature and seal of the issuing competent authority or body.

(b)

(Second page of the licence)

(Text in (one of) the official language(s) of the Member State issuing the licence)

GENERAL PROVISIONS

This licence is issued under Regulation (EC) No 1072/2009.

It entitles the holder to engage in the international carriage of goods by road for hire or reward by any route for journeys or parts of journeys carried out within the territory of the Community and, where appropriate, subject to the conditions laid down herein:

- where the point of departure and the point of arrival are situated in two different Member States, with or without transit through one or more Member States or third countries,
- from a Member State to a third country or vice versa, with or without transit through one or more Member States or third countries,
- between third countries with transit through the territory of one or more Member States,

and unladen journeys in connection with such carriage.

In the case of carriage from a Member State to a third country or vice versa, this licence is valid for that part of the journey carried out within the territory of the Community. It shall be valid in the Member State of loading or unloading only after the conclusion of the necessary agreement between the Community and the third country in question in accordance with Regulation (EC) No 1072/2009.

The licence is personal to the holder and is non-transferable.

It may be withdrawn by the competent authority of the Member State which issued it, notably where the holder has:

- not complied with all the conditions for using the licence,
- supplied incorrect information with regard to the data needed for the issue or extension of the licence.

The original of the licence must be kept by the haulage undertaking.

A certified copy of the licence must be kept in the vehicle ⁽¹⁾. In the case of a coupled combination of vehicles it must accompany the motor vehicle. It covers the coupled combination of vehicles even if the trailer or semi-trailer is not registered or authorised to use the roads in the name of the licence holder or if it is registered or authorised to use the roads in another State.

The licence must be presented at the request of any authorised inspecting officer.

Within the territory of each Member State, the holder must comply with the laws, regulations and administrative provisions in force in that State, in particular with regard to transport and traffic.

⁽¹⁾ 'Vehicle' means a motor vehicle registered in a Member State, or a coupled combination of vehicles the motor vehicle of which at least is registered in a Member State, used exclusively for the carriage of goods.

ANNEX III

**Driver attestation model
EUROPEAN COMMUNITY**

(a)

(Colour Pantone pink, format DIN A4 cellulose paper 100g/m² or more)

(First page of the attestation)

(Text in (one of) the official language(s) of the Member State issuing the attestation)

Distinguishing sign of the Member State ⁽¹⁾ issuing the attestation	Name of the competent authority or body
---	--

DRIVER ATTESTATION No ...

for the carriage of goods by road for hire or reward under a Community licence

(Regulation (EC) No 1072/2009 of the European Parliament and of the Council of 21 October 2009 on common rules for access to the international road haulage market)

This attestation certifies that on the basis of the documents presented by:

.....
⁽²⁾

the following driver:

Name and forename	
Date and place of birth	Nationality
Type and reference number of identity paper	
Date of issue	Place of issue
Driving licence number	
Date of issue	Place of issue
Social security number	

is employed, in accordance with the laws, regulations or administrative provisions and, as appropriate, the collective agreements, in accordance with the rules applicable in the following Member State, on the conditions of employment and of vocational training of drivers applicable in that Member State to carry out road transport operations in that State:

.....⁽³⁾

Particular remarks

This attestation shall be valid from	to
Issued in	on
..... ⁽⁴⁾	

⁽¹⁾ The distinguishing signs of the Member States are: (B) Belgium, (BG) Bulgaria, (CZ) Czech Republic, (DK) Denmark, (D) Germany, (EST) Estonia, (IRL) Ireland, (GR) Greece, (E) Spain, (F) France, (I) Italy, (CY) Cyprus, (LV) Latvia, (LT) Lithuania, (L) Luxembourg, (H) Hungary, (MT) Malta, (NL) Netherlands, (A) Austria, (PL) Poland, (P) Portugal, (RO) Romania, (SLO) Slovenia, (SK) Slovakia, (FIN) Finland, (S) Sweden, (UK) United Kingdom.

⁽²⁾ Name or business name and full address of the haulier.

⁽³⁾ Name of the haulier's Member State of establishment.

⁽⁴⁾ Signature and seal of the issuing competent authority or body.

(b)

(Second page of the attestation)

(Text in (one of) the official language(s) of the Member State issuing the attestation)

GENERAL PROVISIONS

This attestation is issued under Regulation (EC) No 1072/2009.

It certifies that the driver named therein is employed, in accordance with the laws, regulations or administrative provisions and, as appropriate, the collective agreements, in accordance with the rules applicable in the Member State mentioned on the attestation, on the conditions of employment and of vocational training of drivers applicable in that Member State to carry out road operations in that State.

The driver attestation shall belong to the haulier, who puts it at the disposal of the driver designated therein when that driver drives a vehicle ⁽¹⁾ engaged in carriage using a Community licence issued to that haulier. The driver attestation is not transferable. The driver attestation shall be valid only as long as the conditions under which it was issued are still satisfied and must be returned immediately by the haulier to the issuing authorities if these conditions are no longer met.

It may be withdrawn by the competent authority of the Member State which issued it, in particular where the holder has:

- not complied with all the conditions for using the attestation,
- supplied incorrect information with regard to the data needed for the issue or extension of the attestation.

A certified true copy of the attestation must be kept by the haulage undertaking.

An original attestation must be kept in the vehicle and must be presented by the driver at the request of any authorised inspecting officer.

⁽¹⁾ 'Vehicle' means a motor vehicle registered in a Member State, or a coupled combination of vehicles the motor vehicle of which at least is registered in a Member State, used exclusively for the carriage of goods.

ANNEX IV

Correlation Table

Regulation (EEC) No 881/92	Regulation (EEC) No 3118/93	Directive 2006/94/EC	This Regulation
Article 1(1)			Article 1(1)
Article 1(2)			Article 1(2)
Article 1(3)			Article 1(3)
Annex II		Article 1(1) and (2), Annex I; Article 2	Article 1(5)
		Article 2	Article 1(6)
Article 2			Article 2
Article 3(1)			Article 3
Article 3(2)			Article 4(1)
Article 3(3)			Article 5(1)
Article 4			
Article 5(1)			Article 4(2)
Article 5(2)			Article 4(3)
Article 5(3)			Article 4(4)
			Article 4(5)
Article 5(4), Annex I			Article 4(6)
Article 5(5)			Article 4(2)
Article 6(1)			Article 5(2)
Article 6(2)			Article 5(2)
Article 6(3)			Article 5(3)
Article 6(4)			Article 5(6)
Article 6(5)			Article 5(7)
Article 7			Article 6
Article 8(1)			Article 7(1)
Article 8(2)			Article 7(2)
Article 8(3)			Article 12(1)
Article 8(4)			Article 12(2)
Article 9(1) and (2)			Article 12(6)
	Article 1(1)		Article 8(1)
	Article 1(2)		Article 8(5)
	Article 1(3) and (4)		Article 8(6)
	Article 2		
	Article 3		
	Article 4		
	Article 5		
	Article 6(1)		Article 9(1)
	Article 6(2)		
	Article 6(3)		Article 9(2)
	Article 6(4)		
	Article 7		Article 10

Regulation (EEC) No 881/92	Regulation (EEC) No 3118/93	Directive 2006/94/EC	This Regulation
Article 10			Article 17(1)
Article 11(1)	Article 8(1)		Article 11
Article 11(2)			Article 13(1)
Article 11(3)			Article 12(4)
Article 11a			
	Article 8(2) and (3)		Article 13(2)
	Article 8(4), first and third subparagraphs		
	Article 8(4), second subparagraph		Article 12(4)
	Article 8(4), fourth and fifth subparagraphs		Article 12(5)
	Article 9		Article 13(3)
Article 12			Article 18
Article 13			
Article 14	Article 10		
	Article 11		
Article 15	Article 12	Article 4	Article 19
		Article 3	
		Article 5	
		Annex II, III	
Annex I			Annex II
Annex III			Annex III
	Annex I		
	Annex II		
	Annex III		
	Annex IV		

REGULATION (EC) No 1073/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 21 October 2009
on common rules for access to the international market for coach and bus services, and amending
Regulation (EC) No 561/2006
(recast)
(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 71 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee ⁽¹⁾,

After consulting the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty ⁽²⁾,

Whereas:

(1) A number of substantial changes are to be made to Council Regulation (EEC) No 684/92 of 16 March 1992 on common rules for the international carriage of passengers by coach and bus ⁽³⁾ and to Council Regulation (EC) No 12/98 of 11 December 1997 laying down the conditions under which non-resident carriers may operate national road passenger transport services within a Member State ⁽⁴⁾. In the interests of clarity and simplification, those Regulations should be recast and incorporated into one single regulation.

(2) The establishment of a common transport policy entails, inter alia, laying down common rules applicable to the international carriage of passengers by road as well as the conditions under which non-resident carriers may operate national transport services within a Member State.

(3) To ensure a coherent framework for the international carriage of passengers by coach and bus throughout the Community, this Regulation should apply to all international carriage on Community territory. Carriage from Member States to third countries is still largely covered by bilateral agreements between the Member States and those third countries. Therefore, this Regulation should not apply to that part of the journey within the territory of the Member State of picking up or setting down, as long as the necessary agreements between the Community and the third countries concerned have not been concluded. It should, however, apply to the territory of a Member State crossed in transit.

(4) Freedom to provide services constitutes a basic principle of the common transport policy and requires that carriers from all Member States be guaranteed access to international transport markets without discrimination on grounds of nationality or place of establishment.

(5) The international carriage of passengers by coach and bus should be conditional on the possession of a Community licence. Carriers should be required to carry a certified true copy of the Community licence aboard each of their vehicles, in order to facilitate effective controls by enforcement authorities, especially those outside the Member State in which the carrier is established. The conditions governing the issue and withdrawal of Community licences, their periods of validity and the detailed rules for their use should be determined. It is also necessary to lay down detailed specifications as regards the layout and other features of the Community licence and the certified copies thereof.

(6) Roadside checks should be carried out without direct or indirect discrimination on grounds of the nationality of the road transport operator or the country of establishment of the road transport operator or of registration of the vehicle.

(7) There should be provision for flexible arrangements subject to certain conditions for special regular services and certain occasional services, in order to satisfy market demand.

(8) While maintaining authorisation arrangements for regular services, certain rules should be amended, particularly as regards authorisation procedures.

⁽¹⁾ OJ C 10, 15.1.2008, p. 44.

⁽²⁾ Opinion of the European Parliament of 5 June 2008 (not yet published in the Official Journal), Council Common Position of 9 January 2009 (OJ C 62 E, 17.3.2009, p. 25), Position of the European Parliament of 23 April 2009 (not yet published in the Official Journal) and Council Decision of 24 September 2009.

⁽³⁾ OJ L 74, 20.3.1992, p. 1.

⁽⁴⁾ OJ L 4, 8.1.1998, p. 10.

- (9) The authorisation for regular services should henceforth be granted subsequent to an authorisation procedure, unless there are clearly specified grounds for refusal attributable to the applicant. The grounds for refusal relating to the relevant market should be either that the service applied for would seriously affect the viability of a comparable service operated under one or more public service contracts on the direct sections concerned or that the principal purpose of the service is not to carry passengers between stops located in different Member States.
- (10) Non-resident carriers should be allowed to operate national road passenger services, but regard should be had to the specific characteristics of each form of service. When such cabotage operations are performed, they should be subject to Community legislation such as Regulation (EC) No 561/2006 of the European Parliament and of the Council of 15 March 2006 on the harmonisation of certain social legislation relating to road transport ⁽¹⁾ and to national law in force in specified areas in the host Member State.
- (11) The provisions of Directive 96/71/EC of the European Parliament and of the Council of 16 December 1996 concerning the posting of workers in the framework of the provision of services ⁽²⁾ apply to transport undertakings performing a cabotage operation.
- (12) Where regular services are concerned, only regular services provided as part of a regular international service, excluding urban and suburban services, should be opened up to non-resident carriers, subject to certain conditions, and in particular to the legislation in force in the host Member State.
- (13) Member States should grant each other mutual assistance with a view to the sound application of this Regulation.
- (14) Administrative formalities should be reduced as far as possible without abandoning the controls and penalties that guarantee the correct application and effective enforcement of this Regulation. To this end, the existing rules on the withdrawal of the Community licence should be clarified and strengthened. The current rules should be adapted to allow the effective sanctioning of serious infringements committed in a Member State other than the Member State of establishment. Penalties should be non-discriminatory and proportionate to the seriousness of the infringements. It should be possible to lodge an appeal in respect of any penalties imposed.
- (15) Member States should enter in their national electronic register of road transport undertakings all serious infringements attributable to carriers which have led to the imposition of a penalty.
- (16) In order to facilitate and strengthen the exchange of information between national authorities, Member States should exchange the relevant information through the national contact points set up pursuant to Regulation (EC) No 1071/2009 of the European Parliament and of the Council of 21 October 2009 establishing common rules concerning the conditions to be complied with to pursue the occupation of road transport operator ⁽³⁾.
- (17) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission ⁽⁴⁾.
- (18) In particular, the Commission should be empowered to establish the format of certain documents to be used for the application of this Regulation and to adapt Annexes I and II of this Regulation to technical progress. Since those measures are of general scope and are designed to amend non-essential elements of this Regulation by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.
- (19) Member States should take the necessary measures to implement this Regulation, in particular as regards effective, proportionate and dissuasive penalties.
- (20) In order to encourage tourism and the use of environmentally friendly means of transport, Regulation (EC) No 561/2006 should be amended to allow drivers engaged in a single occasional service providing international carriage of passengers to postpone their weekly rest period for up to 12 consecutive 24-hour periods if they are involved in passenger transport activities that typically do not include continuous and long driving hours. Such a postponement should only be allowed under very strict conditions which preserve road safety and take into account the working conditions of drivers, inter alia, the obligation to take weekly rest periods immediately before and after the service. The Commission should monitor closely the use of this derogation. If the factual situation which justifies the use of this derogation changes substantially and the derogation results in a deterioration of road safety, the Commission should take appropriate measures.

⁽¹⁾ OJ L 102, 11.4.2006, p. 1.

⁽²⁾ OJ L 18, 21.1.1997, p. 1.

⁽³⁾ See page 51 of this Official Journal.

⁽⁴⁾ OJ L 184, 17.7.1999, p. 23.

(21) Since the objective of this Regulation, namely to ensure a coherent framework for the international carriage of passengers by coach and bus throughout the Community, cannot be sufficiently achieved by the Member States and can therefore, by reason of its scale and effects, be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Scope

1. This Regulation shall apply to the international carriage of passengers by coach and bus within the territory of the Community by carriers for hire or reward or by own-account carriers established in a Member State in accordance with its law, using vehicles which are registered in that Member State and are suitable and intended, by virtue of their construction and equipment, to carry more than nine persons, including the driver, and to the movement of such vehicles when empty in connection with such carriage.

A change of vehicle or an interruption of carriage to enable part of a journey to be made by another means of transport shall not affect the application of this Regulation.

2. In the event of carriage from a Member State to a third country and vice versa, this Regulation shall apply to the part of the journey on the territory of any Member State crossed in transit. It shall not apply to that part of the journey within the territory of the Member State of picking up or setting down, as long as the necessary agreement between the Community and the third country concerned has not been concluded.

3. Pending the conclusion of the agreements referred to in paragraph 2, this Regulation shall not affect provisions relating to the carriage from a Member State to a third country and vice-versa contained in bilateral agreements concluded between Member States and those third countries.

4. This Regulation shall apply to national road passenger services for hire or reward operated on a temporary basis by a non-resident carrier as provided for in Chapter V.

Article 2

Definitions

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

1. 'international carriage' means:
 - (a) a journey undertaken by a vehicle the point of departure and the point of arrival of which are in two different Member States, with or without transit through one or more Member States or third countries;
 - (b) a journey undertaken by a vehicle of which the point of departure and the point of arrival are in the same Member State, while the picking up or setting down of passengers is in another Member State or in a third country;
 - (c) a journey undertaken by a vehicle from a Member State to a third country or vice versa, with or without transit through one or more Member States or third countries; or
 - (d) a journey undertaken by a vehicle between third countries, with transit through the territory of one or more Member States;
2. 'regular services' means services which provide for the carriage of passengers at specified intervals along specified routes, passengers being picked up and set down at predetermined stopping points;
3. 'special regular services' means regular services, by whomsoever organised, which provide for the carriage of specified categories of passengers to the exclusion of other passengers;
4. 'occasional services' means services which do not fall within the definition of regular services, including special regular services, and the main characteristic of which is the carriage of groups of passengers constituted on the initiative of the customer or the carrier himself;
5. 'own-account transport operations' means operations carried out for non-commercial and non-profit-making purposes by a natural or legal person, whereby:
 - the transport activity is only an ancillary activity for that natural or legal person, and
 - the vehicles used are the property of that natural or legal person or have been obtained by that person on deferred terms or have been the subject of a long-term leasing contract and are driven by a member of the staff of the natural or legal person or by the natural person himself or by personnel employed by, or put at the disposal of, the undertaking under a contractual obligation;

6. 'host Member State' means a Member State in which a carrier operates other than the carrier's Member State of establishment;
7. 'cabotage operations' means either:
- national road passenger services for hire and reward carried out on a temporary basis by a carrier in a host Member State, or
 - the picking up and setting down of passengers within the same Member State, in the course of a regular international service, in compliance with the provisions of this Regulation, provided that it is not the principal purpose of the service;
8. 'serious infringement of Community road transport legislation' means an infringement which may lead to the loss of good repute in accordance with Article 6(1) and (2) of Regulation (EC) No 1071/2009, and/or to the temporary or permanent withdrawal of a Community licence.

Article 3

Freedom to provide services

1. Any carrier for hire or reward referred to in Article 1 shall be permitted in accordance with this Regulation to carry out regular services, including special regular services and occasional services by coach and bus, without discrimination on grounds of nationality or place of establishment if he:
- (a) is authorised in the Member State of establishment to undertake carriage by means of regular services, including special regular services, or occasional services by coach and bus, in accordance with the market access conditions laid down by national legislation;
 - (b) satisfies the conditions laid down in accordance with Community rules on admission to the occupation of road passenger transport operator in national and international transport operations; and
 - (c) meets legal requirements regarding the standards for drivers and vehicles as laid down, in particular, in Council Directive 92/6/EEC of 10 February 1992 on the installation and use of speed limitation devices for certain categories of motor vehicles in the Community ⁽¹⁾, Council Directive 96/53/EC of 25 July 1996 laying down for certain road vehicles circulating within the Community the maximum authorised dimensions in national and international traffic and the maximum authorised weights in international traffic ⁽²⁾ and Directive 2003/59/EC of the European Parliament and of the Council of 15 July 2003 on the initial qualification and periodic training of drivers of certain road vehicles for the carriage of goods or passengers ⁽³⁾.

⁽¹⁾ OJ L 57, 2.3.1992, p. 27.

⁽²⁾ OJ L 235, 17.9.1996, p. 59.

⁽³⁾ OJ L 226, 10.9.2003, p. 4.

2. Any own-account carrier referred to in Article 1 shall be permitted to carry out the transport services pursuant to Article 5(5) without discrimination on grounds of nationality or place of establishment if he:

- (a) is authorised in the Member State of establishment to undertake carriage by coach and bus in accordance with the market-access conditions laid down in national legislation; and
- (b) meets legal requirements regarding the standards for drivers and vehicles as laid down, in particular, in Directives 92/6/EEC, 96/53/EC and 2003/59/EC.

CHAPTER II

COMMUNITY LICENCE AND MARKET ACCESS

Article 4

Community licence

1. International carriage of passengers by coach and bus shall be carried out subject to possession of a Community licence issued by the competent authorities of the Member State of establishment.
2. The competent authorities of the Member State of establishment shall issue the holder with the original of the Community licence, which shall be kept by the carrier, and the number of certified true copies thereof corresponding to the number of vehicles used for the international carriage of passengers at the disposal of the holder of the Community licence, whether those vehicles are wholly owned, or held in another form, particularly under an instalment-purchase, hire or leasing contract.

The Community licence and the certified true copies thereof shall correspond to the model set out in Annex II. They shall contain at least two of the security features listed in Annex I.

The Commission shall adapt Annexes I and II to technical progress. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 26(2).

The Community licence and the certified true copies thereof shall bear the seal of the issuing authority as well as a signature and a serial number. The serial numbers of the Community licence and the certified true copies thereof shall be recorded in the national electronic register of road transport undertakings provided for in Article 16 of Regulation (EC) No 1071/2009 as part of the data relating to the carrier.

3. The Community licence shall be issued in the name of the carrier and shall be non-transferable. A certified true copy of the Community licence shall be kept in each of the carrier's vehicles and shall be presented at the request of any authorised inspecting officer.

4. The Community licence shall be issued for renewable periods of up to 10 years.

Community licences and certified true copies thereof issued before the date of application of this Regulation shall remain valid until their date of expiry.

5. Whenever an application for a Community licence is lodged, or a Community licence is renewed in accordance with paragraph 4 of this Article, the competent authorities of the Member State of establishment shall verify whether the carrier satisfies or continues to satisfy the conditions laid down in Article 3(1).

6. Where the conditions referred to in Article 3(1) are not satisfied, the competent authorities of the Member State of establishment shall refuse to issue or renew or shall withdraw a Community licence by means of a reasoned decision.

7. Member States shall guarantee the right of the applicant for, or holder of, a Community licence to appeal against a decision by the competent authorities of the Member State of establishment to refuse or withdraw this licence.

8. Member States may decide that the Community licence shall also be valid for national transport operations.

Article 5

Access to the market

1. Regular services shall be open to all, subject, where appropriate, to compulsory reservation.

Such services shall be subject to authorisation in accordance with the provisions of Chapter III.

Regular services from a Member State to a third country and vice versa shall be subject to authorisation in accordance with the bilateral agreement between the Member State and the third country and, where appropriate, the transited Member State, as long as the necessary agreement between the Community and the third country concerned has not been concluded.

The regular nature of the service shall not be affected by any adjustment to the service operating conditions.

The organisation of parallel or temporary services, serving the same public as existing regular services, the non-serving of certain stops and the serving of additional stops on existing regular services shall be governed by the same rules as those applicable to existing regular services.

2. Special regular services shall include:

- (a) the carriage of workers between home and work;
- (b) the carriage of school pupils and students to and from the educational institution.

The fact that a special service may be varied according to the needs of users shall not affect its classification as a regular service.

Special regular services shall not be subject to authorisation in accordance with Chapter III where they are covered by a contract concluded between the organiser and the carrier.

3. Occasional services shall not require authorisation in accordance with Chapter III.

However, the organisation of parallel or temporary services comparable to existing regular services and serving the same public as the latter shall be subject to authorisation in accordance with the procedure laid down in Chapter III.

Occasional services shall not cease to be occasional services solely on the grounds that they are provided at certain intervals.

Occasional services may be provided by a group of carriers acting on behalf of the same contractor, and travellers may catch a connection en route, with a different carrier of the same group, on the territory of a Member State.

The Commission shall establish the procedures for the names of such carriers and the connection points en route to be communicated to the competent authorities of the Member States concerned. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 26(2).

4. Empty journeys by vehicles in connection with the transport operations referred to in the third subparagraph of paragraph 2, and in the first subparagraph of paragraph 3, shall likewise not require authorisation.

5. Own-account transport operations shall be exempt from any system of authorisation but shall be subject to a system of certificates.

The certificates shall be issued by the competent authorities of the Member State in which the vehicle is registered and shall be valid for the entire journey including transit.

The Commission shall establish the format of the certificates. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 26(2).

CHAPTER III

REGULAR SERVICES SUBJECT TO AUTHORISATION*Article 6***Nature of authorisation**

1. Authorisations shall be issued in the name of the carrier and shall be non-transferable. However, a carrier who has received an authorisation may, with the consent of the competent authority of the Member State in whose territory the point of departure is situated, hereinafter referred to as the 'authorising authority', operate the service through a subcontractor. In this case, the name of the subcontractor and its role shall be indicated in the authorisation. The subcontractor shall satisfy the conditions laid down in Article 3(1). For the purposes of this paragraph, the point of departure shall mean 'one of the termini of the service'.

In the case of undertakings associated for the purpose of operating a regular service, the authorisation shall be issued in the names of all the undertakings and shall state the names of all the operators. It shall be given to the undertaking that manages the operation and copies shall be given to the other undertakings.

2. The period of validity of an authorisation shall not exceed 5 years. It may be set at less either at the request of the applicant or by mutual consent of the competent authorities of the Member States on whose territory passengers are picked up or set down.

3. Authorisations shall specify the following:

- (a) the type of service;
- (b) the route of the service, giving in particular the point of departure and the point of arrival;
- (c) the period of validity of the authorisation;
- (d) the stops and the timetable.

4. The Commission shall establish the format of the authorisations. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 26(2).

5. Authorisations shall entitle their holder(s) to operate regular services in the territories of all Member States over which the routes of the service pass.

6. The operator of a regular service may use additional vehicles to deal with temporary and exceptional situations. Such additional vehicles may be used only under the same conditions as set out in the authorisation referred to in paragraph 3.

In this case, the carrier shall ensure that the following documents are carried on the vehicle:

- (a) a copy of the authorisation of the regular service;

(b) a copy of the contract between the operator of the regular service and the undertaking providing the additional vehicles or an equivalent document;

(c) a certified true copy of the Community licence issued to the operator providing the additional vehicles for the service.

*Article 7***Submission of application for authorisation**

1. Applications for authorisation of regular services shall be submitted to the authorising authority.

2. The Commission shall establish the format of the applications. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 26(2).

3. Persons applying for authorisation shall provide any further information which they consider relevant or which is requested by the authorising authority, in particular a driving schedule making it possible to monitor compliance with Community legislation on driving and rest periods and a copy of the Community licence.

*Article 8***Authorising procedure**

1. Authorisations shall be issued in agreement with the authorities of all the Member States in whose territories passengers are picked up or set down. The authorising authority shall forward to such authorities, as well as to the competent authorities of Member States whose territories are crossed without passengers being picked up or set down, a copy of the application, together with copies of any other relevant documentation, and its assessment.

2. The competent authorities of the Member States whose agreement has been requested shall notify the authorising authority of their decision on the application within 2 months. This time limit shall be calculated from the date of receipt of the request for agreement which is shown in the acknowledgement of receipt. If the decision received from the competent authorities of the Member States whose agreement has been requested is negative, it shall contain a proper statement of reasons. If the authorising authority does not receive a reply within 2 months, the authorities consulted shall be deemed to have given their agreement and the authorising authority may grant the authorisation.

The authorities of the Member States whose territories are crossed without passengers being picked up or set down may notify the authorising authority of their comments within the time limit laid down in the first subparagraph.

3. The authorising authority shall take a decision on the application within 4 months of the date of submission of the application by the carrier.

4. Authorisation shall be granted unless:
- (a) the applicant is unable to provide the service which is the subject of the application with equipment directly available to him;
 - (b) the applicant has not complied with national or international legislation on road transport, and in particular the conditions and requirements relating to authorisations for international road passenger services, or has committed serious infringements of Community road transport legislation in particular with regard to the rules applicable to vehicles and driving and rest periods for drivers;
 - (c) in the case of an application for renewal of authorisation, the conditions of authorisation have not been complied with;
 - (d) a Member State decides on the basis of a detailed analysis that the service concerned would seriously affect the viability of a comparable service covered by one or more public service contracts conforming to Community law on the direct sections concerned. In such a case, the Member State shall set up criteria, on a non-discriminatory basis, for determining whether the service applied for would seriously affect the viability of the abovementioned comparable service and shall communicate them to the Commission, upon its request;
 - (e) a Member State decides on the basis of a detailed analysis that the principal purpose of the service is not to carry passengers between stops located in different Member States.

In the event that an existing international coach and bus service is seriously affecting the viability of a comparable service covered by one or more public service contracts conforming to Community law on the direct sections concerned, due to exceptional reasons which could not have been foreseen at the time of granting the authorisation, a Member State may, with the agreement of the Commission, suspend or withdraw the authorisation to run the international coach and bus service after having given 6 months' notice to the carrier.

The fact that a carrier offers lower prices than those offered by other road carriers or the fact that the link in question is already operated by other road carriers shall not in itself constitute justification for rejecting the application.

5. The authorising authority and the competent authorities of all the Member States involved in the procedure to reach the agreement provided for in paragraph 1 may refuse applications only on the basis of reasons provided for in this Regulation.

6. Having completed the procedure laid down in paragraphs 1 to 5, the authorising authority shall grant the authorisation or formally refuse the application.

Decisions refusing an application shall state the reasons on which they are based. Member States shall ensure that transport undertakings are given the opportunity to make representations in the event of their application being refused.

The authorising authority shall inform all the authorities referred to in paragraph 1 of its decision, sending them a copy of any authorisation.

7. If the procedure for reaching the agreement referred to in paragraph 1 does not enable the authorising authority to decide on an application, the matter may be referred to the Commission within the time limit of 2 months calculated from the date of communication of a negative decision by one or more of the Member States consulted pursuant to paragraph 1.

8. After having consulted the Member States concerned, the Commission shall, within 4 months from receipt of the communication from the authorising authority, take a decision which shall take effect 30 days after the notification to the Member States concerned.

9. The Commission decision shall continue to apply until an agreement is reached between the Member States concerned.

Article 9

Renewal and alteration of authorisation

Article 8 shall apply, *mutatis mutandis*, to applications for the renewal of authorisations or for alteration of the conditions under which the services subject to authorisation must be carried out.

In the event of a minor alteration to the operating conditions, in particular adjustment of intervals, fares and timetables, the authorising authority need only supply the other Member States concerned with information relating to the alteration.

The Member States concerned may agree that the authorising authority alone shall decide on alterations to the conditions under which a service is operated.

Article 10

Lapse of an authorisation

1. Without prejudice to the provisions of Regulation (EC) No 1370/2007 of the European Parliament and of the Council of 23 October 2007 on public passenger transport services by rail and by road ⁽¹⁾, an authorisation for a regular service shall lapse at the end of its period of validity or 3 months after the authorising authority has received notice from its holder of his intention to withdraw the service. Such notice shall contain a proper statement of reasons.

2. Where demand for a service has ceased to exist, the period of notice provided for in paragraph 1 shall be of 1 month.

3. The authorising authority shall inform the competent authorities of the other Member States concerned that the authorisation has lapsed.

⁽¹⁾ OJ L 315, 3.12.2007, p. 1.

4. The holder of the authorisation shall notify users of the service concerned of its withdrawal 1 month in advance by means of appropriate publicity.

Article 11

Obligations of carriers

1. Save in the event of *force majeure*, the operator of a regular service shall, until the authorisation expires, take all measures to guarantee a transport service that fulfils the standards of continuity, regularity and capacity and complies with the other conditions laid down by the competent authority in accordance with Article 6(3).

2. The carrier shall display the route of the service, the bus stops, the timetable, the fares and the conditions of carriage in such a way as to ensure that such information is readily available to all users.

3. Without prejudice to Regulation (EC) No 1370/2007, it shall be possible for the Member States concerned, by common agreement and in agreement with the holder of the authorisation, to make changes to the operating conditions governing a regular service.

CHAPTER IV

OCCASIONAL SERVICES AND OTHER SERVICES EXEMPT FROM AUTHORISATION

Article 12

Control documents

1. Occasional services shall be carried out under cover of a journey form with the exception of the services referred to in the second subparagraph of Article 5(3).

2. A carrier operating occasional services shall fill out a journey form before each journey.

3. The journey form shall contain at least the following information:

- (a) the type of service;
- (b) the main itinerary;
- (c) the carrier(s) involved.

4. The books of journey forms shall be supplied by the competent authorities of the Member State where the carrier is established or by bodies appointed by those authorities.

5. The Commission shall establish the format of the journey form, the book of journey forms and the way in which they are used. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 26(2).

6. In the case of the special regular services referred to in the third subparagraph of Article 5(2), the contract or a certified true copy thereof shall serve as the control document.

Article 13

Local excursions

Within the framework of an international occasional service, a carrier may carry out occasional services (local excursions) in a Member State other than that in which it is established.

Such services shall be intended for non-resident passengers previously carried by the same carrier on one of the international services mentioned in the first paragraph and shall be carried out with the same vehicle or another vehicle from the same carrier or group of carriers.

CHAPTER V

CABOTAGE

Article 14

General principle

Any carrier who operates road passenger transport services for hire or reward and who holds a Community licence shall be permitted, under the conditions laid down in this Chapter and without discrimination on grounds of the carrier's nationality or place of establishment, to operate the cabotage operations as specified in Article 15.

Article 15

Authorised cabotage operations

Cabotage operations shall be authorised for the following services:

- (a) special regular services provided that they are covered by a contract concluded between the organiser and the carrier;
- (b) occasional services;
- (c) regular services, performed by a carrier not resident in the host Member State in the course of a regular international service in accordance with this Regulation with the exception of transport services meeting the needs of an urban centre or conurbation, or transport needs between it and the surrounding areas. Cabotage operations shall not be performed independently of such international service.

Article 16

Rules applicable to cabotage operations

1. The performance of the cabotage operations shall be subject, save as otherwise provided in Community legislation, to the laws, regulations and administrative provisions in force in the host Member State with regard to the following:

- (a) the conditions governing the transport contract;
- (b) the weights and dimensions of road vehicles;

- (c) the requirements relating to the carriage of certain categories of passengers, namely schoolchildren, children and persons with reduced mobility;
- (d) the driving time and rest periods;
- (e) the value added tax (VAT) on transport services.

The weights and dimensions referred to in point (b) of the first subparagraph may, where appropriate, exceed those applicable in the carrier's Member State of establishment, but they may under no circumstances exceed the limits set by the host Member State for national traffic or the technical characteristics mentioned in the proofs referred to in Article 6(1) of Directive 96/53/EC.

2. Save as otherwise provided in Community legislation, cabotage operations which form part of the transport services provided for in Article 15(c) shall be subject to the laws, regulations and administrative provisions in force in the host Member State regarding authorisations, tendering procedures, the routes to be operated and the regularity, continuity and frequency of services as well as itineraries.

3. The technical standards of construction and equipment which must be met by vehicles used to carry out cabotage operations shall be those laid down for vehicles put into circulation in international transport.

4. The national laws, regulations and administrative provisions referred to in paragraphs 1 and 2 shall be applied to non-resident carriers under the same conditions as those imposed on carriers established in the host Member State, so as to prevent any discrimination on grounds of nationality or place of establishment.

Article 17

Control documents for cabotage operations

1. Cabotage operations in the form of occasional services shall be carried out under cover of a journey form as referred to in Article 12 which shall be kept on board the vehicle and be presented at the request of any authorised inspecting officer.

2. The following information shall be entered in the journey form:

- (a) the points of departure and arrival of the service;
- (b) the date of departure and the date on which the service ends.

3. The journey forms shall be supplied in books as referred to in Article 12 certified by the competent authority or body in the Member State of establishment.

4. In the case of special regular services, the contract concluded between the carrier and the transport organiser, or a certified true copy thereof, shall serve as the control document.

However, a journey form shall be filled out in the form of a monthly statement.

5. The journey forms used shall be returned to the competent authority or body in the Member State of establishment in accordance with procedures to be laid down by that authority or body.

CHAPTER VI

CONTROLS AND PENALTIES

Article 18

Transport tickets

1. Carriers operating a regular service, excluding special regular services, shall issue either individual or collective transport tickets indicating:

- (a) the points of departure and arrival and, where appropriate, the return journey;
- (b) the period of validity of the ticket;
- (c) the fare of transport.

2. The transport ticket provided for in paragraph 1 shall be presented at the request of any authorised inspecting officer.

Article 19

Inspections on the road and in undertakings

1. The authorisation or control document shall be carried on the vehicle and shall be presented at the request of any authorised inspecting officer.

2. Carriers operating international carriage of passengers by coach and bus shall allow all inspections intended to ensure that operations are being conducted correctly, in particular as regards driving and rest periods. In the context of the implementation of this Regulation, authorised inspecting officers shall be empowered to:

- (a) check the books and other documentation relating to the operation of the transport undertaking;
- (b) make copies of, or take extracts from, the books and documentation on the premises;
- (c) have access to all the transport undertaking's premises, sites and vehicles;
- (d) require the production of any information contained in books, documentation or data bases.

Article 20

Mutual assistance

Member States shall assist one another in ensuring the application and monitoring of this Regulation. They shall exchange information via the national contact points established pursuant to Article 18 of Regulation (EC) No 1071/2009.

*Article 21***Withdrawal of Community licences and authorisations**

1. The competent authorities of the Member State where the carrier is established shall withdraw the Community licence where the holder:

- (a) no longer satisfies the conditions laid down in Article 3(1); or
- (b) has supplied inaccurate information concerning the data which were required for the issue of the Community licence.

2. The authorising authority shall withdraw an authorisation where the holder no longer fulfils the conditions on the basis of which the authorisation was issued under this Regulation, in particular where the Member State in which the carrier is established so requests. That authority shall immediately inform the competent authorities of the Member State concerned.

*Article 22***Sanctioning of infringements by the Member State of establishment**

1. In the event of a serious infringement of Community road transport legislation committed or ascertained in any Member State, in particular with regard to the rules applicable to vehicles, driving and rest periods for drivers and the provision without authorisation of parallel or temporary services, as referred to in the fifth subparagraph of Article 5(1), the competent authorities of the Member State of establishment of the carrier who committed the infringement shall take appropriate action, which may include a warning if provided for by national law, to pursue the matter. This may lead, inter alia, to the imposition of the following administrative penalties:

- (a) the temporary or permanent withdrawal of some or all of the certified true copies of the Community licence;
- (b) the temporary or permanent withdrawal of the Community licence.

These penalties may be determined after the final decision on the matter has been taken and shall have regard to the seriousness of the infringement committed by the holder of the Community licence and to the total number of certified true copies of that licence held in respect of international traffic.

2. The competent authorities of the Member State of establishment shall communicate to the competent authorities of the Member State in which the infringements were ascertained, as soon as possible and at the latest within 6 weeks of their final decision on the matter, which, if any, of the penalties provided for in paragraph 1 have been imposed.

If such penalties are not imposed, the competent authorities of the Member State of establishment shall state the reasons therefor.

3. The competent authorities shall ensure that the penalties imposed on the carrier concerned are, as a whole, proportionate to the infringement or infringements which gave rise to such penalties, taking into account any penalty for the same infringement imposed in the Member State in which the infringement was ascertained.

4. This Article is without prejudice to the possibility of the competent authorities of the Member State of establishment of the carrier instituting proceedings before a national court or tribunal. In the event that such proceedings are brought, the competent authority in question shall inform the competent authorities of the Member States in which the infringements were ascertained thereof.

5. Member States shall ensure that carriers have the right to appeal against any administrative penalty imposed on them pursuant to this Article.

*Article 23***Sanctioning of infringements by the host Member State**

1. Where the competent authorities of a Member State are aware of a serious infringement of this Regulation or of Community road transport legislation attributable to a non-resident carrier, the Member State within the territory of which the infringement is ascertained shall transmit to the competent authorities of the carrier's Member State of establishment, as soon as possible and at the latest within 6 weeks of their final decision, the following information:

- (a) a description of the infringement and the date and time when it was committed;
- (b) the category, type and seriousness of the infringement; and
- (c) the penalties imposed and the penalties executed.

The competent authorities of the host Member State may request that the competent authorities of the Member State of establishment impose administrative penalties in accordance with Article 22.

2. Without prejudice to criminal prosecution, the competent authorities of the host Member State may impose penalties on non-resident carriers who have committed infringements of this Regulation or of national or Community road transport legislation in their territory on the occasion of a cabotage operation. The penalties shall be imposed on a non-discriminatory basis and may, inter alia, consist of a warning, or, in the event of a serious infringement, a temporary ban on cabotage operations within the territory of the host Member State where the infringement was committed.

3. Member States shall ensure that carriers have the right to appeal against any administrative penalty imposed on them pursuant to this Article.

*Article 24***Entry in the national electronic registers**

Member States shall ensure that serious infringements of Community road transport legislation attributable to carriers established in their territory, which have led to the imposition of a penalty by any Member State, as well as any temporary or permanent withdrawal of the Community licence or of the certified true copy thereof are recorded in the national electronic register of road transport undertakings. Entries in the register which concern a temporary or permanent withdrawal of a Community licence shall remain in the database for at least 2 years from the time of the expiry of the period of withdrawal, in the case of temporary withdrawal, or from the date of withdrawal, in the case of permanent withdrawal.

CHAPTER VII

IMPLEMENTATION*Article 25***Agreements between Member States**

1. Member States may conclude bilateral and multilateral agreements on the further liberalisation of the services covered by this Regulation, in particular as regards the authorisation system and the simplification or abolition of control documents, especially in border regions.

2. Member States shall inform the Commission of any agreements concluded under paragraph 1.

*Article 26***Committee procedure**

1. The Commission shall be assisted by the committee established by Article 18(1) of Council Regulation (EEC) No 3821/85 of 20 December 1985 on recording equipment in road transport ⁽¹⁾.

2. Where reference is made to this paragraph, Article 5a(1) to (4) and (5)(b), and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

*Article 27***Penalties**

Member States shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission by 4 December 2011 and shall notify it without delay of any subsequent amendment affecting them.

Member States shall ensure that all such measures are taken without discrimination as to the nationality or place of establishment of the carrier.

*Article 28***Reporting**

1. Every 2 years Member States shall communicate to the Commission the number of authorisations for regular services issued the previous year and the total number of authorisations for regular services valid at the end of that reporting period. This information shall be given separately for each country of destination of the regular service. Member States shall also communicate to the Commission the data concerning cabotage operations, in the form of special regular services and occasional services, carried out during the reporting period by resident carriers.

2. Every 2 years the competent authorities in the host Member State shall send the Commission statistics on the number of authorisations issued for cabotage operations in the form of the regular services referred to in Article 15(c).

3. The Commission shall establish the format of the table to be used for the communication of the statistics referred to in paragraph 2. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 26(2).

4. Member States shall inform the Commission no later than 31 January of every year of the number of carriers holding a Community licence as at 31 December of the previous year and of the number of certified true copies corresponding to the number of vehicles in circulation on that date.

*Article 29***Amendment to Regulation (EC) No 561/2006**

In Article 8 of Regulation (EC) No 561/2006, the following paragraph shall be inserted:

‘6a. By way of derogation from paragraph 6, a driver engaged in a single occasional service of international carriage of passengers, as defined in Regulation (EC) No 1073/2009 of the European Parliament and of the Council of 21 October 2009 on common rules for access to the international market for coach and bus services (*), may postpone the weekly rest period for up to 12 consecutive 24-hour periods following a previous regular weekly rest period, provided that:

- (a) the service lasts at least 24 consecutive hours in a Member State or a third country to which this Regulation applies other than the one in which the service started;
- (b) the driver takes after the use of the derogation:
 - (i) either two regular weekly rest periods; or

⁽¹⁾ OJ L 370, 31.12.1985, p. 8.

- (ii) one regular weekly rest period and one reduced weekly rest period of at least 24 hours. However, the reduction shall be compensated by an equivalent period of rest taken en bloc before the end of the third week following the end of the derogation period;
- (c) after 1 January 2014, the vehicle is equipped with recording equipment in accordance with the requirements of Annex IB to Regulation (EEC) No 3821/85; and
- (d) after 1 January 2014, if driving during the period from 22,00 to 06,00, the vehicle is multi-manned or the driving period referred to in Article 7 is reduced to three hours.

The Commission shall monitor closely the use made of this derogation in order to ensure the preservation of road safety under very strict conditions, in particular by checking that the total accumulated driving time during the period covered by the derogation is not excessive. By 4 December 2012, the Commission shall draw up a report assessing the consequences of the derogation in respect of road safety as well as social aspects. If it deems it appropriate, the Commission shall propose amendments to this Regulation in this respect.

(*) OJ L 300, 14.11.2009, p. 88.'

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

Done at Strasbourg, 21 October 2009.

For the European Parliament
The President
J. BUZEK

For the Council
The President
C. MALMSTRÖM

CHAPTER VIII

FINAL PROVISIONS

Article 30

Repeals

Regulations (EEC) No 684/92 and (EC) No 12/98 are hereby repealed.

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

Article 31

Entry into force

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

It shall apply from 4 December 2011, with the exception of Article 29, which shall apply from 4 June 2010.

ANNEX I

Security features of the Community licence

The Community licence must have at least two of the following security features:

- a hologram,
 - special fibres in the paper which become visible under UV-light,
 - at least one microprint line (printing visible only with a magnifying glass and not reproduced by photocopying machines),
 - tactile characters, symbols or patterns,
 - double numbering: serial number and issue number,
 - a security design background with fine guilloche patterns and rainbow printing.
-

ANNEX II

Community licence model**EUROPEAN COMMUNITY**

(a)

(Colour Pantone light blue, format DIN A4 cellulose paper, 100 g/m² or more)

(First page of the licence)

(Text in the official language(s) or one of the official languages of the Member State issuing the licence)

Distinguishing sign of the Member State ⁽¹⁾ issuing the licence

Name of the competent authority or body
--

LICENCE No ...

(or)

CERTIFIED TRUE COPY No

for the international carriage of passengers by coach and bus for hire or reward

The holder of this licence ⁽²⁾

.....

is authorised to carry out international carriage of passengers by road for hire or reward in the territory of the Community pursuant to the conditions laid down by Regulation (EC) No 1073/2009 of the European Parliament and of the Council of 21 October 2009 on common rules for access to the international market for coach and bus service and in accordance with the general provisions of this licence.

Comments:	
.....	
This licence is valid from	To
Issued in	On
..... ⁽³⁾	

⁽¹⁾ The distinguishing signs of the Member States are: (B) Belgium, (BG) Bulgaria, (CZ) Czech Republic, (DK) Denmark, (D) Germany, (EST) Estonia, (IRL) Ireland, (GR) Greece, (E) Spain, (F) France, (I) Italy, (CY) Cyprus, (LV) Latvia, (LT) Lithuania, (L) Luxembourg, (H) Hungary, (MT) Malta, (NL) Netherlands, (A) Austria, (PL) Poland, (P) Portugal, (RO) Romania, (SLO) Slovenia, (SK) Slovakia, (FIN) Finland, (S) Sweden, (UK) United Kingdom.

⁽²⁾ Full name or business name and full address of the carrier.

⁽³⁾ Signature and seal of the competent authority or body issuing the licence.

(b)

(Second page of the licence)

(Text in the official language(s) or one of the official languages of the Member State issuing the licence)

GENERAL PROVISIONS

1. This licence is issued pursuant to Regulation (EC) No 1073/2009.
2. This licence is issued by the competent authorities of the Member State of establishment of the carrier for hire or reward who:
 - (a) is authorised in the Member State of establishment to undertake carriage by means of regular services, including special regular services, or occasional services by coach and bus;
 - (b) satisfies the conditions laid down in accordance with Community rules on admission to the occupation of road passenger transport operator in national and international transport operations;
 - (c) meets legal requirements regarding the standards for drivers and vehicles.
3. This licence permits the international carriage of passengers by coach and bus for hire or reward on all transport links for journeys carried out in the territory of the Community:
 - (a) where the point of departure and point of arrival are situated in two different Member States, with or without transit through one or more Member States or third countries;
 - (b) where the point of departure and the point of arrival are in the same Member State, while the picking up or setting down of passengers is in another Member State or in a third country;
 - (c) from a Member State to a third country and vice versa, with or without transit through one or more Member States or third countries;
 - (d) between third countries crossing the territory of one or more Member States in transit;

and empty journeys in connection with transport operations under the conditions laid down by Regulation (EC) No 1073/2009.

In the case of a transport operation from a Member State to a third country and vice versa, Regulation (EC) No 1073/2009 is applicable, for the part of the journey on the territory of Member States crossed in transit. It does not apply to that part of the journey within the territory of the Member State of picking up or setting down, as long as the necessary agreement between the Community and the third country concerned has not been concluded.

4. This licence is personal and non-transferable.
5. This licence may be withdrawn by the competent authority of the Member State of issue in particular where the carrier:
 - (a) no longer satisfies the conditions laid down in Article 3(1) of Regulation (EC) No 1073/2009;
 - (b) has supplied inaccurate information regarding the data required for the issue or renewal of the licence;
 - (c) has committed a serious infringement or infringements of Community road transport legislation in any Member State, in particular with regard to the rules applicable to vehicles, driving and rest periods for drivers and the provision, without authorisation, of parallel or temporary services as referred to in the fifth subparagraph of Article 5(1) of Regulation (EC) No 1073/2009. The competent authorities of the Member State of establishment of the carrier who committed the infringement may, inter alia, withdraw the Community licence or make temporary or permanent withdrawals of some or all of the certified true copies of the Community licence.

These penalties are determined in accordance with the seriousness of the breach committed by the holder of the Community licence and with the total number of certified true copies that he possesses in respect of his international transport services.

6. The original of the licence must be kept by the carrier. A certified true copy of the licence must be carried on the vehicle carrying out an international transport operation.
7. This licence must be presented at the request of any authorised inspecting officer.
8. The holder must, on the territory of each Member State, comply with the laws, regulations and administrative measures in force in that State, particularly with regard to transport and traffic.
9. 'Regular services' means services which provide for the carriage of passengers at specified intervals along specified routes, passengers being taken up and set down at predetermined stopping points, and which are open to all, subject, where appropriate, to compulsory reservation.

The regular nature of the service shall not be affected by any adjustment to the service operating conditions.

Regular services require authorisation.

'Special regular services' means regular services, by whomsoever organised, which provide for the carriage of specified categories of passengers, to the exclusion of other passengers, at specified intervals along specified routes, passengers being taken up and set down at predetermined stopping points.

Special regular services shall include:

- (a) the carriage of workers between home and work;
- (b) carriage of school pupils and students to and from the educational institution.

The fact that a special service may be varied according to the needs of users shall not affect its classification as a regular service.

Special regular services do not require authorisation if they are covered by a contract between the organiser and the carrier.

The organisation of parallel or temporary services, serving the same public as existing regular services, requires authorisation.

'Occasional services' means services which do not fall within the definition of regular services, including special regular services, and whose main characteristic is that they carry groups constituted on the initiative of a customer or of the carrier himself. The organisation of parallel or temporary services comparable to existing regular services and serving the same public as the latter shall be subject to authorisation in accordance with the procedure laid down in Chapter III of Regulation (EC) No 1073/2009. These services shall not cease to be occasional services solely on the grounds that they are provided at certain intervals.

Occasional services do not require authorisation.

ANNEX III

CORRELATION TABLE

Regulation (EEC) No 684/92	Regulation (EC) No 12/98	This Regulation
Article 1		Article 1
Article 2, point 1.1.	Article 2(1)	Article 2(2), Article 5(1)
Article 2, point 1.2.	Article 2(2)	Article 2(3), Article 5(2)
Article 2, point 1.3.		Article 5(1), fifth subparagraph
Article 2, point 3.1.	Article 2(3)	Article 2(4), Article 5(3)
Article 2, point 3.3.		Article 5(3)
Article 2, point 3.4.		Article 5(3)
Article 2, point 4.		Article 2(5), Article 5(5)
Article 3		Article 3
Article 3a		Article 4
Article 4		Article 5
Article 5		Article 6
Article 6		Article 7
Article 7		Article 8
Article 8		Article 9
Article 9		Article 10
Article 10		Article 11
Article 11		Article 12
Article 12		Article 13
Article 13		Article 5(5)
	Article 1	Article 14
	Article 2(4)	
	Article 3	Article 15
	Article 4	Article 16
	Article 5	Article 4(3)
	Article 6	Article 17
	Article 7	Article 28(3)
	Article 8	Article 26
	Article 9	
Article 14		Article 18
Article 15		Article 19
	Article 11(1)	Article 20
Article 16(1)		Article 21(1)
Article 16(2)		Article 21(2)
Article 16(3)		Article 22(1)
Article 16(4)		Article 23(1)
Article 16(5)		Article 22(2)
	Article 11(2)	Article 23(2)
	Article 11(3)	Article 23(2)
	Article 11(4)	
	Article 12	Article 22(5), Article 23

Regulation (EEC) No 684/92	Regulation (EC) No 12/98	This Regulation
	Article 13	
Article 16a	Article 10	Article 26
Article 17		
Article 18		Article 25
Article 19	Article 14	Article 27
Article 20		
Article 21		Article 30
Article 22	Article 15	Article 31
Annex		Annex II

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